Technological Change in "Ordinary Medicine": The Emergence of Minimally Invasive Gallbladder Surgery, c.1970-1992

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Table of Contents

Abstract

This dissertation examines the emergence of minimally invasive gallbladder removal, or laparoscopic cholecystectomy in the late 1980s and early 1990s. Its rapid adoption is often referred to as the beginning of the "laparoscopic revolution" in general surgery. This alludes both to the effect that the technique had on surgical practice, and to the pace at which it supplanted open cholecystectomy as the "gold standard" treatment for gallstones. First published in an academic medical journal in 1989, by 1993 at least 80% of total gallbladder removals in Canada and the United States were already being performed laparoscopically. This rate of adoption is extraordinary considering that it required practicing surgeons to re-train in a technique that drastically changed the basic motions of surgery, as well as the development of new surgical instrumentation. The uncontrolled adoption of the technique led to higher complication rates ranging from relatively moderate injuries to severe organ damage, and sometimes even death. The dissertation begins with a history of gallstone treatment in order to provide the therapeutic context in which laparoscopic cholecystectomy was accepted. It then discusses how independent groups of surgeons developed techniques for laparoscopic gallbladder removal in the late 1980s, and the varied motivations that drove their work. I go on to explain how widespread advertising and promotion of laparoscopic cholecystectomy in the United States generated patient demand for the procedure, and how this was influenced by shifting judicial attitudes towards anti-trust law in the 1970s. Finally, I discuss how surgeons at academic medical centers attempted to control the adoption of the procedure through the regulation of training courses, and randomized controlled trials.

Résumé

Cette thèse examine l'émergence de l'ablation mini-invasive de la vésicule biliaire, ou cholécystectomie laparoscopique, à la fin des années 1980 et au début des années 1990. L'adoption rapide de cette méthode est souvent qualifiée comme étant le début de la « révolution laparoscopique » en chirurgie générale. Cette expression fait allusion non seulement à l'effet de la technique sur la pratique chirurgicale, mais aussi au rythme auquel elle a supplanté la cholécystectomie ouverte comme traitement « de référence » pour les calculs biliaires. Après la première publication sur cette méthode dans une revue médicale en 1989, dès 1993, au moins 80% des extractions totales de la vésicule biliaire au Canada et aux États-Unis étaient déjà effectuées par voie laparoscopique. Ce taux d'adoption était extraordinaire étant donné qu'il exigeait des chirurgiens pratiquants qu'ils réapprennent une technique qui avait radicalement changé les mouvements de base de la cholécystectomie, ainsi que le développement d'une nouvelle instrumentation chirurgicale. Mais une adoption incontrôlée de cette technique a également conduit à un taux de complications plus élevé allant de blessures relativement modérées à de graves dommages aux organes, et parfois même à la mort. Cette thèse débute avec l'histoire du traitement des calculs biliaires afin de mieux situer l'adoption de la cholécystectomie laparoscopique dans son contexte thérapeutique. Ensuite, elle examine comment des groupes indépendants de chirurgiens ont développé des techniques d'ablation laparoscopique de la vésicule biliaire à la fin des années 1980 et les motivations variées derrière leur travail. Puis, elle explique comment la publicité et la promotion généralisées de la cholécystectomie laparoscopique aux États-Unis ont créé une demande pour la procédure entre les patients, et comment cela a été influencé par un changement d'attitude entre les juges envers la loi anti-trust dans les années 1970. Enfin, elle étudie comment les chirurgiens des centres

médicaux universitaires ont tenté de contrôler l'adoption de la procédure par la réglementation des cours de formation et des essais contrôlés randomisés.

List of Figures

List of Tables

Acknowledgments

My journey into the history of medicine began in April 2013 when I attended a seminar on "A realignment of surgery and laboratory science: asepsis and bacteriology, 1880-1900," hosted by McGill University's Department of Microbiology and Immunology. Six months later, the speaker, Thomas Schlich, hired me as a research assistant to work on his project on the history of minimally invasive surgery. Over the next seven years – and with extraordinary patience, generosity, and kindness – Thomas trained me to be a historian. For this, I am eternally grateful. Along the way, I have also been very fortunate in the level of support I have received from other mentors. George Weisz and Elsbeth Heaman continue to gently (but firmly) push me out of my intellectual comfort zone, ever ready to provide necessary critical feedback on my work. David Jones (at Harvard University) has been an extremely generous reader and committee member and I am grateful for each of the numerous comments he has given on my dissertation chapters.

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Author's Declaration

This dissertation is the result of original scholarship. Chapters 1 to 3, and the first half of Chapter 4 are based entirely on my work. The second half of Chapter 4 is an adapted version of a co-authored paper with Thomas Schlich: Cynthia L. Tang and Thomas Schlich, "Surgical Innovation and the Multiple Meanings of Randomized Controlled Trials: The First RCT on Minimally Invasive Cholecystectomy (1980-2000), *Journal of the History of Medicine and Allied Sciences* 72 (2017): 117-41.

Cynthia L. Tang:

Date:

Introduction

Gallbladder surgery for the treatment of gallstones is one of the most common surgical procedures in Europe and North America. Known medically as a cholecystectomy, gallbladder removal is performed at a rate of 393 per 100,000 inhabitants in the United States[1] and 206 per 100,000 inhabitants in Canada.[2] Though the principle behind removing the gallbladder to treat gallstones has remained the same since Carl Langenbuch performed the first cholecystectomy in 1882,[3] gallbladder surgery today looks radically different from how it did for most of the twentieth century. Before the emergence of minimally invasive gallbladder surgery – or laparoscopic cholecystectomy – in the late 1980s, gallbladder removal required a three to six-inch abdominal incision and could require patients to spend up to seven weeks in recovery, with up to one week in the hospital.

Beginning in 1989, however, patients could have their gallbladders removed through three or four half-inch incisions and be back to their regular activities one to seven days later. It is estimated that by 1993, at least 80% of total gallbladder removals in Canada and the United States were already being performed laparoscopically – less than four years after its introduction to the surgical community.[4] This rate of adoption is extraordinary considering that it required

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[1] Based on data from *Health, United States, 2009: With Special Feature on Medical Technology*, prepared by the National Center for Health Statistics, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (Hyattsville, MD, 2010).

[2] Based on 2018 data from Organisation for Economic Co-operation and Development, "Health: Health Care Utilisation – Surgical procedures, Cholecystectomy," OECD.Stat, accessed October 13, 2020, stats.oecd.org/index.aspx.

[3] Carl Langenbuch, "Ein Fall von Exstirpation der Gallenblase wegen chronischer Cholelithiasis. Heilung," *Berliner Klinische Wochenschrift* 19 (1882): 725-7, translated by Helmut V. Ammon and Alan F. Hofman as "Successful Treatment of Chronic Cholelithiasis by Cholecystectomy: A Case Report," *Gastroenterology* 85 (1983): 1430-3.

[4] David R. Urbach and Thérèse A. Stukel, "Rate of elective cholecystectomy and the incidence of severe gallstone disease," *Canadian Medical Association Journal* 172 (2005): 1015-9; A.P. Legorreta et al, "Increased Cholecystectomy Rate After the Introduction of Laparoscopic Cholecystectomy," *Journal of the American Medical Association* 270 (1993): 1429-1432; "National Institutes of Health Consensus Development Conference Statement on Gallstones and Laparoscopic Cholecystectomy," *American Journal of Surgery* 165 (1993): 390-8, 390.

practicing surgeons to re-train in a technique that drastically changed the basic motions of surgery. Instead of having open access to the abdominal cavity and being able to directly see, feel, and manipulate organs and tissues, surgeons had to learn to perform gallbladder removal from outside of the body.[5] With the new technique, surgeons' only view into the abdomen is through the laparoscope: a telescopic instrument (known more generally as an endoscope) that is specific for visualizing the abdominal cavity and that is usually equipped with a camera. The surgeons' vision is thus mediated through video on a screen while their touch is mediated through long surgical instruments that are manipulated extracorporeally and require a different skillset to operate than conventional instruments. Since general surgeons often had little or no experience with laparoscopy, most required substantial training in this approach to surgery.

In the absence of widespread regulations governing the use of the technique, its uncontrolled uptake led to higher complication rates ranging from relatively moderate injuries to severe organ damage, and sometimes even death. According to the 1993 NIH Consensus Development Statement on laparoscopic cholecystectomy, the rates of bile duct injuries could be up to 1 in 200 patients who underwent the laparoscopic procedure compared to 1 in 500 patients who underwent open cholecystectomy.[6] The overall rate of bile duct injury during laparoscopic cholecystectomy has since decreased but remains a topic of concern for surgical associations.[7]

In the current era of rapid technological innovation and pressure to develop new medical interventions it is imperative to understand the social, cultural, and economic contexts in which new treatments and technologies are developed and adopted, and the repercussions that may

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[5] For a more in-depth discussion of how laparoscopic surgery differs from open surgery see Rachel Prentice, "Swimming in the Joint," *Bodies in Formation: An Ethnography of Anatomy and Surgery Education* (Durham: Duke University Press, 2012), 171-98.
[6] "NIH Consensus Development Statement," 394.
[7] See, for example, Philip H. Pucher et al. on behalf of the SAGES Safe Cholecystectomy Task Force, "Outcome trends and safety measures after 30 years of laparoscopic cholecystectomy: a systematic review and pooled data analysis," *Surgical Endoscopy* 32 (2018): 2175-83.

result. The speedy acceptance of laparoscopic cholecystectomy in the early 1990s provides an ideal historical case study for exploring these issues. This thesis is the first historical analysis of the introduction of laparoscopic cholecystectomy, a pivotal moment in the history of surgery that led to the use of laparoscopic techniques for most procedures in general surgery, and the later development of robotic surgery and telesurgery. Beginning with a history of gallstone treatment since the eighteenth century, it examines the circumstances that facilitated the rapid establishment of laparoscopic cholecystectomy as the dominant treatment for gallstones, including the circumstances of its development by multiple surgeons, the American legal proceedings that contributed to the environment of medical consumerism in which it was marketed to patients, and the ways in which academic surgeons attempted to control the unregulated use of the technique.

Most accounts of the emergence of laparoscopic cholecystectomy have so far been written by surgeons.[8] The authors of many of these accounts are practitioners who witnessed or participated in the "laparoscopic revolution" and provide valuable insights into the early days of laparoscopic cholecystectomy.[9] While a useful starting point, these narratives often lack contextualization within broader histories of surgery and medicine. They tend to offer little explanation for the procedure's emergence beyond the scattered breakthroughs that were made due to the brilliance of individual practitioners and the simple narrative of the dominance of a

[8] See, for example, Alexandros Polychronidis et al., "Twenty Years of Laparoscopic Cholecystectomy: Philippe Mouret – March 17, 1987," *Journal of the Society of Laparoendoscopic Surgeons* 12 (2008): 109-11; Leon Morgenstern, "An Unsung Hero of the Laparoscopic Revolution: Eddie Joe Reddick, MD," *Surgical Innovation* 15 (2008): 245-8; M. A. Reuter, H. J. Reuter and R. M. Engel, *History of Endoscopy, vols. 5-7* (Stuttgart: Max Nitze Museum, 2003); Gilbert Schlogel, *Philippe Mouret: Une (R)évolution par la coelio-chirurgie* (Montpellier: Sauramps Medical, 2017).

[9] See, for example, Jacques Périssat, "Laparoscopic Surgery: A Pioneer's Point of View," *World Journal of Surgery* 23 (1999): 863-68; Nicola Basso, *A Semi Serious History of Laparoscopy* (Rome: Gangemi Editore, 2003); David W. Page, *The Laparoscopic Surgery Revolution: Finding a Capable Surgeon in a Rapidly Advancing Field* (Santa Barbara: Praeger, 2017).

superior technique over an antiquated one. Importantly, however, many surgical accounts of the period credit much of the rapid uptake to immense patient demand for the less invasive surgery.[10]

Grzegorz Litynski's volume, *Highlights in the History of Laparoscopy*, is impressive for its comprehensive use of interviews with the early developers and adopters of laparoscopic cholecystectomy.[11] It provides an excellent chronicle of key events in the procedure's development and adoption, placing them within a longer history of laparoscopy and its use in other medical fields, such as gynecology. Occupational sociologist James Zetka discusses laparoscopic cholecystectomy in the context of intraprofessional turf wars between gastroenterologists and general surgeons over the use of endoscopy.[12] According to him, the development of the less invasive procedure was a welcome advancement for general surgeons who were increasingly worried about the status of their specialty as it continued to be fragmented into subspecialties.

Despite its significance to the history of modern medicine and to current surgical practice, very little is known about the logistical details of the adoption of laparoscopic cholecystectomy. How, for example, did patients know about the existence of the procedure in order to demand that surgeons provide it? Similarly, through what mechanisms did the widespread training of surgeons occur and how did these mechanisms relate to the increased complication rate associated with gallbladder surgery? A central aim of this dissertation is to understand the rapid uptake of laparoscopic cholecystectomy through the flow of information between the surgeons who developed the technique, their surgical colleagues, patients, and the

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[10] See, for example, Herschel A. Graves, "Appraisal of Laparoscopic Cholecystectomy," *Annals of Surgery* 213 (1991): 655-62; George Berci, "Laparoscopic Cholecystectomy Viewed from the USA," *Australian and New Zealand Journal of Surgery* 61 (1991): 249-50; "National Institutes of Health," 393;

[11] Grzegorz S. Litynski, Highlights in the History of Laparoscopy: The Development of Laparoscopic Techniques – a Cumulative Effort of Internists, Gynecologists, and Surgeons (Frankfurt/Main: Barbara Bernert Verlag, 1996).

[12] James R. Zetka, *Surgeons and the Scope* (Ithaca: Cornell University Press, 2003).

wider public. It further examines both the professional and social contexts that influenced the dissemination of this information.

This research contributes to the growing body of work on the history of surgery. Historians have explored the topic of technological change in medicine from a broad perspective, but surgery as one of modern medicine's central technologies has received relatively less attention.[13] Much of the existing historiography is centered on the changing professional status of surgeons,[14] and the position of surgery in modern culture and society.[15] Of the more technical topics, historians have focused on the introduction of anaesthesia in the 1840s,[16] and antisepsis/asepsis in the 1860s and 1870s.[17] While the development of specific surgical

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[13] On the history of technological innovation in modern medicine see Stuart Blume, *Insight and Industry: On the Dynamics of Technological Change in Medicine* (Cambridge: MIT Press, 1992); Jennifer Stanton, *Innovations in Health and Medicine: Diffusion and Resistance in the Twentieth Century* (London: Routledge, 2002); Julie Anderson and Carsten Timmermann, *Devices and Designs: Medical Technologies in Historical Perspective* (Basingstoke: Palgrave Macmillan, 2006); Thomas Schlich and Christopher Crenner (eds.), *Technological Change in Modern Surgery: Historical Perspectives on Innovation* (Rochester: University of Rochester Press, 2017). For a recent historiography of surgical history see Christopher Lawrence, "Surgery and its Histories: Purposes and Contexts," in *The Palgrave Handbook of the History of Surgery*, ed. Thomas Schlich (London: Palgrave MacMillan, 2018), 27-48.

[14] For example, see Toby Gelfand, *Professionalizing Modern Medicine: Paris Surgeons and Medical Science and Institutions in the 18th Century* (Westport: Greenwood Press, 1980); Thomas Schlich, "The Emergence of Modern Surgery," in *Medicine Transformed: Health, Disease and Society in Europe, 1800-1939*, ed. Deborah Brunton (Manchester: Manchester University Press, 2004), 61-91; Peter J. Kernahan, "Surgery Becomes a Specialty: Professional Boundaries and Surgery," in *The Palgrave Handbook of the History of Surgery*, ed. Thomas Schlich (London: Palgrave MacMillan, 2018), 95-113.

[15] On the position of surgery in modern culture and society see Roger Cooter, *Surgery and Society in Peace and War: Orthopaedics and the Organization of Modern Medicine, 1880-1948* (Basingstoke: MacMillan Press, 1993); Susan E. Lederer, "Surgery and Popular Culture: Situating the Surgeon and the Surgical Experience in Popular Media," *The Palgrave Handbook of the History of Surgery*, ed. Thomas Schlich (London: Palgrave MacMillan, 2018), 349-368; Kieran Fitzpatrick, "Surgery, Imperial Rule and Colonial Societies (1800-1930): Technical, Institutional and Social Histories," in *The Palgrave Handbook of the History of Surgery*, ed. Thomas Schlich (London: Palgrave MacMillan, 2018), 369-388.

[16] For example, see Martin S. Pernick, *A Calculus of Suffering: Pain, Professionalism and Anasthesia in Nineteenth-Century America* (New York: Columbia University Press, 1985); Alison Winter, "Ethereal Epidemic: Mesmerism and the Introduction of Inhalation Anaesthesia to early Victorian London," *Social History of Medicine* 4 (1991): 1-27; Stephanie Snow, *Blessed Days of Anaesthesia: How Anaesthetics Changed the World* (Oxford: Oxford University Press, 2008).

[17] See J.T.H. Connor, "Listerism Unmasked: Antisepsis and Asepsis in Victorian Anglo-Canada," *Journal of the History of Medicine and Allied Sciences* 49 (1994): 207-39; Thomas P. Gariepy, "The Introduction and Acceptance of Listerian Antisepsis in the United States," *Journal of the History of Medicine and Allied Sciences* 49 (1994): 167-206; Anna Greenwood, "Lawson Tait and Opposition to Germ Theory: Defining Science in Surgical Practice," *Journal of the History of Medicine and Allied Sciences* 53 (1998): 99-131; Michael Worboys, *Spreading Germs: Disease Theories and Medical Practice in Britain, 1865-1900* (Cambridge: Cambridge University Press, 2000);

procedures have often been written about by surgical practitioners,[18] such topics have also recently piqued more interest in professional medical historians. Among these are Thomas Schlich's study of osteosynthesis, David Jones' work on cardiac surgery, Ayesha Nathoo's volume on heart transplants, Shelley McKellar's history of artificial hearts, Sally Frampton's monograph on ovariotomy and most recently, Justin Barr's examination of arterial repair.[19]

In contrast to these surgical treatments, which are used on relatively few patients and in extraordinary circumstances, cholecystectomy is performed commonly enough that it is often referred to as one of general surgeons' "bread-and-butter" procedures, along with appendectomy and hernia repair.[20] Before the emergence of laparoscopic cholecystectomy, open cholecystectomy already had a relatively low mortality rate (0.4%) and morbidity rate (7%).[21] This research will therefore expand the history of surgery by examining a procedure that is not only common, but replaced an existing treatment that was considered to be acceptably safe and effective by the majority of the medical establishment.

While gallbladder attacks can be painful, they are also quite ordinary. The underlying condition – cholelithiasis – itself is not lethal and most patients have the opportunity to decide

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Thomas Schlich, "Asepsis and Bacteriology: A Realignment of Surgery and Laboratory Science," *Medical History* 56 (2012): 308-343.

[18] For examples of such work by surgical practitioners, see L. William Traverso, "Carl Langenbuch and the First Cholecystectomy," *American Journal of Surgery* 132 (1976): 81-82; J.E. Connolly, "The history of coronary artery surgery," *Journal of Thoracic and Cardiovascular Surgery* 76 (1978): 733-44; Ralph Shackman, "The Story of Kidney Transplantation," *British Medical Journal* 1, no. 5500 (1966): 1379-1383.

[19] Thomas Schlich, *Surgery, Science and Industry: A Revolution in Fracture Care, 1950s-1990s* (Houndsmill, Basingstoke, Hampshire: Palgrave Macmillan, 2002); David S. Jones, *Broken Hearts: The Tangled History of Cardiac Care* (Baltimore: Johns Hopkins University Press, 2013); Shelley McKellar, *Artificial Hearts: The Allure and Ambivalence of a Controversial Medical Technology* (Baltimore: Johns Hopkins University Press, 2018); Ayesha Nathoo, *Hearts Exposed: Transplants and the Media in 1960s Britain* (Basingstoke: Palgrave Macmillan, 2009); Sally Frampton, *Belly-Rippers, Surgical Innovation and the Ovariotomy Controversy* (Basingstoke; Palgrave Macmillan, 2018); Justin Barr, *Of Life and Limb: Surgical Repair of the Arteries in War and Peace, 1880-1960* (Rochester: University of Rochester Press, 2019).

[20] James R. Zetka, "Turf Wars over the Gastrointestinal Tract," *Surgeons and the Scope* (Ithaca: Cornell University Press, 2003), 121.

[21] Ian Forgacs, "Shock News for Gallstones," *British Medical Journal* 295 (1987): 738.

how and when to treat their condition. Cholecystectomy is therefore considered to be an elective procedure. Having one's gallbladder removed also does not come with the judgement generated by abortion or the sensationalism of heart surgery. Thus, at a broader level, this dissertation examines how technological change in medicine occurs under relatively ordinary conditions, for a common treatment that is considered medically necessary, but not urgent. As this dissertation will show, it is these characteristics of cholelithiasis that are important for understanding how laparoscopic cholecystectomy supplanted the more traditional method of open surgery in less than four years.

Much of the history of medicine focuses on fascinating yet exceptional cases. Its historiography is brimming with studies of cancer, sexually transmitted illnesses, and epidemics, to name just a few of the most popular topics. While these studies contribute to a richer understanding of the human experience and provide valuable insight into our interactions with health and disease, they are also studies of extraordinary circumstances and the emotions that they generate. Histories of HIV/AIDS, for example, must take into account issues of morality and immense fear, while histories of mental illness need to grapple with the effects brought by social stigma. In contrast, less effort has been spent trying to understand how medicine works under less dramatic circumstances.

Though gallstones and gallbladder surgery themselves are relatively unremarkable, surgeons often refer to the rapid adoption of laparoscopic cholecystectomy as the beginning of the "laparoscopic revolution" in general surgery.[22] This description alludes both to the pace at which it supplanted open cholecystectomy as the "gold standard" treatment for gallstones, as

[22] See, for example, A. Cuschieri, "The laparoscopic revolution – walk carefully before we run," *Journal of the Royal College of Surgeons of Edinburgh* 34 (1989): 295; Polychronidis et al., "Twenty Years," 111; Page, *The Laparoscopic Surgery Revolution*.

well as to the effect that the technique had on surgical practice. But as Nicholas Whitfield argues, the use of "revolution" as a way to understand laparoscopic cholecystectomy's impact – though apt in many ways – fails to acknowledge the continuities with earlier endoscopic and surgical methods that were preserved in its development.[23] In the codification of the technique, for example, surgeons sought to replicate the maneuvers used in the open procedure with the laparoscopic instruments so that it was ultimately the same procedure but with a laparoscopic approach.[24]

Similarly, the 2016 volume – *Therapeutic Revolutions: Pharmaceuticals and Social Change in the Twentieth Century* – co-edited by Jeremy Greene, Flurin Condrau, and Elizabeth Siegel Watkins, examines how historical actors have employed narratives of therapeutic revolutions to further their agendas.[25] While describing the emergence of laparoscopic cholecystectomy as a revolution was not solely rhetorical, it also did the work of conveying a feeling that its adoption was out of control and urgently needed to be reined in. Other accounts of the period, both contemporary and retrospective, also make comparisons to an "explosion,"[26] or a "wildfire,"[27] or the "Wild West."[28]

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[23] Nicholas Whitfield, "A Revolution Through the Keyhole: Technology, Innovation, and the Rise of Minimally Invasive Surgery," *The Palgrave Handbook of the History of Surgery* ed. Thomas Schlich (London: Palgrave Macmillan, 2018), 525-48.
[24] Jacques Périssat, interview by Cynthia L. Tang, Bordeaux, France, November 9, 2017; A. Cuschieri and J. Terblanche, "Laparoscopic cholecystectomy: evolution, not revolution," *Surgical Endoscopy* 4 (1990): 125-6.
[25] Jeremy A. Greene, Flurin Condrau, Elizabeth Siegel Watkins, eds., "Medicine Made Modern by Medicines," *Therapeutic Revolutions: Pharmaceuticals and Social Change in the Twentieth Century* (Chicago: University of Chicago Press, 2016), 1-12.
[26] Nathanial J. Soper "Laparoscopic Cholecystectomy," *Current Problems in Surgery* 28 (1991): 591.
[27] Morgenstern, "Unsung Hero," 245.
[28] Jeffrey Barkun, interview by Thomas Schlich and Cynthia L. Tang, Montreal, Canada, September 24, 2014.

Methodology

This dissertation analyzes how the adoption of laparoscopic cholecystectomy was adopted in a way that was perceived as lacking control and discusses how surgeons tried to manage this situation. The starting point of this research was to reconstruct the personal networks, pathways of dissemination, discussions, and logistical infrastructure that facilitated the rise of laparoscopic cholecystectomy as the predominant treatment method for gallstones. The specific questions that the project aimed to address included: 1) How did the technique for laparoscopic cholecystectomy develop in the contexts of competing treatments for gallstones, competition between multiple medical specialties, and evolving technologies? 2) What was the motivation behind developing a less invasive procedure for gallbladder removal? 3) Through what media did knowledge of laparoscopic cholecystectomy disseminate amongst surgeons and patients? 4) How was the use of laparoscopic cholecystectomy regulated with respect to surgical training and the safety of the procedure?

Key actors in the procedure's development and evaluation were identified through a review of the early medical literature on laparoscopic cholecystectomy. The relatively recent development of the procedure allowed for the use of oral history methods to collect personal narratives and perspectives from these actors. Following established oral history approaches, interviews were conducted using a semi-structured, open-ended format in order to maximize the potential for unanticipated data.[29] Each interview began with an invitation for the participant to describe how they first encountered laparoscopic cholecystectomy. Based on the information provided in the participant's initial testimony, follow-up questions were asked to obtain more specific details of the participant's perspectives on the relevant research questions, as well as

[29] See Paul Thompson and Joanna Bornat, *The Voice of the Past: Oral History* (Oxford: Oxford University Press, 2000).

their biographical background (for example, training, employment, professional standing, etc.) in order to contextualize their individual experiences. Many of the participants in the first round of oral history interviews provided suggestions of additional actors who might have relevant testimony, in accordance with the snowball sampling method of participant recruitment.[30]

As with most historical sources, the data obtained from oral history interviews should be assessed for reliability, such as through cross-checking with other sources and searching for internal consistency.[31] Much of the value of oral history interviews, however, comes from its potential to uncover information that may be overlooked or even unpreserved in textual and archival sources. Though it was sometimes impossible to confirm a particular anecdote, such testimonies were often still useful in providing new perspectives in the analysis of, for example, individual surgeons' personal motivations.[32] When possible, details that were provided in interviews were corroborated by primary published material (i.e. medical research papers, editorials, commemorative articles, textbooks, etc.), newspaper reports, and archival material. Visits to the archives of the Royal College of Physicians and Surgeons of Canada, the Royal College of Physicians and Surgeons of Glasgow, the Royal College of Surgeons of Edinburgh, the Royal College of Surgeons of England, and the American College of Surgeons resulted in surprisingly few archival sources related to the development and adoption of laparoscopic cholecystectomy. Since these events occurred relatively recently, it is possible that relevant collections have yet to make their way to these or other archives. Some archival material was provided by oral history participants.

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[30] See David L. Morgan, "Snowball Sampling," *The SAGE Encyclopedia of Qualitative Research Methods* ed. Lisa M. Given (Thousand Oaks, CA: SAGE Publications, Inc., 2008), 816.
[31] See Thompson and Bornat, "Evidence," *Voice of the Past: Oral History*, 118-172, 153.
[32] See Thompson and Bornat, "Interpretation," *Voice of the Past: Oral History*, 265-308, 273.

Limitations

The history of laparoscopic cholecystectomy that is discussed in this dissertation focuses predominantly on the procedure's development and adoption from the perspective of surgeons. For the medical profession, the adoption of laparoscopic cholecystectomy is an undisputed success story. In addition to allowing patients to recover from gallbladder removal in less time and with less trauma, the procedure provided a proof of concept that abdominal surgery could be performed laparoscopically. While the majority of patients benefited from the incorporation of laparoscopy into general surgery, there were also many patients who suffered during its introduction. The increased complication rate associated with laparoscopic cholecystectomy in the early days of its adoption was indeed of great concern to the surgical establishment. Still, in the triumphalist accounts of the "laparoscopic revolution," these patients are reduced to statistics and their experiences are overlooked. Though one of the aims of this research was to better understand the role of patient demand in the rush to offer the less invasive procedure, it is with great regret that the experiences of early laparoscopic cholecystectomy patients were beyond the scope of this project. Future work will hopefully use this dissertation as a starting point to examine both the positive and negative experiences that patients had in the transition to laparoscopic techniques in general surgery.

Another limitation of this work is its geographical scope. The history of laparoscopic cholecystectomy is very much an international story with its development occurring independently in France and the United States and its concurrent uptake throughout Europe and North America. However the focus of this analysis is on its adoption in the more market-driven American healthcare environment where laparoscopic cholecystectomy was more quickly and widely made available to patients than in countries that have publicly-funded healthcare systems,

for example, Canada and the United Kingdom.[33] A comparison of how such a major technological change in medicine took place in differing national contexts, with their distinct healthcare infrastructures, would be both interesting and instructive but is unfortunately also outside the scope of this dissertation.

Dissertation Structure

The dissertation begins with a "pre-history" of laparoscopic cholecystectomy and a discussion of the therapeutic context in which it was developed. Chapter 1 provides a brief history of gallbladder surgery in the nineteenth century before analyzing the medical discourse on the non-surgical treatment options for gallstones that gastroenterologists started to develop in the 1960s. In contrast to James Zetka, I argue that the development of these treatments was not seen as a major threat to surgeons. Rather than being a major cause of competition between general surgeons and gastroenterologists, the non-surgical options allowed practitioners to offer alternatives for patients who were poor surgical candidates or who did not want to undergo surgery.

Chapter 2 explores the ways in which the multiple pioneers of laparoscopic cholecystectomy – in France and the United States – narrate its development. Bringing together published retrospectives with new oral history interviews, this chapter examines the differing motivations that each surgeon had for being interested in a laparoscopic approach to gallbladder removal.[34] In addition to a discussion of the gendered attitudes towards gallstones and surgical

[33] For example, approximately 75% of cholecystectomies in southeastern Pennsylvania, US were performed laparoscopically in 1991. Comparatively, only 30% of cholecystectomies were laparoscopic in both Ontario, Canada and in Scotland, UK that same year. See Legorreta et al., "Increased Cholecystectomy Rate," 1430; Urbach and Stukel, "Rate of elective cholecystectomy," 1017; Andrew J. McMahon et al., "Impact of laparoscopic cholecystectomy: a population-based study," *Lancet* 356 (2000): 1632-7, 1633.

[34] Though some of the developers of laparoscopic cholecystectomy cite their previous experience in gynecological laparoscopy as facilitating their work, the history of laparoscopy in gynecology is beyond the scope of this dissertation. For more on this topic, see Jesse Olszynko-Gryn, "Laparoscopy as a technology of population control:

scars that emerged from this research, Chapter 2 demonstrates how the contrasting features of academic and non-academic medical spaces facilitated or impeded each stage of laparoscopic cholecystectomy.

Chapter 3 examines surgeons' claims that the rapid adoption of laparoscopic cholecystectomy was a patient demand-driven revolution. It shows that this demand was generated though widespread efforts to promote the less invasive procedure in newspaper articles and, in the United States, advertisements. It discusses how such publicity was previously considered to be unethical, however, changing judicial attitudes towards American anti-trust law in the late 1970s forced the American Medical Association to amend its Code of Ethics to allow physician advertising. I argue that by the emergence of laparoscopic cholecystectomy in 1990, self-promotion by physicians was considered to be acceptable professional behaviour, resulting in widespread publicity for the procedure.

Chapter 4 discusses concerns that some surgeons would offer laparoscopic cholecystectomy to patients without adequate training and cause serious complications. It discusses the attempts that academic surgeons made to control the adoption of the procedure, the ways in which surgeons in the United States trained in the laparoscopic technique and how surgical societies attempted to regulate the first training courses. I argue that the amount of training that surgeons sought in addition to attending a course was often more important for ensuring successful results. The second half of this chapter discusses the struggle to complete a randomized controlled trial for the evaluation of laparoscopic cholecystectomy. It demonstrates how the completion of the first successful clinical trial comparing the laparoscopic procedure to

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A use-centered history of surgical sterilization," in H. Hartmann and C. R. Unger eds., *A World of Populations: The Production, Transfer and Application of Demographic Knowledge in the Twentieth Century in Transnational Perspective* (New York: Berghahn, 2014), 147-77; Ramona Braun, "Laparoscopy as a neo-eugenic practice, 1940s-60s," PhD diss., University of Cambridge, 2015, ProQuest (AAI10657843).

open cholecystectomy was contingent on a confluence of local conditions that existed at McGill University in Montreal, Canada.

Finally, the concluding section will consider why general surgeons became interested in laparoscopic techniques only after their application to cholecystectomy in the late 1980s and early 1990s. This is in contrast to the increasing use of interventional laparoscopy and endoscopy in gynecology and gastroenterology. I will discuss the particular characteristics of gallstones and gallbladder surgery, as well as the conditions of American medical practice that facilitated the expedited adoption of laparoscopic cholecystectomy. Lastly, I will comment on further avenues of research on the transition from open to laparoscopic techniques in general surgery that would provide valuable insights into our understandings of technological change in medicine.

Chapter 1: Against a Backdrop of Alternative Treatment Options

> In 1994 [my doctor] noticed that I had quite a few gallstones…and advised that I get them and my gallbladder removed…[A]s the stones weren't affecting my appetite or my general health, I decided against surgery. Ten years later, when I was having my appendix out, the surgeon spied the gallstones…It wasn't a life-threatening condition, so I wasn't particularly worried about them, but I had been experiencing some symptoms. I'd been feeling a lot of pain after eating cream or dairy products. It was a peculiar pain because it was behind my ribs and went right through into my back. The discomfort was becoming more frequent, so…I opted for [a] laparoscopic cholecystectomy…[After the surgery,] movement was slightly restricted…but after about 10 days everything returned to normal…[T]he pain caused by eating dairy products has totally disappeared…I haven't had any other problems since and am so glad that I finally had the surgery.[35]

This vignette of a British patient's experience with gallstones demonstrates some typical features of the condition that are important for understanding the emergence of laparoscopic cholecystectomy. Importantly, patients who have gallstones are not always symptomatic. Of the 20% of adults who develop gallstones in their lifetime approximately 20% experience symptoms

[35] Phyllis Long, "Patient story: 'I was having my appendix out and the surgeon spied the gallstones – all 19 of them,'" Medical Conditions: Laparoscopic Cholecystectomy, Zana Technologies, published November 28, 2016, accessed August 8, 2020, https://zana.com/a/laparoscopic-cholecystectomy-patient-story-having-appendix-surgeon-spied-gallstones-19.1054.

or complications.[36] Though patients are often advised to have their gallbladders removed even when they are asymptomatic, the non-fatal nature of the disease means that patients have more agency to decide whether they want to seek treatment. This is especially the case since symptoms can often be managed through dietary changes, such as the avoidance of certain foods.

The gallbladder is a small, pear-shaped organ that is connected to the liver via the cystic duct and the common bile duct, which drains into the small intestine (Figure 1.1). Its function is to store bile, a digestive fluid that the liver produces, and which contains water, cholesterol, fats, bile acids, and a pigment known as bilirubin. When these elements are out of proportion, they can precipitate out and form gallstones. These stones can cause immense pain if they become lodged in the cystic or common bile ducts and block the flow of bile into the small intestine.

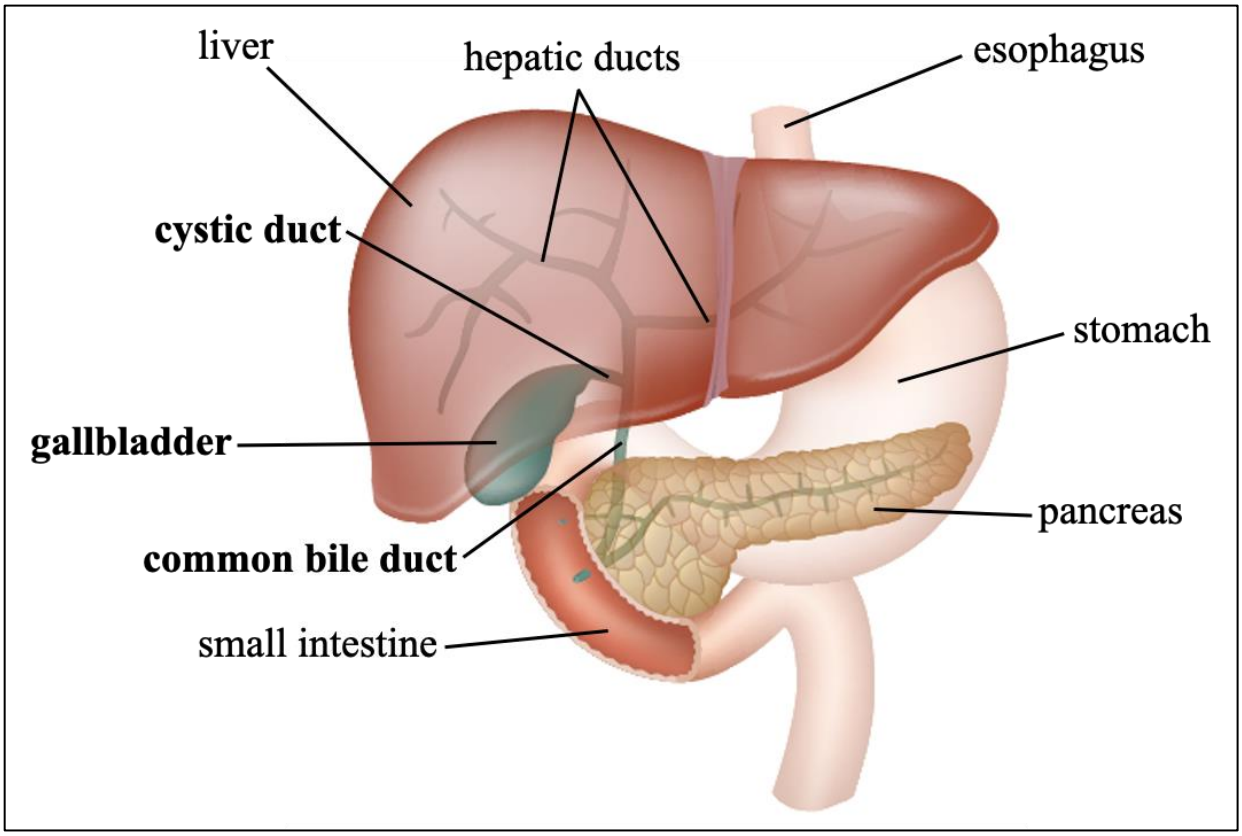

Figure 1.1: Anatomy of the Biliary System.

[36] Frank Lammert et al., "Gallstones," *Nature Reviews: Disease Primers* 2 (2016) 1-17, 1.

For most of the twentieth century, surgical gallbladder removal through an open abdominal incision was considered to be the gold standard treatment for cholelithiasis. The procedure, known as a cholecystectomy, has a minimal risk of complications and usually resolves the problem completely by preventing the further formation of stones. But by 1989, when general surgeons began to adopt laparoscopic cholecystectomy, patients could also choose to treat their gallstones with non-surgical interventions. Oral bile acids, for example, could be taken in an attempt to dissolve stones. Bile acid therapy was later enhanced with the use of ultrasonic lithotripsy to fragment the stones for better surface area contact with the solvent. To remove stones that were blocking the biliary system, gastroenterologists could use flexible endoscopes to access the common bile duct through the esophagus in a procedure called endoscopic sphincterotomy. Any stones that were further back in the cystic duct or still in the gallbladder would not have been accessible with this technique in the 1980s.[37] In contrast to cholecystectomy, neither of these treatments are permanent solutions and allow the possibility for symptoms to recur.

Depending on the severity of any symptoms or complications (as well as availability in their area), patients could often take their time in considering these options. According to occupational sociologist James Zetka, with their decisions, patients were unwittingly participating as adjudicators in a turf war over the treatment of the gastrointestinal tract between general surgeons and gastroenterologists.[38] Zetka argues that general surgeons became concerned about losing their share of the medical marketplace as gastroenterologists used the endoscope to perform more interventional procedures in addition to their usual diagnostic ones. He shows that

[37] Though it is now possible to retrieve stones from the cystic duct and sometimes the gallbladder, this still requires a high level of skill.
[38] James Zetka, "Turf Wars Over the Gastrointestinal Tract," *Surgeons and the Scope* (Ithaca: Cornell University Press, 2003), 120-35.

this was part of broader existential anxieties over general surgery's future as common surgical procedures were increasingly challenged and replaced by emerging pharmaceutical, radiographic, and/or endoscopic procedures during the 1980s. He claims that the development of lithotripsy to break up gallstones and endoscopic sphincterotomy to remove them was "especially threatening to surgeons" because of their superior treatment outcomes.[39] "Gastroenterologists, emboldened by their endoscopic successes," he explains, "began to challenge the general surgeons' time-honored control over the management of the traditional gallbladder case."[40] In this narrative, laparoscopic cholecystectomy is implied to have been consciously developed in an effort to keep gallstone treatment within the surgical jurisdiction.[41]

Alternative treatment options, differing techniques, and the way medical practitioners arrive at a consensus about best practices have been of continuing interest to historians of surgery. David Jones, for example, explores the tangled histories of coronary artery bypass surgery and coronary angioplasty in the treatment of cardiac disease as a way to understand the complexities of medical decision-making.[42] He shows how the emergence of competing treatment options in the 1970s, 80s, and 90s influenced medical theories about coronary artery disease. Competition, however, is not confined to being between completely different treatment modalities but can also arise between variants of the same procedure, as Sally Frampton demonstrates in her work on ovariotomy in the nineteenth century.[43] Meanwhile, Sally Wilde's study on the different techniques that were used for prostate surgery in the 1930s illustrates how

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[39] Zetka, "Turf Wars over the Gastrointestinal Tract," 124.
[40] Zetka, "Turf Wars over the Gastrointestinal Tract," 125.
[41] Zetka, "Technological Innovation in the Surgical Craft," *Surgeons and the Scope* (Ithaca: Cornell University Press, 2003), 136-56, 137.
[42] David S. Jones, *Broken Hearts: The Tangled History of Cardiac Care* (Baltimore, Johns Hopkins University Press, 2013).
[43] Sally Frampton, "Defining Difference: Competing Forms of Ovarian Surgery in the Nineteenth Century," *Technological Change in Modern Surgery*, eds. Thomas Schlich and Christopher Crenner (Rochester: University of Rochester Press, 2017), 51-70.

the technique that produced the best results often depended on individual surgeons' personal preferences, skill levels, and experiences.[44] The problem thus became how to arrive at a consensus on best practice for better patient outcomes with such variability between practitioners.[45] Along these lines, the introductory chapter of a collected volume by Thomas Schlich and Christopher Crenner challenges historians to look past developments of the "one best way" to treat a condition in order to better understand the issues that historical actors faced when making decisions about how to provide patients with favourable outcomes.[46] Taking this approach in examining the treatment of gallstones allows us to see that the existence of alternative treatments does not necessarily indicate that they are in competition with one another.

Competition-based analyses can have the effect of ignoring individual differences between patients: what may be the best option for one patient may not be the best option for another. In the case of twentieth century gallstone treatment, the development of non-surgical options provided alternatives for relief to patients who were poor surgical candidates – as well as those who did not want to undergo open abdominal surgery for non-medical reasons. Arguments that rely on a strict occupational demarcation between gastroenterologists and general surgeons are too simplistic and can result in an inaccurate analysis. A closer reading of the medical literature reveals that surgeons were also involved in the pursuit of non-surgical interventions for gallstone treatment. For them, it was also within their professional interests for patients who were poor surgical candidates to have access to less invasive gallstone treatments – a point that more cynical, market-based arguments can overlook. Though there were indeed tensions

[44] Sally Wilde, "See One, Do One, Modify One: Prostate Surgery in the 1930s," *Medical History* 48 (2004): 351-66.
[45] Wilde, "See One, Do One," 366.
[46] Thomas Schlich and Christopher Crenner, "Technological Change in Surgery: An Introductory Essay," *Technological Change in Modern Surgery*, eds. Thomas Schlich and Christopher Crenner (Rochester: University of Rochester Press, 2017), 1-20.

between general surgeons and gastroenterologists during the 1970s and 80s, this chapter argues that surgeons did not see the development of non-surgical alternatives for gallstone treatment as a major threat to their practice. For them, cholecystectomy was the only reliable cure for gallstones and any treatment that kept the gallbladder attached to the patient would result in stone recurrence. At the same time, many surgeons acknowledged that non-surgical treatments had a place in gallstone management. Rather than an intraprofessional turf war over gallstone treatment, the tensions that Zetka identifies were over the right to use gastrointestinal endoscopy, as he also suggests.

This chapter presents the therapeutic landscape in which laparoscopic cholecystectomy emerged as a treatment for gallstones in the late 1980s and early 1990s. It begins with a brief history of gallbladder surgery in the nineteenth century and then discusses the medical discourse on bile acid dissolution therapy and endoscopic sphincterotomy amongst gastroenterologists and general surgeons. Lastly, it discusses the tensions that did exist between the specialty groups over access to endoscopy training and facilities.

Re-Framing Cholelithiasis As A Surgical Disease

In his 1757 *Treatise on Biliary Concretions: Or, Stones in the Gall-bladder and Ducts,* Thomas Coe wrote, "The indications of cure are, to dislodge and expel the calculi, when it can be done; to relieve the symptoms in the mean while; to alter and amend the habit of body, so as to remove the disposition to breed more; and, when they cannot be expelled, to palliate the case and prevent the consequences as much as may be."[47] In other words, treatments for gallstones aimed to assist the patient in expelling the stones, relieve any pain caused by the stones, and to prevent

[47] Thomas Coe, "Of the Cure of Biliary Concretions," *Biliary Concretions: Or, Stones in the Gall-bladder and Ducts*, London: Printed for D. Wilson and T. Durham, at Plato's Head, in the Strand, 1757, 235-6.

the production of more stones, likely through dietary changes. Expulsion of gallstones was encouraged through the use of emetics and purgatives, and pain was managed with belladonna and opiates.[48] Such treatment was typical of medical thought at the time when physicians' course of action aimed at assisting the body in expelling harmful materials and changing the patient's environment. As surgeons achieved increasing levels of control with the introduction of anaesthesia and antiseptic/aseptic practices, abdominal surgery – which previously referred almost exclusively to ovariotomy – expanded in scope to include procedures for other internal organs such as the stomach, liver, spleen, and of course, the gallbladder. By the early twentieth century, abdominal surgery was considered to be a part of general surgery and no longer included procedures of the female pelvis performed by gynecological specialists.[49]

Carl Langenbuch, Director of the Lazarus Hospital in Berlin, became particularly interested in the gallbladder after witnessing the painful death of a hospital administrator suffering from chronic cholelithiasis.[50] While Langenbuch believed that it was the gallbladder that was the object of disease, other surgeons who had also become interested in the topic focused on the gallstones. In particular, John Stough Bobbs, Marion Sims, Theodor Kocher, and Lawson Tait, developed techniques that left the gallbladder *in situ* and either removed stones directly (cholecysto-TOMY) or enhanced the gallbladder's drainage with the construction of a fistula/stoma (cholecysto-STOMY).[51] To Langenbuch this was not sufficient, arguing that "these

[48] John M. Beal, "Historical Perspective of Gallstone Disease," *Surgery, Gynecology & Obstetrics* 138 (1984): 184.
[49] For a detailed account of the re-orientation of abdominal surgery, see Sally Frampton, "Opening the Abdomen: The Expansion of Surgery," in *The Palgrave Handbook of the History of Surgery* ed. Thomas Schlich, (Basingstoke: Palgrave Macmillan, 2018), 175-194.
[50] Carl Langenbuch, "Ein Fall von Exstirpation der Gallenblase wegen chronischer Cholelithiasis. Heilung," *Berliner Klinische Wochenschrift* 19 (1882): 725-7, translated by Helmut V. Ammon and Alan F. Hofman as "Successful Treatment of Chronic Cholelithiasis by Cholecystectomy: A Case Report," *Gastroenterology* 85 (1983): 1430-3.
[51] For more on these developments, see L. William Traverso, "Carl Langenbuch and the First Cholecystectomy," *American Journal of Surgery* 132 (1976): 81-82; Kenneth J. Hardy, "Carl Langenbuch and the Lazarus Hospital:

approaches treat only the end result of the disease and do not eliminate the underlying disease itself."[52] Noting that elephants and horses do not have gallbladders, and that the organ has been observed to be congenitally absent in man, he reasoned, "Physiologically, therefore, there is no a priori objection to the removal of the gallbladder."[53] After experimenting on cadavers to develop his technique, Langenbuch performed the first cholecyst-ECTOMY to remove a patient's gallbladder in July 1882.[54] Four months later, the patient – who had previously required increasing doses of morphine – "stated that he was completely relieved of his painful ailment of many years and of any desire for morphine."[55] Its successful outcome, along with three additional cases, were presented to the Congress of the German Surgical Society the following year.[56]

In response to Langenbuch's approach, the highly regarded British surgeon Lawson Tait – a fierce proponent of enhancing the gallbladder's drainage through a cholecystostomy – argued that it was wrong to remove a healthy organ. As he asserted in the *British Medical Journal*, "Langenbuch's proposal to remove the gallbladder…is intrinsically absurd, for there can be no reason for removing any bladder merely because it has some stones in it."[57] According to Tait, it was difficult to ensure that there were no remaining stones in the common bile duct after a procedure and any stone that remained after removing the gallbladder would continue to block the flow of bile from the liver to the small intestine. The blockage would then cause pressure to

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Events and Circumstances Surrounding the First Cholecystectomy," *Australian and New Zealand Journal of Surgery* 63 (1993): 58; Lawson Tait, "Note on Cholecystectomy," *British Medical Journal* 1218 (1884): 853.

[52] Langenbuch, "Cholecystectomy," 1431.

[53] Langenbuch, "Cholecystectomy," 1431. As Lisa Haushofer has shown in an unpublished paper, similar issues regarding the dispensability of the spleen and the therapeutic utility of the procedure were addressed in arguments over whether splenectomies were justifiable: "Addition by Subtraction – Surgery, Experimental Physiology and the removal of the Spleen in Nineteenth-Century Germany," (working paper, Harvard University, 2013).

[54] Langenbuch, "Cholecystectomy," 1431-2.

[55] Langenbuch, "Cholecystectomy," 1433.

[56] Hardy, "Carl Langenbuch," 60-61.

[57] Tait, "Note on Cholecystostomy," 853.

build up in the duct, opening the stitches, and allow bile to flow into the abdominal cavity.[58] But as Langenbuch reasoned, surgical gallbladder drainage was "at least as dangerous as cholecystectomy because of the required laparotomy and even more dangerous because of the manipulation of the gallbladder…in most cases the ailment is not definitely cured because…of new stone formation…"[59] Despite some initial controversy, cholecystectomy (gallbladder removal) was eventually seen as the superior treatment.[60]

Gallstone or gallbladder, the increasing use of the scalpel to address cholelithiasis, meant that it was being transformed from a medical to a surgical disease. There is at least one indication that this transformation was not without opposition. According to a surgical history of Carl Langenbuch and the first cholecystectomy published in the *Australian and New Zealand Journal of Surgery*, internists "described the operation of cholecystectomy as 'merely the mutilation of a patient to get rid of morphine dependency'" and were "considerably angered at the interference by surgeons in what they considered their territory."[61] Unfortunately, there are no citations for this claim. There is little evidence in the medical literature on gallstones or gallbladder surgery that physicians were concerned with surgeons encroaching on their therapeutic territory. According to the *British Medical Journal*, "The indications for biliary operations in general are acute or persistent symptoms and signs of cholelithiasis unrelieved by medical treatment," which the editors acknowledged, "Of these none are very satisfactory…"[62] The famous Johns Hopkins physician, William Osler, similarly commented, "The remarkable success which has recently been obtained by surgeons, indicates clearly the line of treatment which should be followed…Of

[58] Tait, "Note on Cholecystectomy," 853.
[59] Langenbuch, "Cholecystectomy," 1433.
[60] For similar discussions about the therapeutic utility of appendectomy and splenectomy see Dale C. Smith, "Appendicitis, Appendectomy, and the Surgeon," *Bulletin of the History of Medicine* 70 (1996): 414-41; and Haushofer, "Addition by Subtraction."
[61] Hardy, "Langenbuch," 61.
[62] "The Surgery of the Gall Bladder," *British Medical Journal* 1785 (1895): 602-3, 603.

medicinal agents I have not found any of the slightest value, either in preventing the onset of the paroxysm or causing the solution or propulsion of the stones."[63] Still, early proponents of surgical approaches to cholelithiasis advised careful contemplation when considering surgical solutions. In a report comparing the outcomes of a cholecystotomy case and a cholecystectomy case, one surgeon wrote:

> I do not wish it understood that surgical interference is necessary in all cases of gall-stones; it is only required…[in] dangerous conditions which internal medicine is unable to avert, and which, as a rule, without surgical aid, will sooner or later cause the death of the patient.[64]

Langenbuch himself asserted in his report of the first cholecystectomy in the *Berliner Klinische Wochenschrift*, "In my opinion, cholecystectomy is at the moment suitable only for those cases in which the patient and physician have reached the end of their patience. It is only a last resort…"[65]

Further, the professional boundaries between surgery and internal medicine were in flux during this period. Though specialization was increasing towards the end of the nineteenth century, much of the medical profession included general practitioners who also performed surgical procedures.[66] As Dale Smith notes in his study of appendectomy in the United States,

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[63] William Osler, "On the Symptoms of Chronic Obstruction of the Common Bile Duct by Gallstones," *Annals of Surgery* 11 (1890): 161-85, 185. As Dale Smith demonstrates in his study of appendectomy, Osler was also in favour of early surgery in the treatment of appendicitis. See Smith, "Appendicitis," 423.
[64] Justus Ohage, "The Surgical Treatment of Diseases of the Gall-Bladder," *The Medical News* 50 (1887): 203.
[65] Langenbuch, "Cholecystectomy," 1433.
[66] For more on specialization, see George Weisz, *Divide and Conquer: A Comparative History of Medical Specialization* (New York: Oxford University Press, 2006); Peter Kernahan, "Surgery Becomes a Specialty: Professional Boundaries and Surgery," *The Palgrave Handbook of the History of Surgery*, ed. Thomas Schlich (London: Palgrave Macmillan, 2018), 95-114.

very few could make a living as a full-time surgeon at the turn of the century.[67] Many who claimed to be surgeons, in fact belonged to a "large mass of general practitioners, some of whom did some surgical procedures on some patients some of the time."[68] Similarly in Britain, general practitioners often supplemented their medical training with surgical degrees.[69] In such a professional context, there was no need for jurisdictional disputes over whether patients should be treated medically or surgically.

Non-Surgical Alternatives to Cholecystectomy

By the 1920s, cholecystectomy was seen as the standard treatment for cholelithiasis and remained largely unchanged as a surgical procedure for most of the twentieth century.[70] In his Presidential Address before the Ramsey County Medical Society, sixty years after his father introduced Langenbuch's technique to the United States, Justus Ohage reflected, "It is interesting also to note that cholecystectomy has been a fairly stable operation. Except for general improvements in operative technique…we are doing it today in much the same fashion that it was done by European and American surgeons who first attempted it."[71] Yet despite cholecystectomy's high curative success rate with low morbidity and mortality rates, research into developing less invasive treatments continued. Since post-operative care required a

[67] Smith, "Appendicitis," 418-419.
[68] Smith, "Appendicitis," 418.
[69] George Weisz, "Regulating Specialists in the British Manner," *Divide and Conquer: A Comparative History of Medical Specialization* (New York: Oxford University Press, 2006), 164-181, 167.
[70] A. J. Harding Rains, "A thought for Carl Langenbuch (1846-1901): a centenary," *Annals of the Royal College of Surgeons of England* 64 (1982): 269; Charles K. McSherry, "Cholecystectomy: The Gold Standard," *The American Journal of Surgery* 158 (1989): 174-8; Uptal De, "Evolution of cholecystectomy: A tribute to Carl August Langenbuch," *Indian Journal of Surgery* 66 (2003): 98.
[71] Justus Ohage, "Cholecystectomy: Its Origin and Present Status," *Minnesota Medicine* 29 (1946): 313.

minimum of 3-6 weeks off work, there was also a major economic incentive for the development of non-surgical methods to treat gallbladder disease.[72]

The post-war era brought major investments in biomedical research, resulting in rapid therapeutic innovation and an unanticipated expansion of the pharmaceutical market that, according to Jeremy Greene, was "popularly termed the 'drug explosion.'"[73] As Zetka argues, much of this research and development occurred in the hopes of the discovery of pharmaceutical treatments for conditions that were previously being treated surgically.[74] For cholelithiasis, the surge in biomedical research resulted in an increased understanding of the biological basis for the disease and the biochemical nature of gallstones. The August 1970 issue of *Gastroenterology* reported that patients suffering from gallstones had decreased levels of bile acid.[75] This observation led the Gastroenterology Unit of the Mayo Clinic to hypothesize that cholesterol gallstones, which make up an estimated 75-85% of those suffered, were the result of insufficient levels of bile acid in the gallbladder to keep cholesterol in solution.[76] The unit, consisting of Rudy Danzinger, Alan Hofmann, Leslie Schoenfield and Jonathan Thistle, believed that cholelithiasis was "a disease of decreased bile acid secretion" and could therefore be remedied with the oral administration of bile acids, such as chenodeoxycholic acid (CDCA).[77] In theory, CDCA would increase the solubility of cholesterol thereby preventing the formation of

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[72] R. Hermon Dowling, "The Goose that Laid the Golden Bile: Gallstone Dissolution in Man with Chenodeoxycholic Acid," *Irish Journal of Medical Science* 0 (1974): 116.
[73] Jeremy A. Greene, "Releasing the Flood Waters – The Development and Promotion of Diuril," *Prescribing by Numbers: Drugs and the Definition of Disease* (Baltimore: The Johns Hopkins University Press, 2006), 23. For discussions of the use of descriptions such as "drug explosion" or "therapeutic revolution" by both historians and historical actors in narratives of medical progress see, Jeremy A. Greene, Flurin Condrau, and Elizabeth Siegel Watkins (eds.), *Therapeutic Revolutions: Pharmaceuticals and Social Change in the Twentieth Century* (Chicago: University of Chicago Press, 2016).
[74] Zetka, "Turf Wars," 122.
[75] Z. R. Vlahcevic et al., "Diminished bile acid pool size in patients with gallstones," *Gastroenterology* 59 (1970): 165-173
[76] Rudy G. Danzinger et al., "Dissolution of cholesterol gallstones with chenodeoxycholic acid," *The New England Journal of Medicine* 286 (1972): 1-8.
[77] Danzinger et al., "Dissolution," 1.

gallstones as well as dissolving existing gallstones. In 1972, the group reported in the *New England Journal of Medicine* that gallstones in six women were seen to either decrease in size or disappear completely after six to 18 months of taking CDCA orally, with no observed toxicity.[78] The results were replicated by Duncan Bell, Brian Whitney and Hermon Dowling in Britain and published later that year in *The Lancet.*[79]

Early reports of the "novel and exciting form of therapy" for cholelithiasis were encouraging and sparked hopeful comments that it would soon replace the need for cholecystectomy.[80] According to an editorial in the *Journal of the American Medical Association (JAMA)*, "The false claim of quacks and faint hope of physicians – the dissolution of gallstones has now crossed the threshold of reality."[81] It was recognized, however, that there were still many important questions about oral bile acid treatment that needed to be answered before it could be offered to patients. As the *JAMA* editorial concluded, "The time may not yet be ripe for surgeons to beat their gallstone scoops into medicine spoons."[82] Still by 1973, enough potential was seen in dissolution therapy to invest in a national cooperative study to evaluate its safety and efficacy.[83] Co-ordinated by Leslie Schoenfield (a member of the original Mayo Clinic research team) and funded by the National Institute of Arthritis, Metabolism, and Digestive Disease, the National Cooperative Gallstone Study began in 1976 and was concluded in 1980.[84] "In the

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[78] Danzinger, "Dissolution," 1-8; The results were also presented at the spring meeting of the British Society of Gastroenterology: R. G. Danzinger et al., "Expansion of Decreased Bile Acid Pool and Dissolution of Gallstones by Chenodeoxycholic Acid," *Gut* 13 (1972): 321.
[79] G. Duncan Bell, Brian Whitney and R. Hermon Dowling, "Gallstone Dissolution in Chenodeoxycholic Acid," *The Lancet* 7789 (1972): 1213-1216.
[80] Kurt J. Isselbacher, "A Medical Treatment for Gallstones?" *The New England Journal of Medicine* 286 (1972): 41; Hugh Gainsborough, "Gallstone Dissolution by Chenodeoxycholic Acid," *The Lancet* 7793 (1973): 42; Johnson L. Thistle, "Cholesterol Gallstone Dissolution: Current Status," *Archives of Surgery* 107 (1973): 832.
[81] S. V., "Dissolution of Gallstones," *Journal of the American Medical Association* 221 (1972): 600.
[82] S. V., "Dissolution," 600.
[83] Thistle, "Cholesterol Gallstone Dissolution," 832.
[84] Leslie J. Schoenfield et al., "Chenodiol (Chenodeoxycholic Acid) for Dissolution of Gallstones: The National Cooperative Gallstone Study," *Annals of Internal Medicine* 95 (1981): 257-282.

meantime," as one commentator wrote, "our surgical colleagues can relax, their treatment of gallstones, although threatened, is not yet outmoded."[85]

Such remarks could be read as an indication that tensions were rising over the jurisdiction of the disease. The economic burden of cholecystectomy as the only treatment for gallstones was certainly used as a justification for the development of medical treatments.[86] However, the discussion over how to treat cholelithiasis was not as clear-cut as surgeons arguing for surgical treatments and internists arguing for medical treatments. In a 1975 editorial published in *JAMA*, for example, one gastroenterologist questioned the wisdom in investing "such a generous allocation of precious research dollars" to study a condition for which "my surgical friends can give my patients an acceptably safe, sure, rapid, and lasting remedy."[87] In contrast, an editorial in the *American Journal of Surgery* claimed,

> For the most part, surgeons around the world have welcomed the recent reports of stone dissolution…and have shown enthusiasm for the promise of a nonsurgical mode of therapy for gallstones…The progress reported to date makes it increasingly likely that a biochemical or nutritional means will be developed that will be effective in preventing or dissolving gallstones in man. Research in these areas should be encouraged and supported.[88]

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[85] Isselbacher, "Medical," 42.
[86] For example, Isselbacher, "Medical," 40; Dowling, "Goose That Laid The Golden Bile," 116; Alan F. Hofmann, "The Medical Treatment of Cholesterol Gallstones: A Major Advance in Preventive Gastroenterology," *American Journal of Medicine* 69 (1980): 4; D. Roy Ferguson, "The Dissolution of Gallstones," *Primary Care* 8 (1981): 266.
[87] William S. Haubrich, "Getting Rid of Gallstones Without Surgery," *Journal of the American Medical Association* 231 (1975): 747-8.
[88] Ronald K. Tompkins, "Comments on Chemotherapy of Cholesterol Cholelithiasis," *American Journal of Surgery* 127 (1974): 501-2.

Though mortality and morbidity rates for cholecystectomy were relatively low, they increased significantly with the age of the patient and any co-existing conditions. As Schoenfield explained, "Medical dissolution might be preferable in candidates who are not suitable for cholecystectomy because of severe heart or pulmonary disease or obesity."[89] Bile acid dissolution research thus had much to do with providing alternatives to surgery, which would ultimately help to improve cholecystectomy's success rates, rather than with replacing the surgical treatment entirely. Some hoped that if the safety and efficacy of CDCA could be shown, oral bile acid therapy would have a role in the treatment of patients for whom surgery was contraindicated or as a prophylactic treatment for patients with gallstones but still had a functioning gallbladder, that is, one that continued to empty and fill.[90]

Although there were some initial concerns about the dissolution treatment's potential for liver toxicity based on animal studies,[91] the British gallstone group (led by Dowling) was quick to dispel fears of hepatotoxicity in humans.[92] However, cases of gallstone recurrence upon cessation of bile acid treatment also began to emerge.[93] A 1975 report in the *British Medical Journal* asserted, "at present the decision to place a patient on CDC[A] therapy is probably a life sentence."[94] Even proponents of CDCA treatment recognized that prolonged reliance on bile

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[89] Leslie J. Schoenfield, "Medical Therapy for Gallstones," *Gastroenterology* 67 (1974): 728.
[90] For example, see Daniel A. Lahana and Leslie J. Schoenfield, "Progress in Medical Therapy of Gallstones," *Surgical Clinics of North America* 53 (1973): 1060-1; Bell, "Gallstone," 1215; Johnson L. Thistle and Alan F. Hofmann, "Efficacy and specificity of chenodeoxycholic acid therapy for dissolving gallstones," *New England Journal of Medicine* 289 (1973): 659.
[91] R. Heywood et al., "Pathological changes in fetal rhesus monkey induced by oral chenodeoxycholic acid," *The Lancet* 302 (1973): 1021-2; "More about Chenodeoxcycholic Acid," *British Medical Journal* 5893(1973): 629.
[92] G. D. Bell et al., "Liver Structure and Function in Cholelithiasis – Effect of Chenodeoxycholic Acid," *Gut* 15 (1974): 165-172; R. Hermon Dowling, H. Y. I. Mok and G. D. Bell, "Chenodeoxycholic acid and the liver," *The Lancet* 7862 (1974): 875-6.
[93] H. Y. I. Mok, G. D. Bell and R. Hermon Dowling, "The Effects of Different Doses of Chenodeoxycholic Acid and of Withdrawing Treatment on Bile Lipid Composition and Liver Function in Patients with Gallstones, *Gut* 15 (1974): 340; Johnson L. Thistle et al., "Prompt return of bile to supersaturated state followed by gallstone recurrence after discontinuance of chenodeoxycholic acid therapy," *Gastroenterology* 66 (1974): 789.
[94] "Progress in Dissolving Gallstones," *British Medical Journal* 1 (1975): 699.

acids to prevent the recurrence of gallstones would be significantly more expensive than surgery.[95] Still, Dowling's group referred to gallstone recurrence as a separate disease entity, "poststone gall stone disease," rather than as a failure of the treatment.[96] Similarly, Hofmann, another member of the original Gastroenterology Unit of the Mayo Clinic, believed that the inability of bile acids to induce complete dissolution of some gallstones was "because they are resistant. They are the problem, not the drug."[97]

The National Cooperative Gallstone Study was published in the *Annals of Internal Medicine* in 1981 – eight years after it was first proposed.[98] This was a multi-center, double-blind, randomized, controlled trial based at the Cedars-Sinai Medical Center of the University of California at Los Angeles School of Medicine.[99] The trial included 916 randomly assigned patients treated at 10 clinical centers across the United States and ran from November, 1976 to August, 1980.[100] Each patient was treated with 750mg/day, 375mg/day or placebo capsules and followed for two years.[101] The study reported that at the higher dose, complete dissolution of gallstones, confirmed by oral cholecystogram, occurred in 13.5% of patients. Partial or complete dissolution was achieved in 40.8% of patients.[102] This was compared to the results of previous, mostly uncontrolled, studies that observed complete dissolution of gallstones in 20% of patients and partial or complete dissolution in 50% of patients treated for up to 2 years. The difference in dissolution rates between the previous studies and the national study was explained by the lack

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[95] G. D. Bell, "Present position concerning gallstone dissolution," *Gut* 15 (1974): 925.
[96] D. C. Ruppin, G. M. Murphy, R. H. Dowling, and the British Gallstone Study Group., "Gall stone disease without gall stones – bile acid and bile lipid metabolism after complete gall stone dissolution," *Gut* 27 (1986): 565.
[97] Hofmann, "Preventive Gastroenterology," 5.
[98] Schoenfield, "Chenodiol," 257-82.
[99] Schoenfield, "Chenodiol," 271; Schoenfield, "Disappearing," 1162.
[100] Schoenfield, "Chenodiol," 274; John M. Lachin et al., "Design and Methodological Considerations in the National Cooperative Gallstone Study: A Multicenter Clinical Trial," *Controlled Clinical Trials 2* (1981): 178-9.
[101] Schoenfield, "Chenodiol," 271.
[102] Schoenfield, "Chenodiol," 257, 275.

of validation of gallstone dissolution in the previous studies.[103] A later study suggested that the original reports of complete dissolution of gallstones by oral administration of CDCA were misleading because the technology used to detect gallstones after medical therapy was not sensitive enough to pick up smaller stones.[104] Clinically significant liver toxicity was only seen to occur in 3% of the high dose group and was reversible.[105] The study concluded that despite the low rate of complete dissolution, CDCA is an "appropriate therapy for dissolution of gallstones in selected patients who are informed of the risks and benefits."[106]

Editorials published in the same issue as the study results were less optimistic. Referring to his previous comment that "our surgical colleagues can relax, their treatment of gallstones, although threatened, is not yet outmoded," the same observer, Kurt Isselbacher, remarked: "The ensuing years and the National Cooperative Study results thus far regretfully have done little to change this conclusion except to add some disillusion about stone dissolution."[107] Isselbacher, a leading gastroenterologist, questioned who the "selected patients" referred to by the study's authors might be. He argued that since the study showed CDCA to have no effect on any eventual need for cholecystectomy, non-intervention rather than preventative treatment was the best course for asymptomatic patients.[108] He further pointed out that the 10% increase in serum cholesterol seen in some patients meant that CDCA was not a suitable alternative for patients with heart disease.[109] More positively, Canadian gastroenterologist Lloyd Sutherland later pointed out that the study provided valuable information about the patient's experience of

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[103] Schoenfield, "Chenodiol," 257.
[104] K. W. Somerville et al., "Gall-stone dissolution and recurrence: are we being misled?" *British Medical Journal* 284(1982): 1295-1297.
[105] Schoenfield, "Chenodiol," 257.
[106] Schoenfield, "Chenodiol," 257.
[107] Kurt J. Isselbacher, "Chenodiol for Gallstones: Dissolution of Disillusion?" *Annals of Internal Medicine* 1981 (95): 379.
[108] Isselbacher, "Disillusion," 378.
[109] Isselbacher, "Disillusion," 378.

gallstones. The lack of complications in the study's control group – patients who were followed for two years without treatment – meant that the presence of gallstones did not necessitate immediate surgery. Further, the study showed that there was a large group of patients who had enough aversion to surgery that they were willing to endure long clinical trials in an attempt to avoid it.[110]

A surgical perspective on the study was given by Charles McSherry, who later advised caution in the "laparoscopic revolution."[111] After comparing CDCA's reported safety and efficacy with that of cholecystectomy, McSherry found that:

> It is tempting to conclude that chemical dissolution will find its proper role in the elderly and poor-surgical-risk patients. Unfortunately, this is not so. These patients have had their calculous disease for long periods, [and] are more prone to have nonfunctioning gallbladders…The inevitable delay in surgery attendant on any ill-advised use of chenodiol will increase the morbidity and mortality rates of biliary tract operations.[112]

Though he concluded, "The importance of the Cooperative Study is in demonstrating that chemical dissolution of gallstones is possible and not that it provides a satisfactory alternative to surgery," he also encouraged the development of new compounds with better efficacy and less toxicity.[113] Other optimistic views of the study explained its "pitiful" results as being due to the

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[110] Lloyd R. Sutherland, "Medical dissolution of gallstones: an illusion?" *Canadian Medical Association Journal* 129 (1983): 232.
[111] Charles K. McSherry, "The National Cooperative Gallstone Study Report – A Surgeon's Perspective," *Annals of Internal Medicine* 95 (1981): 379-80.
[112] McSherry, "Perspective," 380.
[113] McSherry, "Perspective," 380.

inadequate dosage used in the study.[114] As one observer explained, "The honeymoon is over for medical dissolution of gall stones, but there is no reason to ask for a divorce just because the marriage is settling down to a more commonplace level."[115]

Research in the chemical dissolution of gallstones continued. Hope for a medical treatment of gallstones had been renewed in 1977 with the report from a Japanese research group that ursodeoxycholic acid (USDA), an epimer and metabolite of CDCA, was capable of inducing gallstone dissolution at lower doses.[116] A double-blind randomized controlled study of USDA later showed that it did have a higher, but still disappointing, efficacy rate of 28.4%.[117] Other chemicals to dissolve gallstones such as terpenes, methyl tert-butyl ether (MTBE) and Rowachol, a proprietary preparation of six cyclic monoterpenes in olive oil, were also considered, as well as various combinations of the available solvents.[118] Exploring ways to enhance dissolution through fragmentation, some researchers found inspiration in the successful use of extracorporeal shockwave lithotripsy to break up kidney stones. In 1986, a German group at Ludwig-Maximilian-University's Grosshadern Medical Center in Munich, reported their successful treatment of gallstones with lithotripsy prior to the oral administration of a CDCA/UDCA

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[114] M. C. Bateson, "Dissolving gall stones," *British Medicine Journal* 284 (1982): 2; Robert H. Palmer and Martin C. Carey, "An Optimistic View of the National Cooperative Gallstone Study," *The New England Journal of Medicine* 306 (1982): 1171-2; W. R. Ellis et al., "Pilot study of combination treatment for gall stones with medium dose chenodeoxycholic acid and a terpene preparation," *British Medical Journal* 289 (1984): 153; Alan F. Hofmann, "Medical Treatment of Cholesterol Gallstones by Bile Desaturating Agents," *Hepatology* 4 (1984): 199-208, 200.
[115] Bateson, "Dissolving," 2.
[116] Gerald Salen et al., "Increased Formation of Ursodeoxycholic Acid in Patients Treated with Chenodeoxycholic Acid," *The Journal of Clinical Investigation* 53 (1974): 612; Shoichi Nakagawa et al., "Dissolution of Cholesterol Gallstones by Ursodeoxycholic Acid," *The Lancet* 8034 (1977): 367-369.
[117] S. Erlinger et al., "Franco-Belgian cooperative study of ursodeoxycholic acid in the medical dissolution of gallstones: a double-blind, randomized, dose-response study, and comparison with chenodeoxycholic acid," *Hepatology* 4 (1984): 308-14.
[118] Mark J. Allen et al., "Rapid Dissolution of Gallstones by Methyl Tert-Butyl Ether," *Medical Intelligence* 312 (1985): 217-20; J. Doran, M. R. B. Keighley and G. D. Bell, "Rowachol – a possible treatment for cholesterol gallstones," *Gut* 20 (1979): 312-7; Ian A. D. Bouchier, "Non-surgical treatment of gall stones: many contenders but who will win the crown?" *Gut* 29 (1988): 137-42, 138; Ellis, "Pilot," 153-6.

mixture to allow for increased surface area contact with the acid.[119] The group reported two years later that this combined treatment achieved complete dissolution of gallstones in an impressive 91% of their first 175 cases.[120]

As with the initial reaction to chemical dissolution therapy, the response to the use of lithotripsy was enthusiastic and full of hope.[121] According to the Canadian gastroenterologist Alan Barkun – one of the lead investigators on the first successful clinical trial evaluating laparoscopic cholecystectomy – towards the end of the 1980s, "There was a huge amount of enthusiasm for gallbladder stone lithotripsy…people jumped on the bandwagon at that time. It was like a one-way train going to the lithotripsy, no question about that."[122] Although the success rate of lithotripsy therapy was impressive, the issue remained that gallstone dissolution did not cure the patient of cholelithiasis and was therefore limited by a high recurrence rate.[123] Still, Barkun speculated that a life-long sentence of bile acid treatment would be acceptable to patients since "people are [already] taking pills long-term. We have tons of examples where people take pills for life, as opposed to having a one-shot deal and then you're treated and that's it…So it's acceptable and I think accepted in the medical field that sometimes…you have high blood pressure [and are treated] for life."[124] In Barkun's opinion, "had laparoscopic [cholecystectomy] not hit the scene, we would all be doing gall bladder stone lithotripsy today, even with the high recurrence rate…"[125]

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[119] Tilman Sauerbruch et al., "Fragmentation of Gallstones by Extracorporeal Shockwaves," *The New England Journal of Medicine* 314 (1986): 818-22.
[120] Michael Sackmann et al., "Shock-wave Lithotripsy of Gallbladder Stones: The First 175 Patients," *The New England Journal of Medicine* 318 (1988): 393.
[121] Jeffrey B. Raskin, "The continuing direct assault on the gallstone: enlightening, electrifying, and shocking," *Gastrointestinal Endoscopy* 33 (1987): 263.
[122] Alan Barkun, interview by Thomas Schlich and Cynthia L. Tang, Montréal, Canada, January 12, 2015.
[123] Raskin, "Assault," 263. Henk Vergunst et al., "Extracorporeal Shockwave Lithotripsy of Gallstones: Possibilities and Limitations," *Annals of Surgery* 210 (1989): 565.
[124] Alan Barkun, interview.
[125] Alan Barkun, interview.

Although there were again comments about surgeons feeling threatened by the emergence of less invasive gallstone treatments,[126] in reality many were active participants in the efforts to incorporate lithotripsy into biliary care.[127] The Grosshadern research group, for example, advocated an interdisciplinary approach to gallstones.[128] They predicted that surgery would remain the preferred treatment for patients with more than three stones, stones larger than 30mm in diameter, calcified stones, or a nonfunctioning gallbladder. The emergence of less invasive treatments such as lithotripsy, with or without adjuvant bile acid therapy, or endoscopic sphincterotomy (discussed in the next section), would likely only change the role of surgery for patients who had less than three smaller stones, and/or a functioning gallbladder. Other groups, for example at the University of British Columbia, also began to report that they were bringing together radiologists, surgeons, and gastroenterologists in order to implement a "team approach to the treatment of gallstone disease."[129] Of course, it was recognized that cholecystectomy was still the best option for patients without complications and that lithotripsy would be "most valuable for elderly patients, those with other diseases that make operation particularly risky and those with a few stones in a normal gallbladder."[130]

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[126] See, for example, Neil A. Collier, "Gallstones – Surgery Solvents or Shockwaves," *Australian and New Zealand Journal of Surgery* 57 (1987): 889-90; Frank G. Moody et al., "Lithotripsy for Bile Duct Stones," *American Journal of Surgery* 158 (1989): 245.

[127] See, for example, Michael Sackmann et al., "Biliary stones: treatment by shock-wave lithotripsy," *Surgical Endoscopy* 2 (1988): 224-6; Anthony G. Speer et al., "Extracorporeal shock-wave lithotripsy and the management of common bile-duct calculi," *Medical Journal of Australia* 148 (1988): 590-5; Mark C. Taylor et al., "Extracorporeal Shock Wave Lithotripsy (ESWL) in the Management of Complex Biliary Tract Stone Disease," *Annals of Surgery* 208 (1988): 586-92; Moody, "Lithotripsy for Bile Duct Stones," 241-7; J. Perissat, D.R. Collet, and R. Belliard, "Gallstones: Laparoscopic Treatment, Intracorporeal Lithotripsy Followed by Cholecystostomy or Cholecystectomy – A Personal Technique," *Endoscopy* 21 (1989): 373-4; Reinhard K. Teichmann, "Surgical Intervention following Fragmentation of Gallstones by Extracorporeal Shockwaves," *World Journal of Surgery* 13 (1989): 317-20.

[128] Georg Heberer et al., "A Retrospective Analysis of 3 Years' Experience of an Interdisciplinary Approach to Gallstone Disease Including Shock-waves," *Annals of Surgery* 208 (1988): 274-7.

[129] H. Joachim Burhenne, "The Promise of Extracorporeal Shock-Wave Lithotripsy for the Treatment of Gallstones," *American Journal of Radiology* 149 (1987): 234.

[130] Alan G. Johnson, "Extracorporeal shock wave lithotripsy for gallstones," *Journal of the Royal Society of Medicine* 83 (1990): 66.

Endoscopic Management of Gallstones

In addition to fragmentation and chemical dissolution, gastroenterologists made forays into the use of endoscopic techniques to treat gallstones, as well as other hepatobiliary and gastrointestinal conditions. Improvements in fiberoptic and endoscopic technology in the 1950s and 60s helped to enhance gastroenterology's diagnostic capabilities by providing greater access to the gastrointestinal tract through the esophagus. Whereas previous gastroscopes could only be used to examine the stomach, the introduction of the flexible fiberscope in 1961 meant that internal examinations could now be extended further into the duodenum.[131] Instrument manufacturers quickly developed and released newer fiberscopes that were easier to control and included additional capabilities. Towards the end of the 1960s endoscopes were thinner and had a second channel through which instruments could be passed. This allowed endoscopists to procure photographic documentation and perform biopsies and direct cytology.[132] The initial applications of the enhanced instruments were limited to diagnostic procedures such as locating the source of gastrointestinal bleeding, establishing or confirming the presence of hepatobiliary disease, and detecting ulcers and cancerous lesions.[133] Zetka argues that this limitation in therapeutic utility led to gastroenterologists being quicker in embracing endoscopic techniques than their surgical colleagues because the division of labour between the two specialties is such that the surgeon treats the patient only after the internist provides the diagnosis.[134]

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[131] Basil I. Hirschowitz, "A Personal History of the Fiberscope," *Gastroenterology* 76 (1979): 868; Basil I. Hirschowitz, "Endoscopic Examination of the Stomach and Duodenal Cap with the Fiberscope, *The Lancet* 277 (1951): 1074-78.
[132] John F. Morrissey, "Gastrointestinal Endoscopy," *Gastroenterology* 62 (1972): 1241-68.
[133] For example as described by Alan R. Aronson and Gerald W. Parker, "Peritoneoscopy: Its Value as a Diagnostic Aid," *American Journal of Digestive Diseases* 1960 (5) 931-934; Hubert M. Allen et al., "Gastroduodenal Endoscopy: Management of Acute Upper Gastrointestinal Hemorrhage," *Archives of Surgery* 106 (1973): 450-455; George Berci et al., "The Evaluation of A New Peritoneoscope As a Diagnostic Aid to the Surgeon," *Annals of Surgery* 178 (1973): 37-44.
[134] James R. Zetka, "Gastroenterologists Embrace the Scope," *Surgeons and the Scope* (Ithaca: Cornell University Press, 2003), 80-97, 84.

This delineation in occupational roles, however, is not so clear-cut. A significant portion of a general surgeon's practice during the 1960s and 70s was to perform exploratory laparotomies to aid in diagnosis. While surgeons did not seem to have much interest in peroral endoscopy, there were some who believed that rigid endoscopes could be useful tools for intra-abdominal exploration.[135] The choledochoscope, for example, was promoted to help locate gallstones in the biliary tract during a gallbladder removal, in order to prevent the need for additional surgical procedures.[136] Some surgeons also advocated the use of peritoneoscopy (an earlier term for laparoscopy that was used by general surgeons) to explore the peritoneal cavity as an alternative to exploratory laparotomy.[137] Despite efforts to convince their surgical colleagues that peritoneoscopy would reduce the risks of morbidity and mortality for patients, the procedure was not widely accepted.[138] As one professor of surgery speculated, the surgeon "is usually impatient, and he may feel that a diagnosis is unsatisfactory when he cannot introduce his hands in the abdominal cavity to palpate diseased organs."[139] For Jacques Périssat, one of the early adopters of laparoscopic cholecystectomy, his interest in endoscopic techniques during the 1960s was eventually displaced by the adoption of other visualization technology such as CT scanning.[140] Still, gastroenterologists and general surgeons alike extolled the benefits of endoscopy and attempted to convince their colleagues to adopt the technique for various

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[135] Edward B. Benedict, "Esophagoscopy, Gastroscopy, and Peritoneoscopy," *Progress in Gastroenterology* 42(1962): 171-4.
[136] J. Manny Shore and Harvey N. Lippman, "A Flexible Choledochoscope," *The Lancet* 285 (1965): 1200-1; J. Manny Shore et al., "The Value of Biliary Endoscopy," *Surgery, Gynecology & Obstetrics* 140 (1975): 601-4.
[137] Peritoneoscopy was the term used by surgeons before of laparoscopy was adopted as the preferred term. See Michael Reilly, "Laparoscopy or Peritoneoscopy?" *British Medical Journal* 5872 (1973): 176.
[138] Ivan D. A. Johnston and H.W. Rodgers, "Peritoneoscopy as an aid to diagnosis," *Gut* 5 (1964): 485-7; Berci et al., "Evaluation of A New Peritoneoscope," 37-44.
[139] Rodolfo Herrera-Llerandi, "Peritoneoscopy: Endoscopic Refinement Par Excellence," *British Medical Journal* 5253 (1961): 661-5.
[140] Jacques Périssat, interview by Cynthia L. Tang, Bordeaux, France, November 9, 2017; For more on "modern imaging technology" such as ultrasound, CT scanning, and PET scanning, see Stuart Blume, *Insight and Industry: On the Dynamics of Technological Change in Medicine*, Cambridge: MIT Press, 1991.

applications. Though surgical proponents of endoscopy failed to generate widespread acceptance of the technique as an aid in surgery, the use of gastroscopy, esophagoscopy, and duodenoscopy in North American gastroenterology rose steadily throughout the late 1960s and early 1970s.

As endoscopes with instrument channels became more widely used and endoscopists continued to develop their skills in flexible endoscopy, the repertoire of possible endoscopic procedures broadened to include therapeutic applications. Clinical experiences with interventional procedures through the endoscope, such as electrosurgical control of gastric bleeding and polypectomy, were increasingly reported in the medical literature throughout the 1970s.[141] The therapeutic application of endoscopy quickly expanded into the biliary system. By 1974, a Japanese research group at the Kyoto Prefectural University of Medicine began to report their use of endoscopic sphincterotomy through the esophagus to remove gallstones from the common bile duct.[142] Also briefly referred to as endoscopic/duodenoscopic papillotomy, the technique was a modification of the established endoscopic polypectomy and provided a nonsurgical alternative to choledochotomy – the removal of gallstones from the common bile duct. It is important to emphasize, however, that endoscopic sphincterotomy is limited in its capacity to treat cholelithiasis if more stones are present in the gallbladder.

Surgeons and internists alike recognized that the predominant justification for the experimental use of endoscopic sphincterotomy in the early years was its potential to be a safer alternative for gallstone removal from the common bile duct of high-risk patients.[143] Much of the

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[141] For example, K. Tsuneoka and T. Uchida, "Fibergastroscopic polypectomy with snare method and its significance developed in our department – polyp resection and recover instruments, *Gastroenterological Endoscopy* 11 (1969): 174-81; C. Roger Youmans, "Cystoscopic Control of Gastric Hemorrhage," *Archives of Surgery* 100 (1970): 721-3; William D. Blackwood and Stephen E. Silvis, "Gastroscopic Electrosurgery," *Gastroenterology* 61 (1971): 305-14.

[142] K. Kawai et al., "Endoscopic sphincterotomy of the ampulla of Vater," *Gastrointestinal Endoscopy* 20 (1974): 148-51.

[143] For example, see Kawai, "Endoscopic," 151; P.B. Cotton et al., "Duodenoscopic papillotomy and gallstone removal," *British Journal of Surgery* 63 (1976): 709-14, 713; H. Koch et al., "Endoscopic Papillotomy,"

medical literature advocating for endoscopic sphincterotomy as a therapeutic option was in fact authored by surgeons,[144] as well as by interdisciplinary teams of surgeons and internists.[145] A closer reading of this literature indicates that the interest in the technique was largely aimed towards lowering the risk of biliary tract interventions. Though the mortality rate for surgical common bile duct stone removal could be as low as 1.1%,[146] it could increase to as high as 12.3%[147] with the patient's age and/or presence of co-morbidities (for example, cardiovascular/respiratory/renal disease, diabetes, obesity).[148] Comparatively, the mortality rate for endoscopic sphincterotomy in a higher-risk patient group was reported to be as low as 1.2%, validating its use.[149]

Gastroenterology 73 (1977): 1393-6, 1395; Cl. Liguory and P. Loriga, "Endoscopic Sphincterotomy: Analysis of 155 Cases," *American Journal of Surgery* 136 (1978): 609-13, 609; J. E. Geenan, "Endoscopic sphincterotomy," *Gastrointestinal Endoscopy* 24 (1978): 301-2, 301; Murry G. Fischer and Charles K. McSherry, "Endoscopic Papillotomy: A Plea for Rational Restraint," *Archives of Surgery* 114 (1979): 991-2, 991; Peter B. Cotton, "Non-operative removal of bile duct stones by duodenoscopic sphincterotomy," *British Journal of Surgery* 67 (1980): 1-5, 1; Janice Park et al., "Acute Pancreatitis in Elderly Patients," *American Journal of Surgery* 152 (1986): 638-42; 641.

[144] See, for example, Laszlo Safrany, "Duodenoscopic sphincterotomy and gallstone removal," *Gastroenterology* 72 (1977): 338-43; S. van der Spuy, "Endoscopic Sphincterotomy in the Management of Gallstone Pancreatitis," *Endoscopy* 13 (1981): 25-6; Giovanni Viceconte et al., "Endoscopic sphincterotomy: indications and results," *British Journal of Surgery* 68 (1981): 376-80; Rudolph A. Weltemeyer, "Endoscopic Sphincterotomy: A Procedure of Choice in the Management of Retained Common Bile Duct Stones and Papillary Stenosis," *American Journal of Surgery* 143 (1982): 536-9; J. P. Neoptolemos et al., "The management of common bile duct calculi by endoscopic sphincterotomy in patients with gallbladders *in situ*," *British Journal of Surgery* 71 (1984): 69-71; Jan Helge Solhaug et al., "Endoscopic Papillotomy in Patients with Gallbladder in situ: Is Subsequent Cholecystectomy Necessary?" *Acta Chirurgica Scandinavica* 150 (1984): 475-8.

[145] See, for example, M. Classen and L. Safrany, "Endoscopic papillotomy and removal of gall stones," *British Medical Journal* 4 (1975) 371-374; Cotton, "Duodenoscopic papillotomy," 709-14; M. Slooff et al., "What is involved in endoscopic sphincterotomy for gallstones?" *British Journal of Surgery* 67 (1980): 18-21; Joseph A. Caprini, "Results of Nonsurgical Treatment of Retained Biliary Calculi," *Surgery, gynecology &obstetrics* 151 (1980): 630-4; Bruce Allen et al., "Management of Recurrent and Residual Common Duct Stones," *American Journal of Surgery* 142 (1981): 41-7; Robert J. Mazzeo et al., "Endoscopic Papillotomy for Recurrent Common Bile Duct Stones and Papillary Stenosis," *Archives of Surgery* 118 (1983): 693-5; A. R. Askew et al., "Endoscopic Sphincterotomy For Common Duct Calculi," *Australian and New Zealand Journal of Surgery* 54 (1984): 457-9; T. A. Broughan et al., "The management of retained and recurrent bile duct stones," *Surgery* 98 (1985): 746-51; John P. Neoptolemos, "A Prospective Study of ERCP and Endoscopic Sphincterotomy in the Diagnosis and Treatment of Gallstone Acute Pancreatitis," *Archives of Surgery* 121 (1986): 697-702; J. H. Siegel et al., "Duodenoscopic Sphincterotomy in Patients with Gallbladders *in Situ*: Report of a Series of 1272 Patients," *American Journal of Gastroenterology* 83 (1988): 1255-8.

[146] Safrany, "Duodenoscopic," 338.

[147] Geenen, "Endoscopic," 301.

[148] Liguory and Loriga, "Endoscopic Sphincterotomy," 609.

[149] Safrany, "Duodenoscopic," 338. See also, Laszlo Safrany, "Endoscopic Treatment of Biliary-Tract Diseases: An International Study," *Lancet* 312 (1978): 983-5, 985.

For some surgeons, the availability of the endoscopic alternative was in fact favorable. According to gastroenterologist and professor of endoscopy at the University of Münster, Laszlo Safrany, the recruitment of patients for his 1977 study relied heavily on referrals from surgeons. In his experience, "There have been no controversies with surgeons in Germany and we find that surgeons are most grateful for the handling of difficult cases" through endoscopy.[150] Surgical interest in the endoscopic management of common duct stones was similarly noted in the *British Journal of Surgery*: "It is important to recognize that in most large series patients have been referred for endoscopic sphincterotomy by surgeons who have considered them unsuitable for operation."[151] Even in the United States, where surgeons were somewhat less enthusiastic about the incorporation of the procedure into biliary care,[152] one gastroenterologist commented at the 1981 meeting of the Pacific Coast Surgical Association, "This is strange territory for an internist to invade…and I am delighted to see that no one was terribly vehement about defending his territory, namely the surgical treatment of retained or recurrent common duct stones."[153]

The beneficial effects of the technique on surgical practice were evident. High-risk cholecystectomised patients could be diverted from having a second surgery to remove retained bile duct stones, thereby lowering the overall morbidity/mortality rates of common bile duct surgery. For high-risk patients who still had their gallbladders *in situ*, some surgeons believed that pre-operative endoscopic sphincterotomy to clear the common bile duct made any

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[150] Laszlo Safrany, "Reply of the author," in response to Michael O. Blackstone, "Duodenoscopic Sphincterotomy and Gallstone Removal," *Gastroenterology* 72 (1977): 1368-9, 1369.
[151] D. F. Martin and D. E. F. Tweedle, "Endoscopic management of common duct stones without cholecystectomy," *British Journal of Surgery* 74 (1987): 209-11, 210.
[152] Though not explicitly stated, Zetka's analysis of endoscopy is focused on its adoption in the United States. In fairness, the majority of endoscopic sphincterotomy studies published by/with surgeons were authored by research groups based outside of the United States.
[153] Allen, "Management," 47.

subsequent cholecystectomy easier and safer to perform.[154] As one surgical group explained, "The advantages of [endoscopic sphincterotomy] before the cholecystectomy…are reduction in the duration of operation, its simplification especially when there are inflammatory phenomena, avoidance of perioperative cholangiography, and especially avoidance of the need to open the [common bile duct] and drain it externally or internally."[155] It was reported that in some elderly patients, cholecystectomy could even be postponed indefinitely after a successful endoscopic sphincterotomy.[156]

Though in the early years the non-surgical approach to common bile duct stones was only believed to be justifiable for use in high-risk patients, by the 1980s it was suggested to also be appropriate for some low-risk patients.[157] According to British gastroenterologist Peter Cotton, "The role of endoscopic treatment in the young and fit has yet to be established, but many such patients are now being referred, usually by surgeons."[158] The possibility of an endoscopic recourse also meant that surgeons did not have to take on the additional risks of intraoperative bile duct exploration during a cholecystectomy. By the end of the decade, some surgeons believed that they "no longer [needed to] regard the discovery of retained stones with dismay and

[154] See, for example, Liguory and Loriga, "Endoscopic Sphincterotomy," 610; Peter A. Leckie, "Impacted Common Bile Duct Stones," *American Journal of Surgery* 143 (1982): 540-1, 541; Viceconte, "Indications and Results," 379; M. Heinerman et al., "Combined endoscopic and surgical approach to primary gallstone disease, *Surgical Endoscopy* 1 (1987): 195-8, 195.
[155] J. J. Duron et al., "Biliary lithiasis in the over seventy-five age group: a new therapeutic strategy," *British Journal of Surgery* 74 (1987): 848-9, 849.
[156] See, for example, Koch et al., "Endoscopic Papillotomy," 1395; Cotton, "Non-operative removal," 4; T. Leese et al., "Management of acute cholangitis and the impact of endoscopic sphincterotomy," *British Journal of Surgery* 73 (1986): 988-92, 988; G. Olaison et al., "Routine Cholecystectomy after Endoscopic Removal of Common Bile Duct Stones – An Unnecessary Procedure," *Endoscopy* 19 (1987): 88-9; Gunnar Olaison et al., "Endoscopic Removal of Common Bile Duct Stones Without Subsequent Cholecystectomy," *Acta Chirurgica Scandinavica* 153 (1987): 541-3, 541; Kenneth I. Bickerstaff et al., "Endoscopic sphincterotomy for bile duct stones: an institutional review of 272 patients," *Annals of the Royal College of Surgeons of England* 71 (1989): 384-6, 385.
[157] See, for example, J. A. Summerfield et al., "Endoscopic sphincterotomy for bile duct stones," *British Journal of Radiology* 53 (1980): 1041-6, 1041; Allen at al., "Management of Recurrent," 47; Weltemeyer, "Endoscopic Sphincterotomy," 536.
[158] Cotton, "Apples and Oranges," 594.

indeed there may be instances when it is safer to leave stones behind for later endoscopic removal rather than to risk damaging the bile duct by persistent attempts at operative removal."[159] Unlike what we saw in the nineteenth century debate that pitted gallstone removal against gallbladder removal, endoscopic sphincterotomy was not meant to be used in lieu of cholecystectomy, but in conjunction. As Cotton asserted in 1984, "The spectrum of patients referred to surgeons and endoscopists is not the same, nor should it be."[160] Like the proponents for lithotripsy, proponents of endoscopic sphincterotomy also suggested that biliary disease should be treated with a multidisciplinary approach with teams of surgeons, gastroenterologists, and radiologists determining the best treatment plans for individual patients.[161] According to Cotton, "optimal results are obtained only by skilled endoscopists working with assistants well trained in these procedures, in collaboration with specialist surgeons and radiologists…Poorly trained endoscopists working in isolation are less effective and more dangerous."[162]

Turf War Over Endoscopy

Although there was a general consensus that non-surgical treatments had a place in gallstone management, underlying tensions between general surgeons and gastroenterologists did exist over the right to use endoscopy. With the reports of advances in interventional endoscopy came discussions of who should perform these techniques and what kind of training should be required. According to a 1973 editorial in *Surgery, Gynecology & Obstetrics*, the official journal

[159] K. I. Bickerstaff et al., "Endoscopic sphincterotomy," *British Journal of Surgery* 76 (1989): 316.
[160] Cotton, "Apples and Oranges," 587.
[161] J. P. Neoptolemos et al., "Study of common bile duct exploration and endoscopic sphincterotomy in a consecutive series of 438 patients," *British Journal of Surgery* 74 (1987): 916-21, 920; Peter B. Cotton, "Critical Appraisal of Therapeutic Endoscopy in Biliary Tract Diseases," *Annual Review of Medicine* 41 (1990): 211-22, 212; S. H. Lee and H. J. Burhenne, "Gallbladder surgery following cholecystlithotripsy: suggested guidelines for treatment," *British Journal of Surgery* 77 (1990): 1268-71, 1269.
[162] Cotton, "Critical Appraisal," 212.

of the American College of Surgeons, "It is inappropriate for a physician who has not been trained in the surgical disciplines and who cannot perform operative procedures or treat operative complications to undertake therapeutic procedures with these instruments."[163] Walter Gaisford, a fellow of the American College of Surgeons (ACS), believed that "the surgical therapeutic techniques through the fiberscope will best be performed by surgeons educated and trained in endoscopic procedures."[164] In his view, formal training in endoscopy needed to be offered more widely for surgeons but also, not all surgeons needed to learn the technique. Gaisford proposed fostering a new specialty of surgical gastroenterology where "the long range need for skilled surgical endoscopists [would] best be filled by providing formal fellowship or residency training…as an adjunctive part of existing surgical educational programs."[165] Others later agreed that space needed to be created for endoscopy in surgical training, but that it should not be exclusive. Thomas Bombeck, Professor of Surgery at the University of Illinois at Chicago, for example, argued that "The truth of the situation is that fiberoptic endoscopy is, for the most part, not difficult enough and far too valuable to be reserved as a specialty to any one group."[166] On the other hand, Bombeck acknowledged that there were not enough patients requiring interventional endoscopy to allow for or require the routine endoscopic training of surgeons, and was in agreement with Gaisford that "there is no place for the occasional endoscopist."[167] Most general surgeons, however, remained uninterested in taking up endoscopy and its use continued to be dominated by gastroenterologists.

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[163] Thomas L. Dent, "The Surgeon and Fiberoptic Endoscopy," *Surgery, Gynecology & Obstetrics* 137 (1973): 278.
[164] Walter D. Gaisman, "The Surgical Gastroenterologist," *Surgery, Gynecology & Obstetrics* 140 (1975): 86-7, 86.
[165] Gaisman, "The Surgical Gastroenterologist," 86.
[166] C. Thomas Bombeck, "The Surgeon-Endoscopist," *Current Surgery* 35(1978): 223-5, 223.
[167] Bombeck, "Surgeon-Endoscopist," 224.

By 1975, usage was high enough that concerns emerged over the need to regulate new endoscope models as well as the training and accreditation of endoscopists. That year, the American Society for Gastrointestinal Endoscopy (A/S/G/E) published their *Guidelines for Training and Practice*.[168] Adequate training was defined as having performed as primary endoscopist, 100 cases of upper gastrointestinal endoscopy and 50 cases of colonoscopy, under supervision. In addition, trainees were required to participate in 25 cases each of polypectomy, ductular cannulation, and laparoscopy.[169] The A/S/G/E did not have any legal authority to ensure that these guidelines were faithfully met but hoped that their recommendations would assist hospital and training directors in establishing requirements for credentials and privileges.[170] According to a 1979 editorial in the *American Journal of Gastroenterology*, however, Gastroenterology Training program directors had a difficult time in providing the recommended number of cases for each trainee.[171]

This was similarly a problem amongst surgical training directors when the American Board of Surgery recommended that gastrointestinal endoscopy training be included in surgical residency programs in 1980.[172] The results of a survey presented a year later at the Society for Surgery of the Alimentary Tract (SSAT) Annual Meeting showed that only 30% of the responding academic surgical programs provided formal training in gastrointestinal endoscopy, with an additional 29% offering informal training.[173] With the data collected on the nature of the

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[168] B.F. Overholt, "A/S/G/E guidelines for standards of training and practice," *Gastrointestinal Endoscopy* 1975(22): 46-7.
[169] Overholt, "Guidelines," 47.
[170] Overholt, "Guidelines," 46.
[171] Angelo E. Dagradi, "The Training of a Gastrointestinal Endoscopist," *American Journal of Gastroenterology* 71 (1979): 224-8, 226.
[172] James R. Starling and John F. Morrissey, "One Solution to the Dilemma of Endoscopic Requirements for General Surgical Residents," *Surgery, Gynecology & Obstetrics* 155 (1982): 65-6; Martin H. Max and Hiram C. Polk, Jr., "Perceived Needs for Gastrointestinal Endoscopic Training in Surgical Residencies," *American Journal of Surgery* 143 (1982): 150-4.
[173] Max and Polk, "Perceived Needs," 150-4.

available training programs, the authors reported that most university residency programs did not meet the criteria recommended by the Federation of Digestive Disease Societies Standards of Training Guidelines, which were less than half of those recommended by the A/S/G/E.[174] In their survey responses, surgical program directors complained about the difficulties in getting cases for their trainees. One of the reported issues was that the gastroenterological services at their institutions had a monopoly on gastrointestinal endoscopy, and thus not enough cases were seen in the surgical departments. Just over half of respondents expected resistance to the establishment of separate surgical endoscopy services from their colleagues in gastroenterology.

In light of this, the authors made two suggestions: first, rather than providing inadequate training to all residents, there should be a select group of residents with comprehensive training. Second, institutions with cooperative environments should develop interdisciplinary programs to train both surgical and gastroenterology residents. Although there were audience members at the SSAT presentation that reported successful experiences with such integrated programs, there was also an implication that they understood what a rarity this was. Writing in 1982, Thomas Dent, a professor of surgery at the University of Michigan, credited the ten-year existence of the endoscopic training program for surgical residents at his institution to "an enlightened medical gastroenterology group that views endoscopy as only a part of gastroenterology.[175] Surgeons at the University of Wisconsin Clinical Science Center also found it possible to offer a cooperative training program to their residents (beginning in the early 1980s), where select trainees were assigned to the gastroenterology service. Again, it was acknowledged that this was possible "because of the fundamentally sound relationship between [the] general surgery and

[174] Max and Polk, "Perceived Needs," 150-4.
[175] Thomas L. Dent, "Discussion of Martin H. Max and Hiram C. Polk, Jr., "Perceived Needs for Gastrointestinal Endoscopic Training in Surgical Residencies," *American Journal of Surgery* 143 (1982): 152.

gastroenterology [divisions]."[176] In contrast, the Department of Surgery at the University of Missouri reported in 1983 that the combined approach to endoscopic training was not feasible for their institution due to "difficulties in maintaining a common resource endoscopy laboratory."[177] They showed that in those hospitals where "it may be neither desirable nor possible to achieve such a unified teaching program," a separate surgical endoscopy service, which they had established in 1982, could still be possible.[178]

The push to set up training programs in endoscopy for surgical residents also became a matter of concern amongst gastroenterologists. An editorial in the April 1984 issue of the *American Journal of Gastroenterology* asked the question, "Who Said Surgeons Had To Be Trained in Gastrointestinal Endoscopy," sparking a somewhat heated exchange between internists and surgeons.[179] James Achord, President of the American College of Gastroenterology and Director of the Division of Digestive Diseases at the University of Mississippi Medical Center, argued that despite popular belief, the American Board of Surgery did not require surgeons to be trained in gastrointestinal endoscopy in order to achieve certification. According to his personal communication with the Board's chairman, the Board only required surgeons to be *familiar* with endoscopic techniques in the way that they should be familiar with, for example, diagnostic radiology, sonography, and etc.[180] He urged that the misunderstanding of the Board's requirements should not be used to compel Departments of Medicine to take on the responsibility of training surgeons nor as an excuse to push hospital administrators into setting up separate surgical endoscopy programs.

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[176] Starling and Morrissey, "One Solution," 66.
[177] Brian F. Smale et al., "The creation of a surgical endoscopy training program – Is there sufficient clinical material?" *Surgery* 94 (1983): 180-184, 183.
[178] Smale et al., "Sufficient Clinical Material," 183.
[179] James L. Achord, "Who Said Surgeons Had To Be Trained in Gastrointestinal Endoscopy?" *American Journal for Gastroenterology* 79 (1984): 322-23.
[180] Achord, "Who Said Surgeons," 323.

Though Achord asserted that "few if any of us really object to other disciplines taking up these instruments so long as the individual who does so is thoroughly trained,"[181] some surgeons focused more on his opinion that there is little need for surgeons to learn endoscopy. In particular, Achord's colleagues in the University of Mississippi Medical Center's Department of Surgery responded with their own editorial to explain "The Case *for* Surgical Training in Gastrointestinal Endoscopy."[182] In addition to their belief that surgical planning can be better accomplished with direct endoscopic observation by the surgeon instead of "relying on the written or spoken descriptions of a consultant endoscopist," the authors pointed out that smaller community hospitals often did not have a gastroenterology specialist on staff to carry out any endoscopic needs.[183] Possibly in reference to specific conflicts at their institution, Achord's colleagues argued,

> The general surgeon has as legitimate a need for this tool as the gastroenterologist; but because of the attitudes of many gastroenterologists, who tenaciously perceive gastrointestinal endoscopy as an exclusive gastroenterological right the stage is set for wasteful, needless, and unprofessional turf battles that in some cases have overtones of restraint of trade. If the stethoscope were a recent invention, one might wonder whether its use would be so protectively guarded by a group of specialist practitioners. We suspect that it would be if stethoscopy were remunerated to the same extent as endoscopy…the gastroenterology polemic is suspect

[181] Achord, "Who Said Surgeons," 322.
[182] John S. Kukora, Charles P. Clericuzio and Thomas L. Dent, "The Case *for* Surgical Training in Gastrointestinal Endoscopy," *American Journal of Gastroenterology* 79 (1984): 907-9.
[183] Kukora et al., "The Case *for* Surgical Training," 907.

> because of mercenary factors…We only desire that all physicians who have a valid need to perform endoscopic procedures be permitted to learn these procedures under adequate supervision and to practice them without needless interference by protectionist interests.[184]

Similarly defensive readings of Achord's editorial were also made outside of Mississippi. Another editorial published the following year argued,

> …gastroenterologists cannot expect to dictate to the American Board of Surgery that only gastroenterologists shall do gastrointestinal endoscopy. Dr. Achord has forgotten that until about 15 or 20 years ago surgeons were requested by gastroenterologists to carry out virtually all endoscopic polypectomies in the colon and to do most rigid esophagoscopies…[no] surgical organization has ever taken the position that gastroenterologists should not carry out endoscopies, and yet the converse is the posture adopted by Dr. Achord.[185]

In response to both editorials, Achord reiterated his position that "most gastroenterologists (including myself) do not object to surgeons or other physicians doing endoscopy as long as they are well trained."[186]

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[184] Kukora et al., "The Case *for* Surgical Training," 909.
[185] William Silen, "Surgeons and Gastrointestinal Endoscopy," *American Journal of Gastroenterology* 80 (1985): 232.
[186] James L. Achord, "Reply to 'The Case for Surgical Training in Gastrointestinal Endoscopy,'" *American Journal of Gastroenterology* 79 (1984): 909; See also, James L. Achord, "Reply to 'Surgeons and Gastrointestinal Endoscopy,'" *American Journal of Gastroenterology* 80 (1985): 233.

It is difficult to determine how widespread these tensions were or if they only existed at certain institutions in the United States. According to some anecdotal accounts, surgeons who were interested in learning endoscopy often found it difficult to find an expert who was willing to train them.[187] As one surgeon recalls from his residency experience at Case Western University in the mid-1970s, "I signed up [to learn endoscopy with the gastroenterologists]…the week before, I called the gastroenterologists at the university and I said, 'Where do I meet you?' They said, 'There was a mistake. We're not training a surgeon to do this. We don't have a spot for you.'"[188] Instead, he drove three hours each day to work with a gastroenterologist who wanted an endoscopy trainee. According to him, even after participating in approximately 500 endoscopy procedures, the gastroenterologists at Case Western refused to allow him to work in their endoscopy suite.[189]

Though the American Society of Gastrointestinal Endoscopists welcomed surgeons at their meetings, they were not interested in the same problems as the surgeons. Because of this, one group of surgeons who were interested in endoscopy, decided to form the Society of Gastrointestinal Endoscopic Surgeons (SAGES), establishing it in 1981. Still, most surgeons did not become interested in endoscopic technology until it was shown in 1989 that instead of removing the gallbladder through a 3-6 inch open abdominal incision, it was possible to perform the procedure through half-inch incisions in a laparoscopic cholecystectomy. Within the first year of laparoscopic cholecystectomy's emergence in the United States, SAGES' membership rose from approximately 300 to 2000 members.[190] Though Zetka suggests that laparoscopic

[187] Gerald Fried, interview by Thomas Schlich and Cynthia L. Tang, Montreal, Canada, June 13, 2014.
[188] Jeffrey Ponsky, "Jeffrey Ponsky: Portrait of a SAGES Pioneer," (Video presentation, Society of American Gastrointestinal and Endoscopic Surgeons Annual Meeting, Baltimore, MD, April 3-6, 2019).
[189] Ponsky, video.
[190] Ponsky, video.

cholecystectomy was consciously developed as a countermeasure to gastroenterology's "foreboding threats" against general surgery,[191] as we shall see in the next chapter, the emergence of the minimally invasive technique was not a coordinated event and was inspired by other motivations.

[191] Zetka, "Technological Innovation in the Surgical Craft," 137.

Chapter 2: Spaces and Motivations for Medical Innovation

The emergence of laparoscopic cholecystectomy is often given credit for triggering the "laparoscopic revolution" in general surgery and the development of laparoscopic techniques for other abdominal procedures. Its origin story is thus a popular topic for practitioners to comment on in surgical journals and books.[192] According to one such account published in 2008, "The introduction of laparoscopic cholecystectomy represents a historical turning point that is just as momentous as the discovery of anaesthesia, asepsis…[and etc.]"[193] A detailed chronicle of the development of laparoscopic cholecystectomy is also provided in Grzegorz Litynski's book, *Highlights in The History of Laparoscopy*.[194]

The generally accepted narrative of laparoscopic cholecystectomy's development is that it was first performed by Philippe Mouret in Lyon, France in 1987, and then independently in 1988 by two American surgical teams, Barry McKernan and William Saye in Marietta, Georgia, and Eddie Reddick and Douglas Olsen, in Nashville, Tennessee.[195] The first reports of the

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[192] See, for example, Walker Reynolds, Jr., "The First Laparoscopic Cholecystectomy," *Journal of the Society of Laparoendoscopic Surgeons* 5 (2001): 89-94; Nicola Basso, *A Semi Serious History of Laparoscopy* (Rome: Gangemi Editore, 2003; Alexandros Polychronidis et al., "Twenty Years of Laparoscopic Cholecystectomy: Philippe Mouret – March 17, 1987," *Journal of the Society of Laparoendoscopic Surgeons* 12 (2008): 109-11; Leon Morgenstern, "An Unsung Hero of the Laparoscopic Revolution: Eddie Joe Reddick, MD," *Surgical Innovation* 15 (2008): 245-8; Craig A. Blum and David B. Adams, "Who did the first laparoscopic cholecystectomy?" *Journal of Minimal Access Surgery* 7 (2011): 165-8; Gilbert Schlogel, *Philippe Mouret: Une (R)évolution par la coelio-chirurgie* (Montpellier: Sauramps Medical, 2017). David W. Page, The Laparoscopic Surgery Revolution: Finding a Capable Surgeon in a Rapidly Advancing Field (Santa Barbara: Praeger, 2017).

[193] Polychronidis et al., "Twenty Years," 111.

[194] Grzegorz S. Litynski, Highlights in the History of Laparoscopy: The Development of Laparoscopic Techniques – A Cumulative Effort of Internists, Gynecologists, and Surgeons (Frankfurt/Main: Barbara BERNET VERLAG, 1996).

[195] The German surgeon, Erich Mühe, has also been given credit for performing the first laparoscopic cholecystectomy. For more on this see Grzegorz S. Litynski, "Erich Mühe – A Surgeon ahead of his Time. The First Laparoscopic Cholecystectomy," *Highlights in the History of Laparoscopy: The Development of Laparoscopic Techniques – A Cumulative Effort of Internists, Gynecologists, and Surgeons* (Frankfurt/Main: Barbara BERNET VERLAG, 1996), 157-92. Some surgeons, however, dispute that this was really a laparoscopic procedure since Mühe's technique was through a "galloscope" or an "open laparoscope" – instruments of his own design which allowed him to remove the gallbladder using laparoscopic instruments through a larger incision than would typically be used with a laparoscope. In this view, it might be more accurately described as a cholecystectomy performed through a mini-laparotomy, using laparoscopic instruments.

technique in academic medical journals, however, were published by François Dubois, a Professor of Surgery in Paris, France.[196] Though published in highly prestigious journals, these reports were not the trigger for the "explosion of interest" in laparoscopic cholecystectomy.

Instead, laparoscopic cholecystectomy first came to the attention of many American general surgeons via video demonstrations presented in the trade exhibition halls of the April 1989 meeting of the Society of American Gastrointestinal Endoscopic Surgeons[197] and the October 1989 Clinical Congress of the American College of Surgeons. These videos generated much excitement amongst non-academic/community surgeons, who scrambled to learn the technique and offer it to their patients (discussed further in Chapter 4). According to a report in the *Journal of the American Medical Association*, at least 75% of all gallbladder removals in the United States were performed laparoscopically by the end of 1991.[198] The rush to provide laparoscopic cholecystectomy quickly became a cause for concern in the academic surgical community. Editorials and academic societies promptly warned that the use of the technique needed to be reined in so that it could first be thoroughly assessed through peer-reviewed case reports and clinical trials, and so that academic training courses and accreditation guidelines could be instituted.[199]

Laparoscopic cholecystectomy's trajectory starkly contrasts with the common assumption that medical innovation follows a "path of linear development." In this idealized path, research at

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[196] F. Dubois, G. Berthelot, and H. Levard, "Cholécystectomie par coelioscopie," *La Presse Médicale* 19 (1989): 980-2; F. Dubois et al., "Coelioscopic Cholecystectomy: Preliminary Report of 36 Cases," *Annals of Surgery* 211 (1990): 60-2.

[197] The Society of American Gastrointestinal Endoscopic Surgeons was formed in 1981 to bring together general surgeons who had an interest in flexible endoscopy and intraoperative endoscopy. It was later renamed the Society of American Gastrointestinal *and* Endoscopic Surgeons.

[198] A.P. Legorreta et al., "Increased Cholecystectomy Rate After the Introduction of Laparoscopic Cholecystectomy," *Journal of the American Medical Association* 270 (1993): 1429-1432.

[199] See, for example, A. Cuschieri, "The laparoscopic revolution – walk carefully before we run," *Journal of the Royal College of Surgeons of Edinburgh* 34 (1989): 295; Alfred Cuschieri, George Berci, and Charles K. McSherry, "Laparoscopic Cholecystectomy," *American Journal of Surgery* 159 (1990): 273.

academic medical centers inspires therapeutic innovations, which are then carefully evaluated through case reports and clinical trials, before being made available to the wider public at community hospitals and clinics.[200] But as medical sociologist John McKinlay has acknowledged, while it can be useful to break down the "career" of an innovation into such stages, it cannot be assumed that all innovations pass through each of the stages in a particular order.[201] Historian Thomas Schlich, for example, shows in his study on osteosynthesis that the scientific justification for the technique was only established after it was already used in practice.[202] Similarly, laparoscopic cholecystectomy was widely offered to patients before academic surgeons were able to conduct and publish their studies of it.

Instead of the linear path of development starting in academic medical centers before moving into community hospitals and clinics (or vice versa), the emergence of laparoscopic cholecystectomy can be better understood as moving between the two types of medical spaces. This chapter shows that the success of laparoscopic cholecystectomy relied on both the freedom found in (what can be described as) the medical "periphery" as well as the legitimacy of the medical "Establishment", that were provided at various stages of its development. The stages of development that will be discussed include the development (by multiple surgeons), academic

[200] See, for example, Peter McCulloch et al., "IDEAL framework for surgical innovation 1: the idea and development stages," *British Medical Journal* 346 (2013): f3012; Patrick L. Ergina et al., "IDEAL framework for surgical innovation 2: observational studies in the exploration and assessment stages," *British Medical Journal* 346 (2013): f3011; Jonathan A. Cook, "IDEAL framework for surgical innovation 3: randomised controlled trials in the assessment stage and evaluations in the long term study stage," *British Medical Journal* 346 (2013): f2820.
[201] John B. McKinlay, "From 'Promising Report' to 'Standard Procedure': Seven Stages in the Career of a Medical Innovation," *The Milbank Memorial Fund Quarterly* 59 (1981): 374-411, 375. McKinlay delineated the "seven stages in the career of a medical innovation" as the "promising report," professional and organizational adoption, public acceptance, "standard procedure" and observational reports, randomized controlled trial, professional denunciation, erosion and discreditation.
[202] Thomas Schlich, "Science and Surgery: Bones in the Laboratory," *Surgery, Science and Industry – A Revolution in Fracture Care, 1950s-1990s* (Houndsmill, Basingstoke, Hampshire: Palgrave Macmillan, 2002), 86-109.

publishing, adoption by the surgical community, and control of the technique through evaluation, training, and accreditation.

In addition, this chapter will show that the motivations to develop laparoscopic cholecystectomy did not include, as James Zetka suggests, a concerted desire to re-assert general surgery's claim on the treatment of cholelithiasis.[203] Instead, the developers of the technique each had differing motivations including the reduction of trauma during abdominal surgery, and the incorporation of laparoscopic and laser technology into general surgery. Taking the accepted narrative of laparoscopic cholecystectomy's emergence as a starting point, this chapter brings together the published retrospectives with new oral history interviews to discuss these motivations, and how the two types of medical spaces hindered and facilitated the technique at different points of its development. The examination of how surgeons narrate the development and adoption of laparoscopic cholecystectomy reveals the ways in which the non-academic developers of the technique felt like outsiders in their profession. Interestingly, their narratives also reveal gendered attitudes towards gallstones and surgical scars that may otherwise be obscured.

"The benefits of loneliness": Freedom on the Periphery

The first academic paper describing laparoscopic cholecystectomy is a report of the first 63 cases that François Dubois, Gérard Berthelot, and Hughes Levard performed at the Hôpital international de l'Université de Paris between May 1988 and February 1989.[204] Though the first to publish in a top-tier academic journal, the Parisian surgeons were not the first to perform the

[203] James R. Zetka, "Technological Innovation in the Surgical Craft," *Surgeons and the Scope* Ithaca: ILR Press (2003), 136-56, 137.
[204] Dubois, "Cholécystectomie," 980-2.

technique. In contrast to the distinguished halls of the University of Paris, the first laparoscopic cholecystectomy was actually performed at a small independent surgical clinic in Lyon by Philippe Mouret in 1987.

According to Mouret, "the first cholecystectomy was performed quite naturally, without premeditation."[205] For him, it was a natural progression of his work that had taken place over decades. As a surgical intern in the 1960s, Mouret trained in vascular surgery, orthopedics, pulmonary surgery, and significantly, gynecology, where laparoscopic techniques have their origins. After a year of military service, he returned to Lyon and eventually became *chirurgien de garde* of the Urology Department at L'Hôpital Edouard Herriot.[206] For Mouret, this was the decisive moment of his career. In an interview a few months before his death in 2008, Mouret explained:

> I found myself facing many emergencies with patients suffering from acute stomach aches. At the time, there were no CT scans, no precise diagnostic tests…So we had to open the patient in order to make a diagnosis. As a result, some patients were treated for nothing! With all the risks of mortality that this implied. And this, this scandalized me. So, I decided to apply an examination that was until then reserved for gynecology and created in 1900: laparoscopy…But this examination was confined to gynecology, a discipline which the surgeons scorned.[207]

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[205] Philippe Mouret, "Special Lecture: How I Developed Laparoscopic Cholecystectomy," *Annals of the Academy of Medicine* 25 (1996): 744-7, 746. The original lecture delivered at the ELSA Congress in Singapore on August 8, 1993.

[206] Translated from Philippe Mouret, "Philippe Mouret, l'inventeur lyonnais de la coelioscopie, est mort," *LyonMag*, June 24, 2008, accessed July 2, 2017, https://www.lyonmag.com/article/8141/philippe-mouret-l-8217-inventeur-lyonnais-de-la-coelioscopie-est-mort.

[207] Translated from Mouret, "Philippe Mouret, l'inventeur."

Thus in 1968, after consulting with Yves Rochet and Michel Cognat, two of the top gynecologists in Lyon, Mouret decided to transfer the skills he learned in gynecology to general surgery and test if they would allow him to rule out a diagnosis of appendicitis without having to open up the patient in an exploratory laparotomy.[208] As he recalled in a lecture upon receiving the 2007 Honda Prize, "My first target was to confirm or invalidate the diagnosis of appendicitis in the event of abdominal pain. I was convinced that a lot of appendectomies were not useful (I say 'a lot of', but in my humble opinion 'the majority of')."[209] Although his attempts at diagnosing appendicitis through laparoscopy was successful, they were not well-received by his surgical colleagues. According to Mouret, "For my fellow surgeons, it was an aberration. Indeed, when one operates, the essential thing is to see clearly. And for that, the rule is to open wide. Moreover, it was said at the time: large incisions make great surgeons. As a result, I was marginalized and labelled as a gynecologist!"[210]

In the face of such professional disdain, Mouret opted to leave the constrictive environment of the academic hospital and opened a private practice where he could have the freedom to continue integrating laparoscopy into his surgical practice.[211] Once away from the hospital's disapproving atmosphere, he began to routinely use laparoscopy in his diagnostic procedures as well as in the exploratory steps of his interventional procedures. His frequent use of the technique at his new clinic, La Clinique de la Sauvegarde, provided him with important insights into how even minor surgery could cause major disruption to the peritoneum, which would lead to adhesions and further pain.[212] By using laparoscopy as an exploratory tool in lieu

[208] Mouret, "Philippe Mouret, l'inventeur."
[209] Philippe Mouret, "Laparoscopy: Another means to see in surgery, Another means to appraise surgery," Commemorative Lecture at the Twenty eighth Honda Prize Awarding Ceremony, Tokyo, Japan, November 19, 2007.
[210] Translated from Mouret, "Philippe Mouret, l'inventeur."
[211] Mouret, "Philippe Mouret, l'inventeur."
[212] Mouret, "How I Developed," 745.

of an immediate laparotomy, Mouret felt that he was decreasing the incidence of post-surgical adhesions in his patients and the need for more operations in the future.

Eventually, Mouret's experience with laparoscopy allowed him to use it not just as a diagnostic tool but also in treatment. In March 1972, Mouret began to perform his routine laparoscopic exploration on an 18-year-old male patient with an intestinal occlusion caused by peritoneal adhesions.[213] During the procedure, he came to believe that he could treat the issue without having to open up his patient and proceeded to successfully complete the adhesiolysis laparoscopically.[214] In a retrospective analysis of how he performed the first laparoscopic cholecystectomy, Mouret considered this occasion as the beginning of laparoscopic surgery outside of gynecology.[215]

In 1983, he again pushed the boundaries of how much of a surgical procedure could be performed before an open incision was necessary.[216] Going past the exploratory stage of an appendectomy, he was able to dissect the appendix from its surroundings laparoscopically, then pull it out of the abdomen so that it could be excised extracorporeally. For Mouret, "The role of laparotomy was soon limited to the extraction of the specimen…"[217] Since the ultimate excision of the appendix was performed extracorporeally, he was always careful to describe his technique as being "laparoscopy-aided organ removal."[218] Four years and over a hundred laparoscopy-aided appendectomies later, Mouret found himself in a situation where he once again felt comfortable pushing the boundaries of laparoscopy, this time in a cholecystectomy.

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[213] Mouret, "Philippe Mouret, l'inventeur." See also, Mouret, "How I Developed," 745; Mouret, "Laparoscopy: Another Means."
[214] Mouret, "Philippe Mouret, l'inventeur."
[215] Mouret, "How I Developed," 745.
[216] Mouret, "How I Developed," 745.
[217] Mouret, "How I Developed," 745.
[218] Mouret, "How I Developed," 745.

Mouret's ability to perform laparoscopic adhesiolysis meant that he frequently received patients by referral. One particular patient came to him with painful pelvic adhesions in addition to symptomatic gallstones and asked for both to be treated during the same session.[219] After completing the adhesiolysis on March 13, 1987, Mouret continued in using the laparoscope to conduct the exploratory preparation for the cholecystectomy.[220] With each step of the procedure, it would occur to him that he could continue carrying out the next step laparoscopically, thus delaying the moment that he had to make a larger incision.[221] Similar to his procedure for appendectomy, he was able to dissect the gallbladder through the abdominal puncture but had to make the final excision of the organ extracorporeally. When he checked on his patient the next morning, she was up, ready to leave, and upset at him because without the expected scar, she believed that he had not removed her gallbladder as he had promised.[222] Although Mouret himself saw the procedure he performed that day as being a laparoscopy-aided cholecystectomy, the surgical world came to see it as the first laparoscopic cholecystectomy and the beginning of the laparoscopic revolution in general surgery.

Mouret's description of his experience suggests that for him, the development of laparoscopic cholecystectomy was not about developing a laparoscopic technique for gallbladder removal. Mouret's goal was not simply to perform surgical procedures laparoscopically but rather to use laparoscopy to avoid or delay the expansion of the abdominal incision in the hope of minimizing unnecessary trauma to the patient. As he explained in a special lecture to the 1993 Congress of the Endoscopic and Laparoscopic Surgeons of Asia, "…reducing the indications [for

[219] Mouret, "How I Developed," 746.
[220] "About," Official Website for Dr. Philippe Mouret, accessed October 1, 2020, philippemouret.com/index.php/about.
[221] Mouret, "How I Developed," 746.
[222] Mouret, "How I Developed," 746-7.

peritoneal disturbances] to their bare minimum appeared to me as a priority, in which laparoscopy could prove very helpful…"[223] The way he conceptualized the use of laparoscopy in surgery was that the surgeon should do as much that is possible through the laparoscope until the point that a laparotomy is needed in order to safely complete the procedure.[224] To him, it was not that laparoscopic surgery should be used for increasingly more procedures, it was that surgery should increasingly incorporate more laparoscopic technique.[225] In other words, instead of laparoscopic surgical procedures, Mouret described it as "surgery by laparoscopic approach."[226] As it will be discussed in Chapter 4, this distinction is important for understanding some of the issues that were faced when training surgeons in laparoscopic cholecystectomy.

But why did Mouret not ever publish the results of his work developing laparoscopy-aided cholecystectomy or appendectomy?[227] Practically speaking, he did not believe that the procedural details of his technique, which he described as "a contortionist's exploit," could be easily transmitted in print.[228] As he explained, in the days before video laparoscopy, the procedure required that he spend 2½ hours with one "eye glued to the laparoscope…and literally lying on the patient's right thigh."[229] Further, most general surgeons at the time were not trained in basic laparoscopic techniques. Mouret "was aware at the time that such surgical acrobatics could hardly be taught, and that only my 8000 or so previous laparoscopies had made it possible for me to perform in conditions of reasonable safety."[230] Still, according to his friend and

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[223] Mouret, "How I Developed," 745.
[224] Mouret, "Laparoscopy: Another means."
[225] Mouret, "Laparoscopy: Another means."
[226] Mouret, "Laparoscopy: Another means."
[227] Similarly, as David Jones has noted, the developers of coronary artery bypass grafting did not immediately publish case reports of their innovative work. See Jones, "Selective Inattention," *Broken Hearts: The Tangled History of Cardiac Care* (Baltimore, Johns Hopkins University Press, 2012), 157-169.
[228] Mouret, "How I Developed," 745.
[229] Mouret, "How I Developed," 745. Video laparoscopy became available later that year.
[230] Mouret, "How I Developed," 747.

colleague Jacques Périssat, an early adopter of laparoscopic cholecystectomy, Mouret tried to publish his work but his manuscripts were routinely rejected.[231] As Périssat explained in a 2017 interview, "he tried to publish in Lyon. He showed [his work] to the big academic chairmen of Lyon. And those guys [said], 'You are on the wrong way. You are trespassing on all the guidelines of the correct surgery. And you are endangering your patients.' And when he tried to publish, his publications were rejected by the peer reviewers…He ha[d] a very big gag on [his] mouth."[232]

When Mouret did present his work on laparoscopic surgery at a medical Congress in Paris in April 1988, he was met with strong disapproval and serious accusations of irresponsible behaviour and patient endangerment. As he recalled in a 2007 lecture in Tokyo upon receiving the Honda Foundation Prize, "After my video projection, I was almost reproached by the representatives from a great Parisian institution, shouting that it was disgraceful to show such horrors."[233] Fortunately for Mouret, there were two surgeons in the audience who had academic credentials and were willing to defend his work. Périssat, who was present at the meeting, recounted that Mouret's friend "Jacques Baulieux was the only academic surgeon of Lyon [to] stand up and say, 'I can testify that Philippe is an honest surgeon.'"[234] At the time, Périssat was developing a technique to access the gallbladder through laparoscopy in order to break up the gallstones via intracorporeal lithotripsy, followed by stone removal.[235] Because of this, he "[stood] up also and [said], "I am very pleased to see th[is] because this idea is on my mind

[231] Jacques Périssat, interview by Cynthia L. Tang, Bordeaux, France, November 9, 2017.
[232] Périssat, interview, November 9.
[233] Mouret, "Laparoscopy: Another means."
[234] Périssat, interview, November 9; Mouret also describes Baulieux coming to his defense in his 2007 Honda Prize lecture: Mouret, "Laparoscopy: Another means."
[235] Périssat, interview, November 9; The technique is described in J. Perissat, D.R. Collet, and R. Belliard, "Gallstones: Laparoscopic Treatment, Intracorporeal Lithotripsy Followed by Cholecystostomy or Cholecystectomy – A Personal Technique," *Endoscopy* 21 (1989): 373-4.

also.'"[236] For Mouret, "Jacques [Périssat's] instant adhesion and support gave [my work] the respectability of the University…"[237]

According to Périssat, many of the surgeons who were critical of the technique were part of an older generation.[238] They are often depicted as stodgy old surgeons who were against progress in surgical accounts of the history of laparoscopic cholecystectomy.[239] But this was not simply a case of comfortable and complacent surgeons, jealously guarding the old ways and refusing to consider new ideas. Instead, there was legitimate concern that the process of developing the new technique would inevitably produce unnecessary morbidity in patients. To many surgeons, the potential for a shorter recovery time and a smaller scar after cholecystectomy was not enough of a benefit to warrant the risks involved with developing a new surgical technique. This is in contrast to other areas of surgery, such as trauma surgery and heart surgery, where surgeons have perceived higher levels of risk to be more acceptable. As David Jones has discussed, for example, since many cardiac patients in the 1950s and 60s "would die or suffer terribly without surgery, nearly any surgical risk seemed acceptable" to their surgeons.[240] Not only was cholelithiasis not a death sentence, there was already a well-established cure, and one that incurred a minimal risk of morbidity or mortality. Many surgeons considered any deviation from the classic technique to be reckless and unethical.

Though Mouret lacked the academic affiliation that might have provided him with more legitimacy, he also recognized that working outside of academic/"establishment" medical centers

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[236] Périssat, interview, November 9.
[237] Mouret, "How I Developed," 747; Mouret, "Laparoscopy: Another means."
[238] Périssat, interview, November 9.
[239] See, for example, Leon Morgenstern, "An Unsung Hero of the Laparoscopic Revolution: Eddie Joe Reddick, MD," *Surgical Innovation* 15 (2008): 245-8.
[240] Jones, *Broken Hearts*, 122-3. Similar risk vs. benefit analyses were made with respect to lobotomy in the 1930s and 40s, as discussed in Jack D. Pressman, *Last Resort: Psychosurgery and the Limits of Medicine* (Cambridge: Cambridge University Press, 2002).

gave him the freedom that his endeavours with laparoscopy required. Périssat had, in fact, also considered the use of laparoscopy in abdominal exploration during the 1960s but was dissuaded when his colleagues complained that he was "blocking the time of the OR to make a long lasting time of exploration…[when] by opening, in fifteen minutes, you can see [everything]."[241] As he explained,

> In fact they were not that wrong: the job of laparoscopist was not that attractive after all. He had to hold the laparoscope with one hand in order to keep it in front of his eye; he had only one hand to handle his tools with. I often heard that teasing comment: "Jacques, how can you believe in the future of a surgical technique performed by one-armed surgeons helped by blind assistants?"[242]

The adoption of ultrasound and CT scanning in the late 1960s put an end to Périssat's interest in surgical laparoscopy.[243] In contrast, Mouret continued his work incorporating laparoscopy into his surgical procedures at his private clinic. As he reflected in 2007, "I worked in a complete isolation…But loneliness has had some very important advantages. In return for no assistance…I was not disturbed by external pressures, or suggestions, or academic scientific committees which would have limited my liberty of thinking."[244]

Similar to Mouret, the American developers of laparoscopic cholecystectomy also did not have academic affiliations. The initial spark in the US came from Barry McKernan and William Saye in Marietta, Georgia. McKernan and Saye were both heads of their respective departments,

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[241] Périssat, interview, November 9.
[242] Jacques Périssat, "My affair with Laparoscopy: An endless Romance," in *A semi serious history of laparoscopy* by Nicola Basso (Rome: Gangemi Editore, 2003), 79-82, 80.
[243] Périssat, interview, November 9; For more on the history of these technologies see, Stuart Blume, *Insight and Industry: On the Dynamics of Technological Change in Medicine* (Cambridge: MIT Press, 1992).
[244] Mouret, "Laparoscopy: Another means."

surgery and obstetrics, at Kennestone Hospital.[245] For them, the idea to remove the gallbladder laparoscopically was first triggered in April 1988 while observing a colleague in gynecology perform a laparoscopic adhesiolysis with the use of a laser to burn the adhesions.[246] As a general surgeon, McKernan's reaction was that a gallbladder could be taken out with a laparoscopic technique.[247]

McKernan had experience in gynecological laparoscopy from his days in small-town practice in Jasper, Alabama where generalists had to make up for the lack of specialists.[248] To learn more about the use of laser technology in surgery, McKernan attended a seminar given by Eddie Reddick. Reddick, a general surgeon from Nashville, Tennessee, was already well-known for his work using lasers in the treatment of hemorrhoids and skin lesions.[249] He frequently taught seminars and courses on the surgical applications of laser technology as a spokesperson for laser instrument companies who were interested in increasing their market.[250]

After speaking to McKernan, Reddick also became interested in developing a laser laparoscopic cholecystectomy and brought the idea to his partner, Douglas Olsen. As Olsen recalled, "Eddie came back from that laser course, suddenly light bulb on, and said, 'Hey, wow! Let's start doing this!"[251] According to Olsen, much of the impetus for their efforts to develop laparoscopic cholecystectomy was in "the interest of trying to incorporate laser technology into general surgery. Lasers were being used quite a bit in GYN laparoscopy, doing endometrial

[245] Grzegorz Litynski, "The American Spirit Awakens," Highlights in the History of Laparoscopy: The Development of Laparoscopic Techniques – a Cumulative Effort of Internists, Gynecologists, and Surgeons (Frankfurt/Main: Barbara Bernert Verlag, 1996), 227-70, 229.
[246] Barry McKernan, interview by Cynthia L. Tang, Marietta, Georgia, June 4, 2018; This is also described in Litynski, "American Spirit," 229.
[247] McKernan, interview.
[248] McKernan, interview.
[249] Litinsky, "American Spirit," 230.
[250] Douglas Olsen, interview by Cynthia L. Tang, Nashville, Tennessee, May 29, 2018.
[251] Olsen, interview, May 29.

surgeries…The laser companies were very interested in trying to get general surgery involved with using the laser."[252] Whereas the narratives of the French surgeons primarily focus on their motivations to minimize abdominal trauma, the American surgeons largely focus on how they were inspired by the laparoscopic and laser technologies and their interests in applying them to procedures in general surgery.

Back in Marietta, McKernan and Saye were convinced that the hospital at which they worked would not support their endeavour. Instead, they bought the specialized endoscopic instruments for $20,000 using their own personal funds and arranged to perform the procedure at the Marietta Surgical Center, one of the independent outpatient surgical facilities that became common in the United States in the mid-1970s and 80s.[253] They performed their first laparoscopic cholecystectomy on June 22, 1988. Their initial instincts about how their colleagues would react to their use of laparoscopy in abdominal surgery proved to be correct. As McKernan recalled to Litynski, "the day after we did our first gallbladder, I went across the street into Kennestone Hospital and presented a video tape of the operation to the whole surgical staff at a Medical Education Meeting. They laughed. The surgeons thought I had gone crazy. It took them two years to accept laparoscopic surgery in that hospital."[254]

Meanwhile, after Reddick's discussion with McKernan, he and Olsen quickly began to strategize about how to achieve a laparoscopic cholecystectomy. Because neither had much experience with laparoscopy, their first step was to get more training in the technique. Once they were credentialed for laparoscopy at their hospital, they began to screen potential patients for cases that would be simple and straightforward gallbladder removals. While Olsen was out of

[252] Olsen, interview, May 29.
[253] Litynski, "American Spirit," 230.
[254] Litynski, "American Spirit," 232.

town, Reddick attempted to complete a cholecystectomy laparoscopically but had to convert to open surgery because he could not get control of the cystic duct.[255] To solve the problem, Olsen modified a US Surgical M11 clip applier that was designed for use in open surgery so that it could be used through the laparoscopic cannulas. As Olsen recalled in 2018, "It was jerry-rigged, but it worked! The next case was one of my patients…and it went as smooth as silk."[256]

Reddick and Olsen completed their first laparoscopic cholecystectomy in September 1988, three months after McKernan and Saye. Unlike the Marietta surgeons though, Reddick and Olsen did not feel that it was necessary to perform the surgery at an independent surgical center. For them, once they were granted laparoscopy privileges, they "were credentialed to do laparoscopy. It wasn't procedure-specific. It wasn't, credentialed to do lap chole, it was just credentialed to do laparoscopy. So, we got credentials to do laparoscopy, we already had credentials to do gallbladders, so we just put them together."[257] According to Olsen, "We didn't look at a laparoscopic cholecystectomy as a new operation. It was just really a different approach to an operation we had been doing for over 100 years."[258]

Reddick and Olsen were able to report their first five cases using "Laparoscopic Laser Cholecystectomy" in the February 1989 issue of *Laser Medicine & Surgery News and Advances*,[259] a "bimonthly newsletter…cover[ing] general news of the American Society for Laser Medicine and Surgery."[260] The article included McKernan and Saye as co-authors, as well as their first case. It is unclear, however, if the report was peer-reviewed. As Olsen described it,

[255] Olsen, interview, May 29.
[256] Olsen, interview, May 29.
[257] Olsen, interview, May 29.
[258] Olsen, interview, May 29.
[259] Eddie J. Reddick et al., "Laparoscopic Laser Cholecystectomy, *Laser Medicine & Surgery News and Advances* 7 (1989): 38-40.
[260] "Editor's Note," *Laser Medicine & Surgery News* 1 (1983): 8.

Reddick "very quickly published a paper in a throwaway journal, kind of announcing it."[261] McKernan and Saye also tried to publish but could not get a paper accepted in academic journals. Similar to Mouret's situation, McKernan speculated in a 2018 interview that this was because they were not affiliated with an academic institution.[262]

Legitimacy in the Academy

In contrast, François Dubois held the position of Professor of Surgery at l'Université de Paris and was able to publish his laparoscopic cholecystectomy cases in top-tier academic medical journals in 1989. His initial approach to reducing bodily damage during gallbladder removal was to perform the traditional open technique through as small an incision as possible. Dubois was particularly proud of his technique and believed that he produced the smallest scar in the world after gallbladder removal. As he recalled in a 2017 oral history interview: "One day [in 1987], I'm doing a cholecystectomy on a pretty girl and, in the operating room, I said, 'Well, she's going to be happy. I have not disfigured her.'" But the new nurse on his surgical team was not impressed. Coincidentally, she had just moved to Paris from Lyon where she had worked with Mouret at his clinic. According to Dubois, "The nurse said, 'Yes, but Dr. Mouret does better.' I was furious! and she said "Yes, he does them laparoscopically."[263]

Driven by his desire to minimize the effects on female beauty produced by his scalpel, Dubois overcame his initial indignation and contacted Mouret to inquire about the laparoscopic technique. Mouret, who was planning to be in Paris a few days later, offered to meet with Dubois in his room at the Hilton Hotel and show him videos he had taken of two minimally invasive

[261] Olsen, interview, May 29.
[262] McKernan, interview.
[263] François Dubois, interview by Cynthia L. Tang, Paris, France, November 16, 2017.

gallbladder removals.[264] Impressed, Dubois began to develop the technique further, working in the animal laboratory on pigs and dogs in late 1987. He began offering laparoscopic cholecystectomy to patients in May 1988.[265]

As an academic surgeon, Dubois was in a better position to publish his results with laparoscopic cholecystectomy than Mouret or the American surgeons. But even with his academic affiliation, according to Dubois, "Laparoscopic cholecystectomy was at first ostracized by the surgical and academic establishment, and our first manuscripts were uniformly rejected for publication."[266] His group's initial submission was sent to the French journal, *La Presse Médicale*, in December 1988 but was, according to Dubois, rejected with the comment that the "technique is too dangerous [and] should not be developed at all costs."[267] As he recalls, it was only after the technique began to gain attention in the United States a few months later that their report was accepted for publication.[268] He was thus able to publish the first academic paper reporting the technique in the May 1989 issue of *La Presse Médicale*, followed by an English report in the *Annals of Surgery* in January 1990.[269] In a 2017 interview, Dubois acknowledged that he was successful in publishing the technique because "I was a professor in Paris and I was quite well-known, whereas poor Mouret…was a private surgeon [and] didn't work in hospitals."[270] Still, according to one observer, Leon Morgenstern, the publications received little attention from the medical community.[271]

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[264] Dubois, interview; François Dubois, "Mes Débuts en Coelio-Chirurgie ou Comment L'Esprit Vient Aux (Vieux) Chirurgiens: 1ère rencontre avec Ph. Mouret," *Journal de Coelio-Chirurgie* 5 (1993).
[265] Dubois, interview; Dubois et al., "Cholecystectomie par coelioscopie," 980.
[266] François Dubois, G. Berthelot, and H. Levard, "Laparoscopic Cholecystectomy: Historic Perspective and Personal Experience," *Surgical Laparoscopic and Endoscopy* 1 (1991): 52-7, 53.
[267] Dubois, interview.
[268] Dubois, interview
[269] Dubois et al., "Cholecystectomie par coelioscopie," 980-2; Dubois et al., "Coelioscopic Cholecystectomy," 60-2.
[270] Dubois, interview
[271] Morgenstern, "Unsung Hero," 246.

Gendered Narratives of the Emergence of Laparoscopic Cholecystectomy

Dubois' interest in the consequences of abdominal surgery and work towards reducing the trauma of laparotomy as much as possible began in the 1960s.[272] In 1973, he began to offer cholecystectomy by mini-laparotomy where he removed the gallbladder through a 1 to 2½-inch incision instead of the standard 3 to 6-inch incision, and patients only stayed in the hospital for one or two days instead of a week.[273] When asked what his motivation was to make incisions smaller, he replied, "It was aesthetic…One of my motivations was a Marilyn Monroe photograph. At the end of her life, [a photographer] took nude photos of her…You could see that she was a very beautiful girl, but she had an enormous scar…It was a tragedy! And I thought, we couldn't keep doing things like that," (Figure 2.1).[274]

[272] J. Loygue, F. Dubois, and F. Pottiee Sperry, "Conséquences Générales des Laparotomies et des Interventions Portant sur le Tube Digestif" *Revue du Practiciens* 14 (1964): 719-34; Dubois, "Mes Débuts," 19-20; F. Dubois, B. Berthelot, "Cholécystectomie par mini-laparotomie," *La Nouvelle Presse Médicale* 11 (1982): 1139-41, 1139.
[273] Dubois and Berthelot, "Cholécystectomie," 1139.
[274] Dubois, interview.

Figure 2.1: Marilyn Monroe's Gallbladder Scar – Photographs of Marilyn Monroe taken by Bert Stern for Vogue Magazine on June 21, 1962, a year after her cholecystectomy. These serigraphs, printed in Day-Glo ink, were published in *Avant Garde* magazine in March 1968. This was likely the first publication of the nude photographs from this photo shoot.[275]

Dubois' concern for the aesthetic ramifications of his craft and the motivational power it had over him broadens our understanding of the extent to which cultural beauty standards can inspire surgical innovation. His anecdote places the development of laparoscopic cholecystectomy – where he was motivated by his desire to minimize surgical disfigurement – in contrast with the development of techniques in cosmetic surgery where, as Elizabeth Haiken shows in *Venus Envy*, innovation was often driven by women's desires for surgical enhancement.[276] It also contrasts with the development of alternatives to radical mastectomy that did not destroy one's body image in the treatment of breast cancer which, as Barron Lerner

[275] Bert Stern, "The Marilyn Monroe Trip," *Avant Garde* 2 (1968): 12-24, 20-1.
[276] Elizabeth Haiken, *Venus Envy: A History of Cosmetic Surgery* (Baltimore: Johns Hopkins University Press, 1997).

shows in *Breast Cancer Wars*, was largely driven by patient activism.[277] It demonstrates that the drive to develop surgical techniques that promote bodily perfection does not solely come from women's desires for the ideal body but can also be propelled by surgeons' own perceptions of that ideal. One developer of laparoscopic cholecystectomy, for example, asserted in a 2018 interview that "The only reason a woman should ever have an incision on her abdomen is C-section."[278]

The story also points towards the gendered way in which surgeons often narrativize the emergence of laparoscopic cholecystectomy. It was not just that this one surgeon was interested in minimizing the effects on female beauty that resulted from open abdominal surgery. Many of the other stories that developers of laparoscopic cholecystectomy tell about its early days are also gendered and focus on the aesthetic benefits that they believed the less invasive approach had for women. For example, William Saye's anecdote of how he was encouraged to develop the procedure includes a chance encounter with a woman who was postponing gallbladder surgery because "she was living in Florida, [and] was concerned about a post-operative scar." When Saye told her, "I really think in the very near future we will be able to take out a gallbladder through three or four little punctures, smaller than a postage stamp," the woman enthusiastically replied, "I want to have it now!"[279] According to Jacques Périssat, the availability of laparoscopic cholecystectomy in France was specifically publicized in women's fashion magazines in order to reach "young women having cosmetic concerns."[280]

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[277] Barron H. Lerner, *The Breast Cancer Wars: Hope, Fear, and the Pursuit of a Cure in Twentieth-Century America* (Oxford: Oxford University Press, 2001).
[278] McKernan, interview.
[279] Litynski, "American Spirit," 231.
[280] Périssat, interview, November 9.

Other surgeons point more specifically to women's concerns that surgical scars would make them self-conscious about wearing bikinis as a primary reason for why they would prefer the laparoscopic procedure. As Douglas Olsen explained to *The Galveston Daily News* in August 1990, the smaller incisions used in laparoscopic cholecystectomy meant that women "can still wear their bikinis."[281] Similarly, a surgeon quoted in *The Pittsburgh Press* a month earlier, described the procedure as being "very cosmetic…A woman can still wear a two-piece bathing suit."[282] Edmund Neugebauer, an author of one of the first papers evaluating laparoscopic cholecystectomy (discussed in Chapter 4), explained in a 2017 interview that the technique was promoted in Germany as being "good for ladies' scars" and that "young ladies who would like to go on [wearing] bikinis, they love it."[283]

There are two potential explanations for the gendered narratives of laparoscopic cholecystectomy's emergence. One explanation of why the stories of the first laparoscopic cholecystectomy cases are predominantly about female patients is that gallstones are more likely to occur in women. Epidemiological studies show that gallstones occur more frequently in women than in men. A Swedish study published in 1977, for example, found gallstone disease in 32% of men and 57% of women, at a ratio of 1.78.[284] However, the degree to which there is a gender disparity varies depending on the study population.[285] While a 1987 study of the town of Sirmione, Italy found the prevalence of gallstone disease to be 6.7% in men and 14.6% in

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[281] Malcolm Ritter, Gallbladder Removal Avoids Incision, Speeds Recovery," *Galveston Daily News* (Galveston, TX), August 13, 1990.
[282] Joe Smydo, "New kind of gallbladder surgery hastens recovery," *Pittsburgh Press* (Pittsburgh, PA), July 18, 1990.
[283] Edmund Neugebauer, interview by Cynthia L. Tang, Brandenburg an der Havel, Germany, November 2, 2017.
[284] C. G. Lindström, "Frequency of Gallstone Disease in a Well-defined Swedish Population: A Prospective Necropsy Study. In Malmö," *Scandanavian Journal of Gastroenterology* 12 (1977): 341-6.
[285] For a review of worldwide gallstone prevalence studies, see Wolfgang Kratzer, Richard Andrew Mason and Volker Kächele, "Prevalence of Gallstones in Sonographic Surveys Worldwide," *Journal of Clinical Ultrasound* 27 (1999): 1-7.

women (a ratio of 2.18),[286] a 1998 study in Ulm, Germany found that gallstones occur in 5.8% of men and 6.3% of women (a ratio of 1.08).[287] Further, as a Danish study pointed out, the disparity in gallstone incidence between men and women decreases with age in some populations.[288] Still, gallstones are taught, and therefore, subsequently thought of as a gendered affliction. Risk factors for gallstones are often presented in first year medical school using the mnemonic "fat, female, fertile, and forty." Also known as the "Four F's," the learning aid gives diseased gallbladders and their treatment an intrinsically gendered nature. This helps to account for why most stories about the first patients to receive laparoscopic cholecystectomy are about women.

A second explanation for the gendered narratives of laparoscopic cholecystectomy's emergence is the gendered way in which scars are often regarded and the social/cultural expectation that a surgical technique with a smaller aesthetic footprint would be particularly beneficial or appealing to women. As sociologist Rose Weitz notes, there is much research that reinforces the assumption that scarring affects women more negatively than men.[289] More broadly, this relates to cultural expectations for women to look a certain way and to be concerned about their appearance.

In giving narratives (such as Saye's) of female patients delaying treatment for their gallstones for fear of disfiguring scars, surgeons are also offering a narrative of patient demand and a clinical need for less invasive surgery, since the longer one delays having surgery for symptomatic gallstones, the more risk there is for complications. Indeed, according to Périssat,

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[286] Luigi Barbara et al., "A Population Study on the Prevalence of Gallstone Disease: The Sirmione Study," *Hepatology* 7 (1987): 913-7.
[287] W. Kratzter et al., "Gallstone Prevalence in Germany: The Ulm Gallbladder Stone Study," *Digestive Disease and Sciences* 43 (1998): 1285-1291.
[288] Kirsten Hougaard Jensen and Torben Jørgensen, "Incidence of Gallstones in a Danish Population," *Gastroenterology* 100 (1991): 790-4.
[289] Rose Weitz, "Gender and Degendering in Autobiographical Narratives of Physical Scars," *Gender Issues* 28 (2011): 192-208, 193.

the "features of [the] patients changed. Because with the success of lap chole, we got cases earlier than in the past. Instead of operating [on patients with a long history of] clinical symptoms, and gallbladders [that were] very sclerotic, very dangerous to operate, we got many, many cases at the first alarm. And so this new kind of patient came with [much] easier [cases]."[290] But even after the adoption of laparoscopic cholecystectomy into routine practice, patient demand for less scarring continued to be used to justify the further development of even less invasive surgical techniques. For example, a 1997 paper describing the development of a mini-laparoscopic surgery, the authors report, "As more and more cosmetic requirements were requested by patients, we were encouraged to perform the laparoscopic cholecystectomy by mini-laparoscope…[which] leaves an almost invisible scar within the abdominal wall. This may be important, especially for young female patients."[291]

More recently, a 2017 paper published the results of a study that evaluated the benefits of laparoendoscopic single-site surgery versus conventional laparoscopic surgery, which used an additional one or two port sites.[292] In addition to less pain, single-site surgery was shown to provide better cosmetic results, termed cosmesis in the medical literature, and was more important to women. Therefore, the authors argued, "Cosmesis should [be] carefully considered by the surgeon when selecting a surgical technique, particularly because many patients [requiring the procedure evaluated] are young and female."[293]

Interestingly, cosmesis only became relevant as a surgical outcome for general surgeons with the emergence of laparoscopic cholecystectomy. Prior to this, the use of the term and

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[290] Jacques Périssat, interview by Cynthia L. Tang, Bordeaux, France, November 13, 2017.
[291] Ray-Hwang Yuan et al., "Mini-Laparoscopic Cholecystectomy: A Cosmetically Better, Almost Scarless Procedure," *Journal of Laparoendoscopic & Advanced Surgical Techniques* 7 (1997): 205-11, 205.
[292] Masaaki Yanishi et al., "Influence of scars on body image consciousness with respect to gender following laparoendoscopic single-site versus conventional laparoscopic surgery," *Scandinavian Journal of Urology* 51 (2017): 57-61.
[293] Yanishi et al., "Influence of scars," 61.

interest in minimizing the aesthetic ramifications of surgery was mostly confined to the literature on plastic surgery and breast cancer treatment. In general surgery, the majority of papers about surgical scars were reports of complications such as heterotopic bone formation. The adoption of laparoscopic cholecystectomy led to a re-assessment of acceptable surgical outcomes and general surgeons' inclusion of cosmesis as a legitimate concern. As we saw, it became and continues to be, an important justification for the development of even less invasive cholecystectomies. It is not clear, however, how much proactive demand there is from patients for gallbladder surgery that is less invasive than laparoscopic cholecystectomy, male or female. For example, a 2019 paper that examined the factors that patients considered to be important in their cholecystectomy decision-making found that scar cosmesis was among the least important considerations.[294]

In the original development of laparoscopic cholecystectomy, the multiple reasons that surgeons gave for why they thought it was important to develop a laparoscopic technique do not include that there was specific demand from patients for smaller scars. As we will see in Chapter 3, patient demand for minimally invasive gallbladder removal was generated only after it became available and patients were informed about it. The idea that less invasive surgery is particularly beneficial to women because it produces smaller scars is one that surgeons imposed and continue to impose onto patients.

Focusing on the aesthetic advantages of a procedure as being the principal incentive for women gives the impression that the other factors (pain, recovery time/time away from work or care-taking roles, cost, risks of complications, etc.) are not as important to them. Newspaper interviews with the first laparoscopic cholecystectomy patients, however, indicate that such concerns often were in fact primary considerations in women's decision-making about their

[294] H. Sinan et al., "Comparison of Single-Incision and Conventional Laparoscopic Cholecystectomy in Terms of Quality of Life, Body Image, and Cosmesis," *Nigerian journal of Clinical Practice* 22 (2019): 521-6.

gallstone treatment. As the *Wall Street Journal* reported, Julie Musselman – McKernan and Saye's first laparoscopic cholecystectomy patient, whom Saye claimed to have been "concerned about a post-operative scar" – spent years after being told by doctors to have her gallbladder out,

> prowl[ing] the beaches of Fort Lauderdale, Fla., staring at people's torsos. Whenever she spotted a big scar, she would run up and…interrogate her surprised victims, eliciting tales of painful, three-month recoveries. 'I talked to more than 150 people, and I didn't hear one good story about that operation,' she says…The day after Dr. McKernan did the operation in 1988, she went home. Five days later, she played racquetball against a man – and won.[295]

A patient in New Jersey – who had resisted conventional surgery for eight years – explained to the *Asbury Park Press*, "The surgery didn't look very pleasant…And having two little kids, I didn't think I had six weeks to spare."[296] When the less invasive procedure became available in her area in May 1990, she was able to "squeez[e] it between work [on] Monday and a parent-teacher conference on Thursday."[297] Another patient, "Bonnie Jones, 42, a bookkeeper from Murray, Ky., said the recovery time from the traditional surgery made her put it off."[298] As she told the *Tennessean Sun*, "I couldn't afford to miss that much work…Now, I don't have to."[299]

Surgical narratives that the emergence of laparoscopic cholecystectomy was especially beneficial to women rely on the assumption that women are more self-conscious about their scars

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[295] Ron Winslow, "Cutting Edge: A Tiny TV Camera Is Fast Transforming Gallbladder Surgery – The Keyhole Technique Uses Tiny Incision, May Work For Other Operations Too – Doctors Scramble to Learn It," *Wall Street Journal* (New York, NY), December 10, 1990.
[296] Judy Holmes, "A cut above: Technique cuts recovery time and risk for gallbladder patients," *Asbury Park Press* (Asbury Park, NJ), May 1, 1990.
[297] Holmes, "A cut above."
[298] Rochelle Carter, "Pioneering surgery saves time, money – and insurance pays," *Tennessean Sun* (Nashville, TN), June 24, 1990.
[299] Carter, "Pioneering surgery."

than men and are thus, more vain. Dubois even found it "curious that the aesthetic benefits were appreciated by all ages and genders."[300] Still, narratives about the rise of laparoscopic cholecystectomy disproportionately focus on the aesthetic benefits it has for women, likely resulting from the gendered ways in which scars are considered, and in which gallstones are presented in medical training.

Indifference in the Academy and an "Explosion of Interest" on the Periphery

Another common feature of the laparoscopic cholecystectomy emergence narratives is that the academic surgical community was resistant, and even hostile, to the idea of laparoscopic abdominal surgery outside of gynecology. A retrospective account by the surgeon, Leon Morgenstern, described the technique in the eyes of academic surgeons, as "a renegade experiment, so suspiciously regarded at its inception."[301] He continues, "Strangely silent in all these early proceedings were voices from the Grove of Academe. University departments of surgery watched warily from the sidelines as reports of the new procedure, principally in the news media, grew in volume. The newcomer was perceived initially as an unwelcome upstart rather than a promising newcomer."[302]

When surgeons describe their experiences with the "laparoscopic revolution," what they pinpoint as the trigger for the "explosion of interest" is not the first academic papers, but a video that was shown at the annual meeting of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) in April 1989. Despite Périssat's position as Professor of Surgery at the Université de Bordeaux, SAGES initially rejected his proposal to present his video

[300] Translated from Dubois, "Mes Débuts," 19.
[301] Morgenstern, "Unsung Hero," 247.
[302] Morgenstern, "Unsung Hero," 247.

of laparoscopic cholecystectomy at their meeting in Louisville, Kentucky.[303] As he recalled in a 2017 interview, "They told me, 'We have not selected your paper because it's not a new technique.'…I persisted and [contacted] the president. I say, 'I don't know why you reject[ed] this.' [He replied], 'But it's normal to make a laparotomy to retrieve the gallbladder.' I said, 'It's not a laparotomy. Read, read, read. It's laparoscopy.'"[304]

Instead of presenting in one of the regular academic sessions, Périssat was given space at a trade booth on the exhibition floor in which to show his video throughout the entire meeting. The reception to this video demonstration was unlike anything Périssat had experienced in Europe. As he explained in 2017, when he presented his video at France's *Académie nationale de chirurgie* in February 1989, "everybody [said], 'It's a wrong way.' No discussion. And those who were indifferent [said], 'Maybe, wait and see.' But no one rushed to this."[305] In contrast, the response to the video at the SAGES meeting two months later was almost overwhelmingly eager: "When we saw the enthusiasm of the American surgeons, we thought, '…We have made a Big Bang – the uncontrollable Big Bang."[306]

A few months later, in October 1989, Reddick and Olsen presented their laparoscopic cholecystectomy videos at the American College of Surgeons Clinical Congress, hosted that year in Atlanta, Georgia.[307] Their videos were also presented as part of the technical exhibits. But in contrast to Périssat, they presented their videos on behalf of instrument manufacturers. Olsen showed videos at both the US Surgical booth and the Storz booth, while Reddick worked the crowds at a laser instrument booth.[308] Similar to Périssat's experience, Olsen recalled, "where we

[303] Périssat, interview, November 9.
[304] Périssat, interview, November 9.
[305] Périssat, interview, November 13.
[306] Périssat, interview, November 13.
[307] Olsen, interview, May 29.
[308] Olsen, interview, May 29.

had the videos playing, you couldn't even get standing room to get in to watch them. That's how busy the floor was."[309]

Such enthusiasm for the technique was further seen in how eager surgeons were to be trained. While showing their videos, Reddick and Olsen also spread the word that they were holding training courses for the new technique. According to Olsen, "…within very short order, of us opening up and offering this, every spot was taken and we were booked. There were people bringing out their chequebooks, trying to write cheques to reserve themselves a place."[310] They did their first formal course a few weeks later in November 1989 and continued with them throughout 1990. As it will be discussed in Chapter 4, surgeons throughout the United States and Canada travelled to Nashville to learn the procedure and bring it back to their own hospitals.

The seminars and courses that Reddick taught on behalf of the laser instrumentation companies also became a platform that he used to spread the news about laparoscopic cholecystectomy. According to Morgenstern, after their successful laparoscopic cholecystectomy in September 1988, Reddick began showing a 3-minute video of the procedure at the end of each presentation he gave on his lecture tours.[311] This of course also led to a great deal of interest in laparoscopic laser cholecystectomy and numerous requests for training in the technique.

The academic surgeons, Dubois and Périssat, were able to disseminate their experiences with laparoscopic cholecystectomy through the traditional channels in academic medicine – i.e., publishing in peer-reviewed journals and presenting at academic conferences – but their reports were not taken seriously and mostly ignored. Instead, the developers of laparoscopic cholecystectomy were more successful in generating interest amongst community surgeons on

[309] Olsen, interview, May 29.
[310] Olsen, interview, May 29.
[311] Morgenstern, "Unsung Hero," 247.

what can be called the "periphery" of academic surgery. They overcame the inability to stimulate interest in the academic medical community by reaching out to community surgeons with the help of the instrument manufacturers (described further in Chapter 4). This, in addition to reports in popular news media (discussed in Chapter 3), helped to transmit the news and use of laparoscopic cholecystectomy to community hospitals and clinics in what was later described as a wildfire-like manner.

Academic Attempts to Control the "Laparoscopic Revolution"

As it became apparent that community surgeons were rushing to get trained and to start offering laparoscopic cholecystectomy to patients, academic surgeons quickly voiced concerns about its rapid uptake. As early as December 1989, an editorial in the *Journal of the Royal College of Surgeons of Edinburgh* cautioned, "Unleashing it without adequate safeguards could turn out to be a surgical nightmare."[312] A few months later, commentators in the *American Journal of Surgery* wrote,

> There is little doubt that we shall witness an explosion in laparoscopic surgery. In this respect, there is a real risk that the procedures will be performed by many surgeons without adequate and proper training. The enthusiasm for laparoscopic cholecystectomy must be tempered with the realization that this procedure is dangerous if improperly performed. Unless restraint and adequate training are pursued as active policies by the surgical community, the indiscriminate performance of laparoscopic

[312] Cuschieri, "The laparoscopic revolution," 295.

> cholecystectomy will increase the incidence of catastrophic complications or even death.[313]

The rhetoric used in these commentaries conveyed a sense of urgency in the need to regain control of the technique.

Control over the use of a new surgical procedure was also a concern for other surgical innovations, for example as shown by Thomas Schlich in his volume on osteosynthesis, as well as by Sally Wilde on prostate surgery.[314] As Wilde demonstrates, even a surgical procedure that was considered to be superior, could be rejected from routine practice because of difficulties in mastering the technique and the resulting complication rates.[315] According to Schlich, this was exactly what East German surgeons were afraid would happen with their technique of osteosynthesis[316] – that any complications resulting from the poor execution of the procedure would cause irreparable damage to its reputation.[317] To ensure that their technique would not be misused, early access to the specialized equipment necessary for the procedure was only given to those who underwent their training program and met their standards for proficiency.[318] Similarly, in the case of laparoscopic cholecystectomy, the high complication rates that occurred in the early years, ranging from relatively mild injuries to more serious organ damage and death, did result in a period of negative publicity in the early to mid-1990s (discussed further in Chapter

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[313] Cuschieri et al., "Laparoscopic Cholecystectomy," 273.
[314] Thomas Schlich, "'Tacit Knowledge': Education and Training on a Face-to-Face Basis," *Surgery, Science and Industry: A Revolution in Fracture Care, 1950s-1990s* (Houndsmills, Basingstoke, Hampshire: Palgrave Macmillan, 2002), 65-85; Sally Wilde, "See One, Do One, Modify One: Prostate Surgery in the 1930s," *Medical History* 48 (2004): 351-66.
[315] Wilde, "See One," 359-61.
[316] Schlich, "Tacit Knowledge," 65.
[317] In fact, this was what happened in the United States, where the technique was not applied correctly and resulted in poor outcomes: Thomas Schlich, "The Long Road to Success: The AO in the US," *Surgery, Science and Industry: A Revolution in Fracture Care, 1950s-1990s* (Houndsmills, Basingstoke, Hampshire: Palgrave Macmillan, 2002), 180-95, 183.
[318] Thomas Schlich, "A Symbiosis of Surgery, Science and Industry," *Surgery, Science and Industry: A Revolution in Fracture Care, 1950s-1990s* (Houndsmills, Basingstoke, Hampshire: Palgrave Macmillan, 2002), 46-64, 52.

4).[319] There were enough complications resulting from the unfettered use of the technique by poorly trained surgeons that for the first time, the state government of New York found it necessary to issue regulations on who could perform a particular surgical procedure.[320]

It did not take long for academic surgeons to see the advantages of laparoscopic surgery, when properly executed. The same editorial in *The American Journal of Surgery* that cautioned against "the indiscriminate performance of laparoscopic cholecystectomy," also affirmed that "the significant benefit to the patient and the cost savings of laparoscopic cholecystectomy are unquestionable."[321] The issue now was about reining in the "laparoscopic revolution" and re-gaining control over gallbladder surgery with comprehensive training, accreditation programs and regulations, as well as properly controlled, prospective clinical trials. The institution of these programs and trials will be discussed later in Chapter 4. Incidentally, enacting these measures would bring the use of laparoscopic cholecystectomy under the management of the academic or "Establishment" medical community.

What we see in the way laparoscopic cholecystectomy emerged is that there was a movement between academic or "establishment" medical centers, and the periphery in its developmental trajectory. Both types of spaces were necessary for the procedure to develop, spread, and importantly, remain an accepted surgical innovation. Though one can only speculate, had Mouret stayed at the academic hospital, he likely would have had much less freedom to continue his work with using laparoscopic techniques in his surgical procedures over that twenty-year period leading up to his first laparoscopy-aided cholecystectomy. Mouret,

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[319] See, for example, Harris Meyer, "Danger on the Cutting Edge?" *Los Angeles Times* (Los Angeles, CA), July 29, 1992; Judy Licht, "Risks in Gallbladder Surgery," *Washington Post* (Washington, DC), June 16, 1992.
[320] See, for example, Dennis Kipp, "Surgical procedure warning planned: Gallbladder operation target of state document," *Poughkeepsie Journal* (Poughkeepsie, NY), March 31, 1992; Lawrence K. Altman, "Surgical Injuries Lead To New Rule: New York Assails the Training for a Popular Technique," *New York Times* (New York, NY), June 14, 1992.
[321] Cuschieri et al., "Laparoscopic Cholecystectomy," 273.

McKernan and Saye went around the obstacles that they came across in the more Establishment-type medical centers by literally moving into a different space, on the periphery.

On the periphery, these surgeons were not able to broadcast their surgical innovation to the wider medical community through publishing in reputable journals. In contrast, Dubois' academic credentials provided him with the requisite legitimacy to publish in top-tier medical journals. Still, the academic medical community largely ignored the initial reports. Périssat, Reddick, and Olsen overcame the indifferent attitudes of the medical "Establishment" and quickly generated interest amongst non-academic, community surgeons by promoting laparoscopic cholecystectomy through more commercial channels.

The consequence of laparoscopic cholecystectomy spreading as quickly as it did was that many surgeons were performing the technique without adequate training. This resulted in high rates of complications and generated much negative publicity. To prevent any irreparable damage to both patients and the procedure's reputation, which could lead to it being abandoned or even banned from use, the academic surgical community attempted to bring the use of laparoscopic under control with the establishment of comprehensive training courses, regulations, and controlled clinical trials. Thus, the technique moved between the academic medical centers and the non-academic periphery of the medical community. These two types of medical spaces, at different times, provided the contexts of freedom, legitimacy, and control that facilitated the ultimate sustained success of laparoscopic cholecystectomy.

Chapter 3: Physician Advertising and the "Patient-Driven Revolution" in Surgery

The speed at which laparoscopic cholecystectomy was integrated into surgical practice was explained by surgeons, and by the U.S. National Institutes of Health Consensus Development Conference on Gallstones and Laparoscopic Cholecystectomy, as "ow[ing] much of its rapid growth to market forces generated, not inappropriately, by patient demand."[322] As one surgeon explained in a 2014 oral history interview,

> "[C]holecystectomy was such a common operation and such an important part of most [general] surgeons' practice, that if you didn't do cholecystectomy by laparoscopy, there was a great threat to your practice, and you may lose lots and lots of patients. Surgeons were pushed by patients to do the operation this way, and if they didn't do it that way, patients would go elsewhere. Patients were driving the market."[323]

There was certainly immense enthusiasm from patients for this dramatically less traumatizing procedure which took a surgery that could require an abdominal incision of up to 6 inches and that could take up to 3-6 weeks of recovery, and made it into one that only needed three or four small incisions and 1-7 days of recovery. A study of cholecystectomy rates published in the *Journal of the American Medical Association* showed that from 1988 (before the emergence of laparoscopic cholecystectomy) to 1992 (after its acceptance), there was an increase of approximately 57% in the total number of gallbladder removals in the United States.[324]

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[322] "National Institutes of Health Consensus Development Conference Statement on Gallstones and Laparoscopic Cholecystectomy," *American Journal of Surgery* 165 (1993): 390-8.
[323] Gerald Fried, interview by Thomas Schlich and Cynthia Tang, Montréal, Canada, June 13, 2014.
[324] A.P. Legorreta et al., "Increased Cholecystectomy Rate After the Introduction of Laparoscopic Cholecystectomy," *Journal of the American Medical Association* 270 (1993): 1429-1432.

Comparatively, there were approximate increases of 30% in Canada and 17% in Britain during the same period.[325] In contrast, there were no significant differences in the rates of appendectomy or inguinal hernia repair in the US during the same period.[326] As treatment for symptomatic gallstones is elective, patients could choose to delay surgery for as long as they believed that the pain, risks, and inconvenience associated with open abdominal surgery outweighed the alleviation of pain from gallstone attacks. The increase in cholecystectomy rates after the emergence of laparoscopic cholecystectomy indicates that the availability of the minimally invasive technique reconfigured this analysis and lowered the threshold for patients to decide to undergo surgery. As surgeons claim, there was indeed significant demand from patients for the minimally invasive procedure. Yet, this explanation for the rapid adoption of laparoscopic cholecystectomy does not address how patients initially heard about the procedure in order to demand it.

Dubois' first descriptions of the technique appeared in French in the May 1989 issue of *La Presse Médicale*,[327] followed by an English report in the January 1990 edition of the *Annals of Surgery*.[328] The first American paper was published by the Nashville surgeons Eddie Joe Reddick and Douglas Olsen in September 1989 in *Surgical Endoscopy*.[329] According to multiple accounts, these reports were largely ignored by the academic medical community. As discussed in Chapter 2, the adoption of laparoscopic cholecystectomy did not follow the path of "ideal

[325] David R. Urbach and Thérèse A. Stukel, "Rate of elective cholecystectomy and the incidence of severe gallstone disease," *Canadian Medical Association Journal* 172 (2005): 1015-9; Andrew J. McMahon et al., "Impact of laparoscopic cholecystectomy: a population-based study," *Lancet* 356 (2000): 1632-7.
[326] Legorreta, "Increased Cholecystectomy Rate," 1429.
[327] F. Dubois, G. Berthelot, and H. Levard, "Cholécystectomie par coelioscopie," *La Presse Médicale* 19 (1989): 980-2.
[328] F. Dubois et al., "Coelioscopic Cholecystectomy: Preliminary Report of 36 Cases," *Annals of Surgery* 211 (1990): 60-2.
[329] Eddie Joe Reddick and Douglas Ole Olsen, "Laparoscopic laser cholecystectomy: A comparison with mini-lap cholecystectomy," *Surgical Endoscopy* 3 (1989): 131-3.

development" where medical innovation is developed through academic research and subjected to clinical trials and publication reviews before diffusing out to community physicians so that it can be recommended to patients.

Instead, the enthusiasm for laparoscopic cholecystectomy amongst community surgeons was generated at video demonstrations of the technique at the April 1989 meeting of the Society of American Gastrointestinal Endoscopic Surgeons and the October 1989 Clinical Congress of the American College of Surgeons. News of the procedure's availability was then very quickly and actively publicized in local and national newspapers.[330] This chapter will show that in the United States, surgeons and their hospitals/clinics publicized the availability of laparoscopic cholecystectomy in their communities through newspaper reports and paid advertisements, generating the immense patient demand that they claim was the driving force behind the "laparoscopic revolution." This publicity was possible because of a cultural shift in the medical profession's attitudes towards physician advertising and self-promotion that occurred in the 1980s.

In order to provide historical context for this shift, I will first outline the history of the American Medical Association's code of ethics with respect to physician advertising. Next, I will discuss how changing judicial interpretations of anti-trust law during the 1970s forced the AMA to lift its prohibition on physician advertising. I will then illustrate the resulting effects on the promotion of medical services by examining how publicity for hernia repair at outpatient surgical facilities evolved over the course of the 1970s and 80s. Finally, the last section will return to laparoscopic cholecystectomy and show that its promotion through mainstream media followed the trend towards physician advertising that can be seen for outpatient hernia repair.

[330] Laparoscopic cholecystectomy was also promoted through other forms of mass media, such as radio and television. The discussion and analysis here, however, will be confined to its promotion in newspapers.

Medical Professionalism and Self-Promotion

The American Medical Association (AMA) was founded in 1847 to bring together the medical profession of the United States "for the protection of their interest, for the maintenance of their honor and respectability, for the advancement of their knowledge, and the extension of their usefulness."[331] Intent on standardizing medical practice, establishing a standard of gentlemanly conduct for physicians in North America, and differentiating its members from alternative practitioners, the newly formed association quickly adopted the first edition of its *Code of Ethics*.[332] The document outlined a set of duties and obligations which the founders felt that physicians, patients, the medical profession, and the public owed to each other.[333] With respect to the medical profession at large, the authors of the *Code* instructed that, "It is derogatory to the dignity of the profession, to resort to public advertisements…publicly offering advice…or promising radical cures; or to publish cases and operations in the daily prints…These are the ordinary practices of empirics, and are highly reprehensible in a regular physician."[334] Even being quoted or allowing one's name to appear in newspapers for the promotion of a particular treatment was considered to be indirect advertising of one's services, and a violation of the ethical code. Instead, physicians were expected to build their practices by networking with their more established colleagues and receiving referrals.

Starting in the 1880s, however, with the coverage of Louis Pasteur and his rabies vaccine, medical breakthrough stories were regularly featured in newspapers and magazines by the

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[331] American Medical Association, Proceedings of the National Medical Conventions, held in New York, May 1846, and in Philadelphia, May 1847 (Philadelphia: T.K. and P.G. Collins, 1847), 17.
[332] Isaac Hays et al., *Code of Ethics of the American Medical Association: adopted May 1847*, Philadelphia: T.K. and P.G. Collins, 1848; See also, Nancy Tomes, "Farewell to the Free Trade in Doctoring," *Remaking the American Patient: How Madison Avenue and Modern Medicine Turned Patients Into Consumers* (Chapel Hill: University of North Carolina Press, 2016), 23.
[333] Hays, Code of Ethics, 5.
[334] Hays, *Code of Ethics*, 15-16.

1920s.[335] As Susan Lederer has discussed, Alexis Carrel's successful experimentation with vascular suturing and blood transfusions in the early twentieth century generated much attention in the American press and earned him a reputation as a "surgical wizard."[336] Though the publicity led to desperate requests from readers to be experimented on, it is unclear whether Carrel endured any criticism for his showmanship. It is possible that his status as a researcher at the Rockefeller Institute and his refusals to entertain such requests shielded him from accusations of unprofessionalism.

In Britain, the professional ban on indirect advertising was increasingly challenged during the 1920s and 1930s as physicians increasingly argued that writing newspaper articles on public health was an act of public service.[337] Along with such physician-authored columns on medicine and health, medical advice columns – where physicians responded to queries from readers – also became common and syndicated items in newspapers and magazines across the United States and Canada by the 1940s.[338] This shift in attitude towards the names of physicians appearing in mass media publications is reflected in the AMA's 1949 edition of the *Principles*, which decreed that it was ethical for a physician to "write, act or speak for general readers or audiences…[when] engage[d] in a project aimed at health education of the public."[339] For all other purposes, the 1949 edition maintained the position that:

> Solicitation of patients, directly or indirectly, by a physician, by groups of physicians or by institutions or organizations is

[335] Nancy Tomes, "Farewell to the Free Trade," 40.
[336] Susan Lederer, "Living on the Island of Doctor Moreau: Grafting Tissues in the Early Twentieth Century," *Flesh and Blood: Organ Transplantation and Blood Transfusion in Twentieth-Century America* (New York: Oxford University Press, 2008), 20-1.
[337] Ayesha Nathoo, "Communicating Medicine in Post-War Britain," *Hearts Exposed: Transplants and the Media in 1960s Britain* (Basingstoke: Palgrave Macmillan, 2009), 36-7.
[338] Tomes, "Farewell to the Free Trade", 44.
[339] American Medical Association, "Educational Information Not Advertising," *Principles of Medical Ethics of the American Medical Association* (Chicago: American Medical Association, 1949), 5.

> unethical…Among unethical practices [include]…furnishing or inspiring newspaper or magazine comments concerning cases in which the physician or group or institution has been, or is, concerned. Self laudations defy the traditions and lower the moral standard of the medical profession; they are an infraction of good taste and are disapproved.[340]

While the professional acceptance of engaging with media outlets for the purposes of educating the public on how to maintain good health became relatively established, the limit of how much publicity a physician could participate in with respect to medical breakthroughs was less clear. Reports of the first heart transplants in the 1960s, for example, were certainly considered to be newsworthy and important. But as historian Ayesha Nathoo has shown, the ensuing and prolonged publicity surrounding Christiaan Barnard and the British heart transplant surgeons was frowned upon.[341]

As a 1963 editorial in the *Archives of Otolaryngology* on "Medical 'Advertising' in the Lay Press" explained,

> It is true that the public is increasingly interested in medical and surgical advances and must be informed of them. Such information, properly presented to avoid extravagant claims, can be educational and beneficial when it encourages the public to seek timely help for ailments that might otherwise be neglected.[342]

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[340] American Medical Association, "Advertising," *Principles of Medical Ethics of the American Medical Association* (Chicago: American Medical Association, 1949), 4.
[341] Nathoo, Hearts Exposed.
[342] Editorial Board of the Archives, "Medical 'Advertising' in the Lay Press," *Archives of Otolaryngology* 77 (1963): 232-3.

On the other hand, "the most effective advertising of a physician is to have an article appear in a newspaper or magazine describing a new 'miracle' technique employed by him and including his full name and his city or hospital, so that the prospective patient may easily find him!"[343] Instead, the authors instructed, "a physician who is interviewed by a reporter can and should insist that his name not appear in print for a procedure which could be financially rewarding."[344]

By 1957, the mandate against advertising was distilled down to simply direct physicians that "He should not solicit patients."[345] A "reader's digest" version of previous editions, the 1957 *Principles* sought to "[eliminate] superfluous wording and matters of medical etiquette but [retain] all matters of ethics found in [previous versions]."[346] Thus the directive was meant to incur the same meaning as in the 1949 edition with a firm stance against any advertising of physician services to potential patients.

Changing Attitudes Towards Physician Advertising

In December 1975, the United States Federal Trade Commission (FTC) issued a complaint against the AMA, with the charge of an illegal agreement "to prevent or hinder their members from: (A) Soliciting business, by advertising or otherwise; (B) Engaging in price competition; and (C) Otherwise engaging in competitive practices."[347] The FTC's lawyers argued that the AMA's ban on physician advertising was in violation of anti-trust law, specifically, Section 5 of the Federal Trade Commission Act.[348] According to Alfred Dougherty Jr., deputy director of the FTC's Bureau of Competition, the action was meant "to bring 'to the

[343] Editorial Board of the Archives, "Medical 'Advertising.'"
[344] Editorial Board of the Archives, "Medical 'Advertising.'"
[345] "Principles of Medical Ethics – 1957," *Journal of the American Medical Association* 164 (1957): 1484.
[346] "Principles of Medical Ethics – 1957," *Journal of the American Medical Association* 164 (1957): 1482.
[347] American Medical Association, et al., 94 F.T.C. 701, 702-3 (1979).
[348] *AMA*, 94 F.T.C. at 701.

attention of all professions – not just doctors – that there can be no dallying' in their compliance with the antitrust laws."[349] The action was also part of a much longer contestation over whether anti-trust law was applicable to professional groups and their codes of ethics.[350] In 1938, for example, the Justice Department charged the AMA with conspiracy to restrain trade or commerce in the District of Columbia, in violation of the 1890 Sherman Act.[351] The Justice Department held the position that the AMA effected an illegal group boycott by prohibiting physicians from providing medical services on a salaried basis through the Group Health Association, an early Health Management Organization for federal employees.[352] Ruling that neither medical practice nor the provision of medical services could be defined as "trade" under the Sherman Act, the district court decided in favour of the AMA. The Supreme Court, however, found that regardless of whether medicine was a trade, the AMA was guilty of conspiracy to obstruct the business of the Group Health Association.[353]

Still, until the 1970s, the learned professions – medicine, law, engineering, etc. – were largely considered to be exempt from anti-trust legislation based on the view that their practice did not involve trade or commerce.[354] Subsequent attempts to enforce antitrust law against the AMA and other medical societies were also stymied due to ethical beliefs that the restraints on competitive practices (advertising, solicitation, contract practice) were in fact in the interests of the public good. This "learned professions exemption," as Richard McCoy explains in the *Duke*

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[349] As quoted in Robert M. Smith, "F.T.C. Charges Illegality In Curb on Doctors' Ads," *New York Times* (New York, NY), December 23, 1975.
[350] For a review of such actions, see Thomas D. Morgan, "The Impact of Antitrust Law on the Legal Profession," *Fordham Law Review* 67 (1998): 415-441.
[351] Much of my account of the social context in which the Supreme Court found in favour of the FTC in their case against the AMA relies on Carl F. Ameringer, "Organized Medicine on Trial: The Federal Trade Commission vs. the American Medical Association," *Journal of Policy History* 12 (2000): 445-472; American Medical Association. v. United States, 317 U.S. 519 (1943).
[352] Morgan, "Impact of Antitrust," 422.
[353] Morgan, "Impact of Antitrust," 422.
[354] Morgan, "Impact of Antitrust," 419.

Law Review, was "based on the theory that activities which are presumed to be harmful in a free market context because of anticompetitive effects might in fact not be harmful in a professional context, due to the public interest [benefits]."[355] For example, in a 1952 case against the Oregon State Medical Society, the opinion of the Supreme Court was that "there are ethical considerations where the historic direct relationship between patient and physician is involved which are quite different than the usual considerations prevailing ordinary commercial matters. This Court has recognized that forms of competition usual in the business world may be demoralizing to the ethical standards of a profession."[356]

But this was no longer the prevailing judicial position by the time the FTC's case against the AMA was argued in front of the Supreme Court thirty years later. Just months before the FTC made its 1975 complaint against the AMA, the Supreme Court ruled that the Virginia State Bar and the Fairfax County Bar Association were guilty of price-fixing and thus in violation of the Sherman Act. Lewis Goldfarb and his wife initiated the suit after attempting to purchase a house in Virginia and being unable to find any lawyer in the state willing to provide the necessary legal services for less than one percent of the price of the house.[357] Goldfarb, a lawyer at the FTC, filed a class action suit alleging that this was evidence of a conspiracy to prevent competition. The Supreme Court unanimously agreed. With regards to any leniency that might be afforded to the learned professions, the Court held that "The nature of an occupation, standing alone, does not provide sanctuary from the Sherman Act…nor is the public-service aspect of

[355] Richard Thomas McCoy, "The Antitrust Liability of Professional Associations After *Goldfarb*: Reformulating the Learned Professions Exemption in the Lower Courts," *Duke Law Journal* 26 (1977): 1047-1068, 1060.
[356] United States V. Oregon State Medical Society, 343 U.S. 336 (1952).
[357] Morgan, "Impact of Antitrust," 423.

professional practice controlling in determining whether §1 includes professions."[358] This ruling is widely considered to be the end of professional exemptions to antitrust law.[359]

In a more nuanced analysis, McCoy suggests that although the Supreme Court denied complete exemption from the Sherman Act to the learned professions, the decision did concede an important distinction between a profession and a trade, which should grant special consideration.[360] According to the Court, "The public service aspect, and other features of the professions, may require that a particular practice, which could properly be viewed as a violation of the Sherman Act in another context, be treated differently."[361] This distinction, however, was subsequently eroded through multiple rulings against professional groups in the years following *Goldfarb v. Virginia State Bar*.[362] Two years later, in *Boddicker v. Arizona State Dental Association*, two local dental associations were accused of violating the Sherman Act for requiring concurrent membership in the American Dental Association. For the plaintiffs, this condition was evidence of a conspiracy to "creat[e] an anticompetitive tying arrangement."[363] Though the district court dismissed the complaint as being outside of the jurisdiction of the Sherman Act, the decision was subsequently reversed by the court of appeals.[364] As McCoy notes, the decision to reverse the dismissal provided a standard by which to test whether a professional regulation should be afforded an exemption from the Sherman Act.[365] The court of appeals' opinion held that "to survive a Sherman Act challenge a particular practice, rule, or

[358] Goldfarb et UX. v. Virginia State Bar et al., 421 U.S. 773, 787 (4th Cir. 1975).
[359] For example, see Morgan, "Impact of Anti-Trust," 427-431; Clark C. Havighurst, "Antitrust Enforcement in the Medical Services Industry: What Does It All Mean?" *Milbank Memorial Fund Quarterly: Health and Society* 58 (1980): 89-124, 90.
[360] McCoy, "Antitrust Liability," 1050.
[361] *Goldfarb*, 421 U.S. at 788.
[362] McCoy, "Antitrust Liability," 1056-8; Havighurst, "Antitrust Enforcement," 92.
[363] Boddicker et al. v. Arizona State Dental Association, 549 F.2d 626, 628 (9th Cir. 1977).
[364] McCoy, "Antitrust Liability," 1056.
[365] McCoy, "Antitrust Liability," 1056-57.

regulation of a profession…must serve the purpose for which the profession exists, *viz*. to serve the public. That is, it must contribute directly to improving service to the public. Those which only suppress competition between practitioners will fail to survive the challenge."[366] While this ruling allowed that there were instances in which an anti-competitive practice that was meant to protect the public could be exempt from the Sherman Act, a Supreme Court decision in the following year argued that such defenses were irrelevant. In a case against the National Society of Professional Engineers, the Justice Department argued that the prohibition of competitive price bidding on engineering projects, as stipulated in the Society's Code of Ethics, constituted illegal price-fixing.[367] Upholding the lower court rulings in favour of the Justice Department, the Supreme Court was not swayed by the Society's argument that its policy was in the interest of public safety and was intended as a strategy to minimize any deception or poor execution likely to result from price competition. In the Court's opinion,

> The Sherman Act reflects a legislative judgment that, ultimately, competition will produce not only lower prices but also better goods and services…Even assuming occasional exceptions to the presumed consequences of competition, the statutory policy precludes inquiry into the question whether competition is good or bad. The fact that engineers are often involved in large-scale projects significantly affecting the public safety does not alter our analysis.[368]

[366] *Boddicker*, 549 F.2d at 632.
[367] McCoy, "Antitrust Liability," 1061-3.
[368] National Society of Professional Engineers v. United States, 435 U.S. 679, 695 (1978).

As noted by Morgan, "Not only was the 'learned profession' exemption irrelevant to the Court, even the special importance of the subjects with which professionals deal was irrelevant to antitrust analysis."[369] By the time the Supreme Court ruled on *American Medical Assn. v. FTC* in 1982, it was clear that the interest to promote competition and a free-market economy overruled any professional concerns with protecting consumers from unethical practices.

But the Court's 1975 opinion in *Goldfarb v. Virginia State Bar* – which included the view that "Congress did not intend any sweeping 'learned professions' exclusion from the Sherman Act," – was already enough to provide the FTC with valuable insights into how to structure a successful anti-trust case against the AMA.[370] In addition, rising medical costs for both individuals and – with the establishment of Medicare and Medicaid – the government, provided public and Congressional support to the agency's efforts towards increasing price competition in the healthcare industry.[371] While physicians continued to maintain that market competition was detrimental to maintaining the quality of medical care and that commercial practices undermined patient trust, during the 1970s, the interests of multiple groups came together in a fight against rising health-care costs. Consumer advocates believed that lifting the ban on physician advertising would give patients access to information and promote competition between physicians, which would in turn lead to better quality and value.[372] Payers of medical services (i.e., the government and insurance companies) argued that contract-based practices such as pre-paid health plans were the key to restraining healthcare costs. Health economists and policy experts also contended that pre-paid health plans would provide incentives to limit unnecessary medical services. According to Charles Havighurst, professor of healthcare law and a proponent

[369] Morgan, "Impact of Antitrust," 429.
[370] *Goldfarb*, 421 U.S. 773, 774 (1975); Ameringer, "Organized Medicine," 455.
[371] Havighurst, "Antitrust Enforcement," 90; Ameringer, "Organized Medicine," 453-454.
[372] Ameringer, "Organized Medicine," 464.

of market competition in healthcare, "Public dissatisfaction with the industry's economic performance created a political opportunity that the FTC could not have been expected to resist."[373]

Complaint in the Matter of the American Medical Association, et al.

The initial FTC complaint was made on December 19, 1975 against the AMA, the Connecticut State Medical Society, and the New Haven County Medical Association, Inc. It asserted that adherence to the AMA's ban on the solicitation of patients – as decreed in the 1957 *Principles of Medical Ethics* – constituted an agreement amongst the respondents "to prevent or hinder competition between medical doctors."[374] As a result of this agreement, the FTC contended that "Prices of physician services have been stabilized, fixed, or otherwise interfered with…and [c]onsumers have been deprived of information pertinent to the selection of a physician and of the benefits of competition."[375] In bringing the complaint, the FTC hoped that patients would have access to information that "would provide a decisional basis for selecting one doctor as opposed to another," such as medical service price lists.[376] The *New York Times* reported that according to Peter Ward, an assistant director at the Bureau of Competition, "while the F.T.C. did not have projections of what will happen to the cost of medical care, advertising 'probably would have a substantial' impact on prices."[377]

[373] Havighurst, "Antitrust Enforcement," 93.
[374] *AMA*, 94 F.T.C. at 702. As Ameringer notes, although the initial complaint only made specific reference to the AMA's ban on patient solicitation through advertising as anti-competitive practice, the scope of the FTC's case was later broadened to include the AMA's restrictions on contract practice. The discussion here will be confined to physician advertising.
[375] *AMA*, 94 F.T.C. at 703.
[376] Smith, "F.T.C. Charges Illegality."
[377] Smith, "F.T.C. Charges Illegality."

Though the complaint was presented as being "in the public interest," to the AMA it was "ironic that the FTC should attack a code devised and operated as a standard of conduct in the best interests of the patient."[378] In response to the complaint, the AMA issued a public statement declaring,

> Advertising by a profession is the very anti-thesis of professionalism. Physicians should not solicit patients. A patient should go to a doctor on the basis of need, not the basis of advertising…We think there is enough hucksterism in this country without hucksterizing medicine.[379]

What was at stake, according to the Association's Board of Trustees, included "the effect of advertising on fraudulent misleading of the public by various quacks, [and on] the tendency to restrict the free flow of information on new procedures and other medical findings…"[380] Nevertheless, in an effort to appease the FTC, the AMA Judicial Council published a statement in *JAMA* five months after the initial complaint, clarifying the *Principles of Medical Ethics* and making a clear distinction between advertising and solicitation:

> The *Principles* do not proscribe advertising; they proscribe the solicitation of patients. Advertising means the action of making information or intention known to the public. The public is entitled to know the names of physicians, the type of their practices, the location of their offices, their office hours…[381]

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[378] Statement by Raymond T. Holden, Chairman of the AMA's Board of Trustees and Max H. Parrott, President of the AMA, as quoted in Smith, "F.T.C. Charges Illegality."
[379] Holden and Parrott, as quoted in Smith, "F.T.C. Charges Illegality."
[380] AMA Board of Trustees, "Report Q of Board of Trustees: AMA Plan -1976," *Proceedings of the House of Delegates: 125th Annual Convention* (1976), 121.
[381] Henry I. Fineberg et al., "Statement of the Judicial Council Re: Advertising and Solicitation," *Journal of the American Medical Association* 235 (1976): 2328.

Some analysts described this as a "considerable liberalization by the AMA."[382] But in fact, the statement essentially restored the abridged 1957 directive to the more detailed regulations published in previous editions. While the 1957 *Principles* simply instructed that physicians "should not solicit patients," the 1949 *Principles* provided more specific guidance on ethical practice. It instructs, for example, that "An institution [or individual physician] may use means, approved by the medical profession in its own locality, to inform the public of its address and the special class, if any, of patients accommodated."[383] The Judicial Council's 1976 statement in response to the FTC's complaint argued that the AMA never actually prohibited the advertising of a physician's practice, but rather the solicitation of patients. Though the AMA never specifically prohibited the publication of fee schedules, the statement made it explicitly permitted. The statement further argued that the FTC was wrong in its assumption that the AMA's ethical code was an impediment to market competition. After an explanation of practices that are acceptable in other industries but unethical for physicians, the authors concluded that: "Freedom of choice of physician and free competition among physicians are prerequisites of optimal medical care. The *Principles of Medical Ethics* are intended to curtail abusive practices that impinge on these freedoms and exploit patients and the public."[384]

While the AMA's official position was that physician advertising (under its definition) was already permitted even before the FTC made its complaint, in practice, the profession's attitudes towards self-promotion likely remained unchanged. That same year, the editor of the *Journal of the American Medical Association* published his opinion that,

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[382] William C. Canby, Jr. and Ernest Gellhorn, "Physician Advertising: The First Amendment and the Sherman Act," *Duke Law Journal* 1978 (1978): 543-585, 547.
[383] American Medical Association, *Principles of Medical Ethics*, 1949, 6-7.
[384] Fineberg et al., "Statement of the Judicial Council," 2328.

> The competent physician does not advertise skill; it is self-evident. The compassionate physician does not advertise compassion but practices it. Physicians bring compassion, skill, and knowledge to their patients, and these are not commodities to be advertised in the newspaper or through television…Undoubtedly, most physicians…will shun those who, with the blessings of the FTC, pander in the marketplace.[385]

Editorials and letters in the *New England Journal of Medicine* expressed apprehensions that not only would public trust and confidence in medical practice be annihilated if it were turned into a fully commercialized enterprise, ultimately, the costs of advertising would be passed onto the patient and further increase healthcare costs.[386] One concerned physician described a particularly distasteful future where his colleagues would shamelessly engage in:

> direct mail solicitations…; newspaper and magazine ads, with dramatic before and after photos; radio and TV spots with weekly "specials"; give-aways, such as foodstuffs for Medicare and Medicaid patients to encourage frequent visits, and maybe even TV sets for patients who agree to have extensive surgical procedures; raffle tickets with each visit (the winner to be awarded a free procedure such as an electrocardiographic or proctologic examination); [and] promotional parties for prospective patients…[387]

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[385] W. R. Barclay, "Trade or Profession?" *Journal of the American Medical Association* 235 (1976): 756-757.
[386] F. J. Ingelfinger, "Deprofessionalizing the Profession," *New England Journal of Medicine* 294 (1976): 334-335, 335; Theodore E. Spielberg, "Advertising by M.D.'s," *New England Journal of Medicine* 294 (1976): 851-852, 851.
[387] Spielberg, "Advertising by M.D.'s," 851.

But not all commentators were against lifting the ban on physician advertising. Amid the outcry and doomsday rhetoric, there were some who recognized why the lay public might find the FTC's actions to be reasonable. Referencing recent scandals involving organized medicine, one observer pointed out:

> It is evident that in some aspects the profession abuses its privileged position. The FTC action is an attempt to redress this abuse by making medical care more responsive to free market forces. This approach may lead to deprofessionalization, commercialization and lower quality. On the other hand, the public is upset about the mystification and exploitation that exists now.[388]

The Proceedings in the Matter of The American Medical Association, et al., 94 F.T.C. 701 took place in front of an FTC administrative law judge between September 7, 1977 and May 5, 1978. At trial, the AMA's defense relied more on targeting legislative technicalities than on paternalistic arguments that any anti-competitive restrictions were in the interests of consumer protection[389] – arguments which, as we saw, were unsuccessful for the National Society of Professional Engineers. In addition to asserting that the organization was not a "corporation" and thus not under the FTC's jurisdiction, the AMA argued that the fragmented governance of organized medicine, with its various state and local medical societies, prevented the effective execution of any conspiracy to violate antitrust laws. Further, it was argued, efforts were already taking place to amend the *Principles* to better reflect the Supreme Court's ruling in *Goldfarb v. Virginia State Bar*.[390] A new version was introduced at the association's Interim Meeting in

[388] Jeoffry B. Gordon, "Advertising by M.D.'s," *New England Journal of Medicine* 294 (1976): 851-852, 851.
[389] For a more detailed account of the AMA's defense see Ameringer, "Organized Medicine," 459-460.
[390] Ameringer, "Organized Medicine," 459.

December 1977,[391] and publicized in various medical journals and newsletters.[392] The 1957 directive stating that physicians "should not solicit patients" was replaced with, "A physician should not attempt to obtain patients by deception."[393]

As per the AMA's Bylaws, the revised *Principles* was scheduled for approval at the next Annual Convention of the House of Delegates in June 1978. Though the trial proceedings were concluded in the previous month, the ruling was not made until November. Despite reporting mostly favourable responses to the proposed changes, the Judicial Council recommended that more time be taken to consider further revisions and that a special committee be formed to study the issues. According to the Judicial Council's report, there were "comments, which, though essentially favorable, raised questions of substantive interpretations of the Principles" and thus a delay in the adoption of the revised *Principles* "appears unavoidable under the circumstances."[394]

Unfortunately for the AMA, their arguments failed to convince the FTC's administrative law judge who presided over the initial hearing. The judge ruled that the AMA was guilty of causing

> "a formidable impediment to competition in the delivery of health care services by physicians in the [United States]. That barrier has served to deprive consumers of the free flow of information about the availability of health care services…The costs to the public in terms of less expensive or even, perhaps, more improved forms of medical services are great."[395]

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[391] American Medical Association, Proceedings of the House of Delegates: 31st Interim Meeting (1977), 98-99.
[392] American Medical Association, *Proceedings of the House of Delegates: 127th Annual Convention* (1978), 203. See, for example, Bruce Nortell, "AMA Judicial Council Activities," *Journal of the American Medical Association* 239 (1978): 1396-1397.
[393] American Medical Association, *Proceedings: 127th Annual Convention*, 201-202.
[394] American Medical Association, *Proceedings: 127th Annual Convention*, 204.
[395] *AMA*, 94 F.T.C. 701, 917 (1979).

The association was ordered "to cease engaging in any action that would restrict its members' solicitation of patients by advertising…[and] to amend its *Principles of Medical Ethics*."[396]

After an unsuccessful appeal to the full FTC Commission,[397] the AMA House of Delegates adopted an amended version of the *Principles* at their 129th Annual Convention in July 1980. Instead of instructing members to restrain from advertising or soliciting patients, the revision now stipulated that "A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception…[and] make relevant information available to patients, colleagues, and the public…"[398] Until this point however, judgments of the AMA's activities with respect to antitrust law were made by individuals employed at the FTC. Though administrative law judges are, in theory, impartial, they are also members of staff at the agencies that bring the cases in front of them.[399] Appeals to decisions rendered by the FTC's administrative law judge are then made to the full FTC Commission, a panel of, again, FTC employees.

In the hope that an external court would take into consideration the multiple efforts to comply with post-*Goldfarb* interpretations of antitrust law, made even before the FTC initiated its proceedings, the AMA petitioned the 2nd Circuit Court of Appeals to deny enforcement of the FTC's order as being no longer necessary.[400] Divided two to one, the dissenting judge agreed, finding

> …that the steps promptly taken by the American Medical Association to modify and up-date its ethical standards after the

[396] *AMA*, 94 F.T.C. at 701.
[397] Arguments to the full FTC Commission were made in April 1979 and the appeal was denied in October 1979.
[398] American Medical Association, Proceedings of the House of Delegates: 129th Annual Convention (1980), 207.
[399] Ameringer, "Organized Medicine," 459.
[400] American Medical Association v. Federal Trade Commission, 638 F.2d 443 (2d Cir. 1980).

> Supreme Court's decision in Goldfarb v. Virginia State Bar – revisions that were commenced prior to the FTC's initiation of the present proceeding – satisfy me that the Commission proceeding has been unjustified, unnecessary, and a waste of administrative and judicial resources. In essence the Commission's order…is based on outdated facts that long since have ceased to exist. It merely requires the Association to do what it is doing anyway…the Commission insisted on pressing for its pound of flesh. In my view the FTC is engaged in the futile business of beating a dead horse…the Commission's order in my view constitutes an abuse of discretion.[401]

In contrast, the majority opinion not only held that the petition should be denied, it also determined the 1980 revisions to be insufficient. While acknowledging that "[t]he elimination of the ban on solicitation which appeared in the 1957 version of the Principles reflects a significant and commendable effort to comply with the terms of the FTC order here under review," the Court of Appeals found that "[t]he language of the 1980 Principles is general and imprecise in nature. Moreover, the various written interpretations of the 1957 Principles promulgated by the AMA remain in effect."[402]

Intent on pursuing all opportunities to have the FTC's order overturned, the AMA presented its case to the Supreme Court two years later.[403] But in what was described by one of the AMA's lawyers as "the greatest anticlimax you could imagine," the evenly split Court (with

[401] *AMA*, 638 F.2d at 443.
[402] *AMA*, 638 F.2d at 443.
[403] American Medical Assn. v. FTC, 455 U.S. 676 (1982).

one justice abstaining) provided no further opinion on the case.[404] According to Ameringer, "It was as if the Court had refused to consider the case in the first place."[405] After six and a half years of litigating the complaint, the Supreme Court ruled on March 23, 1982 that the FTC's order should be upheld. Accordingly, the AMA again amended its code of ethics to stipulate that "There are no restrictions on advertising by physicians except those that can be specifically justified to protect the public from deceptive practices. A physician may publicize him or herself as a physician through any commercial publicity or other form of public communication."[406]

Medical Service Advertising on the Rise: Outpatient Hernia Repair

Though the FTC was victorious in expunging the 135-year old prohibition on advertising from organized medicine's ethical code, it did not result in an immediate change in practice. As Nancy Tomes notes, lifting the ban did not mean that physicians, especially older physicians, rushed to promote themselves in popular media. Those that did allow their names to be printed tended to be physicians offering specialized and non-urgent medical services, for example, hernia repair.[407] An examination of references to hernia repair in American newspapers during the 1970s and 80s provides an understanding of how the promotion of physician services changed after the AMA lifted its ban on physician advertising. Hernia repair provides a good baseline for this analysis because it was consistently cited throughout this period as a typical outpatient procedure offered at hospitals and independent clinics.

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[404] Jack Bierig (legal counsel for the AMA), as quoted in Carl Ameringer, "A Question of Jurisdiction," *The Health Care Revolution – From Medical Monopoly to Market Competition* (Berkeley and Los Angeles: University of California Press, 2010), 119-34, 121.
[405] Ameringer, "Question of Jurisdiction," 121.
[406] As quoted in Tomes, "Shopping Mall Medicine," *Remaking the American Patient: How Madison Avenue and Modern Medicine Turned Patients into Consumers* (Chapel Hill: The University of North Carolina Press, 2016), 331.
[407] Tomes, "Shopping Mall Medicine," 331-332.

This was particularly the case as hospitals across the United States increasingly established outpatient surgical units "[i]n an attempt tio[sic] increase hospital efficiency, provide greater convenience to patients, and reduce medical costs to both…"[408] Introduced at the Butterworth Hospital in Grand Rapids, Michigan in 1961, the outpatient approach to surgery was adopted in over 2,000 hospitals across the United States by 1975.[409] The trend towards day surgery can also be observed with the rise of independent surgical clinics following the 1970 establishment of the first "Surgicenter" in Phoenix, Arizona,[410] and the AMA's formal endorsement of outpatient surgery in 1971.[411] These free-standing "ambulatory centres" or "surgicenters" were specifically designed to provide "one-day surgical procedures at fees below those paid by patients who stay in hospitals for several days."[412]

While some hospitals outsourced their outpatient procedures by establishing affiliations with independent clinics,[413] others attempted to block ambulatory centers from being built in their communities.[414] Plans to build such a facility in Indianapolis, for example, were opposed by

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[408] Diane K. Shah, "Many hospitals becoming drive-ins," *The Daily Item* (Sunbury, PA), August 13, 1973.
[409] Sylvia Porter, "Your Money's Worth: Slashing Your Hospital Costs – Walk-In Surgery," *Daily American* (Somerset, PA), October 14, 1975; Nancy Burden, "Outpatient Surgery: A View Through History," *Journal of PeriAnesthesia Nursing* 20 (2005), 435-7;
[410] J. L. Ford and W. A. Reed, "The surgicenter – an innovation in the delivery and cost of medical care," *Journal of Arizona State Medical Association* 26 (1969): 801-4; Wallace A. Reed and John L. Ford, "Development of an Independent Outpatient Surgical Center," *International Anesthesiology Clinics* 14 (1976): 113-30, 121; "Phoenix Doctors Develop Center For 'Quick Surgery," *Cincinnati Enquirer* (Cincinnati, OH), November 29, 1971; Shah, "Many hospitals"; Gordon Slovut, "A 'factory' of surgery cuts costs," *The Minneapolis Star* (Minneapolis, MN), December 26, 1973.
[411] American Medical Association, Proceedings of the House of Delegates: 120th Annual Convention (1971), 278.
[412] "Open House Today: Center To Reduce Cost of Surgery," *Austin American-Statesman* (Austin, TX), August 26, 1973; Ambulatory Centre of Miami, "Variety of Surgical Procedures Performed At Ambulatory Centre of Miami," advertisement in the *Miami News* (Miami, FL), January 28, 1976; William G. Crook, "New surgery approach promising," *Gastonia Gazette*, Gastonia, NC, October 9, 1972; "Surgical Center Offers 1-Day Service," *St. Louis Post-Dispatch* (St. Louis, MO), January 6, 1974.
[413] Christy Schofield, "Surgicenter Ready to Open," *Honolulu Star-Bulletin* (Honolulu, HI), November 2, 1979; Jean Dietz, "Profit surgi-centers proposed," *Boston Globe* (Boston, MA), December 11, 1983; Paula Kriner, "Hospital board backs walk-in surgery center," *Times-Advocate* (Escondido, CA), Dec 19, 1984; Ernestine Williams, "Outpatient surgery center to be built by July," *News-Press* (Fort Myers, FL), February 1, 1985.
[414] Carol Davis, "Doctors to seek state approval of outpatient clinic," *Daily Sentinel* (Grand Junction, CO), April 13, 1982.

officials from local hospitals because of concerns that "the center would siphon off patients needing simple procedures, leaving St. Vincent with the more complicated and expensive surgeries. The result could be raised hospital rates…"[415] In contrast, proponents of independent surgery centers argued that in addition to cutting costs for patients,[416] competition from the centers even helped to push hospitals to adopt the outpatient approach. As the *Tampa Tribune* reported in 1979, "Outpatient surgery also is available at University Community and St. Joseph's hospitals, but a spokesman for the group of physicians who requested Ambucare to build a center in Tampa said those hospitals largely ignored physicians' requests for the service until the threat of competition forced them to provide it."[417] The growth in outpatient surgery was also credited to "pressure by health insurers, Medicare and Medicaid," who were especially interested in the potential for outpatient surgery to help rein in exploding medical costs. [418] As Montgomery Alabama's Jackson Hospital claimed in the promotional spread for their Ambulatory Care Service, "Many insurance companies are now encouraging outpatient surgery by covering 100% of their allowable charges instead of the usual 80% on inpatient costs."[419]

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[415] Richard D. Walton, "Controversy On Surgical Center Boils," *Indianapolis Star* (Indianapolis, IN), October 5, 1980. For other examples see Jeff Hawkes, "Surgery Center To Compete With Hospitals Here: Hospitals Express Concern Over Surgery Center Plans," *Intelligencer Journal* (Lancaster, PA), February 18, 1983; Christopher Simpson, "Panel opposes surgical center," *Daily Press* (Newport News, VA), August 20, 1983.
[416] See, for example, "Open House Today: Center To Reduce Cost of Surgery"; Robin Bulman, "Surgicenters offer consumers a break in their medical bills," *Billings Gazette* (Billings, MT), April 28, 1982; Joe Simmons, "Planned center would cut surgery expenses," *Montgomery Advertiser* (Montgomery, AL), July 19, 1983.
[417] Deborah George, "Alternative To A Stay In The Hospital Established," *Tampa Tribune* (Tampa, FL), January 1, 1979.
[418] Erik Gunn, "Outpatient surgery rises in popularity: Strong Memorial center is opening tomorrow," *Democrat and Chronicle* (Rochester, NY), February 24, 1985; Patricia McCormack, "Blue Cross Calls for More Out-Patient Surgery," *The Town Talk* (Alexandria, LA), February 8, 1981; Robert L. Peirce, "State Medicaid program to pay for surgery at outpatient clinics: State pushing surgery clinics," *The Courier-Journal* (Louisville, KY), July 10, 1981.
[419] "One-Day Surgery Offers Health Care Savings," *Montgomery Advertiser* (Montgomery, AL), May 8, 1983.

Figure 3.1: Speedy Surgery – A journalist's depiction of a surgical drive-through that accompanied an article on outpatient surgery published in the *Colorado Springs Gazette-Telegraph* on March 9, 1978.[420]

Characterized as "drive-in surgery" or "surgery-to-go" (see Figure 3.1), the availability of outpatient surgery services was often announced in local newspapers.[421] In February 1973, for example, the *Detroit Free Press* announced that five local hospitals were to begin offering "extensive outpatient surgery programs…includ[ing] minor skin operations, simple hernia repair,

[420] Patrick O'Grady, "Outpatient Surgery Cuts Costs," *Colorado Springs Gazette-Telegraph* (Colorado Springs, CO), March 9, 1978.
[421] See, for example, Mary Godwin, "'Drive-in' surgery in and out in a day," *The Record-Eagle* (Traverse City, MI), April 13, 1978; Pat Harboult, "'Drive-in' Surgery: New concept promises fast medical service for patients," *Tallahassee Democrat* (Tallahassee, FL), October 24, 1976; Dona Rains, "Looking for bargain? Try surgery-to-go," *The Paducah Sun* (Paducah, KY), January 3, 1986.

tonsillectomies, plastic surgery, [and] hemorrhoidectomies…"[422] Readers were informed that these programs would "enable a patient to check into the hospital at 10 a.m., have his operation at noon, and be on his way home by 5 p.m."[423] Headlines such as "N.C. Memorial Hospital Day-Op Program Reducing Medical Costs,"[424] "New Suite Opens At City Hospital For One-Day Surgical Treatment,"[425] and "Outpatient Unit [at Moore Community Hospital] Slates Open House,"[426] peppered newspapers across the United States throughout the 1970s and 80s (See Table 3.1 for more examples). Independent surgical centers were similarly announced: "Open House Today: Center To Reduce Cost of Surgery,"[427] "A 'factory' of surgery cuts costs,"[428] and "Northwest Surgicare offers 'operations while you wait'"[429] (See Table 3.2 for more examples). As mentioned earlier, hernia repair was consistently used as an example of the type of procedure that would be available at outpatient facilities. The newspaper items that discuss outpatient surgery and are referenced in this chapter were all obtained from a search of "hernia repair" in the newspapers.com database.

[422] Dolores Katz, "5 Hospitals to Offer Quickie Surgery," *Detroit Free Press* (Detroit, MI), February 19, 1973.
[423] Katz, "5 Hospitals."
[424] "N.C. Memorial Hospital Day-Op Program Reducing Medical Costs," *Rocky Mount Telegram* (Rocky Mount, NC), April 2, 1978.
[425] "New Suite Opens At City Hospital For One-Day Surgical Treatment," *St. Louis Post-Dispatch* (St. Louis, MO), February 13, 1985.
[426] "Outpatient Unit Slates Open House," *The Daily Oklahoman* (Oklahoma City, OK), July 18, 1988.
[427] "Open House Today: Center To Reduce Cost of Surgery."
[428] Slovut, "A 'factory' of surgery cuts costs."
[429] Karen Blecha, "Northwest Surgicare offers 'operations while you wait,'" *Wheeling Herald* (Wheeling, IL), May 22, 1974.

Table 3.1: Newspaper Headlines Promoting Hospital Outpatient Unit

Headline	City	Newspaper	Date
Holy Name establishes one-day surgery setup	Teaneck, NJ	*The Record*	Jan 28, 1973
Short Stay Unit Opens At Hospital	San Mateo, CA	*The Times*	Apr 17, 1973
$714,000 ambulatory surgical center dedicated at Tucson	Tucson, AZ	*Arizona Republic*	Jan 31, 1974
John Muir Hospital's New Ambulatory Center Opens	Walnut Creek, CA	*Oakland Tribune*	Oct 27, 1974
Cowlitz starts outpatient surgery	Longview, WA	*Longview Daily News*	Oct 6, 1975
Program Is Formalized For Surgical Outpatients	Nashua, NH	*Nashua Telegraph*	Feb 11, 1977
Day surgery unit popular	Odessa, TX	*The Odessa American*	May 6, 1979
Surgicenter Ready to Open	Honolulu, HI	*Honolulu Star-Bulletin*	Nov 2, 1979
First Surgery Is Performed in Orem	Orem, UT	*The Daily Herald*	Jul 9, 1981
Hospital introduces early testing and same-day surgery to cut patient costs	Ithaca, NY	*Ithaca Journal*	Jul 2, 1982
'Same-day' surgery cuts costs at Mercy	Coon Rapids, MN	*Minneapolis Star and Tribune*	Jan 13, 1983
EMMH opens 'one-day surgery unit'	Danville, KY	*Advocate-Messenger*	Mar 27, 1983
Luther opens surgi-center in bid to lower health costs	Eau Clair, WI	*Leader-Telegram*	Jul 6, 1984
Memorial to open in-out surgery unit	Manhattan, KS	*Manhattan Mercury*	Jul 18, 1984
New Suite Opens At City Hospital For One-Day Surgical Treatment	St. Louis, MO	*St. Louis Post-Dispatch*	Feb 13, 1985
One Day Surgery Unit Opens at A.G. Hospital	Arroyo Grande, CA	*Times-Press-Recorder*	May 1, 1985
Medical Center creates outpatient suite	Menomonie, WI	*Dunn County News*	Mar 19, 1986
Outpatient surgery center opens	Newport News, VA	*Daily Press*	Jan 31, 1987
New hospital day surgery unit greeted with approval	De Kalb, IL	*Daily Chronicle*	Apr 26, 1987
Outpatient center debuts this week	Albany, OR	*Albany Democrat-Herald*	Jun 1, 1988
Outpatient surgery center opens	Pittsburgh, PA	*Pittsburgh Press*	Apr 2, 1989

Table 3.2: Newspaper Headlines Promoting Independent Ambulatory Surgery Centers

Headline	City	Newspaper	Date
Open House Today: Center To Reduce Cost of Surgery	Austin, TX	*Austin-American*	Aug 26, 1973
1-Day Surgical Center Opens	St. Louis, MO	*Decatur Herald*	Jan 9, 1974
Metro board endorses new 'one-day surgical center'	St. Paul, MN	*Star Tribune*	Aug 29, 1974
Surgicenter Ready to Open	Honolulu, HI	*Honolulu Star-Bulletin*	Nov 2, 1979
'Same-day' surgery gets state approval	Des Moines, IO	*The Gazette*	Jul 13, 1980
Controversy on Surgical Center Boils	Indianapolis, IN	*Indianapolis Star*	Oct 5, 1980
Surgical center plan supported	Madison, WI	*Wisconsin State Journal*	Nov 8, 1980
Proposed Out-Patient Center May Trim Some Surgical Costs	Montgomery, AL	*Alabama Journal*	Jul 19, 1982
Surgical center being built in Belleair	Belleair, FL	*Tampa Bay Times*	Dec 16, 1982
Surgical center opening planned	Shreveport, LA	*The Times*	Jan 1, 1983
Surgical center approved	Chattanooga, TN	*The Morning Press*	May 27, 1983
Company may establish outpatient surgery clinic	Newport News, VA	*Daily Press*	Jul 9, 1983
Surgical clinic is proposed	Redlands, CA	*San Bernardino County Sun*	May 4, 1984
Outpatient surgery center nearly done	Butte, MT	*Montana Standard*	Jul 8, 1984
Hospital board backs walk-in surgery center	Escondido, CA	*Times-Advocate*	Dec 19, 1984
Outpatient surgery center to be built by July	Port Charlotte, FL	*News Press*	Feb 1, 1985
One-day surgery center will open April 15 in Elicott City	Elicott City, MD	*Baltimore Sun*	Apt 1, 1985
New Surgery Center Will Open Today	Lancaster, PA	*Intelligencer Journal*	Jun 17, 1985
Parkside Surgery Complex opens	Jackson, TN	*Jackson Sun*	Dec 11, 1985
New Clinic Planning To Open	St. Louis, MO	*St. Louis Post-Dispatch*	Dec 22, 1985
Same-day surgery center wins state approval	Rockland, NY	*The Journal News*	Jan 16, 1987
Same-day surgical center to open tomorrow	Allentown, PA	*Morning Call*	Mar 1, 1989

The initial promotion of outpatient services was generally confined to news reports. But by the early 1980s, both surgicenters and hospitals also began placing advertisements in local newspapers to promote their outpatient surgery services.[430] Listing hernia repair with bunion removal, breast augmentation, tonsillectomy, and other possible outpatient procedures, these advertisements touted the cost-saving, time-saving, and recovery benefits of Same Day Surgery. According to an advertisement for ambulatory surgery at St. Vincent Hospital in Indianapolis, IN, "In 1920 Stephen Scott [fictitious name] had a hernia operation at St. Vincent. He went home 22 days later. Last Monday, Stephen Scott's great-grandson underwent a similar hernia repair at 8:00 a.m. He was at home by 2:00 p.m."[431] Similarly, an advertisement for the Same Day Surgery Center in West Orange, New Jersey claimed, "a breast biopsy in a hospital can take three days and cost as much as $1,445…But if you're a basically healthy person…, that very same operation in same day surgery takes less than four hours and costs only $475."[432] Gottlieb Memorial Hospital's advertisement in the *Chicago Tribune* quoted a satisfied patient's testimonial that they "hardly missed a house showing thanks to Gottlieb's Same Day Surgery," emphasizing how outpatient procedures allowed patients to return to work earlier and minimize loss of income.[433] Valley Presbyterian Hospital's 1983 advertising campaign promised *Los Angeles Times* readers "Surgery With All The Comforts Of Home," and told potential patients

[430] See, for example, Ambulatory Centre, "What you should know about our operation before you have yours," advertisement in the *Miami News* (Miami, FL), May 13, 1977; Ambulatory Surgical Center, "Hernia Repair – local anesthesia," item in the Classified Advertising section of the *Tampa Bay Times* (Tampa Bay, FL), October 30, 1979; Saint Cloud Hospital, "'I'll be home for supper!'" advertisement in the *Saint Cloud Times* (Saint Cloud, MN), January 11, 1983; Jackson Hospital, "One-Day Surgery Offers Health Care Savings," advertisement in the *Montgomery Advertiser* (Montgomery, AL), May 8, 1983.
[431] St. Vincent Hospital and Health Care Center, "In 1920 Stephen Scott* had a hernia operation at St. Vincent," advertisement in the *Indianapolis Star* (Indianapolis, IN), December 5, 1982.
[432] "Why pay for the whole pie when all you're having is one slice?" advertisement in *The Item of Millburn and Short Hills* (Millburn, NJ), October 27, 1983.
[433] "I hardly missed a house showing thanks to Gottlieb's Same Day Surgery," advertisement in *Chicago Tribune* (Chicago, IL), June 6, 1985.

that home "really is the best medicine. Surrounded by family and all that's familiar, young and old alike usually recovery from surgery more quickly than when they spend the night in the hospital."[434]

Seemingly in line with the attitude presented in the 1963 *Archives of Otolaryngology* editorial that physicians "should insist that his name not appear in print for a procedure which could be financially rewarding,"[435] care was taken so that publicity for outpatient facilities did not provide the names of surgeons whom patients could seek out for their procedures. The explanation of day surgery in a 1974 news report on the dedication of Tucson Medical Center's ambulatory surgical center for example, read, "A young child may enter the center at 10 a.m. for a hernia operation and be ready to go home by 2:30 p.m. the same day, doctors say."[436] Rather than relying solely on comments from unnamed sources, early articles on day surgery often profiled nurses or patients who were among the first to benefit from day surgery at a hospital or independent clinic. A story, for example, in the Traverse City *Record-Eagle* on Munson Medical Center's outpatient clinic demonstrated the advantages of "drive-in" surgery by focusing on the experiences of a recent patient and a nurse at the clinic, both of whom were quoted and photographed.[437] Other sources that such promotional pieces routinely relied on for comments

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[434] Valley Presbyterian Hospital, "Surgery With All The Comforts Of Home," advertisement in the *Los Angeles Times* (Los Angeles, CA), July 28, 1983.
[435] Editorial Board of the Archives, "Medical 'Advertising' in the Lay Press."
[436] "$714,000 ambulatory surgical center dedicated at Tucson," *Arizona Republic* (Phoenix, AZ), January 31, 1974.
[437] Godwin, "'Drive-in' surgery in and out in a day." Other examples of articles that used testimonials from patients and nurses include, "Keeping Up With the Times: Reducing the Demand for Beds," *Daily Journal* (Vineland, NJ), February 6, 1974; "Kudos for Day Stay Center," *Daily Register* (Red Bank, NJ), August 7, 1975; Peg Gallagher, "A-O's Day Surgery Program spares child long hospital stay," *Star-Gazette* (Elmira, NY), July 10, 1977; Ginny McPartland, "Outpatient Surgery At Queen," *Napa Valley Register* (Napa, CA), April 27, 1978; "First Surgery Is Performed in Orem," *Daily Herald* (Provo, UT), July 9, 1981; "Hospital introduces early testing and same-day surgery to cut patients costs," *Ithaca Journal* (Ithaca, NY), July 2, 1982; Cathy A. Monroe, "'I went in, had it done, went home,'" *Southern Illinoisan* (Carbondale, IL), June 20, 1982; Joy Owens, "New Technology Aids Same-Day Surgery," *Daily News* (Lebanon, PA), March 7, 1984.

included hospital/clinic administrators, spokespeople for health insurance providers, and medical association representatives.[438]

This is not to say that physicians were never quoted in newspaper articles on day surgery. However, even after the AMA liberalized its stance on physician advertising in 1976, publicity for outpatient units and surgery centers generally refrained from promoting the services of specific surgeons until the mid-1980s. Any physicians that did provide comments were usually either anaesthesiologists or surgeons acting in an administrative capacity.[439] Most surgeons who would be the ones performing the outpatient procedure – and thus likely be whom patients evaluated when choosing where to go for their surgery – did not start allowing themselves to be named in the promotion of specific procedures until later in the 1980s.[440]

In contrast to the earlier articles, a 1987 article promoting the outpatient department at Logan Memorial Hospital in Russellville, KY, included the names of four local surgeons who

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[438] See, for example, Carol Saboe, "No need to stay long for many operations," *Billings Gazette* (Billings, MT), October 22, 1972; Justin L. Faherty, "Holy Name establishes one-day surgery setup," *The Record* (Hackensack, NJ), January 28, 1973; "John Muir Hospital's New Ambulatory Center Opens," *Oakland Tribune* (Oakland, CA), October 27, 1974; Howard Wolinsky, "Surgery Clinic Planned," *Florida Today* (Cocoa, FL), December 26, 1975; "Program Is Formalized For Surgical Outpatients," *Nashua Telegraph* (Nashua, NH), February 11, 1977; "Day surgery unit popular," *Odessa American* (Odessa, TX), May 6, 1979; "Bethesda Plans To Open New Surgical Facility," *Times Recorder* (Zanesville, OH), August 18, 1981; Paul Gustafson, "'Same-day' surgery cuts costs at Mercy," *Star Tribune* (Minneapolis, MN), January 13, 1983; Ronald Sullivan, "Program aims to cut hospital stays," *South Bend Tribune* (South Bend, IN), November 13, 1983; Dietz, "Profit surgi-centers proposed"; "Ambulatory Surgery Offers Same Day Service," *Arizona Republic*, Phoenix, AZ, November 3, 1985; J. J. Jackson, "Center Has Made Impact on Medicine," *Daily Herald*, Provo, UT, February 28, 1986;

[439] See, for example, Christine Bertelson, "Surgicare Speeds Minor Operations, Cuts Costs," *Burlington Free Press* (Burlington, VT), January 11, 1976; Ina Fried, "Anxiety Eased for Youngsters: New Surgery Plan Is Utilized," *Statesville Record and Landmark* (Statesville, NC), March 16, 1977; "N.C. Memorial Hospital Day-Op Program Reducing Medical Costs"; "Minor operations performed in day," *Courier-Post* (Camden, NJ), November 18, 1979; Jana Miller, "Hospital stays being shortened," *Lincoln Journal Star* (Lincoln, NB), August 21, 1981; Anna Marie Lux, "Ambulatory surgery: a sign of the times," *Daily Tribune* (Wisconsin Rapids, WI), September 26, 1981; Ann Daly, "Under the Knife: Hospitals Aim To Reduce Costs With New Surgery Procedures," *Pittsburgh Press*, Pittsburgh, PA, August 18, 1983.

[440] This was not absolute. There were some surgeons who allowed themselves to be profiled early on. See, for example, "Fast Surgery," *Wisconsin State Journal* (Madison, WI), December 12, 1981; Jane Harriman, "Hernia patients get a lift: 'Gimmicky' operation reduces time in hospital, costs," *The News* (Wilmington, DE), August 23, 1982; Tom Dubocq, "One-day surgery has runner out of Dade center by lunch," *Miami News* (Miami, FL), May 12, 1983; William R. Wineke, "Outpatient surgery cuts hernia cost," *Wisconsin State Journal* (Madison, WI), February 13, 1984; Stuart Hirsch, "Memorial surgeons have variety of skills," *Star-Democrat* (Easton, MD), April 24, 1984.

treated patients at the facility, along with examples of possible procedures.[441] Similarly, a 1989 advertisement for ambulatory surgery at Holy Cross Hospital in Taos, New Mexico, invited potential patients to "[e]xperience the miracle of healing – faster and more comfortable than ever in history," and promised that "[w]ith AMBULATORY SURGERY at Holy Cross Hospital, you can be home in just a few hours," (see Figure 3.2).[442] Again, the advertisement listed examples of procedures that could be performed at the clinic as well as the names of the surgeons on staff who specialized in those procedures. While a departure from the previously upheld norm where physicians refrained from publicly promoting one's own medical services, such advertising was likely considered to be acceptable. Since outpatient surgery was already common practice, this publicity would not have been seen as the type of "hucksterizing medicine" that the AMA warned against in 1976.

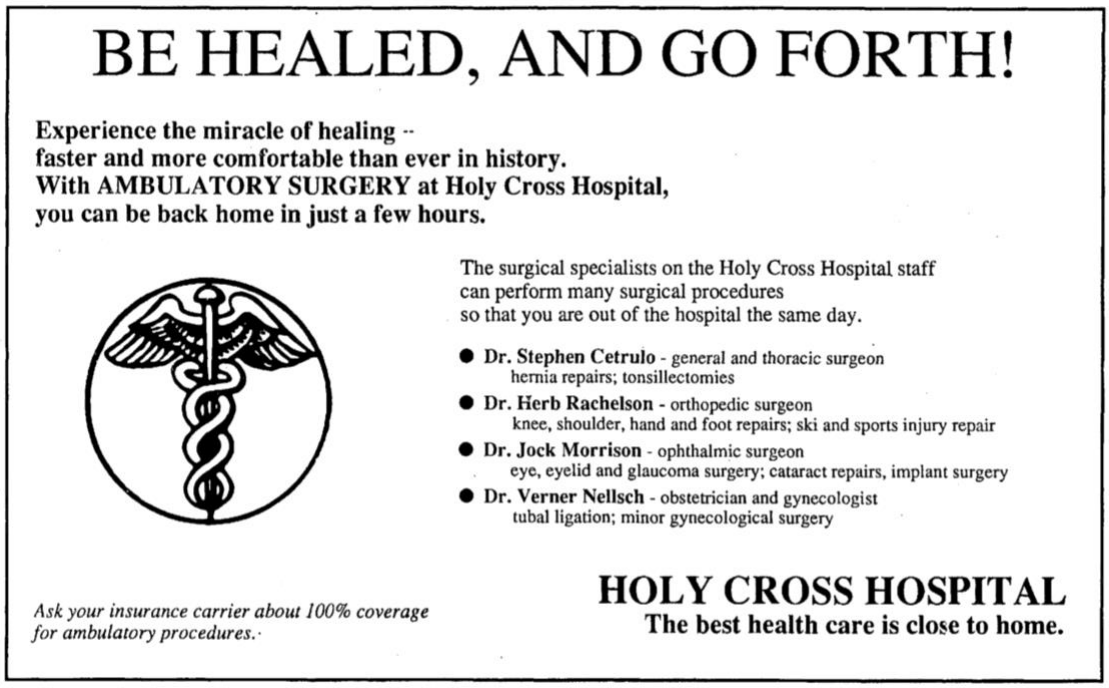

Figure 3.2: Advertisement for Ambulatory Surgery – at Holy Cross Hospital in Taos, New Mexico. Note the promotion of specific surgeons and the outpatient procedures that they offer.

[441] Jeannie L. Bowles, "Outpatient surgeries on the increase," *News-Democrat and Leader* (Russellville, KY), April 6, 1987.
[442] Holy Cross Hospital, "Be Healed, And Go Forth!" advertisement in the *Taos News* (Taos, NM), June 22, 1989.

Some hospitals and clinics, however, did begin to promote themselves in the commercialized way that was feared. As outpatient surgical facilities became more common, many sought to set themselves apart with offers of free consultations,[443] free parking,[444] "free limousine [rides] to and from [the] center on day of surgery,"[445] and "courtesy meal[s]…for an accompanying friend or relative."[446] Reminiscent of the exaggerated prediction – quoted on page 20 – of what commercialized medicine would look like, one Louisiana hospital invited readers to enter their "Draw for our FREE Digital Home Thermometers," in their outpatient surgery advertisement.[447] In an advertisement for "surgical procedures available in his office or Peninsula Health Care, [Surgery Clinic]" one surgeon in Green Bay, WI even offered "A Free 3 Day Winter Weekend At The Maritime Inn After Delivery," to expecting parents who came to him for their "OB Deliveries."[448]

Hernia repair came to be a procedure that some surgeons considered was profitable enough to establish specialized clinics.[449] By 1984, clinics like the Hernia Center of New Jersey

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[443] See for example, Same Day Hernia Repair Center, "Hernia: The Canadian Method With No Disability," advertisement in the *Daily News* (New York, NY), October 28, 1985; Phoenix Hernia Center, "Why Suffer?" advertisement in the *Arizona Republic* (Phoenix, AZ), April 18, 1986; Albany Medical Surgical Center, "hernia. It won't heal itself and it won't get better," advertisement in the *Chicago Tribune* (Chicago, IL), August 10, 1986; Medi-Surg Services, "Hernias: Safe Solutions for Hernia Sufferers," advertisement in the *Daily News* (New York, NY), January 7, 1987; Nicholas R. Wagener, "Announcement," advertisement in the *Green Bay Press* (Green Bay, WI), March 22, 1987.

[444] Santa Monica Hospital Medical Center, "Don't Bother To Pack," advertisement in the *Los Angeles Times* (Los Angeles, CA), September 21, 1984.

[445] Professional Health Care Specialists, "Fully Licensed Outpatient Surgi-center," advertisement in the *Chicago Tribune* (Chicago, IL), April 19, 1987; Coastal Surgical Care, "Costs Are Down For Fixing You Up," advertisement in the *Palm Beach Post* (West Palm Beach, FL), January 18, 1987. Clara Maass Medical Center, "Free Maass transportation," advertisement in the *Belleville Times* (Belleville, NJ), July 7, 1988.

[446] Humana Hospital Phoenix, "One Day Is Enough," advertisement in the *Arizona Republic* (Phoenix, AZ), April 8, 1984.

[447] Bunkie General Hospital," Outpatient Surgery," advertisement in *The Bunkie Record* (Bunkie, LA), February 28, 1986.

[448] Wagener, "Announcement."

[449] See, for example, Hernia Center of New Jersey, "A Medical Center Devoted Solely To The Treatment of Hernias," advertisement in the *Asbury Park Press* (Asbury Park, NJ), April 1, 1984; The United States Hernia Institute, "Modern Hernia Repairs by Experienced Hernia Surgeons," advertisement in *The Record* (Hackensack, NJ), December 3, 1984; The Hernia Center, "Hernias: A Medical Office Devoted Solely To The Treatment of Hernias," advertisement in the *Central New Jersey Home News* (New Brunswick, NJ), January 21, 1985; Palm

or the Palm Beach Hernia Clinic began to emerge across the United States.[450] Advertisements for hernia clinics often offered prospective patients free hernia examinations[451] and even lifetime guarantees/warrantees on their repairs.[452] While some clinics simply publicized that their surgeons had extensive experience in hernia repair, others touted expertise in superior methods (see Figure 3.3). One surgeon in Freehold, New Jersey, for example, advertised his "unique and new approach" and claimed that his patients could "wal[k] immediately after Hernia Repair."[453] Many clinics promoted their use of the Shouldice hernia repair method, or "Canadian Method"[454] – a technique developed by the Canadian surgeon, Edward Earle Shouldice, during World War II.[455] The Trabucco Institute For Hernia Surgery in Queens, New York, even advertised their use of an "Improved Canadian Method"[456] before later promoting a "no tension mesh technique."[457]

Beach Hernia Clinic, "Announcing the Opening Of The Palm Beach Hernia Clinic, Inc.," advertisement in the *Palm Beach Post* (West Palm Beach, FL), February 10, 1985; Same Day Hernia Repair Center, "Hernia: The Canadian Method With No Disability."

[450] Hernia Center of New Jersey, "Medical Center Devoted"; Palm Beach Hernia Clinic, "Announcing the Opening."

[451] Palm Beach Hernia Clinic, "Announcing the Opening Of The Palm Beach Hernia Clinic, Inc."; Arizona Hernia Center at Community Hospital Medical Center, "A hernia can be a serious – even life-threatening – health problem," advertisement in the *Arizona Republic* (Phoenix, AZ), February 1, 1987; Kissimmee Memorial Hospital, "there's nothing funny about it…" advertisement in the *Orlando Sentinel* (Orlando, FL), October 20, 1988; Anaheim General Hospital, "Hernias are not funny," advertisement in the *Los Angeles Times* (Los Angeles, CA), March 2, 1989; Southlake Surgi-Center, "The Time Is Now!" advertisement in *The Times* (Munster, IN), October 25, 1989; Tucson Hernia Center, "The Hernia Specialists," advertisement in the *Arizona Daily Star-Sun* (Tucson, AZ), November 5, 1989.

[452] Trabucco Institute For Hernia Surgery, "Hernia: Improved Canadian Method Without Disability," advertisement in the *Daily News* (New York, NY), January 8, 1986; Hillcrest Surgical Group, "Finally, a hernia repair that comes with more than just a bill," advertisement in *The Los Angeles Times* (Los Angeles, CA), March 17, 1988.

[453] E.P. Vidal, "Announcing…Now Available!" advertisement in the *Asbury Park Press* (Asbury Park, NJ), January 22, 1986.

[454] See, for example, Palm Beach Hernia Clinic, "Announcing the Opening"; Medi-Surg, "Hernias: Safe Solutions for Hernia Sufferers," advertisement in the *Daily News* (New York, NY), January 6, 1986; Surgical Associates, "Canadian Technique Hernia Repair," advertisement in the *Canarsie Courier* (Brooklyn, NY), March 20, 1986; Phoenix Hernia Center, "Why Suffer?" advertisement in the *Arizona Republic* (Phoenix, AZ), April 18, 1986; Center for Hernia Repair at Davenport Medical Center, "A hernia can be quite serious," advertisement in the *Quad-City Times* (Davenport, IO), May 31, 1987; Hernia Center of Ohio, "Specializing in the repair of hernias using the Shouldice (Canadian) hernia repair," advertisement in the *Akron Beacon* (Akron, OH), June 13, 1989.

[455] "About Shouldice: Our History," www.shouldice.com/about/, retrieved February 7, 2020.

[456] Trabucco Institute, "Improved Canadian Method."

[457] Trabucco Hernia Institute, "In Office Hernia Repair at the Trabucco Hernia Institute," advertisement in the *Daily News* (New York, NY), January 28, 1990.

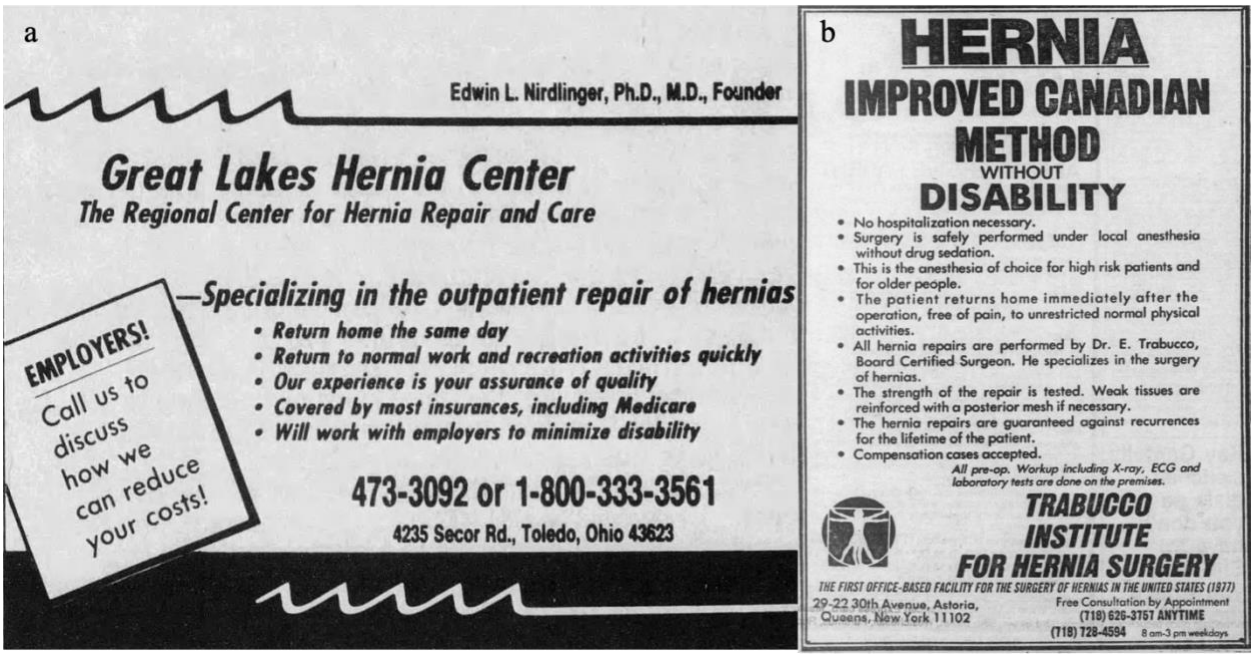

Figure 3.3: Advertisements for Outpatient Clinics Specializing in Hernia Repair: a) Dr. Edwin L. Nirdinger's Great Lakes Hernia Center in Toledo, Ohio and b) Dr. E. Trabucco's Institute for Hernia Surgery in Queens, New York.[458]

These medical service advertisements exemplify the type of patient solicitation that the AMA's code of ethics prohibited before the FTC successfully eroded the "learned professions exemption" in antitrust law. As we will see next, the shifting practices of medical service advertising throughout the 1970s and 80s set the stage to allow laparoscopic cholecystectomy to be widely publicized very quickly.

Gallbladders in the Media

Although news of laparoscopic cholecystectomy only emerged in academic medical circles in April and May 1989, the less invasive technique was already being mentioned in the

[458] Great Lakes Hernia Center, "Specializing in the outpatient repair of hernias," advertisement in the *News-Messenger* (Fremont, OH), January 17, 1989; Trabucco Institute, "Improved Canadian Method."

lay press by June.[459] For the next five years, there was a significant increase in the number of items that mention the gallbladder and gallbladder surgery in North American, English-language newspapers (see Figure 3.4). But even before the emergence of laparoscopic cholecystectomy, gallbladder issues were a common topic of concern and appeared frequently in medical advice columns and stories about celebrities and their health. These items were often syndicated and printed in both widely-circulated newspapers as well as more local publications. Dr. George Thostenson's December 1974 response to an inquiry from Mrs. L.V.T. about what to eat after having her gallbladder and three fourths of her stomach removed, for example, is published into January 1975 in newspapers as diverse as *The Boston Globe*, *The Montana Standard*, the *Asheville Citizen-Times*, and the *Calgary Herald*.[460] Reports of improvements to gallbladder surgery were also of major interest. Others discuss new pharmaceutical treatments for gallstones that allow one to avoid surgery. Results of the Mayo Clinic studies discussed in Chapter 1 on the use of solvents to dissolve gallstones were widely reported as a promising alternative that "Could End Gallbladder Surgery."[461] Many readers also wrote into medical advice columns for opinions on dissolution and lithotripsy treatments and are generally told that surgery is still the recommended treatment.[462]

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[459] The first mention of the less invasive technique in the Proquest Historical Newspapers and Newspapers.com databases was in an advertisement for a public seminar given by Eddie Reddick and sponsored by the West Side Hospital in Nashville, TN. The referenced advertisement appeared in *The Tennessean* on June 4, 1989.
[460] George C. Thosteson, "reply to Mrs. L.V.T.," Dr. George C. Thosteson, *Boston Globe* (Boston, MA), January 3, 1975; George Thosteson, "reply to Mrs. L.V.T.," Ask the doctor, *Montana Standard* (Butte, MT), January 1, 1975; George Thosteson, "reply to Mrs. L.V.T.," Good Health, *Asheville Citizen-Times* (Asheville, NC), January 1, 1975; George C. Thosteson, "reply to Mrs. L.V.T.," Dr. Thosteson, *Windsor Star* (Windsor, ON), December 31, 1974.
[461] "Dissolving Stones: New Technique Could End Gallbladder Surgery," *Philadelphia Daily News* (Philadelphia, PA), January 24, 1985. See also, Gail Bronson, "Chemical Cure? Drug That Dissolves Gallstones Is Focus Of Extensive Study," *Wall Street Journal*, (New York, NY), September, 8, 1976; Lawrence K. Altman, "The Doctor's World: Gallstones Removed Without Major Surgery," *New York Times* (New York, NY), September 17, 1985; Gordon Slovut, "New Mayo procedure dissolves gallstones," *Star Tribune* (Minneapolis, MN), March 9, 1989.
[462] See, for example, H. L. Herschensohn, "Surgery Recommended For Gallstones," Dr. H. L. Herschensohn's Medical Memos, *York Daily Record* (York, PA), April 18, 1975; George C. Thosteson, "Note To Mrs. E. C.," Dear Doctor, *Fort Lauderdale News* (Fort Lauderdale, FL), April 18, 1975; Paul Donohue, "Shock wave treatment not used for crushing stones in gallbladder," *Salina Journal* (Salina, KS), May 14, 1989. Some medical columnists were

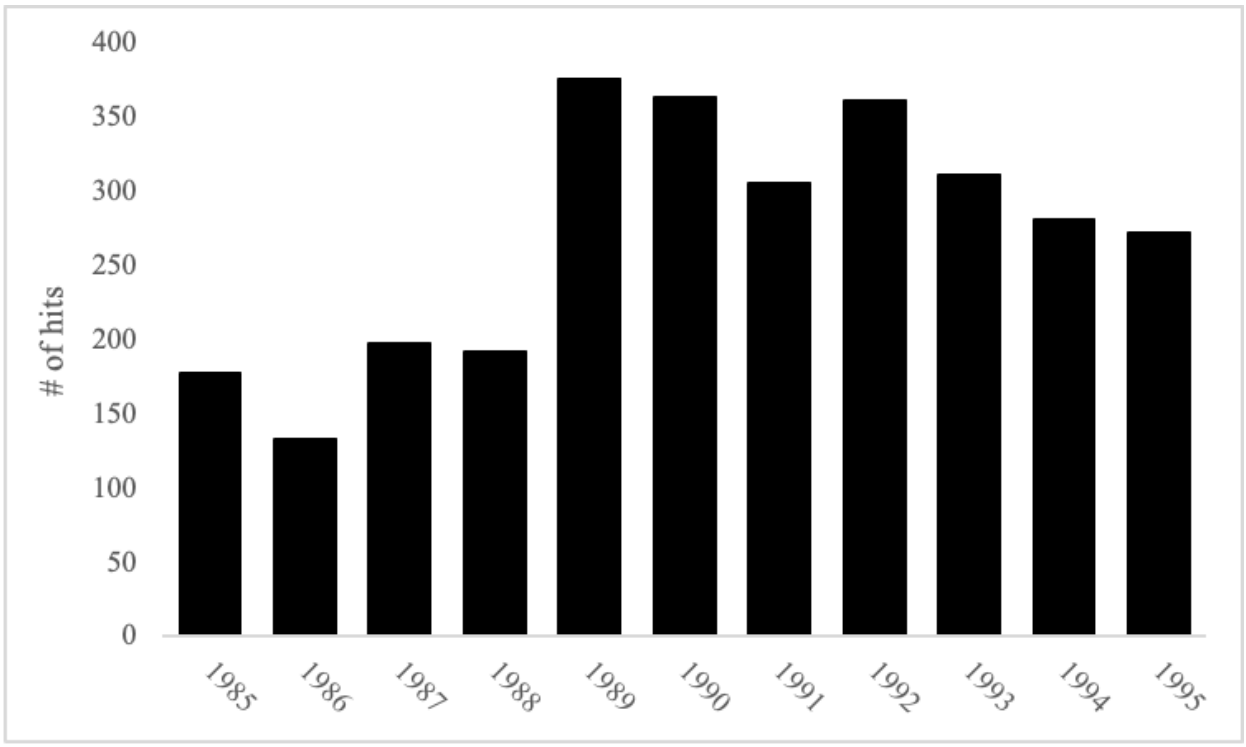

Figure 3.4: Newspaper Items Discussing Gallbladder/Gallbladder Surgery Each Year, 1985-95 – number of hits per year between 1985-95 that are retrieved in the ProQuest Historical Newspapers database with the search terms "gallbladder" OR "gallbladder surgery."

In August 1989, the majority of newspaper items mentioning gallbladders/gallstones began to be about a new minimally invasive technique for gallbladder removal: laparoscopic cholecystectomy. One of the earliest reports was published in *The Plain Dealer* from Cleveland, Ohio, announcing the new "Laser Surgery: On the cutting edge."[463] Though the article begins by reporting a satisfied patient's experience with laparoscopic cholecystectomy, its focus is on the increasing use of lasers in "cutting edge" surgery. Similar headlines that focus on the high-tech nature of laparoscopic cholecystectomy report that "A Tiny TV Camera Is Fast Transforming

more positive towards non-surgical treatments, for example: Allan Bruckheim, "New procedure can remove gallstones without surgery," *Wausau Daily Herald* (Wausau, WI), March 28, 1989.

[463] The first article that reported on laparoscopic cholecystectomy in the Proquest Historical Newspapers and Newspaper.com databases was: Glenn Gamboa, "Laser Surgery: On the cutting edge," *The Plain Dealer* (Cleveland, OH), August 22, 1989.

Gallbladder Surgery," or that a "Laser wand is working new surgical magic."[464] Other articles focus on how "'Keyhole' Incisions Are Making Surgery Less Painful, Cheaper," or that the "New procedure to remove gallbladder reduces cost, eliminates hospital stay."[465] The *New York Times* even named it "The Tiniest, Kindest Cut of All."[466] Though much of the surgical narratives of laparoscopic cholecystectomy's emergence focused on the aesthetic benefits it had for young, female patients, as discussed in Chapter 2, few journalists chose to focus on how patients could have "Fewer Scars After Gallbladder Surgery" or that "Gallbladder surgery becomes nearly invisible."[467] In contrast to surgical narratives, these articles did not highlight the benefits of the laparoscopic technique to female aesthetics. An article in the *Washington Post*, for example, illustrated the significant changes to scarring with the famous photograph of President Lyndon Johnson showing off his gallbladder surgery scar to reporters (see Figure 3.5).[468]

[464] Ron Winslow, "Cutting Edge: A Tiny TV Camera Is Fast Transforming Gallbladder Surgery," *The Wall Street Journal* (New York, NY), December 10, 1990; Lewis Cope, "The Beam of Light That Heals: Laser wand is working new surgical magic," *Star Tribune* (Minneapolis, MN), May 8, 1990.
[465] Shari Roan, "'Keyhole' Incisions Are Making Surgery Less Painful, Cheaper," *Los Angeles Times* (Los Angeles, CA), July 3, 1990; Rebecca Perl, "New procedure to remove gallbladder reduces cost, eliminates hospital stay," *Atlanta Constitution* (Atlanta, GA), January 2, 1990.
[466] Milt Freudenheim, "The Tiniest, Kindest Cut of All," *New York Times* (New York, NY), July 10, 1991.
[467] William Hines, "Fewer Scars After Gallbladder Surgery: New Technique Eliminates Worry About Disfiguring Marks," *Washington Post* (Washington, DC), November 21, 1989; Neil Solomon, "Gallbladder surgery becomes nearly invisible," *The Gazette* (Montréal, QC), May 31, 1990.
[468] Hines, "Fewer Scars."

Figure 3.5: President Johnson's Gallbladder Scar – Photograph of U.S. President Lyndon B. Johnson showing off his gallbladder surgery scar to the White House press corps, three days after his cholecystectomy on November 8, 1965. Photo Credit: Charles Tasnadi, Associated Press.

While many articles reporting laparoscopic cholecystectomy as a breakthrough in surgery are written as public interest stories, others are more promotional in nature. For example, *The Morning Call* of Allentown, Pennsylvania reported on July 24, 1990 that a "New procedure simplifies gallbladder removal: Patient's pain, hospital stay are reduced through technique."[469] The article is presented as a feature piece on laparoscopic cholecystectomy and gallbladder disease and contains interviews with the first patients in the area to undergo the new procedure.

[469] Ann Wlazelek, "New procedure simplifies gallbladder removal," *The Morning Call* (Allentown, PA), July 24, 1990.

Included almost as an aside are the details that the operation was performed by Drs. Earl K. Sipes, Clarence A. Holland, and Vitaly Sawyna at Allentown's Sacred Heart Hospital.

Other reports were more deliberate. The *Daily Press* of Newport News, Virginia, announced on September 12, 1990 that "Laparoscopic cholecystectomy (gallbladder surgery) is now being performed in the surgical department at Riverside Middle Peninsula Hospital in Gloucester," and that "Dr. Carl V. Yutsy and Dr. Neville J. Jackson of Gloucester Surgery, Inc. have been granted privileges in the procedure."[470] Such local stories about laparoscopic cholecystectomy were published in newspapers throughout the United States and Canada. When a surgeon received training in laparoscopic cholecystectomy and brought the technique home to their hospital and community, local newspapers often published a promotional piece to announce that the new and less invasive treatment for gallstones was available in the area.[471] Many articles commemorate the first laparoscopic cholecystectomy performed in a city or state and celebrate the first surgeons or hospitals to provide the new procedure as local pioneers.[472] In addition to being reported in the newspaper of the city in which the operation is offered, these stories were often re-printed or reported on separately in the newspapers of the surrounding area. For example, the first laparoscopic cholecystectomy in the state of Wisconsin was performed by Dr. Thomas Chua at St. Francis Hospital in Milwaukee and was reported in the Wisconsin Rapids'

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[470] "New gallbladder surgery offered in Gloucester," *Daily Press* (Newport News, VA), September 12, 1990.
[471] For example, see Richard D. Walton, 'New method eases pain of gallbladder removal," *Indianapolis Star* (Indianapolis, IN), November 19, 1989; Jonathan Bor, "New technique eases gallbladder surgery: Surgeons at UM use laparoscope," *Baltimore Sun* (Baltimore MD), October 27, 1989; Kelly Carson, "Doctor zaps gallbladder for 1st operation in state: New laser surgery saves recovery time," *Hattiesburg American* (Hattiesburg, MS), December 17, 1989.
[472] See, for example, Steve Twedt, "Gallbladder technique used here first time," *Pittsburgh Press* (Pittsburgh, PA), October 20, 1989; "Laser surgery first in state," *Greenwood Commonwealth* (Greenwood, MS), December 18, 1989; Deborah Skipper, "The sky's the limit for laser surgery applications: Doctors at the Surgery Clinic of Hattiesburg were the first to perform laser laparoscopic cholecystectomy," *Clarion-Ledger* (Jackson, MS), March 18, 1990; "Atlanta Physician Pioneers Laser Gallbladder Surgery," *Atlanta Daily World* (Atlanta, GA), January 25, 1990; "Methodist pioneers laser gallbladder removal," *Hattiesburg American* (Hattiesburg, MS), January 25, 1990; Charlene Nevada, "Gallbladder surgery technique being done in Ohio," *Akron Beacon-Journal* (Akron, OH), February 13, 1990.

Daily Tribune, Green Bay's *Press-Gazette*, Racine's *Journal-Times*, the *La Crosse Tribune*, Eau Claire's *Leader-Telegram*, the *Oshkosh Northwestern*, Appleton's *Post-Crescent*, and the *Wausau Daily Herald*.[473]

Some surgeons provided comments for the articles, in violation of the previously held ethical ideal that a physician should not extol the benefits of new treatments that would be financially rewarding to their practice. In an article about laparoscopic cholecystectomy being used at Kentucky's Owensboro-Davies County Hospital, the Owensboro *Messenger-Inquirer* reported, "'The procedure is significantly less painful than the conventional procedure,' said Dr. George Gilliam, an Owensboro surgeon who did the procedure. 'It can have significant benefits – shorter hospital stay, shorter recovery times, and is less painful and traumatic to the patient.'"[474] Karl Zucker, associate professor of surgery at the University of Maryland, not only provided Baltimore's *Evening Sun* with comments but also allowed a photograph of himself to be published with their piece reporting the use of laparoscopic cholecystectomy at University Hospital.[475] That the use of such publicity tactics was not just confined to community surgeons but were also practiced by academic surgeons indicates the depth of the cultural shift in attitudes towards self-promotion.

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[473] "New technique for gallbladder surgery is used in Milwaukee," *Daily Tribune* (Wisconsin Rapids, WI), December 31, 1989; "State's first laser removals of gallbladders performed," *Green Bay Press-Gazette* (Green Bay, WI), December 31, 1989; "Surgeons perform new procedure," *Journal-Times* (Racine, WI), December 31, 1989; "Surgeons use lasers to remove gallbladders through navels of 2," *La Crosse Tribune* (La Crosse, WI), December 31, 1989; "New laser surgery performed in state," *Leader-Telegram* (Eau Claire, WI), December 31, 1989; "New gallbladder surgery performed in state," *Oshkosh Northwestern* (Oshkosh, WI), December 31, 1989; "Relief: Laser use means better gallbladder surgery," *Post-Crescent* (Appleton, WI), December 31, 1989; "New gallbladder surgery performed in Milwaukee," *Wausau Daily Herald* (Wausau, WI), December 31, 1989. Unfortunately, during the time of COVID-19, I do not have access to the original article that was published in the *Milwaukee Journal* or the *Milwaukee Sentinel*.

[474] Laura Skillman, "New laser technique upgrades traditional gallbladder surgery," *Messenger-Inquirer* (Owensboro, KY), February 10, 1990.

[475] Mark Bomster, "Laparoscope eases pain of gallbladder surgery, *The Evening Sun* (Baltimore, MD), October 27, 1989.

Hospitals and surgeons in the United States also went further in promoting their services. In June 1989, the West Side Hospital in Nashville, TN began spreading the word about laparoscopic cholecystectomy through their "Step Into A Year of Good Health" educational seminar series, advertising Eddie Reddick's public talk on "Laser Surgery For Gallbladder."[476] As more surgeons began using the technique, hospitals and outpatient clinics throughout the United States followed suit in hosting seminars (often with free refreshments) and advertising the "revolutionary new outpatient surgical treatment for gallbladder disease that dramatically reduces the pain and recovery time associated with conventional surgery."[477]

Similar to the news reports, most advertisements emphasized the futuristic nature of laparoscopic cholecystectomy and its state-of-the-art technology. An advertisement for Dr. Colathur Palani's clinic in Riverside, Illinois, for example, described the procedure as a "surgical breakthrough" where surgeons use a "lighted telescope ([or] laparoscope) introduced through the navel."[478] The Tarzana Regional Medical Center's advertisement invited prospective patients to "look into the future of medicine…[at] one of the few forward-looking Los Angeles hospitals."[479] Not only did these advertisements promote laparoscopic cholecystectomy, they signalled to readers that the hospital or clinic was on the cutting edge of medicine, regardless of whether they needed gallbladder surgery.

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[476] West Side Hospital, "Step Into A Year Of Good Health," advertisement in *The Tennessean* (Nashville, TN), June 6, 1989.
[477] Dekalb Medical Center, "Gallbladder Surgery: New laser technology cuts pain and recovery time," advertisement in the *Atlanta Constitution* (Atlanta, GA), February 17, 1990. See also, G.C.O.C. Institute for Special Surgery of Joint Diseases, "G.C.O.C. Lecture Series…Newest Innovations in Laser Gallbladder Surgery," advertisement in the *Tampa Bay Times* (Tampa Bay, FL), April 22, 1990; Somerset Hospital, "Shedding A Light On Laser Surgery," advertisement in the *Daily American* (Somerset County, PA), May 4, 1990; Montclair Community Hospital, "On April 23, 1990 we performed the first Laser Gallbladder Surgery in the area," advertisement in the *Verona-Cedar Grove Times* (Verona/Cedar Grove, NJ), May 10, 1990; Los Alamitos Medical Center, "Gallbladder Surgery Redefined," advertisement in the *Los Angeles Times* (Los Angeles, CA), July 5, 1990.
[478] Colathur K. Palani, "Revolution in Gallbladder Surgery. Laparoscopic Cholecystectomy.," advertisement in the *Chicago Tribune* (Chicago, IL), September 12, 1990.
[479] Tarzana Regional Medical Center, "Keyhole Surgery: Look into the Future of Medicine," advertisement in the *Los Angeles Times* (Los Angeles, CA), November 8, 1990.

Though the laser ultimately gave way to electrocautery, as discussed in Chapter 2, for at least the first year of laparoscopic cholecystectomy's publicity, laser technology was heavily featured in advertisements as a major selling point of the procedure.[480] This was particularly the case with the promotion of the procedure at laser surgery centers.[481] Hospital clinics associated with Laser Centers of America, Inc., for example, described the new gallbladder surgery as "Gentle surgery with lasers," and implied that it was the laser, rather than laparoscopic technology, that made gallbladder removal easier on patients.[482] Advertisements informed potential patients that in comparison with conventional surgery, laser laparoscopic cholecystectomy offered less pain, less time in the hospital, lower medical bills, and less time away from work. According to one Mississippi hospital, "With Southwest Regional's Laser Gallbladder Surgery, you can SAVE your days off for Vacation."[483]

Again, like the newspaper articles, less scarring was not emphasized as a gendered benefit. Instead, the cosmetic benefits of laparoscopic cholecystectomy were presented in a neutral way. Advertisements generally listed minimal scarring along with the other advantages (see Figure 3.6a) and visual demonstrations of the impact on incision/scar size often used gender neutral figures (see Figure 3.6b), or even male torsos (see Figure 3.6d). That gallstones are not

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[480] See, for example, DeKalb Medical Center, "New laser technology"; Georgia Baptist Medical Center, "Gallstone Surgery? Consider The Georgia Baptist LASER alternative," advertisement in the *Atlanta Constitution* (Atlanta, GA), March 4, 1990; Rose Surgical Clinic, "…is pleased to announce that they are performing Laparoscopic Laser Cholecystectomy," advertisement in the *Des Moines Register* (Des Moines, IO), March 18, 1990; Bayonet Point Surgical Associates, "Announcing…New Laser Surgery For Gallbladder Removal," advertisement in the *Tampa Bay Times* (Tampa Bay, FL), May 16, 1990.

[481] See, for example, The Laser Institute at St. Mary's Health Center, "Traditional Gallbladder Surgery May Soon Become A Thing Of The Past, Thanks To A Tool Of The Future," advertisement in the *St. Louis Post-Dispatch* (St. Louis, MO), April 12, 1990; St. Vincent's Laser Center, "Light Touch," advertisement in the *Anniston Star* (Anniston, AL), April 22, 1990; Lasercare at Anaheim Memorial Hospital, "We can remove gallstones without the unpleasant side effect," advertisement in the *Los Angeles Times* (Los Angeles, CA), June 7, 1990.

[482] See, for example, The Dayton Laser Center at Good Samaritan Hospital, "One very small reason to choose us for your gallbladder surgery," advertisement in the *Dayton Daily News* (Dayton, OH), February 4, 1990.

[483] Southwest Mississippi Regional Medical Center, "With Southwest Regional's Laser Gallbladder Surgery, you can SAVE your days off for Vacation," advertisement in the *Enterprise Journal* (McComb, MS), June 28, 1990.

particularly uncommon in men is also apparent when you look at how gender neutral, or even male-oriented, the majority of advertisements for laparoscopic cholecystectomy were, suggesting that men make up a significant enough portion of the market that hospitals and clinics knew that it would be unwise to only target women in the promotion of the procedure. Advertisements that did feature women did not emphasize smaller scars but rather what one could be doing in the time not spent recuperating from a conventional gallbladder removal (see Figure 3.6c).

Figure 3.6: Advertisements for Laparoscopic Cholecystectomy – a) Advertisement for laser laparoscopic cholecystectomy in the *St. Petersburg Times* lists minimal scarring as one of several advantages of less invasive procedure; b) Advertisement for laparoscopic cholecystectomy in the *San Francisco Chronicle* uses a gender neutral figure to illustrate the smaller incision; c)

Advertisement for laparoscopic laser surgery in the *Times Leader* of Wilkes-Barre, PA features women but emphasizes rapid recovery rather than aesthetic benefits. Note that the advertisement is somewhat misleading since swimming/bathing would likely not have been a recommended activity for the day after surgery; d) Advertisement for gallbladder laser surgery in the *Los Angeles Times* uses a male torso to demonstrate the size of the incision used in conventional gallbladder surgery.[484]

Some hospitals included the names of their laparoscopic cholecystectomy-trained surgeons in their advertisements,[485] sometimes with congratulations for performing the first in the area.[486] One particularly self-congratulatory advertisement praised the "Board of Directors and Administrator…[at] Mid-Valley Hospital Association for their progressive thinking and approach which made it possible for Candonino C. Gazmen, M.D. to successfully perform the first belly button gallbladder removal using laser technique at Mid-Valley Hospital."[487] Individual surgeons also promoted themselves and their newly acquired skills with advertisements for their private practices.[488] Michael Abraham and Larry Cohen of Cherry Hill,

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[484] Aziz Al'Kafali, "…Announces the availability of the new surgical procedure LASER LAPAROSCOPIC CHOLECYSTECTOMY," advertisement in the *St. Petersburg Times* (St. Petersburg, FL), April 27, 1990; San Ramon Regional Medical Center, "A Special Update on Advanced Gallbladder Surgery," advertisement in the *San Francisco Chronicle* (San Francisco, CA), June 27, 1990; Anaheim Memorial Hospital, "We can remove gallstones without the unpleasant side effect," advertisement in the *Los Angeles Times* (Los Angeles, CA), June 7, 1990.

[485] See, for example, Women's Medical Center, "Yesterday, this was the cutting edge in gallbladder surgery," advertisement in the *St. Petersburg Times* (St. Petersburg, FL), January 24, 1990; Wesley Health System, Inc., "Where technology meets TLC," advertisement in the *Hattiesburg American* (Hattiesburg, MS), February 25, 1990; Lower Bucks Hospital, "The New Gall Bladder Surgery," advertisement in the *Philadelphia Inquirer* (Philadelphia, PA), May 20, 1990.

[486] Regional Medical Center, "Congratulations R. Lewis Foss…On performing the first laser cholecystotomy [sic]," advertisement in the *Anniston Star* (Anniston, AL), April 4, 1990; Sentara Hampton General Hospital, "Sentara Hampton General Hospital recognizes Dr. A. Sobhan and Dr. G. Ricciarelli for successfully performing the Peninsula's first laparoscopic cholecystectomy," advertisement in the *Daily Press* (Newport News, VA), April 9, 1990.

[487] Friends of Mid-Valley Hospital, "Congratulations to Board of Directors…" advertisement in the *Times-Tribune* (Scranton, PA), September 9, 1990.

[488] Danny Cantwell, "Danny Cantwell, M.D. Announces the opening of his office…" advertisement in the *Palm Beach Post* (Palm Beach, FL), February 11, 1990; R. Bryan Freeman, "Laser Choleoystectomy [sic]: Laser Gallbladder Surgery will be offered by Dr. Bryan Freeman beginning in April, 1990," advertisement in the *Anniston Star* (Anniston, AL), March 18, 1990; Steven I. Becker, "A Medical Breakthrough! Gallbladder Removal," advertisement in the *Herald & News* (Woodland Park, New Jersey), April 4, 1990; Aziz Al'Kafaji, "…Announces the availability of the new surgical procedure"; Adam Naaman, "Removal of the Gallbladder Through a Bellybutton Incision," advertisement in the *Galveston Daily News* (Galveston, TX), May 6, 1990.

PA, for example, announced that they were "now offering A Revolutionary Technique in Gallbladder Surgery," promising potential patients a shorter hospital stay, less painful recovery, faster return to normal routine, and minimal scarring.[489]

This pattern of direct and indirect advertising that can be seen in the publicisation of laparoscopic cholecystectomy is very similar to the publicity tactics that were used to promote outpatient hernia repair towards the end of the 1980s. Though this type of promotion was considered to be uncouth and unprofessional a decade earlier, by the time laparoscopic cholecystectomy emerged in 1989, such publicity was widespread enough for many surgeons to feel that it was acceptable to advertise that they offered the new technique in their practice. The change in the culture of medical practice in the decade following FTC v. AMA that can be seen in hernia repair advertising, set the stage for laparoscopic cholecystectomy to be widely and boldly publicised just months after its introduction to the surgical community.

[489] Associates in General Surgery, "A Revolutionary Technique in Gallbladder Surgery," advertisement in the *Philadelphia Inquirer* (Philadelphia, PA), August 26, 1990.

Chapter 4: Seeking Control of the "Laparoscopic Revolution"

The enthusiasm that the developers and early adopters of laparoscopic cholecystectomy witnessed at the April 1989 SAGES and October 1989 American College of Surgeons meetings quickly became a cause for concern for the academic surgical establishment. As one surgeon described the "laparoscopic revolution," it was "a patient-driven, non-academic physician and company-supported Wild West."[490] A March 1990 editorial in the *American Journal of Surgery* warned that "Unless restraint and adequate training are pursued as policies by the surgical community, the indiscriminate performance of laparoscopic cholecystectomy will increase the incidence of catastrophic complications or even death."[491] The authors recommended,

> For the present, laparoscopic cholecystectomy in humans should be confined to specialized centers that participate in current or planned prospective studies designed to optimize the technique and carefully refine its indications. These designated centers of laparoscopic surgery should also be required to develop training programs in laparoscopy…Appropriate surgical organizations should immediately consider training and accreditation in this type of surgery and issue guidelines.[492]

The leaderships of SAGES and the newly established European Association for Endoscopic Surgery (EAES) – which included the authors of the editorial – quickly set about developing training courses and credentialing guidelines as well as organizing clinical trials. Surgical

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[490] Jeffrey Barkun, interview with Thomas Schlich and Cynthia L. Tang, Montréal, Canada, September 24, 2014.
[491] Alfred Cuschieri, George Berci, and Charles K. McSherry, "Laparoscopic Cholecystectomy," *American Journal of Surgery* 159 (1990): 273.
[492] Cuschieri et al., "Laparoscopic Cholecystectomy," 273.

organizations in the United States, however, had little power to restrict the availability of laparoscopic cholecystectomy to specialized centers or to monitor whether individual surgeons complied with their recommendations. As the *Los Angeles Times* later reported in 1992, "The meteoric rise of laparoscopic procedures…has exposed holes in professional self-regulation of new operations."[493]

This chapter examines the attempts to control the spread of laparoscopic cholecystectomy through training courses, credentialing guidelines, and clinical trials. The first half of the chapter discusses how surgeons in North America trained to perform laparoscopic cholecystectomy in the early years of its adoption. It then discusses the credentialing guidelines that evolved as the rising number of complications made it increasingly evident that some surgeons were not getting sufficient training before offering the procedure to patients.

Most historical studies of surgical innovations focus on the struggles that surgeons faced in developing new procedures and in convincing colleagues of their value. In these narratives, the act of training practicing surgeons to perform a new technique was often part of the process of gaining acceptance for it. As Sally Wilde muses in her work on prostate surgery, "Seeing was believing and the question arises as to whether, by the standards of the 1930s, practising evidence-based surgery involved traveling to watch new procedures performed by their originators, to see in person what was done in the operating theatre, the nature of pre- and post-operative care, and the state of the patients on the wards."[494] As one surgeon recalled of his first time seeing laparoscopic cholecystectomy performed,

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[493] Harris Meyer, "Danger on the Cutting Edge?" *Los Angeles Times*, Los Angeles, CA, July 29, 1992.
[494] Sally Wilde, "See One, Do One, Modify One: Prostate Surgery in the 1930s,' *Medical History* 48 (2004): 351-66, 364.

> My impression while I was watching the operation was that these are not slick surgeons. This is not an elegant operation. But when I saw the patients the next day, it was absolutely incredible how much better they looked than a patient that we would have operated on through the traditional technique…in those days, patients were staying in the hospital about five days after gallbladder surgery, and it would take them 1.5 months or 2 months before they were really recovered. And after *this* operation, they were usually able to go home the next morning and looked really quite good about a week or ten days after surgery. It was a dramatic improvement.[495]

Additionally, Thomas Schlich notes in his study of osteosynthesis in the 1960s that although the developers' main motivation in establishing their training programme was to safeguard its reputation by ensuring that the technique was performed correctly, it was also "ultimately a major asset in winning general acceptance" for the technique.[496] Similarly, in a well-timed ethnographic study of laparoscopic cholecystectomy training courses held in 1990-91, Jan Armstrong observed that many attendees "came to the workshops full of doubts, worried, in some cases angry, and in many cases resistant. The directors and faculty of the workshops had two or three days to persuade their trainees that the operation could be done safely."[497] But in contrast to the developers of osteosynthesis who were able to maintain surgical standards in their

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[495] Gerald Fried, interview by Thomas Schlich and Cynthia L. Tang, Montreal, Canada, June 13, 2014.
[496] Thomas Schlich, "'Tacit knowledge': Education and Training on a Face-to-Face Basis," *Surgery, Science and Industry: A Revolution in Fracture Care, 1950s-1990s* (Houndsmill, Basingstoke, Hampshire: Palgrave Macmillan, 2002), 65-85.
[497] Jan Armstrong, "Learning Communities of Surgeons in Mid-Career Transformation," in *Learning Trajectories, Innovation and Identity for Professional Development*, eds. Anne McKee and Michael Eraut (Dordrecht: Springer, 2012), 215-34, 221.

trainees by controlling access to the necessary equipment, there was no such mechanism to control the use of laparoscopic cholecystectomy.[498]

Though the SAGES leadership quickly mobilized to develop didactic courses with hands-on training that were to be held at academic medical centers, the immense interest in the technique and the economic pressure that resulted from the publicity-generated patient demand created a seller's market for laparoscopic cholecystectomy training courses. Independent, non-academic training courses were quickly offered, as well as more commercialized courses that were funded by the instrument manufacturers. Accounts of the "laparoscopic revolution" attribute the high complication rate during the early years of laparoscopic cholecystectomy to surgeons who immediately began offering the procedure to patients after attending these 1 to 3-day courses. Jacques Périssat, for example, recalled in a 2017 oral interview that some courses were marketed with claims that, "We have hands-on training in [the] Hilton Hotel in New York and in three days you could be able to perform a lap chole."[499] The emphasis in such anecdotes is often placed on how these surgeons received their training at very short, non-academic courses.[500] This is despite the fact that the courses organized by academic surgeons were similar in length, also taking place over a weekend.

Attendance at a course, however, was only the beginning of one's training. Surgeons often spent additional time practicing how to maneuver with the laparoscopic instruments and assisting their more experienced colleagues in laparoscopic surgery. The training that a surgeon

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[498] Instrument manufacturers were able to quickly form partnerships with the developers and early adopters of laparoscopic cholecystectomy and modify the laparoscopic equipment used in gynecological surgery so that it would be appropriate for abdominal surgery. Instead of only being able to purchase equipment through one supplier who controlled access as in the case of osteosynthesis, surgeons could order laparoscopic instruments from an array of manufacturers. Though there was often a waiting list to receive the instruments, surgeons did not have to first prove competency in the technique.

[499] Jacques Périssat, interview with Cynthia L. Tang, Bordeaux, France, November 13, 2017.

[500] See, for example, L. Michael Brunt, "SAGES presidential address: a SAGES Magical Mystery Tour," *Surgical Endoscopy* 29 (2015): 3423-31, 3424.

pursued after attending a course was more important than the type of course itself. This is reflected in the later credentialing guidelines that the New York State Department of Health issued in response to increased complications involving gallbladder surgery and the updated SAGES guidelines that followed.

The second half of this chapter discusses the ways in which laparoscopic cholecystectomy was evaluated. As a novelty, often described as "disruptive,"[501] it brought with it uncertainty about its risks and benefits, compared to the tried and tested open method that was introduced more than a century earlier. Though the benefits of laparoscopic cholecystectomy with regards to patient recovery were almost immediately obvious when performed correctly, academic surgeons argued that its use should be confined to specialized medical centers so that the procedure could be thoroughly assessed before being used more widely. This was, however, more than simply a way to control the spread of the technique. Many believed that the procedure required rigorous testing in order to optimize various aspects of the technique, as well as its usage in different types of cases. There were still many unknowns with respect to the procedure's contraindications since the early laparoscopic cholecystectomy candidates were usually carefully screened to select for straightforward cases with minimum risks of complications. Reflecting the push towards a particular culture of evidence-based medicine in the late 1980s and early 1990s, with the emergence of laparoscopic cholecystectomy, some surgeons argued that there was a need for prospective clinical trials to compare the safety of the procedure with that of the open method. This was also an argument for limiting the use of the procedure to academic medical

[501] James R. Zetka, *Surgeons and the Scope* (Ithaca: Cornell University Press, 2003) speaks of "disruptive technology" from the perspective of the sociology of occupations. Lawrence Rosenberg and Thomas Schlich, "Surgery: Down for the Count?" *CMAJ*, 2012, *184*, 496, use a different conception of disruption, introduced by in Clayton M. Christensen, *The Innovator's Dilemma: When New Technologies Cause Great Firms to Fail* (Boston: Harvard Business School Press, 1997).

centers as these types of trials generally require the infrastructure and expertise located at such centers.

The emergence and use of clinical trials more generally have been a topic of recent historical investigation. Harry Marks, for example, has shown how the RCT originated in very specific contexts of drug testing, which were shaped by distrust towards drug manufacturers, and often accompanied by a marked scarcity of the drug to be tested.[502] He has also identified control of the use of pharmaceuticals as a key component in the rise of the RCT. In the surgical realm, Thomas Schlich has investigated the construction of a particular culture of evidence associated with the spread of operative fracture care in the second half of the twentieth century.[503] His study on osteosynthesis has shown that for the successful spread of such a new and potentially risky technology, the management and control of its use was also a decisive factor.[504] David Jones has examined the various uses of different kinds of evidence in surgery and internal medicine in the controversies surrounding the treatment of coronary heart disease. His work is remarkable for situating the introduction of new treatments within the context of a whole landscape of other treatments.[505] Such an exploration of various therapeutic options at a particular time is an approach that is much needed in the history of medical innovation.[506]

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[502] Harry M. Marks, "Trust and Mistrust in the Marketplace: Statistics and Clinical Research, 1946-1960," *History of Science*, 2000, *38*, 343-355.
[503] Thomas Schlich, *Surgery, Science and Industry: A Revolution in Fracture Care, 1950s-1990s* (Houndsmill, Basingstoke, Hampshire: Palgrave Macmillan, 2002)
[504] Thomas Schlich, "Degrees of Control: The Spread of Operative Fracture Care with Metal Implants. A Comparative Perspective on Switzerland, East Germany and the USA, 1950s-1990s," in *Innovations in Health and Medicine: Diffusion and Resistance in the Twentieth Century*, ed. Jennifer Stanton (London: Routledge, 2002), 187-194.
[505] David S. Jones, "Visions of a Cure: Visualization, Clinical Trials, and Controversies in Cardiac Therapeutics, 1968-1998," *Isis* 91 (2000): 504-41.
[506] As argued, for example, by Thomas Schlich, "Why Were Surgical Gloves not Used Earlier? History of Medicine and Alternative Paths of Innovation," *Lancet* 386 (2015): 1234-1235.

The second half of the chapter discusses the attempts to conduct a prospective and controlled clinical trial to evaluate and compare laparoscopic cholecystectomy to the open procedure, and the unique circumstances that allowed the first successful trial to be completed at McGill University.[507] It situates the RCT (as a method of evaluation) in the context of its use within the controversies over a particular treatment modality, conducted within a local context that shaped its planning and its performance. An exploration of the local contexts and conditions which both shaped the McGill RCT and made it possible, opens up an additional dimension to the history of RCTs, characterizing it as a locally-rooted and context-dependent phenomenon that is not solely about evaluating a new treatment.

Training and Credentialing: An "Explosion" of Interest in Laparoscopic Cholecystectomy

As discussed in Chapter 2, the trigger for the "explosion" of interest in laparoscopic cholecystectomy was not its first reporting in academic journals, but the videos of the technique that were shown in the trade exhibition halls at the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) and the American College of Surgeons (ACS) annual meetings.[508] According to Jacques Périssat, when he showed his video of laparoscopic cholecystectomy at the April 1989 SAGES meeting in Louisville, Kentucky, surgeons crowded around his booth saying, "Unbelievable! We must do that tomorrow!"[509] Feeling vindicated after the disappointing response from his French colleagues two months earlier, Périssat believed that

[507] This discussion is adapted from a co-authored paper with Thomas Schlich where we explore the local context and conditions of the first successful RCT: see Cynthia L. Tang and Thomas Schlich, "Surgical Innovation and the Multiple Meanings of Randomized Controlled Trials: The First RCT on Minimally Invasive Cholecystectomy (1980-2000), *Journal of the History of Medicine and Allied Sciences* 72 (2017): 117-41.
[508] The Society of American Gastrointestinal Endoscopic Surgeons was renamed the Society of American Gastrointestinal *and* Endoscopic Surgeons.
[509] Jacques Périssat, interview with Cynthia L. Tang, Bordeaux, France, November 9, 2017.

he had finally "met people who are able to understand [this]."[510] To him, "it was like this nuclear explosion."[511] Showing his video on the trade floor instead of in the conference's scientific sessions allowed Périssat to, in some ways, bypass the cynicism of academic surgery. Instead of presenting in one session to a smaller audience, exhibiting his video at a trade booth during the entire conference gave the procedure much more exposure.

Similarly, Douglas Olsen believed that the "pivotal milestone in the development of lap chole" was the October 1989 ACS meeting in Atlanta, Georgia, where he and Eddie Reddick presented their videos of laparoscopic cholecystectomy on behalf of laparoscopic and laser surgical instrument companies.[512] According to Olsen, "everyone was clambering because it was obvious. This was the way to take out gallbladders."[513] As discussed in Chapter 2, Reddick and Olsen announced their formal laparoscopic cholecystectomy training courses at the ACS meeting and had "surgeons falling over themselves to get a slot in the course."[514] In contrast to Olsen's perspective, Nathaniel Soper, who at the time was an assistant professor of surgery at Washington University in St. Louis, Missouri, recalled to Litynski, "Hundreds of surgeons viewed this movie, most of whom left the area muttering and shaking their heads saying it would never work, whereas the remaining few rushed head-on to try to buy instruments and sign up for courses."[515] Regardless of what individual surgeons actually thought of the procedure while watching the videos, slots quickly filled up for Reddick and Olsen's advertised training courses

[510] Périssat, interview, November 9.
[511] Périssat, interview, November 13.
[512] Douglas Olsen, interview with Cynthia L. Tang, Nashville, TN, May 29, 2018.
[513] Olsen, interview, May 29.
[514] Douglas Olsen, e-mail correspondence with Cynthia L. Tang, April 19, 2019.
[515] Grzegorz Litynski, "The American Spirit Awakens," Highlights in the History of Laparoscopy: The Development of Laparoscopic Techniques – a Cumulative Effort of Internists, Gynecologists, and Surgeons (Frankfurt/Main: Barbara Bernert Verlag, 1996), 227-70, 246.

in Nashville.[516] Such training opportunities, as discussed earlier, are often an important step in the process to convince fellow surgeons of a procedure's value.

Unlike Reddick and Olsen, Périssat declined the initial requests for training. Along with a feeling of elation from the enthusiasm that his video generated at SAGES Périssat also felt a sense of caution. Although Périssat was disappointed in the negative reactions to laparoscopic cholecystectomy demonstrated by the "well-established old surgeons, big professors" of France, he agreed with them about the potential harm that could occur in the process of training surgeons in the new technique: "I think they were right in their mind because they sa[id], 'They will put in danger our patients.'"[517] Périssat's conceptualization of laparoscopic cholecystectomy was similar to Philippe Mouret's in that it was not simply a new technique that could be taught through the more traditional "see one, do one, teach one" model where surgeons visited their colleagues to both evaluate and learn to perform new procedures.[518] Laparoscopy was a radically different approach compared to open surgery and as Périssat explained,

> We [could] not put this in the hands of those surgeons, even if they [had] very good mastery of open surgery. They need[ed] to have a new education [in laparoscopy], beginning [with] how to insufflate properly the abdominal cavity. And so the demand after Louisville, 'Please where can I learn laparoscopic cholecystectomy?' It was the wrong question. We could not jump straight to laparoscopic

[516] Olsen, interview, May 29.
[517] Périssat, interview, November 13.
[518] For more on the convention of surgical traveling see Wilde, "See One, Do One," 363; Owen H. Wangensteen, "Surgery and surgical travel groups," *Surgery, Gynecology & Obstetrics* 147 (1978): 246-54; G. Wayne Miller, *King of Hearts: The True Story of the Maverick Who Pioneered Open Heart Surgery* (New York: Times Books, 2000), 181-2.

> cholecystectomy. You have to have an education…It requires a long-lasting period of training.[519]

As his colleague Alfred Cuschieri recommended, "Training programmes in both diagnostic laparoscopy and laparoscopic surgery must be set up…We should aim to teach basic laparoscopic surgical techniques: inspection, exposure, dissection, haemostasis, external slip-knotting by the Roeder technique, suturing etc., rather than laparoscopic cholecystectomy."[520]

In the months following the Louisville meeting the SAGES leadership determined that they needed to get involved in training surgeons to perform laparoscopic cholecystectomy. They quickly realized that not only did proper training courses have to be organized, they had to have surgeons who could teach the courses.[521] To this end, they began organizing a program to "train the trainers." But even before such a program could begin, they needed surgeons with enough experience to teach the trainers.[522] According to Jeffrey Ponsky, who was President of SAGES at the time, the plan to control the spread of laparoscopic cholecystectomy through coordinated training was for interested surgeons who were on the SAGES Board of Governors to go for training with the developers and early adopters in France as well as with Reddick in Nashville, Tennessee.[523] These surgeons, who can be described as first-generation adopters, would then lead courses for academic surgeons and those who were the directors of surgical training programs. The trained trainers, or second-generation adopters, could then return to their institutions to offer training courses to community surgeons, who would belong to the third-generation of adopters. Though it was hoped that the first and second-generation adopters would

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[519] Périssat, interview, November 13.
[520] A. Cuschieri, "The laparoscopic revolution – walk carefully before we run," *Journal of the Royal College of Surgeons of Edinburgh* 34 (1989): 295.
[521] Jeffrey Ponsky, interview with Cynthia L. Tang, Baltimore, Maryland, April 5, 2019.
[522] George Berci, "Laparoscopic Cholecystectomy Viewed from the USA," *Australian and New Zealand Journal of Surgery* 61 (1991): 249-50, 249.
[523] Ponsky, interview.

remain a relatively small group of academic surgeons, as we will see, not all surgeons followed this plan to have a structured spread of the technique.

George Berci, who was part of the SAGES leadership, was already attuned to the European developments in laparoscopic cholecystectomy even before the April 1989 meeting. Berci had been a vocal proponent of integrating endoscopic techniques into general surgery since the 1960s and in 1972 became the Director of Endoscopic Surgery at Cedars-Sinai Medical Center in Los Angeles, California. Upon hearing the news of Reddick and Olsen's achievement in laparoscopic surgery, he travelled to Nashville where the two surgeons were providing training via the "see one, do one, teach one" model. Foreseeing the potential danger to patients if surgeons were not properly trained, in September 1989 Berci organized a meeting of the American pioneers and other interested surgeons to discuss how the technique should be taught.[524] As one of the surgeons in attendance recalled to Grzegorz Litynski, "We showed videos and talked a lot about the philosophy of teaching. We thought very strongly that the proper courses should be structured and…We then set up a course guideline which became the framework for all future endorsed courses in the United States."[525] From these discussions, Berci and his colleagues developed a structure for formal 3-day courses that they hoped would be used to train the second and third-generations of adopters. It was determined that courses would include didactic lectures and hands-on practical training where trainees would practice the laparoscopic technique on pigs in teams of three: "one physician to operate, one to assist, and one to hold the camera. Over the course of three days, each person performed every function once."[526] These "academically-sponsored" training courses were first offered at Cedars-Sinai

[524] Litynski, "American Spirit," 243.
[525] Litynski, "American Spirit," 243.
[526] Litynski, "American Spirit," 245.

Medical Center in January 1990 and then at the University of Utah Medical Center the following month.[527]

Though Berci involved Reddick and Olsen in the conversations about formal 3-day training courses, the Nashville team continued to host surgeons in the operating room. As Olsen recalled, before the October 1989 ACS Clinical Congress, surgeons were visiting him and Reddick in "Nashville to do a 'mini proctorship', where surgeons would come spend time with us in the OR observing. We would 'lecture' them as we would operate and then have discussions in between cases."[528] According to Olsen, "we did our first formal course in November 1989. But they really took off [in] 1990."[529] Newspaper articles on the new "Nintendo surgery," reported that surgeons paid $3,000 to spend two days in Nashville, Tennessee to attend lectures and practice laparoscopic cholecystectomy on pigs.[530] For $1,000, surgeons could spend the day observing Reddick's procedures.[531] By February 1990, Reddick claimed to have already trained over 500 surgeons from around the world.[532]

Economic Pressure to Train in Laparoscopic Cholecystectomy

As more surgeons began to offer the procedure, journalists began to report on the new, less invasive gallbladder surgery. As discussed in Chapter 3, such articles were essentially announcements to the community that their local surgeons and hospitals were offering laparoscopic cholecystectomy, and quickly generated interest in the procedure amongst patients

[527] Litynski, "American Spirit," 251-2
[528] Olsen, e-mail correspondence.
[529] Olsen, interview, May 29.
[530] Jenny Labalme, "RMC lasers cut surgery time," *Anniston Star* (Anniston, AL), March 9, 1990; Ena Naunton, "Doctors call it 'Nintendo surgery': Gallbladder operation is one of hottest surgical advances in years," *Greenville News* (Greenville, NC), March 22, 1990.
[531] Naunton, "Nintendo surgery."
[532] Dorren Klausnitzer, "New gallbladder surgery can't keep patient down," *The Tennessean* (Nashville, TN), February 4, 1990.

suffering from gallstones. John Bagnato, for example, performed the first laparoscopic gallbladder removal in Mississippi on December 15, 1989 at the Methodist Hospital of Hattiesburg.[533] It was reported two days later in the *Hattiesburg American*, followed by reports in the local newspapers of nearby Clarksdale and Greenwood.[534] Bagnato was among the first surgeons to receive training in laparoscopic cholecystectomy from Reddick, which he supplemented with hands-on practice using the instruments at a manufacturer's headquarters in Connecticut.[535]

Just three weeks after his first laparoscopic cholecystectomy was reported, Bagnato told the same reporter, "I have patients coming to Hattiesburg from all over the state…What this is doing for Hattiesburg has really caught me off guard. People are staying in motel rooms until their surgeries. It's really generating business."[536] According to the hospital's vice president of clinical services, "The response from patients…in Mississippi and other states has been tremendous… We've had calls from doctors in Jackson whose patients want to come to Hattiesburg for their gall bladder surgery."[537] Beyond the prestige that came with being the first, there was a major economic incentive to be the only surgeon or hospital in an area offering laparoscopic cholecystectomy. As it was later explained in *The Wall Street Journal*, "The first one in the community who does it gets all the gallbladders for a while."[538]

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[533] Kelly Carson, "Doctor zaps gallbladder for 1st operation in state: New laser surgery saves recovery time," *Hattiesburg American* (Hattiesburg, MS), December 17, 1989.
[534] Carson, "Doctor zaps,"; "Laser gallbladder surgery cuts time in hospital, recuperation," *Clarksdale Press Register* (Clarksdale, MS), December 18, 1989; "Laser surgery first in state," *Greenwood Commonwealth* (Greenwood, MS), December 18, 1989.
[535] Kelly Carson, "Laser surgery may be taught here," *Hattiesburg American* (Hattiesburg, MS), January 8, 1990.
[536] Carson, "Laser surgery may be taught here."
[537] "Methodist pioneers laser gallbladder removal," *Hattiesburg American* (Hattiesburg, MS), January 25, 1990.
[538] Ron Winslow, "Cutting Edge: A Tiny TV Camera Is Fast Transforming Gallbladder Surgery – The Keyhole Technique Uses Tiny Incision, May Work For Other Operations Too – Doctors Scramble to Learn It," *Wall Street Journal* (New York, NY), December 10, 1990. See also, Bob Groves, "New light on gallbladder surgery: Doctors embrace laser method," *The Record* (Woodland Park, NJ), July 27, 1990.

On the other side of this equation, however, was the potential to lose patients the longer a surgeon did not provide the procedure. Surgeons were quickly pressured to learn and offer the procedure as news of the less invasive technique for gallbladder removal spread amongst the public. Once they heard about the benefits of laparoscopic cholecystectomy, some patients chose to postpone treatment until the procedure was available in their area. As one patient in San Antonio, Texas told a reporter in January 1990, though she "was suffering stabs of pain in her right side [in November]…she refused to undergo the conventional technique and insisted on waiting until preparations were finished for the new form of the procedure to be offered."[539] Similarly, a patient in Olyphant, Pennsylvania told a reporter that she had originally planned to have open gallbladder surgery "but waited as long as I could until this new procedure was available.'"[540] And as we saw, many patients were willing to travel to other cities, and even other states to have their gallbladders taken out laparoscopically. A hospital spokesman in Alabama told the *Montgomery Advertiser*, "One of our most recent cases involved a gentleman…from Clearwater, Fla., who came in on a Tuesday and went home on a Thursday…If the technology is not available in their area, they are willing to travel to another state."[541]

There was even more pressure to get training once laparoscopic cholecystectomy became available in the region. For one surgeon in Ozark, Alabama, by the time he performed his first laparoscopic cholecystectomy after months of being on waiting lists to attend one of Reddick's courses and receive the laparoscopic instruments, "he had already lost patients to the hospital in nearby Dothan."[542] According to a June 1990 report in the *Philadelphia Daily News*, "There is a

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[539] Mark Linsalata, "Laser shines in surgery on gallbladder," *San Antonio Express-News* (San Antonio, TX), January 31, 1990.
[540] "CGH Uses Laser Surgery for Gall Bladder," *Times Tribune* (Scranton, PA), July 15, 1990.
[541] Ruth Albright, "New technique speeds gallbladder patients back to their normal lives," *Montgomery Advertiser* (Montgomery, AL), August 14, 1990.
[542] Winslow, "Cutting Edge."

lot of competition among local surgeons to learn the technique and begin practicing this procedure. Within the past few weeks, bellybutton gallbladder surgery has been performed at the University of Pennsylvania Medical Center, Temple, Bryn Mawr Hospital and Hahnemann University Hospital."[543] It was similarly reported in the *Wall Street Journal* that "St. Joseph's Hospital in Wichita, Kan., did its first laparoscopic gallbladder operation last February, and within three months the city's three other major hospitals followed suit."[544] As one health care market analyst described the situation, "Surgeons are scrambling to learn the procedure…"[545]

An Unregulated "Wild West": Demand for Training in Laparoscopic Cholecystectomy

With "hundreds of surgeons…lining up for courses to learn the technique," the high demand for training in laparoscopic cholecystectomy quickly opened the door for a seller's market in laparoscopic surgery training courses.[546] Though some academic centers began offering training courses that were modelled after the ones discussed at Berci's meeting, waiting lists for these courses quickly filled up. In the absence of enough spots in academic courses, some first-generation adopters (and eventually second-generation adopters) quickly began to offer training to the growing number of interested surgeons, independent of the structured spread that the SAGES leadership were hoping would take place. Just weeks after performing his first laparoscopic cholecystectomy in December 1989, John Bagnato was already "hop[ing] to offer classes to teach other surgeons the techniques by March [1990]." By August, it was reported that

[543] Mary Flannery, "The Changing 'Scope' of Surgery: New Technique Minimizes Scarring, Allows Faster Recovery," *Philadelphia Daily News* (Philadelphia, PA), June 6, 1990.
[544] Winslow, "Cutting Edge."
[545] Malcolm Ritter, Gallbladder Removal Avoids Incision, Speeds Recovery," *Galveston Daily News* (Galveston, TX), August 13, 1990.
[546] Ron Winslow, "Cutting Edge: A Tiny TV Camera Is Fast Transforming Gallbladder Surgery – The Keyhole Technique Uses Tiny Incision, May Work For Other Operations Too – Doctors Scramble to Learn It," *Wall Street Journal* (New York, NY), December 10, 1990.

he had provided training for 100 surgeons throughout the United States, including every surgeon in his town.[547] Similarly, surgeons who were the first to perform the procedure in the state of Wisconsin in December 1989 announced that they would be running a two-day training program at the beginning of April 1990.[548] As early as March 1990, Barry McKernan complained about the "proliferation of get-trained-quick courses and hospital hype."[549]

Surgeons, hospitals, and patients were not the only stakeholders to be enthusiastic about the emergence of less invasive gallbladder removal. Laser and laparoscopic instrument manufacturers were also highly invested in the technique's adoption and played a key role in enabling the scramble for training in laparoscopic cholecystectomy. While it was a generally accepted practice for manufacturers to furnish courses with the instruments needed for practical components, some companies made more substantial investments. U.S. Surgical, for example, helped William Saye and Eddie Reddick to establish the Advanced Laparoscopic Training Center in Marietta, Georgia. As the *Wall Street Journal* reported in December 1990, Saye and Reddick

> …ha[ve] trained more than 1,300 doctors since June [1990] at a laboratory with nine operating rooms crammed with $2 millions of equipment… 'U.S. Surgical was so interested in getting us to work with them they said they would support 90 courses in 18 months,' Dr. Saye says. In return for exclusive use of some of its products, the

[547] Chantel Foretich, "Hub doctor led state in new surgery," *Hattiesburg American* (Hattiesburg, MS), July 24, 1990.
[548] Karen B. Tancill, "Surgeons are taking the navel route to remove gall bladders. But it's no Gut Issue," *Journal Times* (Racine, WI), March 14, 1990.
[549] Ena Naunton, "Now there's a smaller cut for gallbladder surgery," *Morning Call-Sun* (Allentown, PA), June 3, 1990.

> Norwalk, Conn. Company pays the tuition for any vacancies in the two-day course. Its sales force recruits doctors to take it.[550]

As one observant described the situation, they "got paid a whole lot of money to make this puppy mill-type training course."[551] In addition, the *Hartford Courant* reported in September 1990 that "U.S. Surgical Corp. of Norwalk…has a nationwide network of two-day seminars it offers for surgeons."[552]

The growing availability of laparoscopic cholecystectomy courses and the variability amongst them quickly became a source of concern for academic surgeons and surgical societies. Courses varied in length between one to three days of training with most courses providing hands-on experience with the laparoscopic instruments where, for example, trainees "took seeds out of cantaloupes [as a] way to practice dexterity."[553] At U.S. Surgical's training facilities, "surgeons develop[ed] eye/hand coordination first by working with an inanimate model, then step[ped] up to store-bought Perdue chickens – the 'oven stuffer roaster' size…"[554] Similarly, at Reddick and Saye's course in Marietta, "Doctors poke[d] instruments through a cardboard box and practice[d] skinning a piece of chicken…"[555]

Some courses then provided animal models on which surgeons practiced removing gallbladders laparoscopically.[556] Since pigs were the preferred animal model, pig farmers became unexpected beneficiaries in the rush for training in laparoscopic cholecystectomy: "They essentially rent pigs to courses for a day, for $50 to $200, and get them back without their

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[550] Winslow, "Cutting Edge."
[551] Olsen, interview, May 29.
[552] Frank Spencer, "A new procedure allows gallbladder removal that's Barely surgery," *Hartford Courant* (Hartford, CT), September 27, 1990.
[553] Flannery, "The Changing 'Scope' of Surgery."
[554] Spencer, "Barely surgery."
[555] Winslow, "Cutting Edge."
[556] For example, see Flannery, "Changing 'Scope'"; Spencer, "Barely surgery";

gallbladders to be fattened for market."[557] Courses also varied in the type of exposure trainees received to the technique itself – whether they watched recorded (and perhaps edited) videos of the procedure or observed laparoscopic cholecystectomy being performed live. As the *New York Times* later reported, "[M]edical experts are concerned that too many surgeons are being trained too fast in courses that vary in length and quality. Some courses last a day, other three days. In some courses surgeons practice on pigs, whose gallbladder anatomy most closely resembles that of humans. In other courses, no animal work is done."[558]

"If you have scheduled your first laparoscopic case for next week, cancel it"

Regardless of how the courses were structured, what often mattered was how surgeons trained in addition to attending a course. As Armstrong noted in her ethnographic study of the early training courses, it was "clear that after the close of the workshop, surgeons needed to organize their own learning process before performing laparoscopic cholecystectomy on their first human patients."[559] A Milwaukee surgeon, for example, learned the technique in Nashville but also spent time practicing it at the Medical College of Wisconsin's animal laboratory before his first procedure in December 1989.[560] Another surgeon from Louisville, Indiana, trained at Abbott Northwestern Hospital in Minneapolis and continued training in laparoscopy with gynecologists at his hospital. He also had gynecologists assist him in his first laparoscopic cholecystectomies beginning in February 1990.[561] Similarly, a surgeon in Pennsylvania spent

[557] Winslow, "Cutting Edge."
[558] Lawrence K. Altman, "Complicated Surgery Through Tiny Incisions," *New York Times* (New York, NY), August 14, 1990.
[559] Armstrong, "Learning Communities of Surgeons," 229.
[560] "State's first laser removals of gallbladders performed," *Green Bay Press-Gazette* (Green Bay, WI0, December 31, 1989.
[561] Michael Quinlan, "Easing the pain: Instrument improves gallbladder surgery for patients," *Courier Journal* (Louisville, KY), April 19, 1990. For examples of other surgeons who trained with gynecologists and/or asked gynecologists to assist in their first laparoscopic cholecystectomies, see Beverly Orndorff, "Procedure Sends Patients Home Sooner," *Richmond Times-Dispatch* (Richmond, VA), January 27, 1990; Joyce Terveen, "Medicine

time at the training centers in Nashville, Baltimore, and Atlanta, as well as assisted in laparoscopic gynecological procedures at his hospital, before performing his first laparoscopic cholecystectomy in May 1990.[562]

A study at the Leonard Davis Institute of Health Economics at the University of Pennsylvania, however, found that amongst surgeons who adopted the technique in 1989 and the first quarter of 1990, 35% performed their first laparoscopic cholecystectomy without having previously assisted in one with a more experienced colleague. When performing their first laparoscopic cholecystectomy, 58% of surgeons were not assisted by a more experienced surgeon.[563] The authors of the study suggested that some surgeons did not think to seek additional training because, "Most new surgical procedures are minor variants of existing ones and specific criteria for granting clinical privileges may not be indicated."[564] In contrast, laparoscopic surgery was a radically different approach that, for the majority of surgeons, required a new set of skills. But since advances in general surgery were perceived to rarely require substantial re-training, some surgeons emerged from the laparoscopic cholecystectomy courses believing themselves to be immediately ready to conduct the procedure on their own. As Périssat explained, after "seeing [it] done by somebody well-trained, it [looked] so simple. [Some surgeons] said, 'I am able to do this tomorrow because I have [done] more than 3,000 open cholecystectomies [and] I know well the positioning of [everything].'"[565] This impression was further reinforced by the videos of laparoscopic cholecystectomy that were shown in

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gets less incisive: Doctors using lasers to remove gallbladder," *Argus Leader* (Sioux Falls, SD), May 22, 1990; "Up and going after gallbladder surgery: Laser, camera give doctors precise tools," *Post-Crescent* (Appleton, WI), May 21, 1990.

[562] Michele McCreary, "Removing an organ in a new procedure," *Philadelphia Inquirer* (Philadelphia, PA), May 31, 1990.

[563] José J. Escarce, Judy A. Shea, and J. Sanford Schwartz, "How Practicing Surgeons Trained for Laparoscopic Cholecystectomy," *Medical Care* 35 (1997): 291-6, 292.

[564] Escarce et al., "Practicing Surgeons," 294.

[565] Périssat, interview, November 13.

promotion of the technique as well as during the training courses. According to Olsen, "for every clip that would actually load and fire properly, in these early prototypes, about four or five would go shooting across the abdomen. But with the magic of editing, we edited that all out…we had these things edited through to the point of where it was very clear that it was a doable, workable procedure."[566]

But the radically different implementation of laparoscopic surgery, compared to traditional open surgery, created a situation where the general standard of "see one, do one, teach one" was no longer sufficient. Perhaps more important than the length of a training course or how much hands-on experience it included was for instructors to explicitly tell trainees that attending the course was only the beginning of their training in laparoscopic surgery. At one of the courses that Armstrong observed, for example, the instructor told attendees, "if you have scheduled your first laparoscopic case for next week, cancel it."[567] Trainees needed to be told that before attempting a laparoscopic cholecystectomy on a patient as the primary surgeon, they needed to first spend time working with a team of colleagues to practice using the instruments, as well as assisting in procedures with more experienced surgeons. There were of course some surgeons who were able to make the transition to laparoscopic surgery almost immediately. As Armstrong observed, "A few of the trainees appeared to be 'born laparoscopists,' adjusting quickly to the constraints imposed by cyborg surgery."[568] However, these surgeons may not have taken slower learning curves into as much consideration when training others. John Bagnato, for example, told reporters: "Within a three- or four-week period of my initiating an interest, I was able to do it…The average surgeon should be able to pick it up and utilize it."[569]

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[566] Olsen, interview, May 29.
[567] Armstrong, "Learning Communities," 229.
[568] Armstrong, "Learning Communities," 228.
[569] Carson, "Laser surgery may be taught here."

Voluntary Compliance: "A wake-up call"

Concerned that many surgeons were not getting adequate training in laparoscopic cholecystectomy before offering it to patients, in May 1990, the Board of Governors of SAGES issued a statement on the "Granting of Privileges for Laparoscopic General Surgery."[570] The statement recommended that in order to qualify for privileges surgeons should a) be credentialled in diagnostic laparoscopy; b) have trained in laparoscopy with an experienced surgeon and/or have taken a didactic course with clinical experience and hands-on laboratory practice; and c) have observed a laparoscopic surgical procedure performed by an experienced surgeon.[571] The statement also emphasized that "attendance at short courses that do not provide supervised hands-on training is not an acceptable substitute…"[572] It further suggested that "it may be desirable" that applicants for privileges be proctored "by a qualified, unbiased staff surgeon experienced in general and laparoscopic surgery."[573] Though procedural privileges are granted to surgeons at the discretion of individual hospitals, the SAGES leadership hoped that the guide would have an influential effect and slow the adoption of laparoscopic cholecystectomy.

But as we saw, hospitals had a major economic incentive to offer the procedure as quickly as possible. This desire to provide cutting-edge medical services sometimes created a dangerous conflict of interest with regards to a hospital's ability to regulate whether a surgeon should be granted privileges in a new procedure. As the *Los Angeles Times* later explained,

> Since most surgeries require neither national consensus nor government approval, the [individual hospital credentialing]

[570] Society of American Gastrointestinal Endoscopic Surgeons, "Granting of Privileges for Laparoscopic General Surgery," *American Journal of Surgery* 161 (1991): 324-5.
[571] SAGES, "Granting of Privileges," 324.
[572] SAGES, "Granting of Privileges," 324.
[573] SAGES, "Granting of Privileges," 325.

> committees are the only check on what operations doctors can perform…In many cases, committee members often include the same doctors who want to perform the operation in question, or close colleagues. Their decisions may significantly affect their own, their colleagues' and their hospitals' incomes.[574]

Responding to the increasing number of gallbladder surgery complications, in March 1992, the New York State Health Department announced that it was preparing a warning to hospitals on the provision of laparoscopic cholecystectomy.[575] As the department's spokeswoman told the *Poughkeepsie Journal*, "Since the fall of 1990, hospitals throughout New York have reported 128 incidents associated with the laparoscopic procedure, including six deaths." [576] According to the *New York Times*, "Among the cases of botched surgery that led the state to act was that of a 66-year-old woman who bled to death after a surgeon accidentally punctured her aorta…The surgeon…learned the laparoscopic technique in a one-day seminar…"[577] In another case, "the bowel of a 42-year-old woman was injured. The hospital said it had no information that the surgeon had any training in laparoscopy. The hospital did not establish qualifications for granting credentials for the procedure until five months after the surgery."[578]

On June 12, 1992, state health officials issued guidelines to New York hospitals stipulating that privileges for laparoscopic cholecystectomy could only be granted to surgeons with experience in assisting an already-privileged surgeon in at least five procedures and in performing at least ten additional procedures as the responsible surgeon under the supervision of

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[574] Harris Meyer, "Danger on the Cutting Edge?" *Los Angeles Times* (Los Angeles, CA), July 29, 1992.
[575] Dennis Kipp, "Surgical procedure warning planned: Gallbladder operation target of state document," *Poughkeepsie Journal* (Poughkeepsie, NY), March 31, 1992.
[576] Kipp, "Surgical procedure warning."
[577] Lawrence K. Altman, "Surgical Injuries Lead To New Rule: New York Assails the Training for a Popular Technique," *New York Times*, New York, NY, June 14, 1992.
[578] Altman, "Surgical Injuries."

an already-privileged surgeon.[579] Unlike the 1990 SAGES statement, these guidelines were more specific with regards to the amount of supervised practical experience that surgeons had to have in order to be granted privileges in laparoscopic surgery. And importantly, these guidelines were mandated by the state government. As the *Los Angeles Times* explained, "To control these problems, medical groups are introducing some unprecedented, though limited, standards. But compliance is voluntary… The biggest surgeons' group, the American College of Surgeons, insists laparoscopic-credentialing is up to individual hospitals."[580]

Though organized medicine is usually known for being averse to management by non-medical entities, the SAGES leadership recognized that "our guidelines have not been embraced universally, and unfortunate occurrences…have occurred which indicate that more stringent and 'outside'-influenced credentialing is appropriate."[581] The May 1990 guidelines were judged to be vague and insufficient and a more detailed statement was approved by the SAGES Board of Governors in October 1992.[582] The additional recommendations for privileging in laparoscopic general surgery included that surgeons should have privileges in the comparable open procedures, experience as a first assistant to a surgeon already privileged in laparoscopic procedures, and have been proctored by an experienced laparoscopic surgeon.[583] The 1992 guidelines further specified that training courses should include "instruction in handling and use of laparoscopic instrumentation, principles of safe trocar insertion, establishment of safe peritoneal access, laparoscopic tissue handling, knot tying, equipment utilization (e.g. staplers),

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[579] Frederick L. Green, "New York State Health Department ruling – a "wake-up call" for all," *Surgical Endoscopy* 6 (1992): 271; New York State Department of Health, "Laparoscopic Surgery," *New York State Department of Health Memorandum – Series 92-20* Albany, June 12, 1992.
[580] Harris Meyer, "Danger on the Cutting Edge?" *Los Angeles Times* (Los Angeles, CA), July 29, 1992.
[581] Green, "New York State Health Department," 271.
[582] SAGES Committee on Credentialing, "Guidelines for granting of privileges for laparoscopic (peritoneoscopic) general surgery," *Surgical Endoscopy* 7 (1993): 67-8.
[583] SAGES, "Guidelines for granting," 67-8.

as well as animal experience in specific categories of procedures for which [the] applicant desires privileges."[584] Trainees were also required to "demonstrate to the satisfaction of an experienced physician course director/preceptor that he/she can perform a given procedure from beginning to end in an animal model."[585] Frederick Greene, the new President of SAGES, urged that "The recent incursion of a state agency for the specific purpose of developing guidelines that mandate hospital credentialing in an operative procedure should arouse all surgeons and serve as a 'wake-up call.' Unless we act responsibly as individuals on our hospital medical staffs…the state and federal governments will take over this activity for us."[586] Though much of the early concern over proper training in the emergence of laparoscopic cholecystectomy was directed towards the structure of the training courses, the inclusion of more specific requirements for post-course training – by both SAGES and the New York State Health Department – suggests that it was the ways in which surgeons trained after attending a course that was often more crucial for preventing complications than the courses themselves.

Randomized Controlled Trials: The Push to Evaluate Laparoscopic Cholecystectomy

In addition to attempting to control the spread of laparoscopic cholecystectomy through training and credentialing guidelines, academic surgeons suggested that the procedure should be initially confined to academic medical centers so that it could be evaluated for safety through properly controlled prospective clinical trials.[587] Historically, the most commonly used method of surgical evaluation has been the case study/series. Surgical innovations are often announced to the community in the form of a case report and are then evaluated through multiple case series to

[584] SAGES, "Guidelines for granting," 68.
[585] SAGES, "Guidelines for granting," 68.
[586] Green, "New York State Health Department," 271.
[587] Cuschieri, "Laparoscopic Revolution,"; Cuschieri et al. "Laparoscopic Cholecystectomy."

chronicle use under various circumstances and importantly, in different hands.[588] Although by the 1980s the RCT had become an important reference method for evaluating pharmaceutical treatment, in surgery, reports of case series were still considered sufficient evidence of therapeutic effect.[589] In many ways the case study reflects the field's emphasis on the individual skill and experience of the operating surgeon. As Christopher Crenner has explained, "The craft nature of surgery with its emphasis on individual judgment and responsibility reinforced the use of case evidence…communications about new surgical treatments still appears today typically in the form of a case report and case series."[590] Along these lines, Dubois' May 1989 report on laparoscopic cholecystectomy consisted of the results of his first 63 cases.[591] As surgeons throughout Europe and North America adopted the technique, more case series documenting their experiences emerged in the surgical literature.[592]

Although these studies unanimously concluded that laparoscopic cholecystectomy was a safe and effective treatment for cholelithiasis with minimal risk when performed by a properly trained surgeon, some investigators remained unconvinced. Surgeons at the University of Maryland, for example, reported at the May 1990 meeting of the Society for Surgery of the

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[588] Thomas Schlich, "The Science of Surgery: Clinical Research," *Surgery, Science and Industry: A Revolution in Fracture Care, 1950s-1990s* (Houndsmills, Basingstoke, Hampshire: Palgrave Macmillan, 2002), 110-137; David S. Jones, "Visions of a Cure. Visualization, Clinical Trials, and Controversies in Cardiac Therapeutics, 1968-1998," *Isis*, 2000, *91*, 504-541.

[589] See, for example, Schlich, "Science of Surgery," 129-137.

[590] Christopher Crenner, "Placebos and the Progress of Surgery," *Technological Change in Modern Surgery: Historical Perspectives on Innovation* eds. Thomas Schlich and Christopher Crenner, (Rochester: University of Rochester Press, 2017), 156-184, 162.

[591] F. Dubois, G. Berthelot, and H. Levard, "Cholécystectomie par coelioscopie," *La Presse Médicale* 18 (1989): 980-2.

[592] Y.M. Dion and J. Morin, "Laparoscopic Cholecystectomy: a report of 60 cases," *Canadian Journal of Surgery* 6 (1990): 483-486; Jeffrey H. Peters et al., "Safety and Efficacy of Laparoscopic Cholecystectomy: A Prospective Analysis of 100 Initial Patients," *Annals of Surgery* 213 (1991), 3-12; Karl A. Zucker et al., "Laparoscopic Guided Cholecystectomy," *American Journal of Surgery* 161 (1991): 36-44; Herschel A. Graves, Jeanne F. Ballinger, and William J. Anderson, "Appraisal of Laparoscopic Cholecystectomy," *Annals of Surgery* 213 (1991): 655-662; Robert J. Fitzgibbons Jr. et al., "Open Laparoscopy for Laparoscopic Cholecystectomy," *Surgical Laparoscopy & Endoscopy* 1 (1991): 216-222; Alfred Cuschieri et al., "The European Experience with Laparoscopic Cholecystectomy," *American Journal of Surgery* 161 (1991): 385-387.

Alimentary Tract that based on their first 100 cases of laparoscopic cholecystectomy, the procedure "appears to offer a number of advantages in patient care…"[593] They warned, however, that "appropriate training is necessary to maintain a low rate of operative complications. Whether laparoscopic surgery will prove as safe as open cholecystectomy is still unclear. Additional data will be necessary to evaluate the complications encountered by surgeons with limited experience…"[594] Similarly, an October 1990 editorial in *Archives of Surgery* argued that "it will be difficult to fully evaluate this procedure without some kind of formal analysis of many cases, as could be done by a registry…"[595]

Such a registry was already being organized by the Southern Surgeons Club and was published in the *New England Journal of Medicine* in April 1991.[596] The registry compiled the results of 1518 laparoscopic cholecystectomies performed amongst 59 surgeons at both academic and private hospitals. The outcomes of the cases were analyzed by the Department of Biometry and Statistics at Duke University. In order to mitigate concerns over "the degree of commercialism already evident in the spread of laparoscopic cholecystectomy," the authors excluded "any surgeon with any kind of contractual arrangement with an instrument manufacturer up to the time of the submission of cases," from participating in the study.[597] Though the report did not indicate the surgeons' experience levels in laparoscopic cholecystectomy at the beginning of the study, the authors noted that the incidence of bile duct injury in the first 13 cases performed by each surgical group was 2.2%.[598] The rate of bile duct

[593] Zucker, "Laparoscopic Guided Cholecystectomy,"36.
[594] Zucker, "Laparoscopic Guided Cholecystectomy,"41.
[595] Ronald K. Tompkins, "Laparoscopic Cholecystectomy – Threat or Opportunity?" *Archives of Surgery* 125 (1990): 1245.
[596] Southern Surgeons Club, "A Prospective Analysis of 1518 Laparoscopic Cholecystectomies," *New England Journal of Medicine* 324 (1991): 1073-8.
[597] Southern Surgeons Club, "Prospective Analysis of 1518," 1073.
[598] Southern Surgeons Club, "Prospective Analysis of 1518," 1076-7.

injury decreased to 0.1% in the subsequent cases leading the authors to conclude that "a large proportion of such injuries can be attributed to the learning experience."[599] Though overall frequency of bile duct injury (0.5%) was higher than the rate of 0.1-0.2% reported for open cholecystectomy, the total rate of complications was 5.1% "which compares favorably with the rates of 6 percent, 13 percent, and 21 percent reported for three series of patients undergoing conventional cholecystectomy."[600] The authors concluded, "Skilled surgeons can learn the procedure rapidly…as with conventional cholecystectomy, inexperience can lead to mishaps."[601]

Despite the increasing number of reports documenting experiences with laparoscopic cholecystectomy, none of the evaluations were a truly randomized controlled clinical trial comparing the new technique to the prevailing standard of the open procedure. As a September 1991 editorial in *The Lancet* lamented, "amid all the optimism there is one cause for regret – that once again a surgical procedure is finding a niche in standard practice after uncontrolled evaluations that would never pass muster for a new drug."[602] Without randomization, blinding, and prospective, parallel controls, bias could influence the assessment of results, causing some observers to consider the question of whether the procedure was as safe as the open surgery to be unresolved.[603]

One surgeon in particular, Hans Troidl, combined a skeptical attitude towards evidence in surgery with strong interest in epistemic questions, mainly, as it was typical for the time, based on Karl Popper's critical epistemology.[604] As one of his colleagues described him, the German surgeon was a "total disciple of randomized trials" at a time when RCTs were "not even on

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[599] Southern Surgeons Club, "Prospective Analysis of 1518," 1077.
[600] Southern Surgeons Club, "Prospective Analysis of 1518," 1077.
[601] Southern Surgeons Club, "Prospective Analysis of 1518," 1077.
[602] "Cholecystectomy practice transformed," *Lancet*, 1991, *338*, 789-790.
[603] For example: Graves, "Appraisal," 655; Thomas V. Holohan, "Laparoscopic Cholecystectomy," *Lancet*, 1991, *338*, 802; Zucker, "Guided," 36-42; Soper, "Laparoscopic," 651.
[604] Hans Troidl, interview by Nils Hannson, Starnberg, Germany, March 25, 2015.

anyone's radar in surgery."[605] Troidl was an early adopter of laparoscopic cholecystectomy and had heard about the technique from his friend Jacques Périssat, even accompanying him to the April 1989 SAGES meeting in Louisville, Kentucky.[606] Troidl and Périssat met previously at a conference in Paris on biliary tree treatment where they bonded over their mutual interest in flexible endoscopy. As Périssat recalled, "When we started this laparoscopic cholecystectomy, I ma[de] a phone call to him and said, 'I have something new to show you in Louisville.'"[607] According to Périssat, Troidl "came and he [said] just after my presentation, 'We must establish a European society. Because I think it is the best way to prevent catastrophe. Because everybody will learn this quickly and do this. And we need to establish a very correct educational program. Because we could have a disaster."[608] Together, Périssat and Troidl quickly set about recruiting their European colleagues to establish the European Association of Endoscopic Surgeons (EAES) and were able to organize their first meeting in Erlangen, Germany as early as June 1989.[609]

Troidl and his colleagues at the University of Cologne introduced laparoscopic cholecystectomy to their clinic in October 1989.[610] Since in their view, "it is no longer acceptable or tolerable to describe the clinical significance of technologies in terms of case studies or empirical judgements," the group (led by Edmund Neugebauer) attempted to compare laparoscopic cholecystectomy to the open procedure in an RCT.[611] While setting up the trial, however, the group was confronted with several practical problems that ultimately led them to

[605] Jeffrey Barkun, interview.
[606] Périssat, interview, November 13.
[607] Périssat, interview, November 9.
[608] Périssat, interview, November 9.
[609] Périssat, interview, November 9.
[610] E. Neugebauer et al., "Conventional *versus* laparoscopic cholecystectomy and the randomized controlled trial," *British Journal of Surgery* 78 (1991): 150-154, 150.
[611] Neugebauer, "Conventional *versus* laparoscopic," 150-154.

convert their trial into an observational study. One of the biggest problems included the controversial issue of when to begin the trial. According to the Neugebauer group, on the one hand, "purists even state that it is scientifically and ethically inexcusable not to undertake randomized controlled trials as soon as possible."[612] However, surgery posed specific problems that complicated early RCTs, not only for laparoscopic cholecystectomy but for surgery in general. Whereas drug therapy does not usually require special skills to administer new treatments, the results of a surgical treatment are highly dependent on the skill and experience of the operating surgeon. Therefore, participating surgeons must attain a certain level of skill with the new technique before the initiation of a trial.

In surgery, skill has always been an important factor for the introduction of new techniques. However, the evaluation and appreciation of skill has been dependent on the contexts in which it was to be applied. Since the late nineteenth century the skill of following exact step-by-step instructions in a standardized way, and thus enabling the replication of innovative surgical interventions, has been considered a particularly important asset for surgeons.[613] In the context of clinical trials, surgical skill – however elusive it seemed to be – needed to be standardized to a certain degree. Thus, all surgeons taking part in the trial had to reach a predetermined level of skill in order to render their operations somewhat comparable. In addition, investigators' experience with the technique is also necessary in order to determine appropriate endpoints and outcome indices.[614]

But as David Jones notes in his study on coronary artery bypass grafting, RCTs in surgery are further complicated by the experience of immediate success (with respect to certain

[612] Neugebauer, "Conventional *versus* laparoscopic," 150.
[613] See Thomas Schlich, "'The Days of Brilliancy are Past': Skill, Styles and the Changing Rules of Surgical Performance, ca. 1820-1920", *Medical History* 59 (2015), 379-403.
[614] Neugebauer, "Conventional *versus* laparoscopic," 150.

endpoints) achieved by practitioners possessing the required skills, convincing surgeons of the efficacy of a new technique.[615] This makes it often seem unethical to conduct an RCT and randomize patients to another, inferior treatment. Harvey Sigman, for example, who was associated with the McGill Gallstone Group and contributed several patients to the trial, reported how his vast experience with laparoscopic cholecystectomy by the time the trial was organized made it ethically problematic for him to convince patients to join the study.[616] This attitude aligns with sociologist James Zetka's generalized observations on surgeons' concerns over the ethical admissibility of assigning patients to control groups "when they believed that the new technique could better help them."[617] The concern was also reiterated by the Neugebauer group, who argued that it is "quite wrong for surgeons to engage in a randomized controlled trial unless they are convinced that the answers to the questions being addressed are truly unknown."[618] This means that surgeons at the time doubted the presence of "clinical equipoise", a term coined by bioethicist Benjamin Freedman in 1987, who defined it as "a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial."[619] To some, it appeared that the rapid adoption of laparoscopic cholecystectomy had made the performance of prospective trials comparing it to the old technique "all but impossible."[620]

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[615] Jones, "Visions", 531.
[616] Harvey Sigman, interview with Thomas Schlich and Cynthia L. Tang, Montréal, Canada, June 18, 2015.
[617] Zetka, *Surgeons*, 105.
[618] Neugebauer, "Conventional *versus* laparoscopic," 152. However, the Neugebauer group hoped that an RCT evaluating the minimally invasive technique would one day be successfully performed.
[619] Benjamin Freedman, "Equipoise and the Ethics of Clinical Research," *New England Journal of Medicine* 317 (1987): 141-145.
[620] Jeffrey F. Smith et al., "Comparison of Laparoscopic Cholecystectomy versus Elective Open Cholecystectomy," *Journal of Laparoendoscopic Surgery* 2 (1992): 311-7, 312; See also, Lester F. Williams et al., "Comparison of Laparoscopic Cholecystectomy With Open Cholecystectomy in a Single Center," *American Journal of Surgery* 165 (1993): 459-65, 462.

The McGill Gallstone Study

Interestingly, the McGill Gallstone Study – which included the first RCT on laparoscopic cholecystectomy – was not initially conceptualized to test this therapy. In 1988, Alan Barkun, Chief Medical Resident at McGill University hospitals, went to France to train in lithotripsy only to return in 1990 to find that "the most bizarre thing happened, that basically lithotripsies dropped off the map." Although enthusiasm for gallbladder stone lithotripsy was great prior to Barkun's departure to France, the high recurrence rate of gallstones limited its success as a cure.[621] Barkun, who at the time was pursuing a Master's Degree in epidemiology and biostatistics at McGill University, decided to write a proposal to the *Fonds de Recherche Santé Québec* for a randomized trial comparing lithotripsy to open cholecystectomy.

At the time, Barkun's twin brother Jeffrey Barkun was in a biliary surgical fellowship in Toronto and was training in laparoscopic cholecystectomy.[622] The brothers realized that a third arm should be added to the trial to evaluate the emerging technique of laparoscopic cholecystectomy, which looked like it was going to be quite common in the future.[623] Jeffrey Barkun was also in the Master's program in epidemiology and biostatistics at McGill and decided to run the trial with his brother for his thesis work. They felt that this was important because:

> …by the time we're ready to do the trial and we do the trial, it would also come out in a timely fashion rather than always – you want to do the perfect trial, but by the time it comes out it's too late and so on. And so we agreed that the only time we could do it was then

[621] Alan Barkun, interview with Thomas Schlich and Cynthia L. Tang, Montréal, Canada, January 12, 2015.
[622] Jeffrey Barkun, interview.
[623] Alan Barkun, interview.

> because a year, two years down the road, everybody would want lap chole and we wouldn't be able to properly assess it.[624]

According to Jeffrey Barkun, "there was a gun to everyone's head because it became very clear that this procedure…was not going to follow…what we would call an ideal development, where you have a very formal, structured assessment of it…[laparoscopic cholecystectomy] was just happening. It was just out there!"[625] As discussed in Chapter 2, the "ideal development" refers to the wide-spread expectation that, new techniques normally follow a linear development: innovation, thus the idea, comes from medical research and is subsequently subjected to clinical trials and publication reviews, and only from there does it diffuse out to the community hospitals. This is what researchers such as the Barkuns had in mind as a proper way of innovation in medicine. But as James Zetka notes in his study, in the case of laparoscopic cholecystectomy "this course was reversed."[626] Historian David Jones has shown that similar concerns were expressed in the history of coronary artery bypass grafting where cardiologists and surgeons believed that the efficacy of the procedure had to be shown through an RCT and before the procedure "became an uncontrollable force."[627]

Together the twins – a gastroenterologist and a gastrointestinal surgeon – spent a weekend in Montreal writing a second grant proposal for a randomized trial comparing laparoscopic to the mini-open cholecystectomy using some of the same protocols from the first study, which was still being organized. By using the same patient identification and triaging protocols their research plan resulted in "two randomized trials side-by-side, almost like the

[624] Alan Barkun, interview.
[625] Jeffrey Barkun, interview.
[626] Zetka, "Technological," 139.
[627] Jones, "Visions of a Cure," 504-5.

three-way randomization."[628] In order to meet the *Medical Research Council* (now the *Canadian Institute for Health Research*) grant proposal submission deadline, Alan Barkun made the two-hour trek to his parents' house in Ottawa where they were hosting a cocktail party. At the time, the Barkun family patriarch, Harvey Barkun, was the executive director of the Association of Canadian Medical Colleges as well as medical director of the Royal Victoria Hospital, Executive Director of the Montreal General Hospital, and Associate Dean of Professional Affairs of the McGill Faculty of Medicine. Fortunately for the Barkun twins, the Dean of Medicine at McGill was a guest at their parents' party and signed the proposal so that they could meet the deadline.[629]

This episode points to one of the many contingent circumstances in the origins of the first completed RCT evaluating laparoscopic cholecystectomy – in this case, the fact that the Barkun twins were in various ways well-placed to initiate such a trial. Apart from pointing at the role that coincidences might have also contributed to this first RCT on the method taking place at McGill, these kinds of details also demonstrate the importance of personal networks for the initiation of clinical trials. There was, for example, also a German connection to Hans Troidl.[630] In the McGill study, two of the surgeons who helped drive the RCT had previously trained with Troidl in Cologne. Jeffrey Barkun spent a year of his surgical residency training with him in Germany at the University of Cologne.

Additionally, the McGill surgeon Gerald Fried, met Troidl by chance in 1990 when the German surgeon was visiting Montreal to work on a book with David Mulder, then Chief of

[628] Alan Barkun, interview; The original study, which planned to compare lithotripsy therapy to the mini-cholecystectomy, will not be discussed.
[629] Alan Barkun, interview.
[630] Jeffrey Barkun, interview.

Surgery at the Montreal General Hospital.[631] Troidl had co-edited the textbook, *Principle and Practice of Research: Strategies for Surgical Investigators*, with Mulder and Walter Spitzer, Chairman of McGill's Department of Epidemiology and Biostatistics and editor of the Journal of Clinical Epidemiology at the time. Passing by Mulder's office one Saturday morning, Fried was invited to join the two senior surgeons for lunch where Troidl told him about a new surgery he was doing in Cologne: laparoscopic cholecystectomy. According to Fried, Troidl invited him to Germany to learn to do this operation, so that one day he would "be a famous surgeon." Because of this chance encounter on a Saturday morning, Fried had the opportunity to spend a week in Cologne learning the laparoscopic technique from Troidl.[632] It is conceivable that the encounters that both Fried and Jeffrey Barkun had with Troidl contributed to their belief that an RCT evaluating laparoscopic cholecystectomy was necessary. It is also possible that the year that Jeffrey Barkun spent in Germany, allowed Troidl to impress upon him the importance of evidence-based medicine, motivating him and his brother to pursue graduate studies in epidemiology and biostatistics at a time when there were "no more than ten surgeons with epidemiology training in Canada."[633] This configuration can be seen as forming a specific local culture of surgical evidence at McGill (with connections to other places), which was another contingent factor contributing to the background of this RCT. We can also see how the personal network of motivated researchers that formed the condition for the RCT came about.

[631] Jeffrey Barkun, interview; Gerald Fried, interview with Thomas Schlich and Cynthia L. Tang, Montréal, Canada, June 13, 2014.
[632] Fried, interview.
[633] Jeffrey Barkun, interview; this was also discussed in Crenner, "Placebos."

When to Begin the Study: Surgical Skill and Clinical Equipoise

As discussed earlier, one of the problems in conducting a surgical RCT stems from the dependence of the treatment outcome on the skill of the surgeon. Unlike pharmaceutical treatments, with every new surgical innovation there is a learning curve for each surgeon. The McGill RCT needed to be designed in such a way so that it began at the point in the learning curve where the skill levels of the participating surgeons were somewhat equalized. At the same time, however, clinical equipoise had to still exist. In order to address this issue, Jonathan Meakins – one of the leading surgeons in the study and Chair of the Department of Surgery at McGill at the time – established a registry for the McGill Gallstone Group. The registry diligently documented data from 1278 laparoscopic cholecystectomies performed at four Montreal hospitals by twelve individual surgeons.[634] The resulting "McGill Laparoscopic Database" contained a standardized set of information on each patient, the operation done, the post-operative course and the occurrence of complications.[635]

The McGill registry thus allowed the authors to track outcomes of all laparoscopic surgeries done at the institution. Importantly, it also made it possible to determine when the learning curves of the surgeons began to plateau, as well as which endpoints to measure in the study.[636] In order to standardize the surgical skill levels and allow the cases of different surgeons to be comparable, participating surgeons were required to have performed at least 30 laparoscopic procedures prior to the start of the trial as well as have the ability to do both the open and the minimally invasive procedures.[637] The endpoints that were chosen to be measured

[634] Jonathan Meakins, interview by Thomas Schlich and Cynthia Tang, Montreal, Quebec, July 7, 2014; Jeffrey S. Barkun, "A Randomised Controlled Trial Comparing Laparoscopic to Mini Cholecystectomy" (master's thesis, McGill University, 1993), 48.
[635] The McGill Laparoscopic Database, form, undated, private archive, Harvey Sigman, Montréal, Canada.
[636] Fried, interview.
[637] Barkun, "Laparoscopic," 1116.

in the RCT were the duration of the operation, the rate of conversion to open cholecystectomy, the length of the hospital stay, post-operative days to full diet, duration of convalescence, postoperative pain and quality of life.[638] Patients were followed up as outpatients for at least three months after the operation.[639] Postoperative pain was determined from narcotics use during the hospital stay and the first postoperative week, as well as by the McGill pain questionnaire. Quality of life was assessed preoperatively and at 1 and 3 months after the operation, using the Nottingham Health Profile Questionnaire, a German gastrointestinal surgery quality of life index which is based on patients rating their quality of life on a scale of 0 (poor) to 11 (excellent).[640]

Effects of Demand and Scarcity on Clinical Trials

As discussed throughout this dissertation, patient demand for the laparoscopic method was very high. This made it particularly difficult to include the older method of open surgery in clinical trials. According to surgeons' accounts, patients knew that they wanted the laparoscopic surgical procedure for their cholelithiasis treatment, and many were not willing to be randomized in a trial where there was a chance that they would be in the open surgery group. For the Neugebauer group,

> …the publicity surrounding our clinic following reports of the first successful operations in Germany led to a rapid increase in the number of eligible patients with gallbladder symptoms in our clinic…The potential advantage of this increased recruitment of patients, namely that it would enable us to run a trial, was diminished

[638] Barkun, "Laparoscopic," 1117.
[639] Barkun, "Laparoscopic," 1116.
[640] Barkun, "Laparoscopic," 1117.

> by the fact that all these patients wanted only the new 'minor' invasive technique that they had read about.[641]

Similarly, a group in Nashville, Tennessee – who published a retrospective study in April 1993 – noted, " …after the laparoscopic method of cholecystectomy was introduced in our community, it quickly became accepted and requested by the majority of patients, making it very difficult, if not impossible, to conduct such a trial."[642] A major problem in attempts to run an RCT to evaluate laparoscopic cholecystectomy was that patients often dropped out of the study when randomized to a non-laparoscopic group and went elsewhere to have the operation.

This is where Alan and Jeffrey Barkun believed they had an advantage in running their trial. According to the brothers and other authors of the study, the McGill Gallstone Treatment Clinic – which was created to run the cholelithiasis treatment study at multiple hospitals in Montreal – was the only clinic in the area that provided access to laparoscopic cholecystectomy, giving it a relative dominance over the treatment. The situation was also markedly different from the conditions under the market-driven American health care system where patients could more easily switch to another surgeon, hospital, or outpatient surgical clinic. American surgeons, as Fried explained,

> …were eager to build up their practices, and hospitals wanted to attract patients because that generated revenue. And so there [were] conflicting agendas there, whereas the hospitals and doctors wanted to offer what the patients wanted, and patients wanted this…if you would say, "I would only do [laparoscopic cholecystectomy on] patients [who participated in the] trial," patients would go to another

[641] Neugebauer, "Conventional versus laparoscopic," 152.
[642] Williams, "Single Center," 462.

> hospital, another doctor. So you really didn't have the capability of controlling the market.[643]

In Canada, by contrast, surgeons could make the treatment contingent on their patients' participation in a randomized trial in order to have a one in three chance of getting the minimally invasive surgery.[644] Even so, there were patients who were approached to join the trial but refused, citing reasons such as "I won't be a guinea pig" and "I came for the 'Laser' treatment," as Jeffrey Barkun later wrote to the editor of the *Lancet*.[645] This restrictive policy, however, was not uncontroversial among surgeons at the time either. As Harvey Sigman explained, "…if someone comes to you and says, 'I don't want to be in a trial, I just want you to do this operation,' and you say, 'If you don't go in the trial, I'm not going to look after you'…[for] an operation that we already knew was a good operation…to me that would be coercion. And I think coercion and science is a bad mix."[646]

Since Sigman was a surgeon in Montreal who was highly adept at laparoscopic cholecystectomy at the time of the McGill Study but did not contribute many cases to it, the McGill Gallstone Group might not have had as much of a monopoly over the technique as they believe to be the reason for their success. But the Canadian context also allowed for other ways of exerting control over the technology such as the relative scarcity of the equipment. As Alan and Jeffrey Barkun and Jonathan Meakins explained in the *American Journal of Surgery*, "The dissemination of [laparoscopic cholecystectomy] in Canada has been slower than in the United States, mostly because of the availability of equipment."[647] At the time, the Canadian market was

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[643] Fried, interview.
[644] Fried, interview.
[645] Jeffrey Barkun, Letter to Dr. Fox of *The Lancet* dated July 10, 1992. Archival material obtained from Jeffrey Barkun.
[646] Sigman, interview.
[647] Jeffrey S. Barkun, Alan N. Barkun and Jonathan L. Meakins, "Laparoscopic Versus Open Cholecystectomy: The Canadian Experience," *American Journal of Surgery* 165 (1993): 455-458.

given low priority by the manufacturer and it took months before the equipment was delivered, "so that the Americans got first dibs on whatever's coming out." According to Sigman, Canadians were

> using borrowed equipment for about three months…[meaning] that, that equipment was crossing Canada. It would be in Burnaby three days ago, it would be in Toronto yesterday, Laval today, you could have it in two weeks. So you booked the patient ahead of time…then they would call you two days beforehand and would say [that] one piece is broken and needs to be repaired, so you would have to cancel.[648]

Historically, the scarcity of treatment material – that is, of drugs or devices – has often been an important factor in controlling the spread of a new therapy.[649] The scarcity of laparoscopic instruments most likely contributed to the limited access to the minimally invasive treatment in Montreal, making it possible for the McGill Group to recruit enough patients to the randomized controlled trial.

In the McGill study, patients were referred to eight participating surgeons at four university hospitals in Montreal and one in Toronto between September 1990 and September 1991.[650] Despite their relative control over the technique, the McGill group still had difficulty with patients dropping out after being randomized. Of the 32 patients randomized to the mini-cholecystectomy arm of the study, only 25 (78%) remained in the trial after randomization, albeit three of the patients that dropped out are known to still have undergone open cholecystectomies

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[648] Sigman, interview.
[649] For surgery, see for example, Schlich, "Degrees."
[650] Jeffrey S. Barkun et al., "Randomised controlled trial of laparoscopic versus mini cholecystectomy," *The Lancet* 340 (1992): 1116-9, 1116; Barkun, "A Randomised Controlled Trial," 23.

by surgeons who were not participating in the trial. In comparison, only one patient withdrew from the laparoscopic group after randomization.[651] This, as the authors noted, reflected "the poor acceptance of surgical randomization by patients."[652] The challenges with patient recruitment and retention led the McGill group to terminate the study before it reached the sample size that had been calculated as being statistically significant at the start of the trial. As Jeffrey Barkun recalled, "We stopped not because we did an interim analysis but because we couldn't go on more. And then we did our analysis and we saw, 'You know what: we already have differences.'"[653] Additionally, according to Meakins, both the patients and surgeons had lost equipoise.[654] Similarly, a later RCT also published in *The Lancet* by a group at the Prince of Wales Hospital in Hong Kong was likewise terminated due to loss of equipoise.[655]

Despite the early termination of the trial and the small sample size, the study – published in *The Lancet* in November 1992 – showed a statistically significant difference in the duration of convalescence between the mini-cholecystectomy and laparoscopic cholecystectomy groups. It reported that patients recovered from laparoscopic surgery 1.77 times faster than patients who had received the open surgery.[656] The McGill Gallstone Group concluded that laparoscopic cholecystectomy produced superior results in terms of post-operative quality of life, as measured by duration of convalescence and time taken to return to a full diet when compared to the mini-cholecystectomy.[657]

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[651] Barkun et al., "Laparoscopic versus mini," 1117.
[652] Barkun et al., "Laparoscopic versus mini," 1119.
[653] Jeffrey Barkun, interview.
[654] Meakins, interview.
[655] J. J. T. Tate et al., "Laparoscopic versus mini-incision cholecystectomy," *Lancet* 341 (1993): 1214.
[656] Barkun et al., "Laparoscopic versus mini," 1118.
[657] Barkun et al., "Laparoscopic versus mini," 1118.

However, there were also limitations.[658] Among other things, the authors could not draw conclusions about comparative mortality and morbidity rates because of the small sample size.[659] In general, however, RCTs are often not large enough for measuring low rates of complications. As Fried explained, registries are better suited for the detection of infrequent but catastrophic complications such as bile duct injuries.[660] Bile duct injuries occur at a rate of about 0.3% in open cholecystectomy. During the early days of laparoscopic cholecystectomy, the rate of bile duct injuries was estimated to be as high as 1%. A trial with 30 patients per treatment group would not be able to detect such a low frequency complication, whereas a registry, such as the one published by the Southern Surgeons Club could measure the risk of such relatively infrequent occurrences.[661] Thus in Fried's opinion, the laparoscopic versus mini-cholecystectomy RCT did not contribute as much to the understanding of laparoscopic cholecystectomy as the larger registries.[662]

Further, letters to the editor following the publication of the study in *The Lancet* show that there were surgeons who judged the statistical significance of the trial to be insufficient. In particular, a group of surgeons based at the University of Glasgow and the University of Aberdeen commented, "Dr Barkun and colleagues' data hardly justify their conclusion that laparoscopic cholecystectomy is more effective than minicholecystectomy. The small sample size and difficulties with randomization limit the value of this trial."[663] In his author's reply, Jeffrey Barkun defended the RCT. He ascribed the limited size of the study to the loss of equipoise, since the "power of the study allowed us to detect statistically and clinically

[658] Barkun et al., "Laparoscopic versus mini," 1118.
[659] Barkun et al., "Laparoscopic versus mini," 1118.
[660] Fried, interview.
[661] Fried, interview; The Southern Surgeons Club, "1518 Laparoscopic," 1073-8.
[662] Fried, interview; The Southern Surgeons Club, "1518 Laparoscopic," 1073-8.
[663] Andrew J. McMahon et al., "Laparoscopic Cholecystectomy," *Lancet* 341 (1993), 249.

significant differences. To have recruited more would not have altered the study conclusions and would have been ethically difficult to justify in the eyes of patients and surgeons."[664]

Earlier that year, the British group had conducted a survey that randomly sampled 200 British general surgeons to determine whether the surgical community felt that an RCT comparing laparoscopic to open cholecystectomy was ethical.[665] With an assertion that RCTs are "the best method for assessing innovations in health care,"[666] they argued that the higher incidence of bile duct injuries associated with the laparoscopic method meant that "it is all the more urgent that the postulated benefits of laparoscopic cholecystectomy are put to the test of a randomized trial."[667] The group later published their own RCT comparing laparoscopic cholecystectomy to mini-cholecystectomy in *The Lancet* in January 1994.[668] Here they commented, "Although laparoscopic cholecystectomy has rapidly become routine practice in the UK, there has been no rigorous comparison of it with open cholecystectomy," and reported the results from their sample of 302 randomized patients (recruited between August 1991 and March 1993).[669] Even with the larger sample size, however, the study was still unable to detect the difference in complication rate picked up by the registries.

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[664] Jeffrey Barkun, "Laparoscopic Cholecystectomy - Author's reply," *Lancet* 341 (1993), 249.
[665] Andrew J. McMahon et al., "Laparoscopic versus Open Cholecystectomy and the Need for a Randomized Trial: A Survey of Surgeons and Ethical Committees in the British Isles," *Journal of Laparoendoscopic Surgery* 2 (1992): 277-280. The survey found that 58% of surgeons surveyed believed that it was necessary to perform a trial randomizing patients to laparoscopic cholecystectomy against either mini-cholecystectomy or open cholecystectomy, while 31% responded that such a trial would be unethical. It also found that 62% of respondents judged the safety of laparoscopic cholecystectomy to be satisfactory, leaving 38% unsure or concerned.
[666] McMahon, "Survey," 277.
[667] McMahon, "Survey," 280.
[668] Andrew J. McMahon et al., "Laparoscopic versus minilaparotomy cholecystectomy: a randomised trial," *The Lancet* 343 (1994): 135-8.
[669] McMahon, "Laparoscopic versus minilaparotomy," 135.

The Multiple Facets of RCTs

The initial impetus that drove the calls for a randomized controlled trial evaluating laparoscopic cholecystectomy was in part an appeal to bring the procedure under the control of academic surgical centers: "Prospective randomized control trials are needed to define the indications for the laparoscopic approach and to confirm the benefits of this procedure against the standard open cholecystectomy…For these reasons laparoscopic cholecystectomy should be confined to a few specialized centers in the short term."[670] As we have seen, however, the execution of a randomized controlled trial required investigators to have a pre-existing level of control over its availability. The McGill Gallstone Group's local control of laparoscopic cholecystectomy, turned out to be a decisive factor in enabling their RCT. The necessity of control over treatment access has been shown for other historical cases as well, for example, the first RCT conducted by Austin Bradford Hill to evaluate the use of streptomycin in tuberculosis treatment,[671] or the use of the AO system of operative fracture care in communist East Germany in the 1970-80s.[672] In the case of the McGill RCT, this type of control created conditions in which most of the practitioners who offered laparoscopic cholecystectomy in Montreal, as well as a substantial number of the patients who would undergo it, were involved in the study.

We have seen how, by comparison, other research groups were not able to complete their RCTs because they could not retain patients after randomization. This finding points to the importance of patient agency and choice for the history of RCTs more generally, a factor that should be investigated more systematically in accounts of both the history of clinical trials as

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[670] Cuschieri, "The laparoscopic revolution," 295.
[671] Marks, *The Progress*, 136-263, Peter Keating and Alberto Cambrosio, "Before There Were Trials," *Cancer on Trial: Oncology as a New Style of Practice* (Chicago: University of Chicago Press, 2012), 33-52, 52; Marcia L. Meldrum, "Brief History of the Randomized Controlled Trial: From Oranges and Lemons to the Gold Standard," *Hematology/Oncology Clinics of North America* 14 (2000): 745-760, 752.
[672] Schlich, "Degrees."

well as the history of innovation in surgery. By more closely examining the details of patient recruitment, any challenges that are faced, and how they are resolved, it becomes apparent that the RCT as a method of evaluation is not a static procedure but often requires flexibility.[673]

The McGill case also points to the importance of what one could call local cultures of evidence, in which RCTs could be initiated, conducted and appreciated as valuable. Such cultures of evidence have local as well as more dispersed elements. At McGill, this culture was in part institutionalized with the Department of Epidemiology and Biostatistics. In part, it was also a personal network that included clinicians such as Mulder, Fried, and the two Barkuns, with an international reach to Troidl and the Cologne group. Within this network, the RCT as the required standard of evidence was not controversial and thus could be applied to the testing of laparoscopic cholecystectomy. As Jeffrey Barkun explained, "it was a question of doing the right thing because there is a question here, [we've] got to answer it, and it's our job; it's not going to be answered elsewhere."[674] This mentality of needing to answer the unanswered questions was echoed by Fried: "[A]s an academic institution we felt that it was a piece of the puzzle that we should contribute…We felt it was needed because there hadn't been a randomized trial that was done."[675] There was also an acknowledgement that if an RCT evaluating laparoscopic cholecystectomy was to be done, it had to be done then. According to Fried, there "was a window of opportunity – if we didn't do it *then*, we wouldn't be able to do it once [laparoscopic cholecystectomy] was more widely available. And we felt…that we may find information that wouldn't be available without doing a randomized trial."[676]

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[673] For a more extensive discussion of RCTs as a social exercise, see Marcia Meldrum, "'Departures from the Design': The Randomized Clinical Trial in Historical Context, 1946-1970," (PhD diss., State University of New York at Stony Brook, 1994).
[674] Jeffrey Barkun, interview.
[675] Fried, interview.
[676] Fried, interview.

We can also see the importance of motivated researchers for this kind of project. For Fried as a young surgeon, for example, the new technology was an opportunity to build a profile around a particular set of expertise. Similarly, for the Barkun brothers, the testing of treatment methods by RCTs was a plausible and attractive field to apply their research ambition and skill, as well as their personal connections. The study was relevant and timely enough to be financed by a prestigious funding agency and subsequently published in a high impact journal such as *The Lancet*. Marcia Meldrum has similarly argued that RCTs are used as a way to legitimize scientific authority, for example by the National Foundation for Infant Paralysis in its organization of the Salk polio vaccine field trials.[677]

What was the ultimate function and effect of the McGill RCT in the acceptance of laparoscopic cholecystectomy? Since there were reports of a higher incidence of common bile duct injury as a result of the laparoscopic method, the authors of both the McGill study and the British study believed that the advantages of laparoscopic surgery over open surgery needed to be proven. and clearly defined in order to have an accurate risk-versus-benefit analysis.[678] Both trials concluded that laparoscopic cholecystectomy provided superior outcomes compared to mini-cholecystectomy, with the British group predicting that "…as surgeons become more experienced, the relative benefit to patients will increase…"[679] Though neither trial was able to – or even designed to – detect the risk of bile duct injury, their results suggested that the advantages of laparoscopic cholecystectomy outweighed the risks.

The general consensus of the authors that were interviewed was that although an RCT evaluating laparoscopic cholecystectomy was highly anticipated and the McGill study was

[677] Meldrum, "Departures from the Design."
[678] Barkun, "A Randomised Controlled Trial," 17.
[679] McMahon, "Laparoscopic versus minilaparotomy," 138.

published in *The Lancet*, its impact on the technique's general acceptance for the treatment of cholelithiasis was insignificant.[680] By the time the study was published, Alan Barkun, pointed out, "people said, 'Oh, that's nice.' But everybody was already convinced that laparoscopic was the way to go."[681] The high evidence level of the study was appreciated, but the change in practice had already taken place. As Fried explained, "I'm proud we did it…In retrospect, if you ask me whether that trial was of great value, I don't think so. But you don't know what you're going to find in advance. And I think it *was* worth doing."[682]

Even surgeons who had ethical issues about convincing patients to be part of the trial defended the trial because of the method's capacity to detect and objectify shortcomings that had not been noticed before, as it had with "procedures that have been around for a long time and all of a sudden they become discredited because one realizes there are things that are happening that you didn't know about or think about at the time."[683] Examples of this include gastric freezing for ulcers, mentioned by Barkun,[684] and internal mammary artery ligation for the treatment of angina by two independent randomized trials, investigated by historians.[685] Typically, surgeons were sure of the benefits of these treatments, and thus had no clinical equipoise on their part. Similarly, in the debate over clinical trials to evaluate radical versus simple mastectomy, surgeons found it unethical to randomize patients to what they believed would be an inferior treatment.[686]

The history of this RCT is a good example of the importance of the local dimensions of RCTs more generally. The RCT as a method comes with a strong claim of universality and

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[680] Fried, interview; Meakins, interview; Jeffrey Barkun, interview; Alan Barkun, interview.
[681] Alan Barkun, interview.
[682] Fried, interview.
[683] Sigman, interview.
[684] Jeffrey Barkun, interview.
[685] Jones, "Visions."
[686] Lerner, "Reality," 124.

context-independence. Data originating from RCTs is ranked as the most objective and valid form of evidence in Evidence-Based Medicine. However, the historical examination of clinical trials requires the opposite movement: historians need to focus on the local context of an individual RCT's design, use, and effect, and take this local dimension into account.[687]

We have also seen that, apart from determining the benefits and risks of laparoscopic cholecystectomy, the idea of controlling a movement that had gotten out of hands was another important aspect of the RCT. Thus, RCTs are not only about objectively evaluating and determining the use of new therapies. They also represent attempts at managing and controlling the spread of new treatments, keeping them, or drawing them back into the hands of the medical centers that are seen as acting responsibly and in a disciplined way. In the end, the calls for prospective clinical trials to evaluate laparoscopic cholecystectomy failed to restrict its use to specialized surgical centers and bring the "laparoscopic revolution" under control. Still, the efforts to complete such evaluations can be seen as a symbolic demonstration of discipline and in contrast to the surgical "wild west."

[687] This is in line with other historical studies of clinical trials, e.g. Marks, *The Progress*; Jones, "Visions,"; Meldrum, "Departures from the Design."

Conclusion

Surgical accounts contend that the emergence of laparoscopic cholecystectomy in 1989 triggered the "laparoscopic revolution" in general surgery and credit patient demand with its adoption into routine practice in less than four years. The aim of this research was to explain the therapeutic, professional, and social contexts of this rapid uptake as well as the logistics of how it took place. One question that I have yet to address – and will attempt here – asks why gallbladder removal was the procedure that galvanized general surgeons' interest in laparoscopy. As it was briefly mentioned in Chapter 2, Mouret successfully performed an appendectomy via a laparoscopic approach in 1983, four years before his famous cholecystectomy in March 1987.[688] Similarly, the German gynecologist Kurt Semm performed a laparoscopic appendectomy as early as September 1980.[689] Laparoscopic appendectomy, however, did not generate the same enthusiasm that laparoscopic cholecystectomy inspired in 1989. Why was it that general surgeons only became interested in laparoscopy after seeing videos of its successful deployment in gallbladder surgery?

As discussed in Chapters 1 and 2, most general surgeons were not interested in procedures through any type of endoscope until they encountered laparoscopic cholecystectomy. The somewhat supercilious reasons that early adopters of the procedure have given for this include that surgeons were unwilling to learn a technique from gynecologists and that surgical mentality in the 1980s held that "great surgeons [make] great incisions."[690] This explanation,

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[688] Philippe Mouret, "Special Lecture: How I Developed Laparoscopic Cholecystectomy," *Annals of the Academy of Medicine* 25 (1996): 744-7, 745.
[689] Grzegorz S. Litynski, "Kurt Semm – the Magician from Kiel," Highlights in the History of Laparoscopy: The Development of Laparoscopic Techniques – A Cumulative Effort of Internists, Gynecologists, and Surgeons (Frankfurt/Main: Barbara BERNET VERLAG, 1996), 131-44, 136.
[690] See, for example, Philippe Mouret, "Philippe Mouret, l'inventeur lyonnais de la coelioscopie, est mort," *LyonMag*, June 24, 2008, accessed July 2, 2017, https://www.lyonmag.com/article/8141/philippe-mouret-l-8217-inventeur-lyonnais-de-la-coelioscopie-est-mort; Philippe Mouret, "Laparoscopy: Another means to see in surgery,

however, does not satisfyingly address why so many surgeons rushed to learn laparoscopic cholecystectomy after hearing about it in 1989 and 1990. James Zetka argues that surgeons were not interested in diagnostic endoscopy and only became interested once therapeutic applications were developed.[691] But this does not explain why surgeons were not nearly as eager to take on endoscopic interventions such as endoscopic sphincterotomy (gallstone removal via oral access) as they were to learn laparoscopic gallbladder removal. Technological explanations claim that before laparoscopy could be used for procedures in general surgery, more advanced laparoscopic equipment needed to be developed that provided better lighting, visual access for the entire surgical team, and that allowed the operating surgeon the use of both hands.[692] According to some surgeons, the viability and widespread dissemination of laparoscopic cholecystectomy relied on the development of live video laparoscopy, which only became available in 1989.[693] Gynecologists, however, might dispute this explanation as they had been performing interventional laparoscopy for decades before its adoption in general surgery.[694]

While each of these explanations might have played some contributing role, this research shows that it was the basic, ordinary characteristics of gallstones and gallbladder surgery that allowed laparoscopic cholecystectomy to be adopted in the "wildfire-like" manner that surgeons

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Another means to appraise surgery," Commemorative Lecture at the Twenty eighth Honda Prize Awarding Ceremony, Tokyo, Japan, November 19, 2007; Grzegorz S. Litynski, "Erich Mühe – A Surgeon ahead of his Time. The First Laparoscopic Cholecystectomy," *Highlights in the History of Laparoscopy: The Development of Laparoscopic Techniques – A Cumulative Effort of Internists, Gynecologists, and Surgeons* (Frankfurt/Main: Barbara BERNET VERLAG, 1996), 157-92.

[691] James Zetka, "Turf Wars Over the Gastrointestinal Tract," *Surgeons and the Scope* (Ithaca: Cornell University Press, 2003), 120-35.

[692] Jacques Périssat, interview by Cynthia L. Tang, Bordeaux, France, November 13, 2017; See also, Philippe Mouret, "Special Lecture: How I Developed Laparoscopic Cholecystectomy," *Annals of the Academy of Medicine* 25 (1996): 744-7, 746. The original lecture delivered at the ELSA Congress in Singapore on August 8, 1993.

[693] See, for example, Mouret, "How I Developed," 745.

[694] For more on gynecological laparoscopy, see Jesse Olszynko-Gryn, "Laparoscopy as a technology of population control: A use-centered history of surgical sterilization," in H. Hartmann and C. R. Unger eds., *A World of Populations: The Production, Transfer and Application of Demographic Knowledge in the Twentieth Century in Transnational Perspective* (New York: Berghahn, 2014), 147-77; Ramona Braun, "Laparoscopy as a neo-eugenic practice, 1940s-60s," PhD diss., University of Cambridge, 2015, ProQuest (AAI10657843).

describe. Unlike appendectomy, which is more often performed under emergency circumstances, cholecystectomy is usually an elective procedure, allowing surgeons time to prepare and plan their approach. This was especially beneficial since it was important for surgeons who were either developing or learning the new technique to carefully select as their first cases, patients who were likely to have straightforward gallbladder removals with minimal risk of complications.[695]

Additionally, the elective nature of cholecystectomy gives patients time to consider their options.[696] Since gallstones are usually not fatal, patients also have more latitude to weigh any personal costs or benefits to having abdominal surgery. As we saw throughout this dissertation, many patients delayed having their gallbladder removed when first diagnosed with gallstones. Their reasons for refusing surgery ranged from being unable to afford taking the necessary 4-6 weeks off work, to having inflexible familial responsibilities, to simply being unwilling to undergo major surgery for a condition that was asymptomatic. With the emergence of laparoscopic cholecystectomy, however, this cost/benefit analysis was reconfigured.

In addition to allowing patients to decide how and when to undergo treatment, gallstones are common enough that cholecystectomy is described as one of general surgeons' "bread-and-butter" procedures. Because of this, surgeons considered cholecystectomy patients to be such a formidable consumer group that they felt forced to adopt the laparoscopic technique.[697] A commonly-told cautionary tale of the period, for example, describes the surgeon who refused to learn how to perform a laparoscopic cholecystectomy and lost his practice because patients

[695] For example, Douglas Olsen, interview with Cynthia L. Tang, Nashville, Tennessee, May 29, 2018; Périssat, interview, November 13.
[696] Gerald Fried, interview with Thomas Schlich and Cynthia L. Tang, Montréal, Canada, June 13, 2014.
[697] Fried, interview; Olsen, interview, May 29.

refused to undergo the open procedure.[698] And as we saw in Chapter 4, once the procedure became available in an area, surgeons throughout the region felt pressured to offer it as well. In this way, the common, non-urgent, and elective characteristics of cholecystectomy cultivated a situation where patient demand was seen as driving surgeons to adopt the laparoscopic procedure in less than two years. By studying laparoscopic cholecystectomy we see just how powerful patient demand can be for driving technological change in medicine.

Still, this patient demand was not an inevitable consequence of a superior technique. As Chapter 3 demonstrated, the demand for laparoscopic cholecystectomy was generated through widespread promotion in newspapers, as well as other media (i.e. television, radio, and magazines). In the United States, hospitals, independent surgical clinics, and individual surgeons commonly publicised the availability of the cutting-edge procedure in both newspaper reports and advertisements. The extent to which the procedure was promoted in the early 1990s was possible due to changing judicial attitudes towards anti-trust law and the learned professions exemption in the late 1970s. The Federal Trade Commission's 1975 complaint against the American Medical Association ultimately resulted in a Supreme Court order that the Association remove any restrictions on physician advertising from their *Principles of Medical Ethics*. Although the extent to which laparoscopic cholecystectomy was promoted would have been considered both unethical and uncouth just fifteen years earlier, such physician advertising became normalized over the course of the 1980s. This shift in the culture of American medical practice took place in a much larger context in which legal action was sought against multiple professional groups. In addition to the American Medical Association, the American Bar Association, the Virginia State Board of Pharmacy, the National Society of Professional

[698] Jacques Vignal, interview with Cynthia L. Tang, Lyons, France, July 2, 2018.

Engineers, and others, were compelled to remove restraints on competition from their codes of ethics.[699] By the time laparoscopic gallbladder removal emerged in 1989, the stage was set for the procedure to be brazenly advertised to the public.

Again, the patient demand that this publicity generated placed pressure on surgeons to seek training in laparoscopic cholecystectomy and to quickly begin offering it. Since surgical innovations rarely required substantial re-training, some surgeons believed that they could immediately begin offering the procedure after attending a weekend course. The lack of official regulations that specifically outlined how much training was necessary led to higher complication rates in the first few years after laparoscopic cholecystectomy's emergence when compared to the open procedure. The frequency with which gallbladder removal is performed made the failures of the hospital credentialing systems more apparent than they would be with the introduction of a less commonly performed procedure. As discussed in the introduction, rates of bile duct injuries could be up to 1 in 200 patients who underwent the laparoscopic procedure compared to 1 in 500 patients who underwent open cholecystectomy.[700] And according to the Physician Insurers Association of America, this was accompanied by a significant increase in malpractice lawsuits involving gallbladder surgery: 189 claims for bile duct injury during laparoscopic cholecystectomy between 1990 and 1993, up from 35 in open procedures between 1985 and 1990.[701] The case of laparoscopic cholecystectomy illustrates the real-world

[699] For more on these cases, see Richard Thomas McCoy, "The Antitrust Liability of Professional Associations After *Goldfarb*: Reformulating the Learned Professions Exemption in the Lower Courts," *Duke Law Journal* 26 (1977): 1047-1068; William C. Canby, Jr. and Ernest Gellhorn, "Physician Advertising: The First Amendment and the Sherman Act," *Duke Law Journal* 1978 (1978): 543-585.
[700] "National Institutes of Health Consensus Development Conference Statement on Gallstones and Laparoscopic Cholecystectomy," *American Journal of Surgery* 165 (1993): 390-8.
[701] Kenneth A. Kern, "Medicolegal Analysis of Bile Duct Injury During Open Cholecystectomy and Abdominal Surgery," *American Journal of Surgery* 168 (1994): 217-22, 217.

repercussions that the shift towards enforcing anti-trust law on professional groups had on American medical practice.

Even today, many law firms continue to promote themselves as specializing in laparoscopic cholecystectomy malpractice suits. Future historical research on laparoscopic cholecystectomy should explore the interactions of its adoption with medico-legal practice. An examination of laparoscopic cholecystectomy malpractice suits will provide important insights into the types of direct or indirect legal powers that patients have in the regulation of new medical treatments and technology.

Another avenue to investigate the indirect regulation of medical innovation is to look at the role played by insurance providers for both patients and medical practitioners. For instance, did insurance companies mandate specific laparoscopic cholecystectomy training requirements for surgeons to be eligible for malpractice coverage or, by extension, medical liability coverage for hospitals or clinics? Alternatively, what types of conditions did health insurance providers set before agreeing to cover the new procedure? According to Douglas Olsen, "One of the things we had to struggle with in the early days was getting reimbursed because a lot of the insurance companies would take the posture that this is an experimental [procedure]."[702] He was able to convince one insurance executive to cover laparoscopic cholecystectomy by agreeing to keep patients overnight instead of providing it as an outpatient surgery. As discussed in Chapter 3, insurance companies encouraged the growth of outpatient surgery in the early 1980s[703] by covering more of the patient's bill than would be covered if they were admitted as an inpatient – for example, 100% versus 80%.[704] But, as Olsen explained, inpatient surgery was billed on a per

[702] Douglas Olsen, interview with Cynthia L. Tang, Nashville, Tennessee, May 31, 2018.
[703] Chapter 3 also draws attention to the current lack of knowledge about the history of outpatient surgery and independent surgical clinics.
[704] "One-Day Surgery Offers Health Care Savings," *Montgomery Advertiser* (Montgomery, AL), May 8, 1983.

diem basis, and laparoscopic cholecystectomy patients could usually be discharged after one night rather than the average 3-5 nights after open cholecystectomy. Insurance companies therefore saved much more by insisting that laparoscopic cholecystectomy patients were admitted as inpatients.

Though Chapter 4 explains the role that patients played in driving the adoption of laparoscopic cholecystectomy, much additional work is needed to understand how patients experienced general surgery's transition to laparoscopic techniques. Such an approach would have the potential to bring a more patient-centered focus to the literature on medical consumerism by considering the experiences that patients had as individual consumers of a surgical innovation rather than their role in changing surgical practice as a consumer group. With the increasingly rapid pace of technological innovation practitioners and healthcare institutions face the challenges of determining how a) to balance the costs of adopting new medical technologies with the provision of better patient outcomes; and b) to prevent the uptake of ineffective or inefficient technologies without delaying the introduction of beneficial ones. A 2017 commentary on health policy in Canada argues that one way to achieve this balance and to encourage productivity and efficiency in the healthcare system is to empower patients as consumers and end-users of health services, and to include patient preferences in the evaluation of healthcare innovations.[705] Healthcare systems would thus greatly benefit from a better understanding of how patients experience technological change in medicine including, for example, how patients make sense of information about new treatment options that is communicated in the media and how patients make decisions based on their interpretations of the information.

[705] A. Blomqvist and C. Busby, "The Paradox of Productivity, Technology, and Innovation in Canadian Healthcare," *C.D. Howe Institute Commentary* 480 (2017).

Chapter 4 also reveals that more work is necessary to understand the part that instrument manufacturers played in propelling the rapid adoption of laparoscopic surgery. Many of the developers and early adopters of laparoscopic cholecystectomy were heavily involved in designing and testing new laparoscopic instruments. As Jacques Périssat recalled, for example, "It [was] like Santa Claus, every six months you have plenty of fantastic, modern [new instruments.]"[706] But as we saw, instrument manufacturers had a much greater role in the laparoscopic cholecystectomy story than as simply the provisioner of cutting-edge equipment. Their participation in organizing training courses and in recruiting surgeons to those courses merits more consideration. And in addition to demonstrating the extent to which commercial forces took effect in medical care after the AMA was forced to lift its physician advertising ban, the adoption of laparoscopic cholecystectomy accentuates the consumerism that exists in medical practice itself. Both laser and laparoscopic instruments very quickly became heavily and aggressively marketed to general surgeons. For laser instrument manufacturers especially, there were considerable incentives to promote "laser laparoscopic cholecystectomy."[707] Already in the first quarter of 1990, the surgical laser manufacturer, Laserscope, reported earnings that were more than double that of the same quarter in 1989.[708]

The emergence of laparoscopic cholecystectomy represents a pivotal moment in the history of modern surgery which practitioners have described as being akin to the introduction of anaesthesia in the 1840s and antisepsis/asepsis in the 1860s and 70s.[709] Its development was a successful proof of concept that laparoscopic techniques had a place in general surgery and led to

[706] Périssat, interview, November 9.
[707] Ultimately, however, surgeons determined that electrocautery was still the best tool for the job.
[708] Mary Hayes, "New Uses of Lasers Boosts Sales of 2 Surgical Laser Firms," *The Business Journal* 8 (1990): 31.
[709] See, for example, Alexandros Polychronidis et al., "Twenty Years of Laparoscopic Cholecystectomy: Philippe Mouret – March 17, 1987," *Journal of the Society of Laparoendoscopic Surgeons* 12 (2008): 109-11, 111.

the expansion of its use for hernia repair, bowel resections, and bariatric surgery, to name just a few of the procedures that are now routinely performed via laparoscopy. In addition to providing a historical analysis of this moment, I hope that this dissertation inspires researchers to pay more attention to the humble gallbladder – especially as surgeons continue to expand the ways in which they can perform its removal, whether experimenting with transatlantic robot-assisted telesurgery or attempting to make the procedure "scarless" by accessing the abdominal cavity through natural orifices.[710]

[710] See, for example, Jacques Marescaux et al., "Transatlantic robot-assisted telesurgery: ATM technology now enables operations to be performed over huge distances," *Nature* 413 (2001): 379-80; Jacques Marescaux et al., "Surgery Without Scars: Report of Transluminal Cholecystectomy in a Human Being," *Archives of Surgery* 142 (2007): 823-6; Pascal Alain Robert Bucher et al., "Female population perception of conventional laparoscopy, transumbilical LESS, and transvaginal NOTES for cholecystectomy," *Surgical Endoscopy* 25 (2011): 2308-15.

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