EVALUATION OF A NOVEL SURGICAL PROCEDURE FOR REMOVAL OF THE NUCLEUS PULPOSUS IN LUMBAR INTERVERTEBRAL DISCS

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Dedication

To my brother Stefan

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Abstract

Chronic low back pain is one of the most common problems of all age groups worldwide. If conservative treatment fails, the following surgical options - depending on the underlying cause - currently apply: lumbar discectomy, disc arthroplasty or fusion surgery as the ultimate procedure. An emerging technique, nucleoplasty, aims at targeting early stages of disc degeneration. There are various mechanical, polymeric or tissue engineered devices for nucleus pulposus replacement, some of which have been subjects of studies and clinical trials. We are already looking back at a history of failed devices; as well, complications have been reported such as migration, extrusion and subsidence. On most devices, no long-term data are available yet. Our theory is that for any successful nucleus pulposus replacement in order to stabilize, delay or even improve lumbar disc degeneration, an appropriate cavity has to be created prior to injection or implantation of a new device. The current gold standard procedure to get nucleus pulposus material out of the intervertebral disc is the classic open microdiscectomy which is performed with pituitary rongeurs. Another surgical procedure of a percutaneous nuclectomy via arthroscopic shavers was investigated and the outcome - size and location of the created cavity - compared with the established rongeur-method, using three different approaches: anteriolateral, posteriolateral and posterior access to the intervertebral disc. The cavities were larger when created with the rongeurs, however, after some modification of instruments, for example curved shavers, nuclectomy via automated shavers might be a good and less invasive surgical alternative.

Résumé

Les lombalgies chroniques sont l'un des problèmes les plus communs de tous les groupes d'âges dans le monde entier. Dans le cas d'un échec du traitement conservateur, les options chirurgicales suivantes - dépendamment des causes sous-jacentes - s'appliquent couramment : une discectomie lombaire, une arthroplastie du disque ou une arthrodèse comme procédure ultime. Une technique émergeante, la nucléoplastie, vise à cibler les stades précoces de la dégénération des disques. Il existe plusieurs implants variés pour le remplacement du nucléus pulposus tels que mécaniques, polymériques ou la régénérescence tissulaire, dont certains ont été le sujet d'études et d'épreuves cliniques. L'histoire nous ramène à une série d'implants ayant échouées puisqu'en effet, plusieurs complications ont été rapportées telles que la migration, l'extrusion et la rémission de l'implant. Présentement, aucune donnée à long-terme n'est disponible sur la plupart des procédures. Notre théorie est qu'une cavité appropriée doit être créée afin d'injecter ou d'insérer de façon optimale un nouvel implant pour qu'ainsi les remplacements de nucléus pulposus puissent stabiliser, retarder ou même améliorer la dégénération des disques intervertébraux. La procédure courante préconisée pour extraire la matière du nucleus pulposus du disque intervertébral est la microdiscectomie classique performée avec des rongeurs pituitaires. En utilisant les trois approches suivantes; antérolatérale, posterolatérale et l'accès postérieure au disque intervertébral, une autre procédure chirurgicale; nucléectomie percutanée via lames d'arthroscopies a été étudiée. Ses résultats – la grandeur et la localisation de la cavité crééeont été comparé à la méthode-rongeur déjà établie. Les résultats démontrent que les cavités étaient plus larges lorsque créées avec les rongeurs. Toutefois, la modification de certains instruments, comme par exemple des lames plus incurvées, pourrait rendre la nuclectomie via lames automatisées une alternative chirurgicale meilleure et moins envahissante.

Chapter 1: Introduction

Degenerative disc disease is a fairly common problem that affects approximately 80 % of the adult population in their lifetime. It refers to a syndrome in which a compromised disc causes low back pain, and it is estimated that at least 30 % of people aged 30 – 50 years old will have some degree of disc space degeneration, which is not necessarily a disease but refers to normal physiologic changes in our spinal discs as we age. These age-related changes include the decrease of water content in our discs which reduces the ability of the discs to function as shock absorbers and decreases their flexibility. Loss of fluid also makes the disc thinner and thus narrows the distance between the vertebraes. Furthermore, tiny cracks in the outer layer, the annulus fibrosus of the disc, force the jellylike nucleus pulposus out, which causes the disc to bulge, rupture or even break into fragments. Not all people experience symptoms, however, in some patients the changes in the disc can result in the aforementioned disc herniation, osteoarthritis or spinal stenosis and thus require surgery.

Disabling low back pain costs the United States approximately 50 billion dollars [1] and the United Kingdom 12 billion pounds [2].

For patients who are not responding to conservative treatment, such as pain medication or physiotherapy, spinal fusion is the ultimate surgical option until date. However, there is no guarantee that spinal fusion will eliminate the pain. Unsuccessful fusion (pseudarthrosis) may occur, leaving the patient with the same problem after the operation. Spinal fusion as a surgical method also increases the risk of future collapse in local and adjacent intervertebral segments. These disadvantages led to the development of alternate surgical interventions, mainly total disc replacement (disc arthroplasty) and nucleus pulposus replacement (nucleoplasty).

Nucleus pulposus replacement aims on applying treatment in the early stages of disc degeneration in order to delay or even reverse / stop the process of lumbar disc degeneration [3]. It might lead to the establishment of a much less invasive, less risky and more cost effective surgical procedure compared to spinal fusion surgery. Numerous devices for nucleus pulposus replacement have been developed and tested over the past years [4], injectable hydrogels as well as prosthetic disc nucleus.

Poly(vinylalcohol), PVA, hydrogels are very biocompatible and capable of retaining considerable amounts of water. This action of water absorption and expulsion mimics closely the physiological function of a nucleus pulposus as a shock absorber. The current goal of the industry is to create injectable PVA hydrogel systems to replace the nucleus pulposus of the intervertebral disc.

Prosthetic disc nucleus, such as the PDN® device, showed promising results in clinical trials. However, there are still some problems to be solved, mainly avoiding migration of the implanted device.

For any device to stay in place and function as a physiological shock absorber, our theory is that an appropriate cavity has to be created in the intervertebral disc first before replacing the nucleus pulposus.

This thesis has attempted to compare two surgical methods to remove the nucleus pulposus of lumbar intervertebral discs: the standard microdiscectomy using pituitary rongeurs and a novel procedure by using arthroscopic shavers. Furthermore, by using either of these two surgical methods, three different accesses to the intervertebral disc were evaluated: the anterio-lateral, posterio-lateral and posterior access to the lumbar disc. Templates were designed to measure the important parameters: size and location of the created cavity as well as the pressure that the cavity was able to withstand.

Chapter 2: Literature Review

2.1 Anatomy of the Intervertebral Disc

The human spine, interconnected by a complex system of facet joints, ligaments and muscles, can be classified into three sections, starting from the top: the cervical (7 vertebral bodies), thoracic (12 vertebral bodies) and lumbar (5 vertebral bodies) spine. An intervertebral disc is sandwiching between two adjacent vertebral segments. Two parts define this intervertebral disc: the <u>annulus fibrosus</u> which is arranged in layers of parallel fibers that crisscross those of the next layer, and the center of the disc, the <u>nucleus pulposus</u> which is filled with fibrogelatinous pulp and acts as a shock absorber. As a result of aging, the nucleus pulposus becomes increasingly fibrocartilaginous and contains less water.

An intervertebral foramen, resulting from the apposition of a superior and inferior vertebral notch, is bounded superiorly and inferiorly by pedicles, anteriorly by the intervertebral disc and parts of the two bodies united by that disc, and posteriorly by a capsular ligament and parts of the two articular processes united by that capsular ligament. The anterior part of the capsule is strengthened by the lateral border of the ligamentum flavum.

Disc heights are approximately 3 - 5 mm at the cervical levels and 11 - 16 mm at the lumbar levels [5]. The lower lumbar levels have to carry the highest loads and are more susceptible to degeneration.

2.2 Function of the Intervertebral Disc

The intervertebral disc functions as a spacer, as a shock absorber and as a motion unit. 90% of the gelatinous central nucleus pulposus is water. The solid portion of the nucleus is type II collagen and non-aggregated proteoglycanes. The outer ligamentous ring around the nucleus is the annulus fibrosus which hydraulically seals the nucleus. The disc functions as a hydraulic cylinder. As the nucleus is pressurized, the annular fibers function as a containment to prevent the nucleus from bulging or herniating. The gelatinous nuclear material directs the forces of axial loading outward. The hoop stress carried by annular fibers help distribute that force atraumatically [6,7].

Intervertebral disc pressures significantly vary depending on the load and the posture of the subject. They can vary between 0.1 - 2.3 MPa [8,9]. The physiologic loads on the spine during daily activities result in diurnal fluctuations of about 25% of the disc's fluid, being expelled during daytime and imbibed overnight.

Biologically, the nucleus pulposus functions as a fluid pump, facilitating body fluid diffusion, which carries the nutrients and removes the metabolites for the avascular disc. Biomechanically, the nucleus inflates the annulus and shares a significant portion of compressive load with the annulus. The annulus fibrosus dictates the elastic and tension-resisting properties on the intervertebral disc, allowing a degree of flexion, extension, lateral bending and axial rotation movements [10,11]. The fibrous tissue limits the segmental deformation that occurs during spinal movements. It does, however, not bear axial loads as well as the nucleus pulposus does.

2.3 Degenerative Disc Disease

Low back pain in the general population is an ubiquitous malady. Up to 80 % of the population of industrialized nations experience some form of low back pain at some point [12, 13]. In the general population, evaluation and treatment of low back pain is centered around determination of the cause of the symptoms. Low back pain has been associated with characteristic behaviour patterns that include decreased physical conditioning, tobacco use, a sedentary lifestyle, obesity and diabetes. However, symptoms also occur in otherwise perfectly healthy individuals and even athletes without the relation to an injury or a specific inciting event. And the profile of the athlete with complaints of low back pain usually include a physically fit, highly motivated individual. Often in not acutely injured athletes an origin of low back pain like facet joint degeneration, spondylolisthesis, nerve compression or musculoligamentous strain cannot be diagnosed.

Persistent back pain is almost always a clinical manifestation of disc degeneration. This refers especially to the lower lumbar discs, as they carry the highest loads [14].

Until today, the initiators of disc degeneration are still a subject of heavy debates. Despite its prevalence, there is no clear distinction between disc degeneration and normal maturation, nor is it clear why disc degeneration progresses slowly in some patients, whereas in others more rapid destruction of the intervertebral discs occurs [15]. However, one of the most cited mechanisms is the compromised nutrient supply to the intervertebral disc [16 - 18].

Degenerative disc disease is believed to begin as early as the second decade of life [19]. Mechanical overloading from hyperflexion, torsion and fatigue loading is considered a potential cause of disc failure [20 - 23]. The concentration of proteoglycans within the nucleus pulposus drops from an average of 65 % to about 30 % dry weight of nucleus. This decline of proteoglycans directly leads to a loss of other matrix proteins. In consequence, the nucleus pulposus starts to lose its ability to re-take in water and to exert osmotic pressure. When this point is reached, loads cannot be absorbed and distributed efficiently enough anymore [24 - 26].

As the nucleus pulposus degenerates, the disc space narrows, and redundant annular fibers bulge. With progressive nuclear disintegration, the annular fibers can crack and tear. Annulus fibrosus tears include radial tears (perpendicular to the endplates and cut through the annulus layers), circumferential tears (ruptures between annulus layers along the circumference of the disc), and rim lesions (radial tears at the periphery of the annulus adjacent to endplates [27, 28].



Figure 1: Disc rupture and nuclear herniation [Frank H. Netter, "Atlas of Human Anatomy", 4th edition, Saunders WB Company]

2.4 Grading of Degenerated Lumbar Discs

A five-category grading scheme for assessing the gross morphology of midsagittal sections of the human lumbar intervertebral disc was developed by Thompson et al [28]. The grading scheme involves the nucleus pulposus, annulus fibrosus, the cartilaginous and bony endplates and the periphery of the vertebral body in the processes of aging and degeneration, as shown in Figure 2.



Figure 2: Grading scheme of age-related disc morphology by Thompson et al [29]

2.5 Current Treatment Options

Low back pain can have a variety of origins and reasons. Before undergoing any surgical intervention, the patient and indications for surgical management have to be examined very carefully. Patients who have had no pain-free intervals after spinal surgery may have had the wrong procedure.

Ideally, the patient is selected who has a specific anatomic abnormality that can be effectively corrected or improved with a high degree of likelihood. There is no perfect classification scheme for degenerative disorders; however, pathologic disc disorders usually can be classified within the categories herniation, stenosis or segmental hypermobility (instability).

Patients with lumbar disc herniation often respond well to nonoperative management strategies that include analgesics, antiinflammatories, muscle relaxants and various exercise programs [29, 30]. Patients who do not respond to conservative treatment or who have frequent recurrences that severely affect their quality of life are considered for surgical intervention, in

most cases elective lumbar discectomy. More than 300.000 lumbar discectomy procedures and 70.000 spinal fusion procedures are performed in the United States annually. The costs associated with the management of patients with various lumbar disorders have been estimated to exceed \$ 16 billion per year [31]. Such large capital outlays have attracted wide-ranging analysis by a variety of interest groups. A widely accepted hypothesis for the variability in the rates of surgical intervention centers around the fact that there is no definite strategy or algorithm that is accepted by all surgeons [29, 32].

Current treatment options are considered to be sub-optimal at combating degenerative disc disease. Researchers all over the world are investigating and developing alternate solutions: disc arthroplasty, nucleus pulposus replacement and biological therapies might hopefully be successful surgical interventions.

2.5.1 Spinal Fusion

Spinal fusion is quite an expensive and aggressive intervention that involves permanently connecting two or more adjacent vertebrae together. First, a discectomy is performed. The respective intervertebral disc has to be removed completely. Then a metal or polymer cage is placed between the vertebrae and filled with bone graft material. The bone fusion process across the intervertebral space usually takes 6 to 12 months. The vertebrae are also often fixed together with screws or plates.

Spinal fusion may be recommended for spinal stenosis, abnormal curvatures of the spine such as kyphosis or scoliosis, spondylolisthesis, in case of fractures or a weak or unstable spine caused by infections or tumors. However, as stated before, it has become increasingly popular for treating low back – discogenic - pain. The long-term efficacy of spinal fusion to treat discogenic pain is highly questionable. A study published in the May 2005 issue of the British Medical Journal concluded that people who are candidates for spinal fusion may obtain benefits similar to those of surgery from an intensive rehabilitation program. A 2007 systematic review of several studies stated it wasn't possible to reach a definitive conclusion about whether fusion surgery might be effective in treating discogenic pain.

Furthermore, spinal fusion has a 7 % rate of instrumentation failure; 15 % of the surgeries fail to achieve a solid fusion mass [33]. It does not restore normal disc function. The areas adjacent to the fusion have to bear more stress and may be mechanically overloaded. This makes those areas more likely to experience future wear and tear. About 20 percent of people who have spinal fusion surgery need another operation within 11 years. A randomized study over 2 years of follow up after spinal fusion surgery showed that 70 % of the patients who underwent spinal fusion still suffered from pain that affected their quality of life [34].

Despite the fact that several studies have shown that the indication for this invasive and expensive procedure remain unclear, spinal fusion continues to be the gold standard and most common surgical treatment of degenerated discs to date.

2.5.2 Disc Arthroplasty

According to two FDA (US Food and Drug Administration) investigational device exemption prospective randomized multicenter studies that were presented at the American Academy of Orthopedic Surgeons 2009 Annual Meeting, a lumbar total disc replacement system is superior to spinal fusion surgery in relieving disability and improving patient quality of life, and it resulted in fewer reoperations. Both studies also showed that patients experienced greater satisfaction with surgery results with the artificial disc than with spinal fusion [35].

Presently, there are four disc arthroplasty devices (total disc replacements) in investigational trials and clinical use in the United States.





Figure 3: Disc arthoplasty devices. ProDisc (Synthes), Charité (DePuy Spine), Maverick (Medtronic Sofamor Danek), FlexiCore (Stryker Spine)

The Charité artificial disc was FDA-approved in October 2004 and was implanted over 15.000 times in over 30 countries [36]. It uses two metal alloy endplates and its unique sliding core. This offers the theoretical advantage of allowing the spacer to shift dynamically within the disc space during spinal motion, which may improve the segmental rotation and decrease the possibility of facet impingement at extremes of motion. This has not yet been clinically demonstrated. The ProDisc-L was approved in August 2006, another metal-on-plastic device with Cobalt-Chromium endplates and a spherical polyethylene insert which articulates with the opposite base plate. ProDisc is the only one of the artificial discs undergoing FDA trials that is being investigated for multiple level lumbar disc disease. The Maverick and FlexiCore lumbar discs have completed their randomized enrollments and are currently in Continued Access non-randomized modes.

These devices do allow certain degrees of spinal motion, and first results of follow-up studies indicate them to be superior to spinal fusion for degenerative disc disease, it is noted that none of these total disc replacement devices has the ability to undergo axial compression. This translates to a limited ability to attenuate shock and distribute stress. Furthermore, the problems caused by artificial discs might be implant migration or osteolysis, which might seriously compromise further treatment alternatives. The longterm biomechanical behaviour and performance of these devices are still unknown.

2.5.3 Nucleus Pulposus Replacement

Because the nucleus is a major component and often involved with the pathologic changes of the disc, it is logical to consider the replacement of the degenerated nucleus with a prosthetic nucleus. There are several advantages of having a nucleus prosthesis over a total disc prosthesis. By replacing only the nucleus, the rest of the disc tissues (i.e. annulus fibrosus and endplates) are preserved and therefore so are their functions. This not only makes it easier for product design and fabrication than total disc prosthesis but also reduces the complexity and risk of implantation.

Nucleus pulposus (NP) replacement aims to restore disc height and even re-establish load distribution without removing the still viable annulus fibrosus (AF). However, NP replacement strategy includes only those with early stages of disc degeneration, when the AF and endplates are still relatively healthy.

Nucleus replacements using a variety of technologies have been patented or described in the literature. The treatments can be divided into two main categories: biological therapies and non-biological substitutions. Biological therapies aim to restore function by implanting viable NP cells into the defect intervertebral disc in order to re-establish NP function. Biological disc therapies are an application in human tissue engineering [37]. Contrary, non-biological substitutions utilize non-biologically active materials to mimic the functions of a healthy NP.

Initial attempts were made by injecting an acrylic mass, which was later followed by silicone implantations [38 - 40]. The concept of a compressible material, encased by a strong, inelastic outer layer was first tested in vivo by Hou et al [41], and brought to clinical use by Ray and Corbin [42]. The Raymedica PDN (Prosthetic Disc Nucleus) has been implanted in several experimental series [43,44]. The PDN is composed of a hydrogel core in a flexible, inelastic, loosely woven constraining polyethylene jacket. The hydrogel undergoes a cyclic swelling and shrinking, depending on load. Some problems with device migration were initially reported.



Figure 4: Raymedica Prosthetic Disc Nucleus (PDN) device

Some surgical exclusion criteria have been proposed by Ray [44] which include: total body weights above 90 kg, back pain deriving from sciatica, a disc height less than 5 mm, signs of an incompetent annulus, Schmorl's nodes or spondylolisthesis Meyerding grade 1 or more.

The Centerpulse (Mathys) Newcleus utilizes an elongated elastic memory coiling spiral made of polycarbonate urethane. It is inserted through a posterolateral annulotomy after discectomy, and the spirals around within the annulus to fill the nuclear cavity. This device has undergone laboratory and animal investigation, and has been implanted in a small number of patients in Europe [45, 46].



Figure 5: Newcleus device by Zimmer Spine (www.spine-health.com)

More recent work is directed towards the development of materials that better mimic the physiological fluid exchange behavior of the nucleus [47, 48]. Lately, an increasing number of companies have decided to develop viable NP replacement devices. The following table (adapted from Di Martino et al [49]) provides an overview of companies developing NP replacement devices.

Table 1: A summary of non-cell seeded nuclear replacements under

investigation			
Device & Company	Biomaterial	Studies	Technology
PDN SOLO® and	Hydrogel	CE approved ^a	Disc implant
PDN-SOLO XL™	(undisclosed) pellet		
	encased in a	Approved by FDA for	
Raymedica Inc.	polyethylene jacket	investigational use only	
Aquarelle	Semihydrated	Preclinical Baboon trials	Disc implant
	polyvinyl alcohol	have been completed	
Stryker Spine	(PVA) hydrogel 80% water		
NeuDisc	2 grades of modified	Biocompatibility testing	Disc implant
Replication Medical	hydrolyzed	with New Zealand	
Inc.	polyacrylonitrile	rabbits	
	polymer (Aquacryl)		
	reinforced by a		
	Dacron mesh		
Newcleus	Polycarbonate	Implanted in 5 patients	Disc implant
Zimmer Spine	urethane (PCU)		
	elastomer curled into		
	a preformed spiral		
EBI Regain	Pyrocarbon material	Baboon studies	Disc implant
Biomet Inc.			
Modular	Modular intervertebral	In-vitro cadaveric calf	Disc implant
intervertebral	prosthetic disc	spine models	
prosthetic disc (IPD)	(annulus-sparing		
Dynamic Spine	prosthesis)		
DASCOR® Disc	Curable polyurethane	CE approved ^a	In-situ curing
Arthroplasty Device	and an expandable	Implanted in 16 patients	polymer
Disc Dynamics Inc.	polyurethane balloon	Clinical trials in Europe	
SINUX ANR	Curable	CE approved ^a	In-situ curing
Sinitec/De Puy	polymethylsiloxane		polymer
Spine Inc.	polymer without		
	restraining jacket		
BioDisc	Protein hydrogel	Filed for CE ^a in February	In-situ curing
Cryolife Inc.		2007	polymer
NuCore®	Synthetic recombinant	Clinical trials in Europe	In-situ curing
Injectable Nucleus	protein hydrogel	and United States	polymer
Adapted from Di Ma	rtino et al [49]		

^a CE = Conformité Européenne mark, required for European sales of the product

2.6 Surgical Nuclectomy Procedures

Whatever kind of nucleus replacement will be carried out, it seems logical that it is necessary to create an appropriate cavity in the intervertebral disc prior to implanting / injecting a device. There are several surgical options to get disc material out. A surgical procedure that allows to perform a thorough total nucleus pulposus removal (nuclectomy) in a minimal invasive fashion is yet to be found. The specific surgical goals are: to maintain a minimal annulotomy, to reach as many zones of the disc as possible and getting as much nuclear material out as possible within an appropriate time, to avoid damage to the bony endplates and taking too much annulus fibrosus tissue. Current concepts in minimally invasive discectomy are:

2.6.1 Chemonucleolysis

Chymopapain is a proteolytic enzyme derived from papaya latex. It acts as a catalyst which promotes rapid hydrolysis of the chondromucoprotein portion of the nucleus pulposus [50 - 52]. Although the specific substrate(s) remain obscure, it is known that the enzyme inhibits the ability of proteoglycan to adsorb water which then leads to a breakdown of cartilage. Patients with unremitting sciatica and neurologic changes due to a herniated nucleus pulposus should be considered if they do not respond to conservative treatment. A good candidate was considered one with single level involvement, leg pain exceeding back pain, and good correlation of the findings on physical and imaging examinations.

According to van Alphen et al [53], chemonucleolysis was performed under general anesthesia or local anaesthesia with sedation and radiographic control with the patient in the lateral position. Discography was carried out, using 1 to 2 ml water-soluble contrast medium, for verification of the proper position of the needle in the disc and to check whether the anulus fibrosus was ruptured. After an interval of at least 15 minutes, 2 ml (4000 U) of chymopapain (Chymodiactin) was injected.

Other than there was a trend to decrease the amount of enzyme injected down to 2000 U or even to 500 U by some, there was no essential change in recommended technique over that described previously [54]. A major disadvantage of chemonucleolysis is the occurrence of back spasm, which can be quite severe in approximately 10% of patients. The complications may be summarized by citing 121 adverse events in approximately 135,000 patients [55]. Included are seven cases of fatal anaphylaxis, 24 patients with infection, 32 patients with hemorrhage, 32 neurologic events, and 15 miscellaneous occurrences with an overall mortality rate of 0.019%. One hundred five of the 121 events reported to the Food and Drug Administration occurred before the end of 1984.

Of considerable concern were six cases reported as acute transverse myelitis. Study of these reports shows that spasticity or hyperrreflexia did not develop in patients to fit the diagnosis and was more likely two cases of multiple sclerosis and one each of cauda equina syndrome, diabetic neuropathy, intrathecal injection, and after a viral infection. Three of the six patients recovered. The relationship of these adverse events to chymopapain or the procedure was assessed, and it was found that 47 instances were probably related, 38 were probably not related, and in the remaining instances, there was insufficient information to make a determination [55].

Despite the reported success and low morbidity of the procedure, the reputation of chemonucleolysis in the United States has been severely damaged, because of the severity of the complications, and the use of chemonucleolysis has drastically decreased. In their 1994 review of the status of percutaneous discectomy, Haines and Watridge concluded that chemonucleolysis has been discarded in most centers in the United States because of efficacy lower than the currently presumed standard for conventional discectomy and complication rates higher than can be justified on the basis of the efficacy. In October 1999, Boots Pharmaceuticals ceased manufacturing and distributing Chymodiactin, thus ending, for now, its use in the United States [56].

2.6.2 Percutaneous Laser-Assisted Discectomy

The development of laser light amplification dates back to 1958 and was accomplished by Arthur L. Schawlow and Charles H. Townes [57]. The first paper on percutaneous laser nuclectomy was published by Choy in 1987 [58]. Since then, numerous applications of laser technology in medicine have

been reported in various specialties. Laser-assisted discectomy evolved from percutaneous discectomy techniques. After percutaneous placement of a single needle in the disc space, laser energy is passed through a fiber into the disc space. The laser energy is transmitted in short bursts to avoid excessive heating of adjacent tissue. In 1984, Ascher and Heppner used carbon dioxide and Nd lasers to treat lumbar disc disease [59]. Their method involved measuring intradisc pressure before and after laser discectomy by using a saline manometer. These autors postulated that the removal of even a small volume of tissue from the disc caused a corresponding decrease in intradisc pressure, thus relieving back pain and inflammation.

In 1990, Yonezawa et al. [60] used an Nd-YAG laser to transmit energy through a double-lumen needle with a bare quartz fiber; their tip-type pressure transducer was similarly able to record pressure. The use of a KTP laser for lumbar disc ablation was introduced in 1992 [61]. Further advances have allowed the development of side-firing probes, which provide better directional control and visualization. The side-firing laser probe reduces the risk of injury to anterior structures such as the vena cava, aorta and iliac vessels. The holmium-YAG system involves a unique pulsed laser that enables the adjustment of pulse width and frequency to cause disc cavitation and reduce intradisc pressure while minimizing injury to adjacent structures.

Overall, the combined results of several series demonstrated a 70 to 80 % rate of long-lasting pain relief [59, 62]. The only reported complication was one case of discitis in a series of 333 procedures, which was described by Choy et al. [63]. However, possible complications of laser-assisted discectomy can include perforation of the aorta, vena cava, iliac vessels, or abdominal organs, and cauda equine syndrome.

To date there are no reported prospective controlled studies involving percutaneous laser discectomy. As such, the results of percutaneous laser discectomy for back and leg pain due to disc protrusions are still inconclusive. The largest experience in the literature, reported by Choy et al [63] documented a 78.4 % success rate with a 26-month-period follow up. Yeung reported an 84 % rate of good or excellent results with the KTP/532 device [64]. On the other hand, Sherk and associates observed no differences between treated and control goups in an analysis [65].

Clear disadvantages of percutaneous laser discectomy are the high initial costs of the equipment and also the bulkiness of the equipment. Even though the procedure was described to be effective for contained, nonsequestered herniated lumbar intervertebral disc disease, the risk of possible severe complications as described above, is quite high.

2.6.3 Open Standard Lumbar Discectomy

At present, open lumbar discectomy, either performed with a microscope or without, is the gold standard procedure for treatment of disc herniation. It has become the most common spinal surgery in the US, with nearly 300.000 procedures performed each year because of the epidemic problem of low back pain, which leads to 15 million physician visits per year and has created a tremendous financial burden on society exceeding \$50 billion annually [66, 67].

The operative treatment of lumbar disc disease has challenged spine surgeons since the first reported case in 1929 by Dandy [68]. In 1934, Mixter and Barr published a milestone paper on the pathology and surgical findings associated with a ruptured nucleus pulposus [69]. The surgical procedure of choice for many of these pioneering surgeons was complete laminectomy. Mixter and Barr favored a hemilaminectomy approach, as did Love for the cases of simple herniated disc that were amenable to preoperative localization.

The indications for surgery were and still are: radicular signs and symptoms of nerve root compression due to a disc herniation, unresponsive or inadequately responsive to symptomatic nonoperative treatment with the offending disc herniation with nerve root compression demonstrated on an MRI scan, a CT scan or a myelogram.

The surgical approach is described as follows [70]: patients are placed in a slightly flexed lateral decubitus position with the affected side up. Fluoroscopic or radiographic confirmation of the correct interspace is obtained with a radiopaque skin marker. A 15- to 25-mm skin incision is made just lateral to the appropriate spinous process; the lumbodorsal fascia is incised 2 mm from its insertion and a subperiosteal dissection exposes the inferior third of the lamina above the ligamentum flavum, the medial facet and the upper portion of the inferior lamina. A retractor, einer 1 or 2 cm wide and 5 to 7 cm long, maintains the exposure. At this point, a second radiograph may be obtained. A low-profile, angled, high-speed drill with a 4- to 5-mm coarse diamond bit is used to thin the inferior lamina, medial facet and superior lamina surrounding the interspace. A small curette is used to detach the ligamentum flavum directly over the nerve root inferolaterally and a 2-mm angled Kerrison rongeur is used to begin the simultaneous bone removal over the nerve root and then laterally and superiorly to detach the ligamentum flavum and obtain a minimal medial facetectomy and achieve removal of the thinned inferior bone of the superior lamina. 2- and 3-mm rongeurs are used to remove the ligamentum flavum as needed. The disc is palpated with a blunt Penfield dissector or right angle nerve hook, and the nerve root is retracted using a blunt suction tip. Free disc fragments should be removed. After radiographic confirmation, the disc space is entered sharply using a scalpel. A small window is made through the annulus to allow access to the disc space. Up and down facing right-angle curettes and various sizes of pituitary punches are used to perform the discectomy. Care must be taken not to violate the anterior disc margin, as catastrophic vascular injuries could occur. After thorough superior, medial and inferior exploration, irrigation and stopping of bleeding, the fascia and the skin are closed. The mean operating time is usually 40 to 60 minutes.

Open discectomy and microdiscectomy are accepted as highly effective and well tolerated. Most percutaneous techniques provide some advantage over an open exposure, such as avoidance of epidural cicatrice formation. However, convincing efficacy data, compared with open discectomy, are lacking.

2.6.4 Lumbar MED – Micro Endoscopic Discectomy

Throughout the years, the endoscope has been used in various ways to examine or facilitate removal of herniated lumbar discs. In 1986, Schreiber and Suizawa described a biportal approach, with working instruments on one side and an endoscope on the other [71]. Disc material was initially removed blindly, creating a working space within the disc for insertion of the endoscope. In 1993, Mayer and Brock reported a similar endoscopic technique using an angled scope, thus directing attention more dorsally [72]. A study comparing percutaneous endoscopic techniques with open microdiscectomy, we reported by Mayer and Brock in 1993, demonstrated equal efficacy for the two procedures.

The most popular and successful endoscopic system currently in use combines the technique of standard open microsurgical disc removal with endoscopic observation, the so-called microendoscopic discectomy (MED). In 1998, Smith and Foley, who were the first to describe MED, presented results for their first 100 patients. They reported excellent results for 85 patients and good results for 11 patients [73]. Muramatsu et al. reported a series of 70 patients who underwent the MED procedure. Overall, earlier postoperative ambulation, reduced intraoperative blood loss and decreased postoperative consumption of analgesic medications were noted in patients who underwent the MED procedure [74]. At several centers this procedure was performed as a routine outpatient procedure without general anesthesia.

The technique is essentially the same as the surgical operation. A laminotomy, medial facetectomy, nerve root retraction and discectomy are all performed in the same manner, with the exception of the use of an endoscope and reportedly smaller incisions. The other significant reported difference is that a transmuscular and not subperiosteal dissection is performed for insertion of the endoscope.

Because of the learning curve and because most spine surgeons are more familiar with microscopic approaches than with endoscopic approaches, Smith and Foley [75] introduced a series of dilators that allow the use of standard microscopic techniques, via a small tubular retractor, to perform essentially the same operation as with MED, a system called METRx (manufactured by Medtronic Sofamor Danek), which provided increased working space and better illumination. Surgery can be performed using the operating microscopes, loupes, an endoscope or a combination of techniques. Essentially, one can follow the same method as the open microdiscectomy. Overall, indications for the use of the MED system are similar to conventional open procedures. Its applications have also been successfully performed in obese patients and in patients who have undergone previous spinal operations. Why these procedures have not become popular is unclear.

2.6.5 APLD – Automated Percutaneous Lumbar Discectomy

Hijikata et al developed and applied specialized grasping forceps and curettes to be inserted through a cannula placed percutaneously [76]. Kambin and Gellman developed a power shaver, various angled suction forceps, punches and rongeurs [77]. Schreiber and co-workers added discoscopy with an endoscope, to allow direct observation of the instruments inserted via the contralateral side and to allow removal, under direct observation, of more of the nuclear material.

Although percutaneous manual nucleotomy has been reported by its innovators to be effective, the techniques have not been widely accepted and applied, because of several factors, as follows:

- o the large cannula size (5-8 mm in diameter)
- o the potential for nerve root or vascular injury
- the repeated entrance into the disc space, which might increase the risk of infection
- o the inability to relieve foraminal or lateral recess stenosis
- the lack of applicability among patients who have previously undergone surgery
- o the diffuculty among obese patients
- \circ the inaccessibility of the L5/S1 interspace in the majority of patients

Refinements of the method lead to the next innovation: the use of an automated system [78,79]. The instruments were designed to remove disc material from the center of the disc and to decrease the amount of nucleus pulposus posterolaterally.

In 1984 Gary Onik designed and introduced an automated percutaneous technique for disc removal. A 2-mm, 8-inch-long probe with a rounded tip, a closed end, and a single side port is introduced through a 2.5-mm cannula that has previously been fluoroscopically positioned against the annulus. The probe functions on the same principle as do the guillotine cutting instruments used for vitrectomy and arthroscopic surgical procedures. Suction aspiration and cutting occurs simultaneously. As suction is applied through the

inner cannula, disc fragments are aspirated into the port of the needle. The sharpened end of the inner cannula is pneumatically driven across the port, thus cutting off the aspirated disc material. This material then flows distally and is aspirated into a collecting bottle.

The introduction of arthroscopic illumination and magnification allowed identification of the triangular working zone. It has been identified as a safe zone in the posteriolateral annulus, which allows safe passage of instruments with minimal risk to the exiting nerve [80-85].

Onik and Maroon published initial results for 20 patients in 1987. With a short follow-up period of 6 months, 80% of the patients experienced good to excellent results, with four requiring subsequent microsurgical excision of free disc fragments. No complications were encountered.

In 1990, a prospective multi-institutional study involving 327 patients undergoing treatment of lumbar disc disease was performed by 20 senior investigators. They reported a 75% success rate among patients monitored for more than 1 year. The procedure was considered safe and effective, provided that strict criteria were applied in patient selection and appropriate surgical technique were used. Many other publications supported APLD, and its use spread throughout North America and Europe. Because of its simplicity and safety record and the desire of both physicians and patients for less invasive approaches to the treatment of lumbar disc disease, several hundred thousand patients have undergone successful disc aspiration.

However, many investigators have taken a negative stance regarding the application of APLD. Neuroimaging is a critical factor in patient selection. Extruded disc fragments and >=50% compromise of the spinal canal by the herniated disc are contraindications to APLD. In some cases, however, it may be impossible to determine whether a disc herniation is indeed contained. This fact prompted Fager, one of the most vocal opponents of this and all percutaneous techniques, to state that the logic underlying percutaneous techniques is incorrect, because in his experience the majority of patients who exhibit symptoms of sciatica have extruded fragments. Indeed, in a retrospective review of APLD treatment failures, 70% of cases were demonstrated to involve unrecognized sequestered or free fragments. It might not be possible to safely remove sequestrated and migrated disc fragments using the arthroscopic microdiscectomy method. However, the arthroscopic approach provides the opportunity to inspect the annulus, spinal nerve, and foramina. All intraannular, subligamentous and extraligamentous herniations are accessible via the arthroscopic procedure.

The swift rise in the application of APLD has rapidly abated, because the overall success rates do not compare favorably with those of standard discectomy techniques. That is not to deny that thousands of patients have apparently benefited from this minimally invasive approach.

Kambin reported an 87 % successful outcome rate with arthroscopic microdiscectomy [80,81]. Others reported similar successes with this procedure [86,87]. Mayer and Brock, in a paper on a prospective randomized control trial, achieved favourable outcomes with minimal complications [72]. The reported complications in the literature included discitis, instrument breakage and psoas hematomas; no neurovascular complications arising from posteriolateral access to the intervertebral discs of the lumbar spine have been encountered. Proper patient selection makes arthroscopic microdiscectomy an attractive option as a sameday surgical procedure. Negligible blood loss, avoidance of general anaesthesia and minimization of scar tissue can all contribute to desirable outcomes.

All of the above described surgical procedures are aiming at a *decompression* of the intervertebral disc, respectively a decompression of neural structures. They are examples of currently available methods to get nuclear material out of a disc. However, none of the procedures was designed to specifically perform a nuclectomy as effective as possible.

With the emerging extensive worldwide research on finding an ideal material / device for nucleus pulposus replacement, it should also be a concern to find the best suitable method for getting the degenerated nucleus pulposus out prior to replacing it.

2.7 Surgical Approaches to the Lumbar Intervertebral Disc

The principles of any surgical procedure must be strictly adhered to when operating upon the lumbar spine. As in any surgical procedure, the anatomy of the proposed operative site needs to be reviewed and understood prior to embarking on surgery.

2.7.1 Anterior / Anterior-lateral Access

For satisfactory anterior exposure of the L5 and S1 vertebrae, the *transperitoneal approach* is often required. Although the approach is simple in concept, sometimes the assistance of a general surgeon is appreciated. A longitudinal midline incision is made from the umbilicus to the pubic symphysis and extended superiorly, ending 2 to 3 cm above the umbilicus. Fatter patients need longer incisions. The rectus sheath is incised, the two rectus abdominis muscles revealed and then the peritoneum exposed. The peritoneum is then carefully excised from distal to proximal, cutting through the linea alba. The abdominal muscles and bladder are retracted and an abdominal exploration performed. The L5 / S1 disc lies below the bifurcation of the aorta. Exposing the L4 / L5 disc requires a larger exposure; mobilizing the great vessels (aorta, vena cava, left common iliac vessels) is necessary unless the vascular bifurcation occurs much higher up. Care must be taken to not injure the left ureter. The transperitoneal approach is difficult to use above the level of L4.

The anterior-lateral retroperitoneal approach is slightly more difficult for reaching the L5 / S1 space, but provides access to all vertebrae from L1 to the sacrum. An oblique flank incision is made extending down from the posterior half of the twelfth rib toward the rectus abdominis muscle and stopped at its lateral border, approximately midway between the umbilicus and pubic symphysis, then the aponeurosis of the external oblique is exposed and divided, the muscle then split. Next, the internal oblique and transversus abdominis are divided in line with the skin incision, and the retroperitoneal space exposed. The peritoneal cavity and its contents are gently mobilized and retracted medially. The psoas fascia is identified and the muscle's surface followed medially to reach the anterior lateral surface of the vertebral bodies. Smaller lumbar arteries and veins are located individually on the vertebra involved and tied, so that the aorta and vena cava can be mobilized to reach the anterior part of the vertebral body.

2.7.2 Posterior-lateral Access

The posterior-lateral approach can be used for posterior-lateral lumbosacral fusions and can provide direct access to the transverse processes, as well as the mamillary processes of the facets and to the pedicle. Through this approach the transverse process may be removed, exposing nerve root from the level above. Two types of skin incisions may be used. A midline incision is made and the thoracodorsal fascia exposed. Then, bilateral paraspinous incisions are made to expose the sacrospinalis muscle groups. Muscle splitting between the multifidus and longissimus provides direct access to the facet joints and transverse process. Alternatively, bilateral paraspinal skin incisions can be made, approximately three finger breadths lateral to the midline, followed by a muscle-splitting division of the sacrospinalis group. This provides a direct approach to the facet joints and transverse processes. This approach has been described as advantageous because it provides less muscle mass retraction medially and may decrease operative bleeding [].

Additional advantages of this approach are access to far lateral disc herniations, some intraforaminal discs, decompressions of the "far out syndrome", and access to the iliac crest for harvesting bone graft.

2.7.3 Posterior Access

The posterior approach to the lumbar spine is by far the most common and widely used surgical exposure. It provides access to the cauda equine and intervertebral discs, the spinous processes, laminae, facet joints and pedicles. The uses include excision of herniated discs, exploration of nerve roots, spinal fusion and removal of tumors.

Usually a small needle is inserted into the spinous process and a radiograph taken to determine the exact level. A midline longitudinal incision over the spinous processes is made, extending from the spinous process above to the spinous process below the pathologic level. The internervous plane lies between the two erector spinae muscles. The paraspinal muscles are detached subperiosteally, then dissected down the spinous process and along the lamina to the facet joint. Close to the facet joints are the vessels supplying the paraspinal muscles on a semental basis. These branches frequently bleed as the dissection is carried out, cauterization may be necessary. The ligamentum flavum is removed. Immediately beneath are epidural fat and the dura. Using blunt dissection and staying lateral to the dura, it is carefully continued down to the floor of the spinal canal, and the dura and its nerve roots retracted medially.

In our specific case – creating a cavity in the intervertebral disc – there is no standard approach. Percutaneous procedures aim at a posterior-lateral access; some devices are implanted by using a posterior approach while the anterior-lateral approach provides excellent exposure of the levels L2, L3 and L4.
Research Aims

The goal of this study is to compare two surgical procedures to remove the nucleus pulposus of the intervertebral disc, using three different surgical approaches to the lumbar disc (1. anterior, 2. posterior and 3. posterior-lateral) while using two different methods (creating a cavity / performing a nuclectomy by using 1. arthroscopic shavers and 2. pituitary rongeurs as the control group).

What should be compared in the groups of three surgical approaches are

- o the size of the created nuclear cavity
- o the amount of nuclear material removed
- the location of the nuclear cavity in relation to the annulus fibrosus and the entire disc
- o (unwanted) material removed from the annulus fibrosus-area

We also wanted to see if there is a difference, e. g. if more nuclear material can be removed in discs that show a higher degeneration of the nucleus pulposus.

To evaluate the level of degeneration, we used the Grading System according to Thompson - grade 1 - 5, with 5 meaning "fused, no disc space" and thus being excluded. As well, grade 1 is hardly ever found in humans above the age of 30.

We distributed an equal number of lumbar disc levels graded 2 - 4 to the different groups. As well, we distributed an equal number of smaller/larger discs to each group.

The distribution of our three different surgical approaches (anterior, posterior, posterior-lateral) was 1:1:1 for the arthroscopic shaver- as well as the control-group.

However, since the method used for our control-group (nuclectomy using pituitary rongeurs) is a standardized well-established procedure, we used a total of 30 specimen (10 specimen for each surgical access) for that group versus a total of 42 (14 specimen for each surgical access) for the experimental group.

Chapter 3: Materials and Methods

3.1 Specimen Selection and Study Design

Human lumbar spine specimens were pre-selected according to ap and lateral x-ray views to exclude specimens with the following abnormalities:

- degenerative spondylolisthesis greater than Grade I (> 25% slippage)
 or lytic spondylolisthesis
- o large osteophytes as seen on plain radiographic films
- o fractured degenerated facet joints
- o pronounced Schmorl's nodules at the relevant level
- o disc height at the relevant level < 5 mm
- o severe osteoporosis
- o any tumours at the relevant level

20 pre-selected lumbar specimens underwent an MRI scan to assess the grade of degeneration of the lumbar discs.

The imaging protocol included sagittal T1-weighted spin-echo (repetition time [TR] 700 msec/echo time [TE] 12 msec) and T2-weighted FSE (TR 5000 msec/TE 130 msec) images with the following parameters: matrix, 512 x 225; field of view, 225 x 300 mm; slice thickness, 4 mm; interslice gap, 0.8 mm; number of excitations, 4; echo train length (ETL), 15 (the first echo of this sequence is discarded), and axial T2-weighted axial FSE scans (TR 5000 msec/TE 72 msec; matrix, 210 x 256; field of view, 150 x 150 mm; interslice gap, 0.8 mm; number of excitations, 2; echo train length, 7). All the sequences were acquired without fat saturation.

To assess the grade of degeneration, we used the following algorithm and grading scheme developed by Pfirrmann et al., which assigns a grade 1 through 5 according to the level of degeneration:



Figure 6: Determination of Degeneration Grade



Figure 7: Grading scheme of age-related disc morphology by Thompson et al [49]

Grade I: The structure of the disc is homogeneous, with a bright hyperintense white signal intensity and a normal disc height.

Grade II: The structure of the disc is inhomogeneous, with a hyperintense white signal. The distinction between nucleus and annulus is clear, and the disc height is normal, with or without horizontal gray bands.

Grade III: The structure of the disc is inhomogeneous, with an intermediate gray signal intensity. The distinction between nucleus and annulus is unclear, and the disc height is normal or slightly decreased.

Grade IV: The structure of the disc is inhomogeneous, with an hypointense dark gray signal intensity. The distinction between nucleus and annulus is lost, and the disc height is normal or moderately decreased.

Grade V: The structure of the disc is inhomogeneous, with a hypointense black signal intensity. The distinction between nucleus and annulus is lost, and the disc space is collapsed.

The images were graded by two observers (an R5 radiology resident and an R1 orthopaedic resident) on the T2-weighted sagittal images. A third observer (senior staff radiologist) graded the levels where no agreement could be made for (the two residents were not able to agree on).

72 intervertebral discs (levels L1/L2 through L5/S1 from as many spine specimens as required to get a uniform distribution) were selected and distributed based on IVD degeneration grade (MRI grading scheme) and level.

These selected intervertebral discs were assigned to six comparable groups according to a block randomization. Group 1, 2 and 3 (control) had 10 specimens each. Group 4, 5 and 6 (experimental) had 14 specimens each. Three approaches were performed: anterior-lateral access (groups 1 and 4), posterior-lateral access (groups 2 and 5) and posterior access (groups 3 and 6) Each group had the same ratio of IVDs of one of three degeneration levels: 20 - 25 % little or no degeneration (grade 2), 50 - 60 % moderate degeneration (grade 3), and 20 - 25 % severe degeneration (grade 4). For the purpose of this study, no specimens with a degeneration grade of 5 were considered, as, by definition, these specimens have a collapsed disc space. Therefore, group 1, 2 and 3 (control) had 4 specimens with little or no degeneration, 5 specimens with moderate degeneration, and 1 specimen with severe degeneration. Group 4, 5 and 6 (experimental) had 14 specimens equally distributed (see table). It is thought that the number of specimens in the control group could be less than of the experimental group because the

traditional nuclectomy procedure used for specimens in the control group is well-known and established, and the spine surgeons performing this procedure therefore have no learning curve, and can produce reproducible results in fewer specimens than with the novel experimental procedure.

Although the grade of degeneration is the principal deciding factor for distributing IVD specimens equally between the groups, we also aimed at including an equal number of IVD levels within each sub-group. The following table shows the distribution of each group:

Table 2: Numbers of specimen assigned to each group; distribution of degeneration grades 2 – 3 and L1/L2 through L5/S1 levels

		Shaver		Rongeurs		
	ant	post	post	ant	post	post
	lat	lat		lat	lat	
Degeneration Grade 2	4	4	4	4	5	4
Degeneration Grade 3	8	8	8	5	4	5
Degeneration Grade 4	2	2	2	1	1	1
Level L1/L2	1	2	2	2	1	0
Level L2/L3	3	3	2	1	2	3
Level L3/L4	2	1	3	3	3	2
Level L4/L5	5	5	3	1	2	2
Level L5/S1	3	3	4	3	2	2

ant lat = anterior-lateral access post lat = posterior-lateral access post = posterior access

3.2 Specimen Preparation

Spine specimens were harvested < 24 hrs post-mortem and stored at -20 C^o. Specimens were left frozen during the radiographs, but thawed thoroughly before MRI (and then re-frozen).

MRI scans were used to measure the disc height in mm for each IVD. These measurements were taken on sagittal T2 weighted images, just below the discovertebral junction (dark line). If the disc was symmetrical (had a normal typically curved contour), the maximal disc height was measured close to the midline. If there were asymmetric protrusions, bulges or Schmorl's nodes, the disc height was measured on the next image where both end of the disc were close to a parallel condition.

Prior to performing the surgical procedures, spine specimens were again thawed and surrounding fat and muscle tissue removed.

The lumbar spines were dissected into single levels to allow as precise an orientation of the tools on the vertebral body's surface as possible (since there was no other visualization / guidance). As well, it allowed to pick only the levels needed for the experimental procedure per day and not a whole spine had to be thawed when for example only one level of that spine was needed.

The resections were performed on a bandsaw by using a template to get an even cutting surface, as shown in the following image:



Figure 8: Cutting the specimens on a bandsaw

Each vertebral body's disc was then measured with a calliper (ap and lateral diameters). The dimensions of each specimen were needed for further evaluations (see chapter 4.4.2).

3.3 Surgical Procedures

The respective spine levels were taken out of the freezer 12 hours prior to the procedure and thawed at room temperature. The disc level was fixed on a wood plate with two screws holding the transverse process on each side. To mimic the surgical reality respectively the anatomic limitations, a fence was created according to the spine surgeon's experience in the respective angle to allow the surgical steps and instrumentation within the appropriate range in a real patient when the surrounding tissue and organs are being held aside. For the anteriolateral access, this angle was 45°(22,5 °to each the right and left side) and for the posteriolateral access 35°. It was not necessary to set up a limitation for the posterior access, since in this case the approach is limited naturally by the bony structures of the disc level.



Figure 9: Set-up for the anteriolateral access with a total limitation of 45°(22,5° on each side)



Figure 10: Set-up for the posteriolateral access with a total limitation of 35°



Figure 11: Set-up for the posterior access which is "naturally" limited by the posterior bone elements of the vertebral body

3.3.1 Gold Standard Traditional Nuclectomy (Control Group)

The following equipment was needed to perform the procedures:

- o 1 wood plate
- o 2 metallic borders fixed to the wood plate with screws
- o 2 screws to fix the specimen on the wood plate
- o 1 anatomic forceps
- Kirschner-wires of different sizes
- o 1 scalpel
- o 3.5 mm straight and curved rongeurs
- o surgical sponges

The surgeon did five specimen per day – and was blinded with regard to detailed information about the respective disc levels (such as age, grade of degeneration).

The procedures were performed by an orthopaedic R4 resident as follows:

3.3.1.1 Anteriolateral Access

Using a scalpel, an annulotomy of a minimum of 8 mm width was made in the anteriolateral part of the annulus to allow entry of the surgical instruments. Rongeurs of two different sizes (3.5 mm and 4.5 mm) were used to perform the nuclectomy. Caution was applied to not damage the end plates during the procedure; curettage had to be avoided.

The surgeon went in and out the disc and made as many bites with the rongeurs as necessary until he could not get any nuclear tissue out of the disc anymore. Rongeurs of different shapes were used: straight and goose-necked shaped tools to make sure to get the maximal possible material out. The time limit for one procedure was set to 30 minutes.

3.3.1.2 Posteriolateral Access

Same procedure as described in 4.3.1.1 with the entry point being the posteriolateral part of the disc, typically 1 cm lateral to the nerve root exit (see figure 5).

3.3.1.3 Posterior Access

Same procedure as described in 4.3.1.1 with the entry point being the posterior part of the disc which is naturally limited by the spinous process and facet joint (see figure 6).

3.3.2 Nuclectomy by using arthroscopic shavers (experimental groups) The following equipment was needed:

- Arthroscopic shaver unit (provided by Smith & Nephew) including footswitch, 2 water bags connected to suction / irrigation, 1 container, 1 flexible handpiece
- o 1 plastic box

- o 1 wood plate
- o 2 metallic borders fixed to the wood plate with screws
- $\circ~$ 2 screws to fix the specimen on the wood plate
- o 1 anatomic forceps
- Arthroscopic surgery blades (3.5 mm RazorCut® Blade)
- o 1 concentric cannula
- o 1 indication stick
- o 1 scalpel
- o 4.0 mm K-wire



Figure 12: Arthroscopic Shaver Unit (Smith & Nephew)

Also in this experimental group, the surgeon did five specimen per day and was blinded with regard to detailed information about the respective disc levels such as age and grade of degeneration.

The procedures were performed by a non-orthopaedic trained physician who was blinded in terms of degeneration grade of the disc levels as follows:

3.3.2.1 Anteriolateral Approach

After fixing the specimen to the wood plate in the above described fashion, a small incision was made into the disc with the scalpel approx. 1 cm from the midline (according to measurements taken before). A 4.0 mm and 4.5 mm diameter k-wire was inserted into the center of the disc to dilate the annulus. Then a 3.5 mm concentric cannula was inserted into the center of the disc. A stick that had the exact length of the shaver was attached to the shaver in order to indicate the exact position of the shaver tip within the disc space. Additionally, the cannula itself had a scale (5 mm marks) to measure the depth of insertion, as shown in the following image:



Figure 13: Set-up for the anteriolateral approach to the disc and insertion of the cannula guided by an indication stick

The cannula and shaver were placed in the center of the disc. Time of insertion of the shaver was noted. For all specimens of all groups we used the same device: the 3.5 mm RazorCut® by Smith & Nephew. All procedures were carried out at a rotation speed of 800 rpm and pressure of 650 mmHg.

The shaver was moved back and forth and upside down within a range of approximately 5 mm, until the first chunk of nucleus material was grasped, which created some space to allow suction and irrigation to work. As soon as shaving was possible, the starting time was noted again. This time was noted again because it could not be predicted how long it would take to get the suction / irrigation working in each specimen (the more degenerated the disc, the easier it is to establish a connection). From now on, the shaving procedure was performed as follows: starting from the center with the shaver tip down, the shaver was moved to the left in a 20°-angle, back to the center of the disc and then to the right in a 20°-angle. The same procedure was repeated with the shaver tip aiming at the upside. The shaver then with the tip downside, again starting from the disc center, was moved forward towards the posterior part of the annulus (approx. 1 cm distance from the posterior border of the vertebral body) and under withdrawal of about 3 - 5 mm moved to the left in a 15°-angle, back to the center and to the right. Same procedure with the shaver tip upside. The shaver was moved back to the center with the tip downside and then withdrawn towards the anterior part of the annulus (again, 1 cm safety-distance from the anterior border of the vertebral body) and moved to the left and right as far as the fence allowed. Same procedure with the shaver tip upside.

The shaving process was stopped when no disc material had to be obtained anymore after meticulously following the directions described above. Time of the procedure end was noted again.

3.3.2.2 Posteriolateral Approach

The incision was made in the area where in a patient we would find the gap between exiting nerve and traversing nerve root - the so-called "Kambin's triangle" as shown in figure 5 above and in the following figures:



Figure 14: Kambin's Triangle [85]. Space between the exiting and traversing nerve root pointed out by the trocar



Figure 15: Posterior-lateral Access [85]

The rest of the procedure was performed as described for the anteriolateral access in a range of a 15°-angle, respectively according to the limitation of the metal borders.

3.3.2.3 Posterior Approach

For this procedure, the posterior elements of the vertebral body function as the natural anatomic borders. The incision is made as far lateral as possible from where the spinal cord would be in surgical reality:



Figure 16: Insertion of the trocar for the posterior approach to the intervertebral disc

After insertion of the instruments, the procedure was performed as described for the anteriolateral access above within the possible range of motion.

3.4 Surgical Outcome Evaluation

We used the same data analysis for all specimens of all groups and noted the same parameters for each procedure: specimen number and level, degeneration grade, surgical procedure – rongeur or shaver - and the total time of the procedure (see attachment "data collection").

3.4.1 Balloon Tests

After completion of the nuclectomy, a size12- Foley catheter was inserted into the created cavity of the disc through the surgical entry point. A 10cc syringe was filled with 8ml contrast medium and plugged to the catheter. As well, a pressure gauge was connected to the syringe.



Figure 17: Inserted Foley catheter and PSI gauge (which was connected to the syringe with a t-valve to measure the pressure of the injected contrast liquid)

The balloon at the tip of the catheter was then inflated up to the maximal pressure of 120 PSI with the maximum of liquid that was possible to get in just until the balloon would extrude out of the disc space as shown in the image below:



Figure 18: Specimen No. 512 of the anterior-lateral shaver group, level L5/S1 Inflation of the blue Foley-catheter by gradual injection of 9.2 cc contrast medium; the white balloon coming out of the disc space at 80 PSI

We noted the pressure and amount of injected liquid at which the balloon popped out of the disc space and in a second procedure inflated the balloon will approximately the same amount of liquid, but at a lower pressure: usually 5 PSI less than during the first inflation. The PSI values and injected volume of both inflations were documented.

The syringe and pressure device were deconnected and then a thin copper wire wrapped around the vertebral body in order to visualize the contour of the disc. Lateral and cranio-caudal x-rays were taken to evaluate the position (central / posterior / anterior?) of the balloon relative to the borders of the intervertebral disc. The x-rays were taken after setting up the following parameters on the x-ray machine:

- o distance from tube to specimen: 40 inches FFD
- o settings: 55 kV, 1.7 mAS
- o small filament
- o receptor: none
- o placing a calibration ball next to the specimen

An example of the x-rays obtained:



Figure 19: x-ray cranio-caudal view of specimen 505 L4/L5 shaver group including the surrounding copper wire; calibration ball on the left



Figure 20: x-ray lateral view of specimen 505 L4/5 shaver group including the surrounding copper wire

After the x-rays were taken, the balloon and copper wire were removed and the specimens prepared for the next evaluation procedure.

3.4.2 Aquasil Injection

A material was needed to be injected into the cavity and find out the extent of the created space and the leakage, which shows if annular fibers were damaged. The material used for this evaluation was Aquasil Ultra XLV®, a liquid dental impression material (polyvinylsiloxane) that turns into a soft rubbery consistency after setting.

Aquasil Ultra WETTING "IMPRESSION MATERIAL Quadrafunctional Hydrophilic Addition Reaction Silicone ight-Bodied Consistency (ISO 482 0

Figure 21: Aquasil® Ultra XLV impression material

When injecting the material into the disc space, we created a vacuum in order to accomplish a proper filling: a cannula (length 4 cm, diameter 4 mm) was placed in the cavity, the specimen was put into a Ziploc Sandwich bag and the bag was sealed. For the vacuum state – avoidance of air bubbles while injecting the material into the disc space), a luer lock was connected to the cannula through the Ziploc bag, the luer then connected to the suction of the arthroscopic shaver unit and all air sucked out of the specimen at a pressure of 650 mmHg.

Figure 22 shows how the Aquasil Ultra XLV ® was injected into the disc space by using a Dentsply Caulk gun according to the company's instructions. The gun was connected to the valve and the material injected until it came out of the annulus.



Figure 22: Setup for Injection of Aquasil® *The cartridge connected via a t-valve to a smaller cannula and the suction line connected to the cannula*



Figure 23: Close-up Injection of Aquasil® showing the *t*-valve and created vacuum by sucking the air out of the sealed plastic bag prior to injection of the silicone



Figure 24: Aquasil® injected

The specimen was then taken out of the plastic bag and put aside for the polyvinylsiloxane to cure at room temperature. Setting time is usually 5 minutes.

3.5 Data Analysis

3.5.1 "Squirrels' Olympics" = Template for precise cutting of the silicone

After the appropriate polyvinylsiloxane-setting time, the specimen was carefully cut through the midline of the intervertebral disc with a scalpel while leaving the Aquasil®-lump intact. The two disc halfs were set apart, then pictures taken of each half with a calibration ball and ruler added as shown in the following example:



Figure 25: Specimen No 498 L1/L2 of the posterior-lateral shaver group after dissection, showing the Aquasil® lump, calibration ball and ruler



Figure 26: Specimen No 498 L1/L2 of the posterior-lateral shaver group after removal of the Aquasil® lump

A total of 8 pictures were taken of each specimen, 4 of each half with the Aquasil®-lump in place and removed. All pictures were taken at a fixed distance of 40 cm with a Canon camera.

Ahrens et al [78] came up with a surgical map for total nucleus removal, which we revised. The accurate relation (proportion of) annulus fibrosus / nucleus pulposus-area is impossible to tell. We agreed to work with an average relation (annulus/nucleus) of 50 / 50 % for each specimen, and assigned a total of 16 zones to the intervertebral disc, 8 for the nucleus pulposus and 8 for the annulus fibrosus.

According to the measurements – ap and lateral diameter - of the vertebral bodies that were taken before, an individual grid was created for each specimen:

The ap and lateral diameter data were entered in a computer paintprogram, an ellipse was created indicating the 16 zones and printed on acetate. This individual grid was overlaid on top of the respective intervertebral disc which contained the Aquasil®-lump as shown in the following figure 27:



Figure 27: Individually designed grid overlaying the intervertebral disc, indicating the 16 designated zones. The thick lines serve as the cutting guidelines.

The specimen containing the polyvinylsiloxane was then placed on an specially designed alignment platform (see picture).



Figure 28: "Squirrels' Olympics". Specially designed template that allows proper positioning of the specimen and precise dissection

A ruler was placed across the template and the Aquasil lump carefully cut with a scalpel according to the 16 zones:



Figure 29: Precise dissection of the Aquasil®-lump with the scalpel



The separate chunks were put into a labelled wellplate:

Figure 30: Wellplate containing the Aquasil®-pieces of each designated zone

Each piece was weighed and the weight of each zone documented in g Aquasil®, as shown in the following example:

AF 1	AF 2	AF 3	AF 4
	0.3006	0.0762	
NP 1	NP 2	NP 3	NP 4
0.0710	0.6269	0.4935	0.0120
NP 5	NP 6	NP 7	NP 8
0.0580	0.7030	0.6592	0.0648
AF 5	AF 6	AF 7	AF 8
			0.3788

Table 3: Documentation of the weight of the Aquasil-pieces of specimen 411L5/S1

The different groups (shaver vs rongeur procedures) and the results within the groups using the three different approaches were then compared.

3.5.2 Centroid calculation of the Aquasil® mass

The shape of the disc was assumed to be in the shape of two concentric circles. The inner circle with an area of half of the outer circle and a radius of 0.707 was assumed to be the region of the nucleus pulposus and the outer circle with a radius of 1 giving an area of 3.1415 was the region of the total disc. Figure 24 depicts how the two circles were further divided into zones of interest. The geometric center of each zone of interest x and y was calculated. The nucleus pulposus had regions of N1 through N8 while the annulus fibrosus contains the zones A1 through A8.



Figure 31: Division of the intervertebral discs into zones of interest

Nucleus x and y center of zones

The x center of each nucleus zone measured from the origin (red dot) is as follows: N1 = -0.49852, N4 = 0.49852, N5 = -0.49852, and N8 = 0.49852

The y center of each nucleus zone measured from the origin (red dot) is as follows: N1= 0.23985, N4= 0.23985,N5= -0.23985, and N8= -0.23985

The x center of each nucleus zone measured from the origin (red dot) is as follows: N2= -0.11868,N3= 0.11868,N6= -0.11868, and N7= 0.11868

The y center of each nucleus zone measured from the origin (red dot) is as follows: N2= 0.33879, N3= 0.33879, N6= -0.33879, and N7= -0.33879

Annulus Pulposus x and y center of zones

The x center of each AP zone measured from the origin (red dot) is as follows: N1 = -0.6876, N4 = 0.6876, N5 = -0.6876, and N8 = 0.6876

The y center of each AP zone measured from the origin (red dot) is as follows. N1= 0.44468, N4= 0.44468, N5= -0.44468, and N8= -0.44468

The x center of each AP zone measured from the origin (red dot) is as follows. N2= -0.17962,N3= 0.17962,N6= -0.17962, and N7= 0.17962

The y center of each AP zone measured from the origin (red dot) is as follows. N2= 0.82691, N3= 0.82691, N6= -0.82691, and N7= -0.82691

A mass weighted value of each zone for both x and y was calculated by using the x and y centers for each zone multiplied by the mass of silicone that was cast in that zone during dissection. For example: N1x=mass in zone 1 of nucleus and multiplied by x center of zone 1.

Next, the x center of mass of the entire Nucleus pulposus was calculated by summing up all the mass weighted x values of the NP zones. The same was done for the y values of the NP.

Finally the x and y center of mass of the total Disc (both the NP and AF) was calculated in a similar manner as described above with the exception that the mass weighted x values of the NP and AF were summed up and divided by the total mass of the disc. The same procedure holds true for the y mass weighted values.

3.5.3 Centroid calculation of the balloon according to x-rays

A computer program was used with tracing tools to mark the balloon boundaries and the center of mass / density, which allowed the calculation of the balloon area expression in a coordinate system.



Figure 32: ap x-ray, sample orientation of a specimen, showing the calibration ball and the grid of parallels and medians according to which the center of the balloon was calculated

Chapter 4: Results

4.1 Time of Surgery

The time of each surgical procedure was precisely documented in minutes and lead to the following results as shown in figure 30:



Figure 33: Time of surgery for each group and each access. Each error bar is constructed using a 95% confidence interval of the mean.

Overall, less time was needed when performing the nuclectomy with shavers. The anterior-lateral access carried out with the rongeurs was the procedure that required the least time with an average of 10,90 minutes. Most time was needed for the posterior approach with the rongeurs with a mean of 29,0 minutes. The times of surgery in the shaver group are pretty equal with a mean of 13,14 minutes for the anterior-lateral access, 18,0 for the posterior-lateral access and 10,07 for the posterior access.

4.2 Balloon Pressure

The following figure represents the applied pressure in PSI at which the balloon was inflated. The mean values (with error bars for +/- SEM) are shown for each removal method and separately for each surgical approach. There was a significant difference in the two groups. Overall, we found higher balloon pressures at expulsion in the entire shaver group. The specimens of the experimental shaver group with the nuclectomy performed via posteriolateral access were able to withstand the highest pressure with a mean of 80,76 PSI, followed by the nuclectomy procedure performed via anteriolateral access with a mean of 75,14 PSI. There was no great difference between the three rongeur-groups; the average resistance in the posterior-lateral group was noted at 35,10 PSI. The difference between the two methods can also be seen from the p-value, which is 0,0086 for the shaver group versus 0,2218 for the rongeur group.



Figure 34: Balloon pressure in PSI for the different groups and surgical approaches. Each error bar is constructed using 1 standard error of the mean.

The PSI value of the second inflation did not differ much as compared to the first inflation. In fact, there was a high correlation between the first and second measurement which is expressed by the r²-value of 0,938.



Figure 35: Balloon pressure including the 2nd PSI value. Each error bar is constructed using 1 standard error of the mean.

4.3 Injected Volume of Contrast Medium

The injected volumes of contrast medium were higher in all three rongeur groups. The highest volume could be injected into the specimens of the anterior-lateral rongeur group (average of 4,93 ml) and of the posteriorlateral rongeur group (mean volume 5,32 ml), which is about double as much as in the respective groups of the shaver method: average of 2,50 ml in the anterior-lateral shaver group and 2,41 ml in the posterior-lateral shaver group. In both the rongeur and shaver group we documented the least volume in the posterior approach group: 3,67 ml and 1,55 ml.



Figure 36: Injected contrast medium in ml. Each error bar is constructed using 1 standard error of the mean.

4.4 Center of the Balloon / Center of the the created Cavity within the

Disc

The geometric center of each zone of interest x and y was calculated.

The density ellipse is defined as the least area ellipse that includes 80% of all points.





Figure 37: Sample orientation
4.4.1 Rongeur Method anterior-lateral Approach

According to our calculation of the balloon center, this approach and procedure carried out with rongeurs shows the optimal left-right-centralized location of the created cavity with regard to the x- and y-axis and entry point and little distribution.



Figure 38: Center of Cavity Approach anterior lateral Rongeur Method

4.4.2 Shaver Method anterior-lateral Approach

For this method and approach, the cavity was centralized, however, shifted more posteriorly. The left-right-centricity is correct and the size of the ellipse small, which indicates little variety.



Figure 39: Center of Cavity Approach anterior-lateral Shaver Method

4.4.3 Rongeur Method posterior-lateral Approach

Similar to the anterior-lateral approach, also here a centered area / cavity can be found:



Figure 40: Center of Cavity Approach posterior-lateral Rongeur Method

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4.4.4 Shaver Method posterior-lateral Approach

The following figure shows a big oval shape of the ellipse and a considerable variety of the points. The left-right-centricity is quite correct, however, the center with regard to the x- and y-axis is both too posterior and too far anterior:



Figure 41: Center of Cavity Approach posterior-lateral Shaver Method

4.4.5 Rongeur Method posterior Approach

When using this approach, the center of the cavity is a bit too far anterio-lateral and a slight shift to the left. However, the small size of the ellipse indicates little variety.



Figure 42: Center of Cavity Approach posterior Rongeur Method

4.4.6 Shaver Method posterior Approach

The center was found to be mostly posteriorly with regard to the x- and y-axis. The left-right-centricity is not quite correct, there is a shift to the left. The big ellipse indicates a high variety of the points:



Figure 43: Center of Cavity Approach posterior Shaver Method

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4.5 Correlation of injected volume and pressure for rongeur method

High volumes could be injected (average of 6 - 7 ml) at values up to 65 PSI before extrusion of the balloon. Figure 44 and 45 plot for each specimen the relationship between the maximum injected fluid volume in milliliters, measured just before expulsion of the balloon, and the related maximum pressure recorded in PSI for the same experiment. Despite several readings were performed for each specimen, only the values for the 1st readings were used for these plots. The green line is a least square linear regression fit for all measurement points, with the dotted curved lines delimiting the 95 % confidence interval for the estimated regression line. For the rongeur group shown in figure 44 the adjusted r2 value for the fitted line is 0.112842, with a p-value of 0.039 indicating a significant direct/indirect interdependency between maximum filling pressure and maximum filling volume. The estimated coefficient for the interdependency was calculated at 0.0665 milliliter volume increase for every PSI pressure increase.



Figure 44: Correlation of injected volume and pressure for rongeur method

4.6 Correlation of injected volume and pressure for shaver method

Smaller volumes could be injected as compared to the rongeur group, however, higher pressures (up to 120 PSI) could be applied before extrusion. The PSI value of 120 was the maximum pressure applied, also without extrusion of the balloon. The predictability of volume and pressure shows a high correlation and is highly significant with a p-value of < 0,0001. The adjusted r2 value for the fitted line is 0.506481, with a p-value of < 0,0001 indicating a highly significant direct/indirect interdependency between maximum filling pressure and maximum filling volume. The estimated coefficient for the interdependency was calculated at 0.0342 milliliter volume increase for every PSI pressure increase.



Figure 45: Correlation of injected volume and pressure for shaver method

4.7 Injected Aquasil® Volume

Figure 46 depicts mean values (with error bars for +/- SEM) for the weight of the injected Aquasil implant in grams, with individual representations for each surgical approach experimental group, and shown separately for each removal method. There is a very significant difference between the rongeur and the shaver group. The following table shows the average weight

of the Aquasil®-lump for the nucleus pulposus and annulus fibrosus. Between 72% and 85% of the mass was in the region of the nucleus pulpusus. For the nucleus pulposus the average is 3,60 g for the rongeur versus 0,83 g for the shaver posterior-lateral approach. The anterior-lateral approach shows similar results, with a mean of 3,25 g for the rongeur group and only 0,76 g for the shaver group. In both groups the least Aquasil®-material could be injected into the specimens of the posterior access: average of 2,09 g nucleus pulposus area in the rongeur group and 0,48 g in the shaver group.



Figure 46: Aquasil® average weight in gram for each procedure. Each error bar is constructed using 1 standard error of the mean.

4.8 Injected Aquasil® Volume and Relation to the Degeneration Grade

In both groups more Aquasil®-material could be injected the higher the degeneration grade of the disc. The difference in the rongeur group was more significant: at degeneration grade 2 the average of injected material was 2,52 g; at degeneration grade 3 it was 3,19 g and at degeneration grade 4 a mean of 4,02 g was noted with a p-value of 0,1243. In the shaver group, the same trend was noted, however, not that significant as compared to the rongeur specimens with a p-value of 0,5216. In an ANOVA model including the approach and the degeneration grade, no significant difference for the grade was found with respect to the Aquasil® weight of the nucleus pulposus; only a trend was found for the rongeur group.



Figure 47: Aquasil® filling (nucleus pulposus) in gram in relation to degeneration grade. Each error bar is constructed using 1 standard error of the mean.

Chapter 5: Discussions and Conclusions

5.1 Shavers

The first tool that was designed for disc removal via an automated percutaneous technique was a 2-mm, 8-inch-long probe with a rounded tip, a closed end, and a single side port, which is introduced through a 2.5-mm cannula and functions on the same principle as the guillotine cutting instruments used for vitrectomy and arthroscopic surgical procedures. Suction aspiration and cutting occur simultaneously. The question for our experimental procedure was how the tip of a rotating electric shaver should be designed for the purpose of removing as much of the jelly-like nucleus material as possible. After preliminary tests using various shaver tips we chose the 3,5 mm full radius razorcut blade, shown in figure 48



Figure 48: Razor Cut Blade by Smith & Nephew

Also, a unilateral access was chosen and a standard speed of 500 revolutions per minute in routine use according to the literature. More tests should be pursued in order to figure out if it is possible to get more nucleus material out by changing the size of the cannula or the mechanical parameters. As well, the use of a curved shaver should be evaluated.

5.2 Experimental set-up

In surgical reality, entry and positioning of the instruments is fluoroscopically verified. In our experimental set-up, two very important points were the dissection of the lumbar spines and working with single specimens which allowed full view of the cross section of the vertebral body, and the attachment of an indication stick to the shaver handpiece. The indication stick had the exact same length as the shaver and was fixed to the handpiece in a 2 inch-distance to the shaver cannula, so that its position was the surface of the specimen. It allowed to estimate the position of the shaver tip in the disc during the procedure. A simple but reliable method when imaging is not available. The limiting metallic borders were fixed to the wood plate in angles according to known values from the literature and according to the practice of experienced spine surgeons. The range of movements of the shaver should only have been possible as it would be in a real patient when using either the anterior-lateral or posterior-lateral approach. However, an absolute correct working field could not be guaranteed with this set-up. Only the posterior access ensured surgical reality, since in this case the anatomic limitations were given by the posterior bony elements of the vertebral body which were left intact.

5.3 Tests for Outcome Evaluation

5.3.1 Balloon tests

An uncomplicated and cheap yet effective method was needed to evaluate the volume that could be injected into the created cavity under measuring the pressure that the intervertebral disc could withstand until the balloon popped out. We modified simple Foley catheters for this purpose by inserting a thin K-wire all the way to the tip to facilitate insertion into the disc space. Sometimes the balloons ruptured during the inflation. However, overall this method can be considered very useful, and the values (injected volume and PSI) very important.

5.3.2 Use of Aquasil®

The Aquasil Ultra XLV Smart Wetting® material that was used for injection into the disc space is actually used in dentistry, a quadrafunctional hydrophilic addition reaction silicone, light body, elastomeric impression material with excellent hydrophilic properties, dimensional accuracy and high tear strength. This vinyl polysiloxane material is designed to minimize the problems of voids, bubbles, pulls and drags. It is available in cartridge delivery and has a working time of 2,15 - 2,45 minutes. Setting time is 5,0 minutes from start of mix (mixing ratio = 1 part base to 1 part catalyst).

For our purpose, the injection mode had to be modified a little bit, since the dispensing gun was too big to be inserted into the entry point of the disc, which made the attachment of a smaller cannula to the dispenser necessary. Since the diameter of this cannula was less than the actual dispenser's, the injection had to occur very quick after creating the vacuum in the disc space to avoid an increase in viscosity and thus a difficult injection. The procedure went very well and the material was very useful, since it was leaking everywhere and able to indicate damage to the annular fibers, either pre-existing due to degeneration or caused by the surgical procedure.

However, the entire evaluation process – injection of the material, dissecting the specimen, photographs, precisely cutting the silicone mass according to the 16 zones of nucleus pulposus and annulus fibrosus, weighing each part - was extremely time-consuming and did not deliver values that were as important as the data obtained with the balloon inflation and calculation of the center.

5.4 Time of Surgical Procedure

The total time of each surgical procedure of all six groups was documented in minutes starting from the point of annulus incision and ending at removal of the shaver and cannula, and after the last bite with the rongeur respectively. One difference has to be pointed out between the two groups: removal of nucleus material in the rongeur group started right away after creating the entry window in the disc. However, in the shaver group the timespan between the shaver insertion and start of nucleus material removal could vary considerably. In order for the shaving, cutting, suction to work, one small chunk of nuclear material had to be gotten out first. As we could see retrospectively, this could be accomplished quickly – sometimes immediately - in more degenerated discs. However, in intact discs (degeneration grade 2) the time until start of actual shaving / nucleus material removal was in some cases up to 10 minutes. Nevertheless, in our experiments the total time of each procedure was considered as described above.

What was striking, was the little resp. least required surgical time with an average of 10,90 minutes for one anterior-lateral procedure carried out with the rongeurs. This fact could indicate the best surgical exposure and possible range of motion of the instruments for this approach, especially when a goosenecked rongeur is used additionally. Also in the shaver group the mean value of 16,07 minutes in the anterior-lateral procedure was relatively low. Most time was invested trying to get as much nuclear material out as possible in the posterior access rongeur group (mean of 29 minutes). The posterior elements of the vertebral body seem to not allow a greater flexibility of the instruments. The surgeon was apparently trying for almost half an hour with various rongeurs, but had to acknowledge the fact that more material could not be removed. This applies even more to the posterior procedure carried out with the shavers; only short time was dedicated (mean of 13,14 minutes) for this very limited exposure. The total times for the posterior-lateral access were similar in both the rongeur (mean of 20,4 minutes) and shaver (mean of 18,0 minutes) group.

The overall time for removal of the nucleus pulposus should not exceed 30 minutes, which was accomplished in all six groups. The 95% confidence interval for the posterior-lateral access for the shaver method was 15,17 – 20,83 minutes. In summary, the shaver method could be ideal for the percutaneous and thus minimally invasive posterior-lateral access in terms of operating time when performed by an experienced surgeon.

5.5 Balloon Pressure at Expulsion

The balloon of the inserted Foley-catheter was very slowly and carefully inflated with the contrast medium using a luer lock syringe to the PSI value that could be sustained by the disc before the balloon would completely extrude. According to Wilke et al [88] the intradiscal pressure is approximately 0,85 MPA (320 PSI) in a sitting position with maximum flexion. The DASCOR device, a two-part in situ-cured polyurethane injected within an expandable polyurethane balloon, is inflated up to approximately 120 PSI after insertion into the disc space [89]. Based on these data, we defined 120 PSI to be the maximum pressure applied in our balloon tests. A few specimens of the rongeur group were able to maintain the balloon at 120 pounds per square inch; in all other cases the PSI value at the point of balloon expulsion was noted and a second inflation performed.

Very obvious was that the specimens of the shaver group were able to sustain higher pressures than all the rongeur group specimens, with the posterior-lateral shaver group showing the highest resistance with a mean of 80,76 PSI, compared to 35,10 PSI average in the rongeur group. Similar observations were made in the anterior-lateral groups.

Our explanation for this significant difference is the size of the incision of the annulus fibrosus. A nucleus-removal via rongeurs requires open surgery. The insertion of the instruments depend upon a bigger entry point – 8 to 10 mm - as opposed to a percutaneous access and insertion of a 4 mm-diameter cannula into the disc. The larger the entry point, the higher the likelihood of an extrusion.

The cannula and shaver are inserted into the disc space once for the procedure, whereas the access might even widen a bit more during the course of the procedure carried out with the rongeurs by going in and out with the instruments repetitively.

5.6 Injected Volume

The higher volumes that could be injected into the specimens of the rongeur group suggested for the first time that greater cavities were created using this surgical procedure. The amount of millilitres injected into all groups of the rongeur-specimens was almost double the amount of contrast medium of all shaver-specimens. This observation was later confirmed by the injected Aquasil® volume:

5.7 Center of the created Cavities

According to the x-ray evaluation and center-calculations, a centralized left-right-cavity was created in the specimens of the rongeur-group via anterior-lateral access. Only little variation was seen in this group, which suggests that this might be an optimal approach in terms of exposure and range of motion of the instruments. The anterior-lateral access procedures carried out with the shaver show a similar ellipse, however, shifted a bit posteriorly. This result can be explained by the fact that the anterior zone of the disc cannot be reached with a shaver in a triangular fashion. As well, it is not possible to get around the corner with a straight shaver.

For the posterior-lateral access similar correct centralization was seen in the rongeur group with an equally stable distribution. Obviously, by choosing this approach, a centralized cavity can be created easily with the rongeurs. On the contrary, the oval ellipse for the same access carried out with the shavers was striking and the extent a bit surprising, but can be explained by the axis and elongate shape of the shaver which apparently makes it difficult to control the depth and direction of the shaving procedure. Certain zones are impossible to reach, especially the anterior-lateral right zone of the disc when the entry point is the posterior-lateral right side.

When we look at the results for the posterior access, it clearly indicates that this does not seem to be a very appropriate approach for the creation of a centralized cavity. Whereas centralization could be accomplished via the anterior-lateral and posterior-lateral access with the rongeurs, the center of the cavity via the posterior access shifted into the anterior-lateral direction.

The centers of the shaver group for the posterior approach had the emphasis posteriorly, which is not a surprising result if the very limited range of motion of a straight shaver is considered for this approach. However, we also found a great variation of centerpoints here which means that the uncertainty where the cavity would be generated was too high and the outcome too unpredictable.

According to these findings, the conclusion of the posterior being the least suitable approach for both surgical procedures, must be drawn.

5.8 Correlation of injected Volume and applied Pressure

The linear regression for the rongeur group specimens showed a significant direct / indirect interdependency between maximum filling pressure and maximum filling volume. The values for the specimens of the rongeur group indicated a highly significant direct / indirect interdependency between maximum filling pressure and maximum filling volume.

The applied experimental methods can therefore be regarded as very reliable.

5.9 Injected Aquasil® Volume

For this evaluation, only the injected mass into the nucleus pulposus was considered. As pointed out before, we designated a total of 16 zones to the nucleus pulposus and annulus fibrosus (8 respectively) and weighed the content and obtained all data of each individual zone. For this calculation, we

modified a surgical map for total nucleus removal from a posterior approach by Ahrens et al [90]. In general, there is no definite agreement where in the intervertebral disc the nucleus pulposus ends and the annulus fibrosus begins – and perhaps a precise distinction can never be made. From our experience, this "border" is especially hard to define the more degenerated a disc is.

We decided to create our grid of the several zones based on the designation of 1 cm width to the annulus fibrosus for each specimen.

For the calculation of removed nucleus material, we were referring to the total of removed nucleus pulposus, and failed to take the individual amounts of these 8 zones into account, since we considered this detailed information as not significantly relevant.

Overall, the amount of polyvinylsiloxane was much higher in the specimens of the rongeur group, especially via anterior-lateral and posteriorlateral access. The created cavities were clearly bigger by using the rongeur method. This fact is very likely due to

- a larger surgical entry point
- more flexibility in terms of range of motion of the instruments
- the shape of the rongeurs, e. g. use of curved tools

If it would have been possible to create bigger cavities in the experimental shaver group by choosing different technical parameters, such as higher rotation speed or more suction, is unclear.

5.10 Injected Aquasil® Volume and Relation to the Degeneration Grade

The surgeon was blinded with regard to the degeneration grade of the specimen, and nobody has investigated the question before if there might be a difference in the outcome depending on the condition of the disc.

According to our results, more nuclear material was obtained from the disc the higher the degeneration grade was when using the rongeur method. Apparently, the less jelly-like the nucleus pulposus is, the easier is it to grasp the tissue with the rongeurs.

Surprising was that the relation of injected silicone volume to the degeneration grade was not nearly as significant in the shaver group. Also here, more nuclear material could be gotten out from discs graded as 4 than of those graded as 2 or 3, but this was a slight difference, so that we can at

best call this finding a trend. Actually one would have expected that the more "crumbly" the disc material is, the more effective the shaver would be, since in non-degenerated discs it was sometimes difficult to get the flow and suction working until the first chunk of tissue could be removed, as opposed to higher degenerated discs. We would have assumed a bigger role of increasing degeneration grade and obtained material in the shaver group.

5.11 Choice of Approach

Current devices for nucleus replacement are using the following surgical approaches:

- DASCOR (= two-part in situ-cured polyurethane injected within an expandable polyurethane balloon to form the final nucleus replacement device that conforms to the nucleus cavity created): multiple surgical approaches possible: anterior, anterior-lateral, posterior-lateral

- PDN HydraFlex (= inner copolymer hydrogel pellet, outer woven jacket of ultra-high-molecular-weight polyethylene): preferably ARPA = anterior retroperitoneal approach or ALPA = anterolateral trans-psoatic approach; traditional posterior approach

- NeuDisc (= synthetic hydrogel): posterior or anteriolateral approach

- NuCore (= injectable nucleus): interlaminar approach

- Aquarelle (= hydrogel device): posterior, posterior-lateral or anteriorlateral approach

- BioDisc (= biocompatible hydrogel prepared for immediate injection): posterior or posterior-lateral approach

The list shows that the choice of the surgical access varies. However, any manufacturer of a current or potential future device states that the key to any approach was achieving total nucleus removal and minimizing annular disruption and that the implantation of a nucleus replacement device should not be perceived to be a simple adjunct to a standard discectomy for herniated nucleus pulposus.

Our results show that both surgical procedures (rongeurs and shavers) do have the potential to perform a proper total nucleus removal prior to implantation of a new device. However, the optimal method and instrumentation to succeed in a best total nucleus removal possible has yet to

be found, and more research should address this issue in order to minimize the risk of implant failure. It is a well-known fact from clinical experience that anterior / anterior-lateral approaches are the most extensive and risky ones, even when performed by a skilled experienced surgeon. For the patients, these approaches are also the most painful ones that require the most postoperative care. In our opinion, the choice of any anterior approach to the lumbar disc must be justified and thus should aim at creating the best possible pre-conditions for a nucleus implant to function properly without migrating.

5.12 Use of Shavers for Total Nucleus Removal

The average shaving time for all three approaches of the shaver group was 13,74 minutes which can be considered as very low. The specimens of the shaver group were able to withstand a mean pressure of 68,47 PSI. The created cavities showed a fair centralization for the anterior-lateral and posterior access. The access and penetration of the annulus can be kept very small, and only a single entry is needed for the procedure as opposed to the rongeur method where a larger entry point is needed and the surgeon needs to go in and out with the instruments countless times. However, according to the literature, an average volume of 4 to 5 ml is needed [91-95]. For a successful implantation of a device the required cavity needs to be bigger than it was possible to accomplish with our shaver method.

The shavers might be a good minimal-invasive alternative to the rongeurs for a percutaneous posterior-lateral access, if the instruments can be modified, like for example by designing a curved shaver, and if a bilateral access is taken into consideration.

5.13 Annulus Repair

A very significant result of our experiments showed the correlation of sustained pressure and size of entry point, and thus how important an intact annulus fibrosus seems to be. Reconstruction of the annulus fibrosus is an important consideration, because current procedures without reconstruction might have unsatisfactory clinical outcomes requiring repeat surgery.

Since to date a total nucleus removal is performed with the standard discectomy using rongeurs, and no other method that would require a smaller

penetration of the annulus fibrosus is established yet, ongoing research should also include repair and reconstruction of the annulus.

Little is on the current market. The Inclose Surgical Mesh System has reportedly been used in more than 47 patients in both standard loupe-assisted and microscope-assisted discectomy as well as through endoscopic portal systems [96]. This system is composed of a braided mesh cylinder that is biocompatible and expandable. The basic material is polyethyleneterephtalate (PET) and can be used to support the soft tissue of the annulus.

The potential advantages of repairing the annulus following discectomy have been suggested previously [97-99] and might also be a useful adjunctive to nucleus replacement.

5.14 Summary and Conclusions

To evaluate the novel surgical procedure for total nucleus pulposus removal with arthroscopic shavers, specific experiments were designed and carried out for three different approaches: anterior-lateral, posterior-lateral and posterior access and compared to the standard discectomy. The parameters that were identified to be important for a successful removal were: total time of the surgical procedure, sustained balloon pressure, size of the created cavity and localization / centralization of the created cavity.

The average surgical time for the shaver method was 13,47 minutes and 20,1 minutes for the rongeur method, considering all three approaches. After an appropriate learning curve, nucleus removal via shavers could be a simple and time-saving method.

A balloon was inserted into the disc space, resp. into the created cavity and inflated with contrast medium under monitored pressure. The specimens of the shaver group were able to withstand greater pressures until extrusion of the balloon – average of 68,47 PSI as compared to the specimens of the rongeur group with a mean value of 29,88 PSI. This observation is probably mainly due to the smaller size of the surgical entry point.

The amount of injected contrast medium (in ml) and of polyvinylsiloxane (in g) into the disc space was documented. Greater volumes were injected into the specimens of the rongeur group, the average value was 4.64 ml liquid and 2,98 g Aquasil® respectively. For the shaver specimens, the mean values

were 2,15 ml liquid and 0,69 g Aquasil®. The cavities that were created with the rongeurs were clearly bigger in size.

X-rays were taken of all specimens with the contrast-medium filled balloon inside the disc and the center of the balloon calculated. A correct centricity of the cavity was seen in the anterior-lateral and posterior-lateral access rongeur groups. The results of the experimental shaver group showed a slightly posteriorly shifted but otherwise good left-right-centricity with regard to the entry point for the anterior-lateral access, and an unsatisfying outcome of the posterior-lateral approach, in which a proper centricity with regard to the entry point was achieved, but certain zones could technically not be reached with a straight shaver.

Considering that according to our results an as small as possible entry point is the key to higher intradiscal pressures being able to sustained and thus the likelihood of a new implant to stay in place being increased, a modification and new curved designs of shaver-instruments should be tested that might allow the removal of more nucleus material with arthroscopic shavers in a less invasive fashion, especially for the posterior-lateral approach to the intervertebral disc.

At the same time, more work should be done in the field of research of possible annular repair devices.

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Appendices

Group 4 experimental Shaver	Group 5 experimental Shaver	Group 6 experimental	Group 1 control Rongeur	Group 2 control Rongeur	Group 3 control
anterior- lateral	posterior- lateral	Shaver posterior	anterior- lateral	posterior- lateral	Rongeur posterior
L1/L2 498 G2	L1/L2 494 G2	L1/L2 509 G2	L1/L2 411 G2	L2/L3 523 G2	L2/L3 518 G2
L2/L3 501 G2	L2/L3 509 G2	L2/L3 494 G2	L3/L4 494 G2	L3/L4 501 G2	L2/L3 512 G2
L4/L5 523 G2	L4/L5 411 G2	L3/L4 505 G2	L3/L4 516 G2	L3/L4 514 G2	L3/L4 517 G2
L5/S1 509 G2	L5/S1 507 G2	L5/S1 501 G2	L5/S1 523 G2	L5/S1 411 G2	L5/S1 514 G2
L2/L3 522 G3 L3/L4 509 G3 L3/L4 521 G3 L4/L5 556 G3 L4/L5 472 G3 L4/L5 521 G3 L4/L5 518 G3 L5/S1 510 G3	L1/L2 521 G3 L2/L3 498 G3 L2/L3 521 G3 L3/L4 472 G3 L4/L5 505 G3 L4/L5 510 G3 L4/L5 517 G3 L5/S1 498 G3	L1/L2 517 G3 L2/L3 510 G3 L3/L4 518 G3 L4/L5 507 G3 L4/L5 509 G3 L4/L5 516 G3 L5/S1 556 G3 L5/S1 494 G3	L1/L2 507 G3 L2/L3 335 G3 L3/L4 510 G3 L4/L5 498 G3 L5/S1 518 G3	L1/L2 505 G3 L2/L3 516 G3 L3/L4 498 G3 L4/L5 512 G3 L5/S1 522 G3	L2/L3 411 G3 L3/L4 556 G3 L4/L5 514 G3 L5/S1 472 G3 L5/S1 521 G3
L2/L3 505 G4 L5/S1 512 G4	L4/L5 501 G4 L5/S1 516 G4	L3/L4 507 G4 L5/S1 517 G4	L5/S1 505 G4	L4/L5 522 G4	L4/L5 494 G4
G2 = degeneration grade 2 G3 = degeneration grade 3 G4 = degeneration grade 4					

Appendix 1: Distribution of Levels L1/L2 through L5/S1 and Grades 2 through 3 within the six groups

Specimen	No.:	523 L4/L5

Degeneration grade:

Procedure: anterior-lateral access shaver nuclectomy

2

Date of procedure: May 29 2006

TIME specimen was taken out of the freezer and put into the fridge:

(night before May 27, 20:30 PM)

TIME insertion of shaver: 10:49 AM

TIME start of shaving: 10:56 AM

TIME end of shaving: 11:10 AM

Actual shaving time: 14 minutes

Rotation speed:	Pressure:
800 rpm >>> 500 rpm	650 mmHg

Procedure notes:

shaver plugged in the beginning – and it was very difficult to get any flow!!

DATA COLLECTION

Balloon Testing

1st inflation:

- contrast fluid in syringe in cc: 7.4
- PSI at which balloon popped out: 54
- contrast fluid in syringe in cc: 6.0

2nd inflation:

contrast fluid in syringe in cc:	7.4
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inflation up to 48 PSI

contrast fluid in syringe in cc: 6.0

Procedure notes: pictures taken

X-rays (cranio-caudal and lateral views)

Distance from tube to specimen: 40 inches FFD Settings: 55 kV, 1.7 mAS, small filament, receptor none Processed as finger

Computer: Name = lab test / First name = 523 L4L5 / MRN = ORL523L4L5date

Aquasil Evaluation

AF 1	AF 2	AF 3	AF 4
NP 1	NP 2	NP 3	NP 4
	0.4391	0.1219	
NP 5	NP 6	NP 7	NP 8
	0.2106	0.0057	
AF 5	AF 6	AF 7	AF 8
0.0283	0.0511		

Appendix 2: Example of the Documentation of a Surgical Procedure and Evaluation