Surgical Innovation: Fracture Fixation Targeting Device

Vijidha Shree Rajkumar

Experimental Surgery, McGill University, Montreal

December 2016

A thesis submitted to McGill University in partial fulfillment of the requirements of the degree of Master of Science

Table of contents

Abstract

EN

This surgical innovation project aims to address the clinical needs present in the orthopaedics department at the Montreal General Hospital. This multidisciplinary group consists of business, engineering and experimental surgery Masters students. Together, the students underwent the process of innovation: from the identification phase to invention phase. From a broad spectrum of diverse clinical needs in various aspects of orthopaedic clinical and surgical practice, the group narrowed the scope to optimizing the intra-medullary (IM) nailing procedure for long bone fractures. The innovation team generated four innovative solutions - guide wire, novel bone drill, mini c-arm and nail stress sensors - to increase the efficiency of the procedure: the nail guiding, sizing, channel reaming, and the nail fixation portion of the procedure. As part of the concept-screening step in the identification phase, the team received feedback from surgeons, innovators, medical technology business representatives and professors to choose and optimize the final solution to the intra-medullary nailing procedure. The team's innovation is the Hawk-eye: Fracture Fixation Targeting Device that utilizes radio frequency to locate distal holes on the intra-medullary nails. This device aims to increase the efficiency of distal locking during IM nailing, while reducing the amount of radiation both surgeons and patient receives during fracture fixation.

FR

Ce projet d'innovation chirurgicale vise à répondre aux besoins cliniques présents dans le service d'orthopédie à l'Hôpital général de Montréal. Notre groupe multidisciplinaire se compose d'étudiants au niveau maîtrise en administration, ingénierie et chirurgie expérimentale. Ensemble, nous suivons le processus d'innovation: de la phase d'identification à la phase d'invention. D'un vaste éventail de besoins cliniques divers dans plusieurs aspects de la pratique clinique et chirurgicale orthopédique, nous concentrons notre étude à l'optimisation de la procédure de clouage intramédullaire (IM) pour les fractures des os longs. Nous produisons quatre solutions innovantes - fil de guidage, nouveau foret pour l'os, mini c-arm, et capteurs de stress des clous - pour accroître l'efficacité de la procédure: guidage du clou, dimensionnement, alésage du canal, et la partie de fixation des clous de la procédure. Dans le cadre de l'étape de sélection de concept de la phase d'identification, nous recueillons les commentaires de chirurgiens, d’innovateurs, de représentants d'entreprises de technologie médicale et de professeurs afin de choisir et d'optimiser notre solution finale à la procédure de clouage intramédullaires. Notre innovation est le Hawk-eye : Fracture Fixation Targeting Device qui utilise les fréquences radio pour localiser des trous distaux sur les clous intramédullaires. Ce dispositif vise à accroître l'efficacité du verrouillage distal pendant le clouage IM, tout en réduisant l’exposition à la radiation reçue à la fois par les chirurgiens et par le patient pendant la fixation

Acknowledgements

I would like to express my gratitude and appreciation to my Supervisor, Dr. Edward Harvey, without whom I could not have undertaken this innovative journey in the Experimental Surgery – Surgical Innovation program.

I would like to thank my program directors, Dr. Kevin Lachapelle and Dr. Jake Barralet, at McGill University and all other coordinators and supervisors from the John Molson School of Business and École de Technologie Supérieure. I would also like to thank the Orthopaedic Department at the Montreal General Hospital for their time and invaluable feedback for our project.

I would like to express my profound appreciation for my group members: engineers Avijit Das, Fernando Quevedo Gonzalez and Mariana Marroco Martinez, MBA students: Dr. Max Talbot and Jonathon Yeh. This multidisciplinary collaborative work would not have been possible without all of them. From the initial clinical screening to the final phase of invention, generating ideas to the analysis of results, we have explored the process of innovation together. This project is a result of all our efforts.

I would like to thank McGill University Graduate School and the department of Experimental Surgery for their support and guidance throughout the program.

Last, but most certainly not least, I would like to thank my mother, Uma Rajkumar, and brother, Iyengaran Rajkumar. Without my beloved family's support and unconditional love, my dreams and my goals thus far would not have been possible. They both are my blessings and inspiration.

1. Introduction

The Surgical Innovation program is offered to Experimental Surgery Masters students at McGill University and it is an introduction to the field of medical innovation. It is a multidisciplinary collaboration between business students from John Molson School of Business, engineering students from École de Technologie Supérieure (ETS) and experimental surgery students from McGill. This Surgical Innovation Masters provided hands-on learning experience for the students to develop skills necessary for the creation of novel surgical and medical devices.

The students were designated into their respective teams based on their preferences for either orthopaedic, cardiac or plastic surgery specialities. This team consisted of engineering students: Avijit Das, Fernando Quevedo Gonzalez and Mariana Marroco Martinez, MBA students: Dr. Max Talbot and Jonathon Yeh and lastly myself, Vijidha Rajkumar, an Experimental Surgery Masters student. Dr. Edward Harvey, an orthopaedic surgeon at the Montreal General Hospital, supervised the group for the innovation project and with his help the innovation group was able to make observations in both surgical and clinical settings in the hospital.

Innovation is a bottom up process, where invention of a prototype is determined by the needs that currently exist in the field [1]. The process of innovation can be broken down into three phases: identification, invention and implementation [1]. Through the course of this project, this team went through these specific phases to arrive at the Hawk-Eye prototype.

2. Identification

During the identification phase of innovation, the group first needed to identify the clinical needs in orthopaedic surgery. Needs finding is a process where innovators observe real people in their working environment to understand not only their clinical practice, but also the obstacles or difficulties the staff encounter in the field [1,2]. Only once the clinical needs have been identified can the current challenges be addressed through innovation.

Therefore, starting on September 18, 2015, the group performed a series of visits to the Montreal General Hospital (MGH) in Montreal, Quebec, to observe the clinical environment of surgical practice and follow-up trauma clinics and find current needs at the hospital. In particular, the group focused the observations on the sub-specialty of orthopaedic traumatology.

The group initially visited the fracture or trauma clinic, where patients come in for follow-up treatments after their clinical intervention. A variety of procedures were performed at the trauma clinic including cast application and disassembly, removal of stitches and surgical hardware from patients' surgeries, and medical imaging and assessment of patients' prognosis. In addition to visiting the trauma clinics, this group also observed trauma surgeries in the operation room at the MGH. The group had the opportunity to observe numerous different procedures including delayed fixation of a bi-malleolar ankle fracture, a fixation of a fractured tibia and a total hip replacement after a femoral neck fracture.

Over a hundred observations were made in these two settings – the OR and the trauma clinic – in order to analyze the clinical needs of orthopaedic practice (see **Appendix A**). From the variety of observations made to choose from, the group was then able to proceed onto the needs screening step of the identification phase.

3. Overview of Needs

The innovation group decided to narrow the observations based on which needs were identified as the most relevant to the field, challenging for the staff, and were within this group's fields of expertise. The twenty specific needs were chosen and each of them were further explored by the creation of detailed observation, problem and needs statement (see **Appendix B**). Below is the overview of the twenty clinical needs at the Montreal General Hospital.

1. Clinical Data Access for Doctors

Doctors in the fracture clinics had to shuffle back and forth between the patient rooms and the doctors' lounge to access patient records and scans on the computer.

Need: A way to provide doctors in the MGH with portable access to the patients' necessary health records and up to date scans in order to reduce the time needed to evaluate patients.

2. Clinic/Patient management

The trauma clinic at the Montreal General Hospital is not optimally organized. Patients are not prioritized and organized and therefore some patients who have their appointments at 8 am are not seen until 3 pm. The staffs also do not know where patients are inside the clinic.

Need: A way to improve patient management process in the clinics in order to increase their efficiency, time management and patient satisfaction.

3. Paperwork assistance

There are numerous forms and paperwork that needs to be completed by physicians after each patient visit in the trauma clinic, causing delays in between patient appointments and backlog.

Need: A way to improve the manner in which the medical staffs complete their paperwork in order to increase the efficiency of this task.

4. Mass Casualty Incidents Management Training

Hospitals regularly exercise mass casualty simulations to increase disaster preparedness. However, this process needs to become more efficient to adequately train the staff at the MGH.

Need: A way to increase medical staff preparedness in mass-casualty incidents in order to improve the handling of critical situations.

5. Post-operative Infection

Low-grade infection following internal fixation is difficult to diagnose. The clinical signs and symptoms are non-specific, laboratory tests are overly sensitive, and current imaging rarely provides useful information.

Need: In patients with orthopaedic implants, a technique to monitor the surgical site for infection, which allows the surgeon to take early intervention with surgery and/or antibiotics.

6. Telemedicine

MUHC's catchment area comprises a vast area of Northern Quebec that extends 1700 km north of Montreal. Trauma patients in this isolated location are at least 6-24 hours from a trauma center. Consequently, family physicians and nurses with limited resources are called on to manage trauma patients until they can be moved.

Need: A robust and interactive capacity that integrates all aspects of trauma care between the MUHC and remote areas in its catchment area to improve trauma outcomes.

7. Intra-operative Situational Awareness

Orthopaedic surgeons have limited real-time awareness of various physiological events during surgery notably blood loss; fat embolism load; oxygen saturation; and coagulation parameters. There is often a delay between an event being noticed by anaesthesia and the communication of this finding to the surgeon. In many cases, significant events are not communicated at all to the surgeon. This may result in inappropriate decision-making.

Need: A system to promote total surgeon awareness of intra-operative physiology to improve intra-operative decision-making.

8. External Fixation in Damage-control Surgery

In damage-control surgery, swift and coordinated actions by the general surgeon, vascular surgeon, orthopaedic surgeon and anaesthetist are required to ensure patient survival. External fixation is often required in these cases. The radiology equipment required for external fixation emits radiation; is cumbersome; heavy; and difficult to manoeuvre around the operating table. This slows the procedure and limits the mobility of all team members.

Need: A technique to apply external fixators safely and quickly while minimizing obstruction of the operating room.

9. Intramedullary Nail Fixation

When a patient is being operated for a tibia or femur fracture, an intramedullary nail is used to reduce and stabilize the fracture. The nail is fixated both distally and proximally with two screws on each side. Large amount of fluoroscopic images are taken to insert the locking screws for the intramedullary nail fixation, especially for the distal screws. During this trial-error procedure, the patient receives too much irradiation. Operation time is increased and often inaccurate screw placement that results in patient morbidity.

Need: A way to improve the accuracy of insertion of distal interlocking screws during intramedullary nail fixation, in order to reduce the operation time and to decrease the amount of radiation exposure.

10. Cast Application

In the Orthopaedic Clinic, when patients need their full-arm cast to be replaced, they need to hold up their own arm for a minimum of fifteen minutes for the cast to dry. Patients often voice their frustration during the procedure because of the fatigue and pain they experience, especially for the elderly population.

Need: A way to improve casting procedures that avoids uncomfortable posture and positioning of the patients and reduces their fatigue.

11. Pre-op Skin Preparation

The nurses sterilize the skin with iodine during the pre-operation preparation. During the procedure, the nurses need to hold up the patient's limb up while they apply the iodine and wait for it to dry. It is often complicated to perform because the limbs must be positioned properly while not harming the patient and reduces the available OR space.

Need: A way to simplify the skin preparation in surgical procedures, in order to decrease the fatigue of the medical staff and to improve the efficiency of the pre-op procedure.

12. Patient Transfer

When a patient is transferred from the operation table to the hospital bed, a minimum of five personnel is needed to lift the patient. Patients can undergo significant mechanical stress during patient transfers and moving patients in this manner may harm the patient or the staff performing it.

Need: A way to improve patient transfer between the surgical table and the hospital bed in order to avoid injuries to the patient and medical staff.

13. Undisplaced Fracture Diagnosis

Undisplaced fractures, a term that described when fractures radiate in different directions without the bone separating, are difficult to diagnose and often go unnoticed. The misdiagnosis of these fractures cause delays in treatment intervention and patient morbidity.

Need: A way to improve the diagnosis of undisplaced fractures that will allow the surgeon to identify the fracture and select the adequate treatments in its early stages.

14. Plunging Depth During Bone Drilling

Doctors have to rely on their experience and intuition to guide drilling procedures during long bone fracture fixations. They pierce through the cortex and sometimes plunge into the surrounding soft tissues since it is a free-hand technique. Plunging can result in damage to soft tissues, nerves and vessels.

Need: A way to reduce plunging with drill bits in order to prevent soft tissue damage and patient morbidity.

15. Peripheral Nerve Damage

Some surgical procedures can result in damage to the peripheral nerves. This secondary complication from surgery results in patient morbidity – including muscle paralysis, hypoesthesia and neurogenic pain.

Need: A way to visualize peripheral superficial and deep nerves in trauma patients that decreases accidental nerve damage due to surgery.

16. Nerve Grafting

Nerve grafting for peripheral nerve injury is less successful when longer nerve grafts are required. This often results in unsuccessful grafting procedure and has less predictable outcomes with an increased risk of nerve atrophy.

Need: A different methodology for repairing peripheral nerve damage in patients requiring long nerve grafts (>7 cm) that increases success of the surgical intervention.

17. Articular Cartilage Repair

High-energy trauma and/or articular incongruity can result in chondrocyte apoptosis and a loss in articular cartilage turnover. Cartilage damage can result in decreased range of motion, joint pain, and may progress to osteoarthritis.

Need: A method that can facilitate cartilage regeneration in patients with permanent joint damage.

18. Producing Implants

Implants, nails, and screws are available in numerous standardized sizes, which require a large space to house the diverse inventory. The ability to maintain an inventory can be a luxury to rural areas, developing nations, and mobile clinics.

Need: The ability for rural areas, developing nations, and mobile clinics to request and acquire necessary implants while circumventing the need for housing an extensive inventory.

19. Encouraging Bone Union in Arthrodesis

Ankle fusion occurs when there is bone union between the distal tibia and the talus. This complication requires the removal of the articular cartilage with an osteotome. However, this procedure is a meticulous and time-consuming procedure that is subject to significant variability.

Need: An automated means for surgeons to remove articular cartilage to obtain perfectly matching arthrodesis surfaces.

20. Critical Bone Deficit

Fractures that have large segmented bone defects present a situation where intervention (e.g. bone grafting) may be required to avoid delayed healing or non-union. Bone grafting is associated with inherent problems, such as limited availability, donor site pain, prolonged surgery time, and increased risk of infection.

Need: A suitable means that promotes proper bone union in patients with a critical-size bone defect, which avoids bone-graft associated morbidity

4. Factors for Needs Selection

From the twenty specific needs identified, the group further narrowed the scope into the five final needs. To become experts on the five specific needs, the innovation team performed a deep dive a second step in the needs screening process [1,2]. In order to guarantee the widest possible variety of needs, each team member voted for the four observations that they considered the most promising, amongst all the observations performed. Once the clinical needs were properly formulated through the twenty "observation-problem-need" statements, the team further evaluated each need. During the team meeting, each member presented their opinions on the twenty needs, and as a team, the five final needs were chosen based on the pre-set criteria described below (see **Appendix C**).

The same criteria was used for both the initial filtering of observations for the twenty specific needs and the selection of the five final needs:

1. Feasibility within one year: The group wanted to have the product specifications or a working prototype within the given time frame of one year for the innovation project.

2. Clinical relevance: The group wanted to confirm and validate whether the needs that were chosen do indeed address relevant clinical problems in orthopaedic practice.

3. Immediate impact on the surgical field: The group wanted to choose needs that can be addressed immediately, where the product can seamlessly integrate into the existing practise without pro-longed clinical trials.

4. Within the group's expertise: The group chose projects that were possible to successfully execute based on the team's background strengths in engineering and biomedical sciences.

5. Market: The group was mindful of the existing markets available for the innovations and its competitors.

5. Detailed needs

Using the criteria above, five specific clinical needs were chosen: better mass-casualty management training, optimising the intra-medullary nailing procedure, telemedicine healthcare access for remote areas in Northern Quebec, a method to promote bone union in patients with critical bone deficit and lastly, reducing plunging depth during orthopaedic bone drilling procedures. For the deep dive needs screening step, these five needs were investigated on their clinical characteristics, current state of the art or solutions, market dynamics, competitors, and stakeholder requirements for a specific solution [1].

Mass Casualty Management Training

"A way to increase medical staff preparedness in mass-casualty incidents in order to improve the handling of critical situations"

Mass casualty incidents (MCI) are an unfortunate reality in the present day from a diverse number of sources. Firstly, terrorist attacks and mass shootings are more frequent now than ever [3] and there have been numerous outbreaks in diseases such as SARS and Ebola recently [4]. Furthermore, natural disasters including hurricane Katrina, the tsunami of 2004 in the Indian Ocean, and the Tohoku earthquake and tsunami of 2011 have all been overwhelming for the healthcare systems [5]. Lastly, major accidents involving mass transit systems are always unforeseeable unfortunate events that the hospitals should be prepared to handle.

These incidents are in low frequency, but they do require high-acuity performance from the medical staff [4]. Training and drills have been shown to be essential for effective disaster response [6]. However, the retention of knowledge and preparedness are impeded by the low frequency of these kinds of events [5,6]. Hence it has become increasingly important to have regular drills and practice sessions of MCI events. Currently there are three kinds of training available:

Tabletop card game: Participants verbally walk through set-up scenarios with their index cards for the various stages of the game. Although the tabletop training event is typically held in a conference room with the coordinators and participants, it can be coordinated via tele-conference as well. This method of training has been argued as a cost-effective alternative to the live drills [7,8]. However, staffs at the MGH have reported that organizing this game still requires planning, facilitators, and resources such as meeting rooms or tele-conference facilities. One downfall of this system is that it can be hard to collaborate with experts outside the venue and it will be difficult to start over scenarios if mistakes are made.

Live drill: This is an exercise held at hospitals that integrates doctors, nurses, paramedics, police and actors as patients in practice MCI scenarios. This drill provides the best training and preparedness for real events [9]. However, holding a live drill requires a massive amount of planning and organization with many healthcare and community workers involved. The preparation time and execution time can take hours and thus, not ideal for the healthcare facilities or parties involved. Furthermore, it is very expensive to hold this exercise routinely. Therefore, it is usually only held annually, thus not frequent enough to keep the staff best prepared for a mass – casualty incident.

Simulation applications: There are few simulation applications for example, Arena simulation software and Advanced Disaster Management Simulator from ETC that can be used to mimic an MCI event. Depending on the application, it can be very sophisticated with advanced 3D graphics and AI engine to drive the simulation [10]. These applications are still cheaper than holding live drills and can simulate many different scenarios easily. It is advantageous for evaluating and improving preparedness before a full-scale drill. Some of these applications can support many features including how police, swat teams, and fire brigade handle an attack. However, setting up scenarios will still require time and expertise from coordinators. Another shortcoming of this solution is that participants cannot share and collaborate on scenarios, which is an important aspect in handling mass-casualty incidents.

The current solutions do not provide an integrated approach to collaborate with experts and professionals from outside the organized simulations and meetings. Simulation engines that can run the scenarios and provide a solution have not been identified. Moreover, a simulation engine that would allow changing one or more resources and seeing its impact on a solution for a scenario has not been developed. Next, there is no easy access to these simulations such as availability from app-stores. Finally, there is no integrated way to get feedback for a solution of a given scenario from outside experts [10]. These are all challenges the current solutions fail to address and this clinical challenge is in need of an innovative solution.

According to Medec, training of the healthcare staff has been identified as one of the driving forces with significant impact on healthcare system and industry. The MCI management training application is useful for doctors, nurses, paramedics, other medical practitioners, Hospital administration, police, firemen, and other emergency response teams [8,10]. Emergency Management Agencies (e.g. FEMA) and NGOs (e.g. Red Cross, MSF) will also benefit from this kind of simulation. The target availability of this app on various app-stores and the ubiquity of mobile devices should encourage professionals to install and use this app on a more regular basis.

Below, the group has identified the criteria or guidelines for a new innovation. The group has segregated the section into must – haves and nice – to –haves characteristics for the new solution.

Needs Criteria

Must-have	Nice-to-have
• Ease of use – same or better than existing solutions • Availability on mobile platforms. • Ability to share, compare and discuss scenarios • Cheaper than the existing applications	• Ability to add random patients and events into a scenario • Advanced 3D graphics to bring more reality in viewing • Simulation Engine to offer solution to a given scenario

Intramedullary nail fixation

"A way to improve the accuracy in the positioning of distal interlocking screws during intramedullary nail fixation, in order to reduce the operation time and the X-Ray dose received by the medical staff"

The standard treatment for the fractures of the diaphysis of long bones is the intramedullary nail fixation [11]. The system consists of a long rod inserted into the shaft of the long bones that fits within the cortical channel. The rod is fixed proximally and distally by a set of interlocking screws (*Figure 1*).

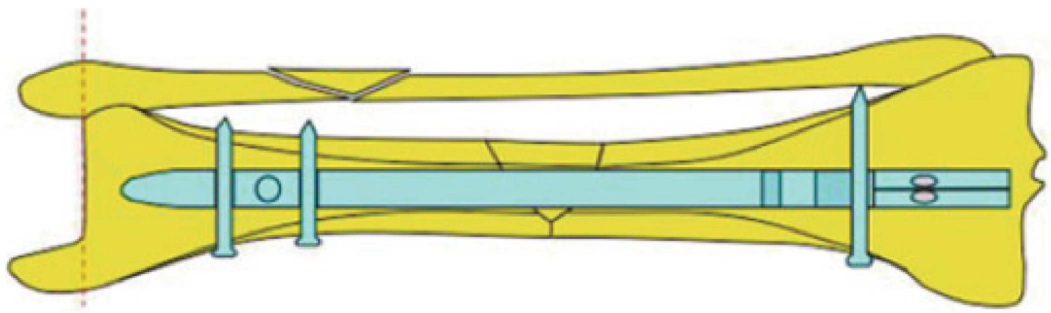


Figure 1 - Intramedullary nail inserted into the tibia (Rommens & Hessmann, 2015)[12].

While there are guides to help place the proximal interlocking screws, the distal screws are usually placed by the freehand technique, guided only by X-Ray images. The success of this trial and error technique largely depends on the skills of the surgeon and generally results in a large amount of X-Rays being taken, which prolongs the time needed for the placement of the distal interlocking screws compared to the proximal ones [13]. Chan et al, (2013) determined an average time per screw is 342 seconds with the freehand technique [14]. Yiannakopoulos (2005) found that using the freehand technique required on average 19 minutes to perform the distal interlocking procedure [15]. This accounts for half of the average duration of the operation of 43 minutes [16]. Additionally, on average, 28.4 radiographs were required for this procedure [15], which challenges the FDA white paper “initiative to reduce unnecessary radiation exposure from medical imaging” [17].

The existing techniques for placing the distal interlocking screws can be classified into six categories [13]: nail-mounted guides, comupter assisted screw placement, the free-hand technique, hand-held guides, image-intesifier mounted guide and self-locking nails.

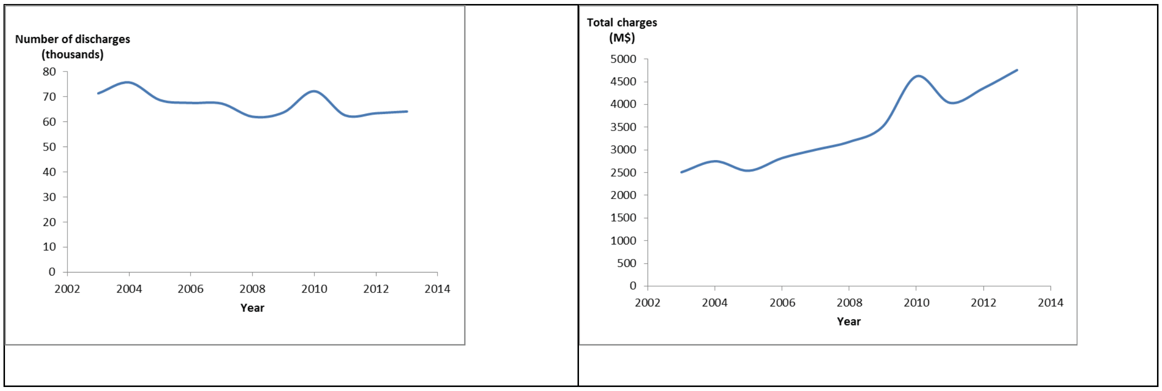
The nail-mounted guides consist of a jig similar to the one used for proximal interlocking screws, which help surgeons orient themselves and place the screws. However, their low bending and torsional stiffness lead to inaccurate positioning during the procedure [18]. Computer-assisted interlocking uses a computer for guidance. Currently, existing prototype have shown good outcomes in studies evaluating the device, however there have been no in-Vivo studies showing efficacy [19]. The free-hand technique is the most widely used technique in orthopaedic practice. Fluoroscopy is used to take X-Ray images that help assess the alignment of the drill to the holes. Conversely, each adjustment requires at least one X-Ray image, leading to prolonged procedure time and increased radiation exposure to patients and medical staff [20]. Next, the hand-held guides help the surgeon to correctly align the drill with the hole, while attempting to keep surgeon’s hands far from radiation [21]. Another options is the image-intensifier mounted guides that consist of guides directly mounted on the X-Ray intensifier, but have no proven benefits to the procedure or decreasing radiation exposure [13]. Finally, there are also self-locking nails that are essentially inflatable nails, which reduce the number of interlocking screws. They have shown lower surgery time and radiation [22]. Furthermore, they have good flexible stiffness, but the reduced torsion stiffness makes them not optimal for use [23].

The hand held guides have not shown larger precision compared to the freehand technique [21]. So far, none of the nail-mounted guides have been proven to provide satisfactory results from surgeons and staff [18]. It has been argued that the magnetic system used may constitute a good solution [19]. However, in its present form, it requires many accessories as well as a specific computer in order to be used [19]. Therefore, there is a need for a device that is not only easier to use, but also provides good accuracy during the screw placement part of the procedure [13].

According to the Agency for Healthcare Research and Quality, in 2013, a total of 64,110 fractures were reported for the femur and/or tibia /fibula. This excludes the reported fractures at the extremities of these bones. The combined cost for these injuries was 1283.9 M$ (Agency for Healthcare Research and Quality, 2015) [24].

The number of discharges related to shaft fractures has slightly decreased between 2003-13, as it can be seen in Figure 2 - a. The number of discharges in 2013 (64110) was similar to 2009 and only 10% smaller than in 2003 (Agency for Healthcare Research and Quality, 2015) [24].

However, the total charges have increased (Figure 2 - b), mainly due to the increase of the mean charges. This value of total charges is the amount charged by the hospital for the entire stay. It accounts for other cares different than the intervention itself, but it does not take into account the professional (MD) fees [24].



a **b**

Figure 2 – a) Evolution of the number of discharges b) The total hospital charges in the 2003-13 decade (Agency for Healthcare Research and Quality, 2015) [24].

Below, the group has identified the criteria or guidelines for a new innovation for the intra-medullary distal interlocking device. The group has segregated the section into must – haves and nice – to –haves characteristics for the new solution.

Needs Criteria

Must-have	Nice-to-have
• Required radiographs <= 15 • Required time < 234 seconds • Easy to set-up/manoeuvre.	• Moderate cost • Integrates with existing technology

Telemedicine

"A robust, seamless and interactive system that integrates all aspects of trauma care between the MUHC and Nunavik"

The MUHC's catchment area includes vast isolated areas, including the James-Bay region and Nunavik. Just the Nunavik landmass has a land area of 443,684.71 km^2. The region is sparsely populated; most inhabitants live in small coastal communities accessible only by aircraft. In these locations, medical care is provided by family physicians or nurse practitioners [25]. Currently, the province has two Challenger aircraft, which are used to evacuate patients to a higher level of care. These aircraft are constantly tasked, which results in unpredictable delays in evacuation (generally 6-24 hours) [26]. In addition, weather conditions in the northern Québec can create significant flight restrictions. A similar situation is present in all of the Canadian arctic [27, 28].

Within the realm of trauma and orthopaedics, two types of cases would benefit from a more robust telemedicine capability. The first consists of polytrauma patients who require resuscitation. In these cases, the time between the injury and evacuation is critical and may include many lifesaving manoeuvres [29]. Local physicians and nurses may benefit from the tele-presence of a surgeon during these procedures. The surgeon may guide them during standard trauma resuscitative procedures such as intubation, chest tube insertion, ventilator adjustments and point of care ultrasound. Eventually, the guidance could also be extended to include life or limb saving surgical procedures such a fasciotomy and evacuation of intra-cranial hematomas [28, 30]. The potential benefits include a reduction in mortality and morbidity by improving continuity of care and improve the quality of trauma resuscitation. The second type of case consists of isolated injuries, such as closed extremity fractures. Many of these cases do not require surgery and can be successfully managed locally with input from subject matter experts. In this case, the surgeon may directly telementor the local physicians during non-critical procedures, such as fracture reduction, cast application and wound exploration [29-31]. For this second category of cases, the benefits would include improved patient satisfaction (less travel) and economic benefits to the health care system.

This needs project could align well with the strengths of the team, the timeline for this project and the core goal of having an immediate impact for trauma patients within McGill's Réseau Universitaire Intégré de Santé.

The use of telemedicine for these indications is not without precedent. A simple system allowing transfer of images and clinical information has been shown to reduce unnecessary transfers to neurosurgical centers in developing countries [32,33]. The University of Alabama's Virtual Interactive Presence and Augmented Reality (VIPAR) system provides surgical-quality video that allows telementoring in neurosurgery and orthopaedics [34-36]. Other investigators have shown preliminary success in telementoring damage-control laparotomy in a medical simulation setting [37]. Another existing technology is MyDocs, a telehealth software package [38].

There is currently no cheap, app-based solution for telemedicine. The existing systems are software packages for large organizations, not for individual providers. This significantly limits its use and accessibility in remote areas in need of similar solutions.

One study conducted at MUHC showed > $4 million CAD in savings over a five year period using e-mail consultations for extremity trauma [39]. While there are competitors in the market, there is place for new products. Specifically, including high definition action cameras, which would allow tele-presence during surgical procedures using widely available, low-cost commercial devices, may improve existing technologies. Additionally, adding a research database option that would allow surgeons to create injury registries would be an interesting improvement that can guarantee market quote.

Below, the group has identified the criteria or guidelines for a new innovation for telemedicine. The group has segregated the section into must – haves and nice – to –haves characteristics for the new solution.

Needs criteria

Must-have	Nice-to-have
• Functions on mobile platforms. • Uses widely available commercial products (GoPro, iphone, etc). • Live-streaming video. • Encryption. • Ability to send x-rays and lab data.	• Reminders for patient follow-up. • Fracture registry (for research).

Critical bone deficit

"A suitable means that promotes proper bone union in patients with a critical-size bone defect, which avoids bone-graft associated morbidity"

Critical-size defects (CSDs), are large-scale defects of fibrous non-union and were initially defined as "the smallest size intraosseous wound in a particular bone and species of animal that will not heal spontaneously during the lifetime of the animal" by Schmitz and Hollinger in 1986 [32,33]. Simply put, CSD occurs when the defect is too large to heal with bony tissue and hence these non-unions require medical assistance. It should be noted that there is a difference between the biology of a bone defect that is healing, but has not completely healed and the defect that has filled with fibrous tissue and will never heal [32]. Clinically, the term "non-union" is given to a defect that is not healed within 8 months of injury [33], but the decision to intervene surgically is to the discretion of individual clinician.

Segmental long bone CSDs can be caused by several injuries such as high-energy trauma, infections, or cancerous bone tumours requiring surgical removal. CSDs were initially described as a means to standardize the testing of bone repair materials that could be used as alternatives to bone allo or autografting, which are associated with inherent problems such as limited availability, donor site pain, prolonged surgery time, and thus an increased risk of infection [34]. The need for such a standardized framework to study CSDs stemmed from the differing animal models studied by every researcher, which made comparison among studies almost impossible. Currently, CSDs remain a model of fibrous non-unions to test BRMs, cellular therapies, and other bone replacement strategies. Clinically, CSDs remain an unmet need for clinicians looking to reduce donor graft-derived morbidities [32, 34].

In cases where different treatment options are available, the choice must take into account the cause, size, and location of the defect. Pre-existing patient risk factors such as immune compromise and osteoporosis can affect the surgical outcome resulting in delayed bone healing, cartilaginous non-unions, or infection. Ideally, treatment options should provide three essential characteristics: osteoconductivity (promote in-growth of local capillaries and attachment of osteoblasts and osteocytes), osteoinductivity (stimulate the osteocytes to form bone), and osteogenic potential (containing cells that can differentiate into osteoblasts and form new bone) [35]. In orthopaedic reconstruction, nonunions are debrided and a new bone defect is created and treated, often by a bone autograft. Bone grafting continues to be the gold standard for bone healing and restoration. However, in addition to donor-associated morbidities, problems can develop at the graft site due to stress fracture, bone resorption, and nonintegration of the graft. Adverse effects can occur at the donor site, including hematomas, bone fractures, infection, and nerve injury [34]. Allogenic bone grafts from human cadaver sources circumvent many donor site complications, but present their own set of complications due to reduced revascularization, increased bacterial and viral infection, and immune rejection. When all other options are exhausted, amputation also remains a viable treatment albeit one of last resort.

Calcium phosphate ceramics, such as hydroxyapatite or tricalcium phosphate have been used as synthetic graft substitutes [36]. These bone substitutes must incorporate materials with structural properties that encourage bioactivity, osteoconductivity, osteoinductivity, and osteogenesis, while ensuring sufficient mechanical stability and compressive strength [36]. A major concern with engineered tissue is a lack of vascularization to nourish the implant and promote integration. Scaffolds that do not fully integrate can cause delayed healing, future fractures, and cartilaginous non-unions. As a result, these approaches can incorporate osteoconductive extracellular matrices, osteoinductive proteins, and/or osteogenic progenitors. In certain cases growth factors have been used to promote the abovementioned characteristics. Specifically, BMP2 and BMP7 have been FDA approved but treatments require supraphysiological dosages and outcomes have been inconsistent [34].

The current gold standard treatment for CBD requires autograft from patient's iliac crest, which are expensive and associated with donor site injury and morbidity. Bioengineered grafts do provide limitless potential, but fundamental challenges limit its adoption including basic research and the need to select most effective materials, scaffolds, cell types, growth factors and so on [40]. Clinical challenges associated with bioengineered scaffolds also exist such as evaluating possible side effects and evaluating growth at implant site. The aforementioned challenges require clinical trials prior to Health Canada/FDA medical device approvals, which is a prolonged process. Statistics report show that there were 2.2 million orthopaedic procedures [41]. It is quoted as a 2.5 B$ Industry where the BMP products: 5ml could cost up to 5 k$ [41].

Below, the group has identified the criteria or guidelines for a new innovation for the critical bone deficit clinical challenge. The group has segregated the section into must – haves and nice – to –haves characteristics for the new solution.

Need criteria

Must-have	Nice-to-have
• Applicable to at least 50% of relevant cases • Must provide osteoconductivity, osteoinductivity, and osteogenesis	• Must take less time to use than autograft procedure • Must be cost-effective, nice to be cost-saving

Plunging During Bone-Drilling

"A way to reduce the plunging depth in orthopaedic surgeries in order to prevent soft tissue damage and patient morbidity"

One common medical device orthopaedic surgeons employ to stabilize fractures and reconstruct the musculoskeletal system are bone-drills [42]. Drilling is used to create channels for the screws and orthopaedic devices to fix the bone and it is one of the fundamental orthopaedic skills learned by the professionals in the field. The amount that the drill projects past the cortex of the distal surface is called the plunge depth. It is common for even experienced surgeons to plunge over 5 mm with ideal conditions such as healthy bone with new drill tips [43]. In non-ideal conditions, surgeons have reported plunge-depths of up to 21 mm [43]. Plunging is a relevant clinical complication during surgical practice because it can result in soft tissue damage and damage to vessels, nerves and tendons in the affected area. Thus it can be a detrimental factor when treating patients, especially vulnerable populations such as the elderly with osteoporotic bone [44]. There is a need to decrease iatrogenic injuries in orthopaedic trauma and surgery from plunging.

Orthopaedic surgeons attempt to decrease the plunge–depth through various ways. Primarily, surgeons learn to get better at the procedure and have increased intuition about drilling through surgical practice [45]. By performing more procedures, they are better able to judge when they will pierce the cortex. Furthermore, multiple studies have also shown that surgeons use their sensory cues as well. For example, surgeons are able to approximate bone density from the pitch of the drilling [46].

Controlled penetration drills are commonly used in cranial surgery. They are successful in preventing the plunging of the drill into the brain and yet, their use has not been extended to the orthopaedic field [46].

Smart Medical Devices is a company specialized in controlled drilling and depth measurement applied to the medical field. They have the technology SMARTdrill (US8821493B2) that automatically stops after the second cortex and allows for measuring the depth [47]. The technology is based on the measure of the applied torque. The information is displayed on a screen, allowing for the monitoring of the bone density. No data about actual medical use was found - only in Vitro testing have been conducted thus far. Additionally, no information about the possibility of diaphyseal drilling was found [47].

To begin, better control of plunge-depth would decrease patient morbidity [42]. It has been reported that the high sound level in operating room makes it unfeasible to use auditory cues from the drilling of the bone [45]. However, the existing stand-alone drill bits with automated control haven not been applied to long bone drilling procedures; no controlled-depth drill-bits found for long bone. The competitor, SMARTdrill, is described as bulky and requires dedicated drill and computer for monitoring [47].

In the US, in 2013 a total of 235,335 discharges were related to bone fractures, resulting in more than 14 thousand M$ in hospital charges (excluding the professional fees) (Agency for Healthcare Research and Quality, 2015) [24]. These fractures involve, in general, drilling of the bone for screw placement, whether they are treated with a fixation plate, an intramedullary nail or an external fixator.

There have been innovations in preventing plunging in neurosurgery due to the extreme adverse effects on plunging into the dura and pia mater, which can induce brain damage [46]. However, currently there are no similar efforts taken in the orthopaedics field.

Below, the group has identified the criteria or guidelines for a new innovative bone drill. The group has segregated the section into must – haves and nice – to –haves characteristics for the new solution.

Needs Criteria

Must-have	Nice-to-have
• Plunge depth <= 2 mm. • Automatic stop. • Easy to operate. • Sterile. • Manually override.	• Usable with existing drills. • Drilled depth measurement. • Power-independent.

6. Conclusion of Needs Finding & Screening

To conclude the needs finding and screening step, the visits to the hospital resulted in an adequate number of clinical observations and needs. The number of clinical needs have been narrowed down to the five needs presented in detail in this paper. Preliminary research in existing technologies and market had been performed for these five needs. The next steps included more detailed research, with the establishment of an evaluation grid that helped choose the final needs to be developed.

7. Invention: Concept Generation

Amongst the five detailed clinical needs, the team narrowed down the scope to focus on one final clinical need. To do so, the ideas were presented to the supervisors at McGill, ETS and John Molson School of Business and received their feedback. Following the comments from the presentation, the team decided to select the need: *A way to improve the accuracy in the* *positioning of distal interlocking screws during intramedullary nail fixation, in order to reduce the operation time and the X-Ray dose received by the medical staff.* However, the team was encouraged to redefine the original need in order to cover larger scope of problems. Therefore, from the restricted field of distal interlocking for intramedullary nail fixation, the team moved to the wider field - the intramedullary nail fixation procedure as a whole. This also allowed for innovative ideas in the nail guiding, sizing, channel reaming, and the nail fixation part of the procedure.

Original Need

"A way to improve the accuracy in the positioning of distal interlocking screws during intramedullary nail fixation, in order to reduce the operation time and the X-Ray dose received by the medical staff"

Reformulated need

"A way to improve the intramedullary nail fixation procedure in order to reduce the operation time and the X-Ray dose received by the medical staff"

Needs Criteria

Redefining the need also required updating the must-have and nice-to-have criteria. Due to the broadness of the new redefined need, these new criteria must be applicable to all the steps of the intramedullary nail fixation procedure. The new criteria are shown in *Table 1*.

Table 1 – Must-have and nice-to-have for the final need

Must have	Nice-to-have
• X-Ray visibility • Easy to use • Visible/audible indication/alarm • Reduction in number of X-Ray necessary • Reduction in operation time • Compatible with existing products / universal	• Reutilization • Easily integrates within the current procedure • Small/compact

8. Concept Generation: Strategic vision

The innovation team had a product-based strategic vision. This meant that the main objective was to produce a device that can be manufactured and commercialized. This would not limit this innovation project to the patent strategic vision [1] – nonetheless, in order to protect this product, a patent is needed – however, the team focused on concepts that could be taken further than the patent step, such as a working prototype or product specifications for the biomedical device.

9. Background: Innovation field

In Canada, it is reported that fractures in long bones make up almost half of all incident fractures. Among all non-vertebral fracture sites, fractures in the hip/femur are the most prevalent at 28.7% [48], while 16.4% are found in the shoulder/humerus, and 4.0% in tibia/fibula. In 2013, a total of 64,110 femoral and/or tibia /fibula fractures were reported in the US (Agency for Healthcare Research and Quality, 2015) [49], while in Canada the number of cases is estimated to be ~10% of this number or approximately 20 per 100,000 people. In Canada, hip/femur fractures were found to be the most expensive non-vertebral fractures resulting in mean direct costs of $11,146 per patient with indirect costs at $4,053 per patient for a total cost of $15,199 per patient or ~$90M in Canadian healthcare expenditures per year [48]. In contrast, tibia /fibula fractures were found to have a mean direct cost of $7,857, indirect costs of $3,279, for a total cost of $11,136 per patient. The standard treatment for the fractures of the diaphysis of long bones (e.g. femur, tibia, fibula) is the intramedullary nail fixation protocol [50] and it is improvement in this procedure that is the focus of this team's innovation.

Background: Nailing procedure

Since the 1990s, intramedullary nailing has become firmly established as the standard of care for diaphyseal fractures of the femur and tibia [50,51]. With fracture union rates greater than 95%, minimally invasive insertion, and the possibility of immediate post-operative weight bearing, IM nailing is arguably the finest procedure in modern fracture surgery. Although the nail and the instruments used for the procedure slightly differ from one manufacturer to another, the surgical steps are consistent and are summarized below.

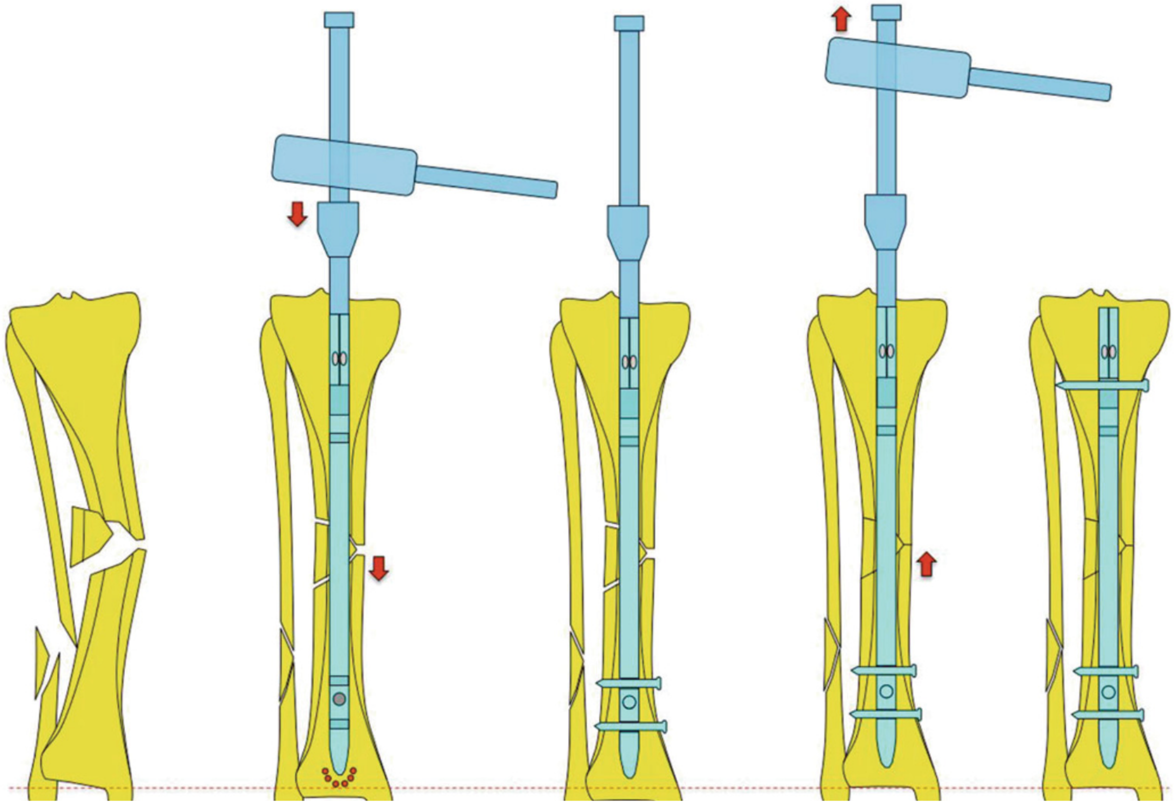


Figure 3: Intramedullary nailing procedure (Rommens & Hessmann, 2015)[12].

1. Insertion of a threaded guide in line with the intramedullary canal: this is done at a precise location in the proximal tibia or femur, under fluoroscopic guidance (Figure 3).

2. "Opening" of the canal with a large bore entry reamer [52].

3. Insertion of the guide wire in the canal: the guide wire crosses the fracture site allowing the alignment of the fragments, and goes all the way down to the distal metaphysis. This wire is the key to the procedure since it allows the passage of all subsequent instruments in the intramedullary canal (Figure 3).

4. Reaming of the canal: the previously inserted wire guides subsequent larger reamers. Typically, the canal (whose diameter is typically smaller than 8 mm) is enlarged to approximately 1mm larger than the nail diameter.

5. Choosing the nail size: multiple techniques exist to measure the appropriate length of the nail. The most common are the double wire technique and the use of commercial rulers. Each of these techniques results in regular measurement errors, leading to the potential waste of implants.

6. Nail insertion: this step depends also on the guide wire.

7. Proximal locking: locking screws are inserted percutaneously with a proximal guide that allows precise alignment with the nail holes [53].

8. Distal locking: the distal bolts are generally inserted via a “free-hand” technique, which involves aligning a drill bit with the interlocking holes with image intensification (X-Rays). This part of the procedure is responsible for a significant proportion of the radiation exposure sustained by the surgeon, particularly to the hands [54], and prolonging the procedure time.

9. Final verifications: after nail insertion and interlocking verified, final images are taken to confirm proper alignment of the femur in the sagittal and coronal planes as well as appropriate length and position of all implants [54].

Equipment

Intramedullary nails

The most commonly used nails consist of a rod having locking screw holes close to both ends, in multiple orientations, to allow for stable fixation. The nails can be either solid or cannulated (hollow) and different cross-sections can be found. The commonly used nails have diameters from 8 to 15 mm and lengths from 240 to 420 mm, depending on the manufacturer.

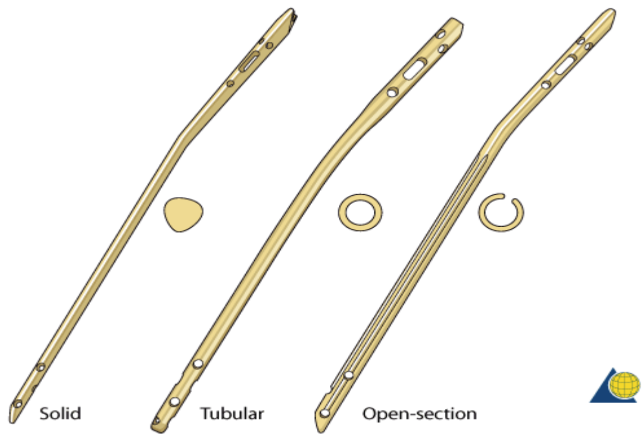


Figure 4: Different types of nails available (Hessmann, Nork, Sommer, & Twaddle, 2008) [53]

Even though other designs exist, such as self-inflatable nails or self-locking, they are less commonly used.

Guide wires

Wires consist of a long, thin rod that generally has a ball tip. The tip can be manually bended, which helps passing though the fracture site. The ball on the tip stops the reamer. Wire diameter and length varies depending on the manufacturer. For example, the dimensions from the three main manufacturers are shown in

Table 2. Other guide wires can also be found, with diameters ranging from 2.5 mm to 3 mm.

	Diameter (mm)	Length (mm)
Stryker (femur)	3	1000
Stryker (tibia)	3	800
Synthes (femur)	3.2	400
Synthes (tibia)	3.2	400
Zimmer (femur)	3.0	1000
Zimmer (tibia)	3	950

Table 2 - Typical diameter and length of guide wire

Reamers

Reamers are flexible and have an end with sharp edges and deep flutes so the canal bone can be easily cut without increasing the pressure in the canal or excessively heating the bone. Two types exist: cannulated-motor driven and solid-hand driven reamers. Figure 5 shows a solid hand reamer (left) and a power reamer (right).

Figure 5 - Solid hand reamer (left) and a power reamer (right) (Hessmann, Nork, Sommer, & Twaddle, 2008) [53]

Length measurement devices

Length measurement is commonly made with the help of a ruler, placed over the bone. An X-Ray image would then show the ruler superimposed to the bone and the length can be directly read on the rule. Canal length gauges also exist, which allow direct measurement of the length. Finally, another common technique involves a second guide wire having the same length of the original (double wire technique), where the wire is placed at the entry point and the length difference between both wires represents the proper nail length.

Locking screws

Locking screws have diameters between 3.9 and 5 mm. The length (commonly between 18 and 120 mm) is chosen so that the screw will pass both cortex but without protruding onto close soft tissues.

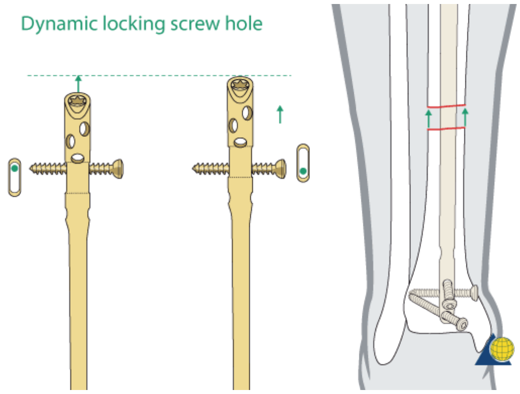


Figure 6 - Locking screws (Hessmann, Nork, Sommer, & Twaddle, 2008) [53]

Nail locking

Nail locking aims at providing enough stability so that the fracture can heal. The number of proximal and distal screws varies, but it is usually more than two. This choice usually depends on the fracture pattern. In general, proximal locking screws are inserted first using guides, which have become the standard for proximal locking screws. These guides facilitate the task and shorten the time needed to complete this step.

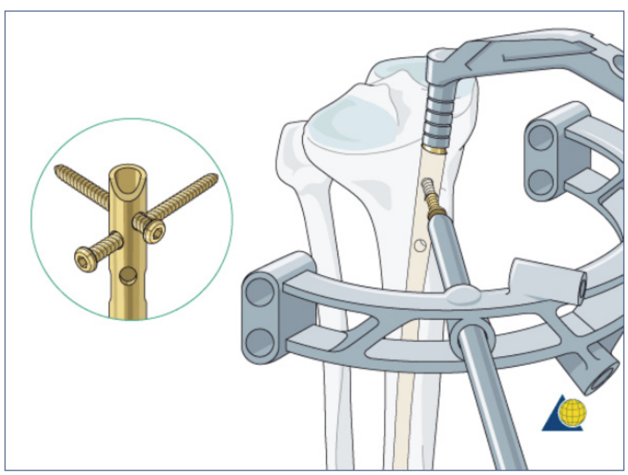


Figure 7 - Guided proximal locking (Hessmann, Nork, Sommer, & Twaddle, 2008) [53]

On the other hand, distal interlocking is far more complicated, especially due to the long distance to the entry point and the instability of the distal part from the fracture. Several techniques exist for this step [55]: nail-mounted guides, which show low bending and torsional stiffness; computer-assisted guidance, that has not proven in Vivo results; free-hand technique , which is the most used technique and is X-Ray intensive; hand-held guides, that try to keep surgeons' hand far from radiation; image-intensifier mounted guides , directly mounted on the C-arm; self-locking nails, which show reduced torsional stiffness [55, 56].

Identification and evaluation of areas for innovation

The items in Table 3 were identified as possible niches for innovation in intramedullary nail fixation. Each point was assigned a score, from 1 (best) to 5 (worst), in four different categories of improvement:

- **Time:** reflects the expected gain in the procedure time that will be obtained with an improvement in the item.
- **X-Ray:** accounts for the expected dose reduction obtained with an improvement in the item.
- **Material:** accounts for the expected material waste/use reduction with an improvement in the item.
- **Space:** reflects the expected space gain in the operation room with an improvement in the item.

Table 3 – Fields for innovation

(Least score is better)	Time	X-Ray	Material	Space	Total
Length measurement	5	4	1	5	15
Screw location/alignment	1	1	5	1	8
Depth stop and measurement	4	5	4	5	18
Guide wire guidance	2	2	5	5	14
Is reamer at the end?	3	3	5	5	16
Fracture heal detection	3	3	5	5	16

The scores were assigned based on the study of the current procedure and validated by medical expertise. The total score was used to identify the priorities for innovation. In this way, the screw location was identified as the most promising item for innovation, while the automatic depth stop and measurement while drilling was identified as the least promising.

10. Brainstorming

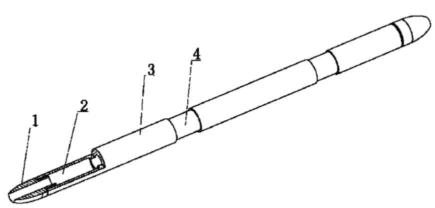
By choosing the intramedullary nailing procedure as the final need, the group needed to employ brainstorming sessions to reformulate the need. The innovation team held a total of four group brainstorming sessions regarding idea generation, concept generation, organizing ideas into concepts [1]. Please see **Appendix D** for a mind map of the results from the brainstorming sessions.

From the brainstorming session, the team generated four possible medical devices that could optimize the intramedullary nailing procedure: guide wire, novel bone drill, mini c-arm and nail stress sensors. Below is a detailed description of the team’s innovation proposals.

Guide wire

As previously mentioned, the length of the intramedullary nail is critical (mistakes lead to nail waste and increased operation time) and yet the process of determining this length (by a radiographic ruler or the two wire technique) is inaccurate and particularly cumbersome [57]. On the other hand, external pressure is applied to align the fractured fragments and allow the wire to pass the fracture site. The slight bent of the tip of the wire helps during this stage. However, even with this aid, the step can be time-consuming, especially if the fracture is severe enough (i.e. misaligned). In addition, in extreme cases, X-Ray images are needed to help with the fragment alignment.

Existing Technologies/ Patents



This is a patented guide wire in China (CN202105018U) with hollow guide chamber (elastic pipes), steel locking caps at the end [58].

The team's proposed solution (Figure 8) consists of a guide wire that would have markers indicating the nail length. These markers would be at least radio-opaque, so that the surgeon can directly measure the length on the X-Ray image. Ideally, the markers would be visible without X-Rays. This can be made either with RFID technology, where a reader provides the length based on RF tags placed on the wire; with visible markings -- in a similar way to the canal length gauge -- or with an external sensor that detects the amount of wire that has been inserted.

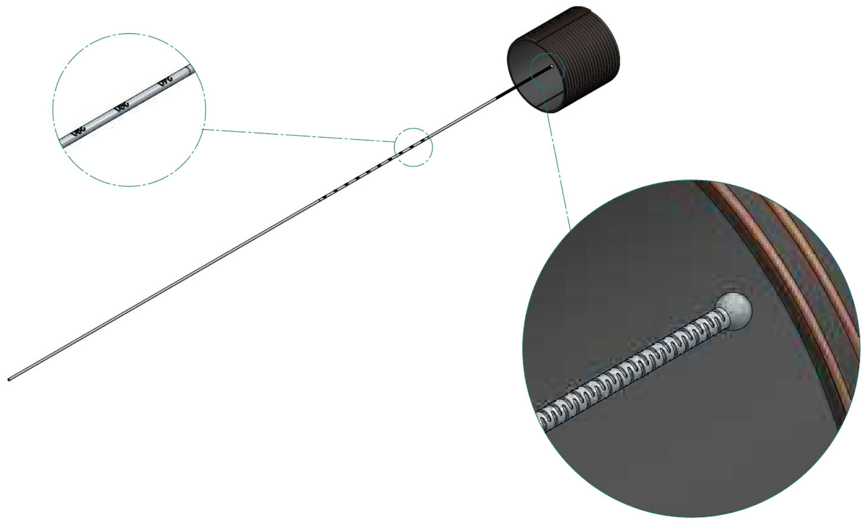


Figure 8 - Guided wire concept

The tip of the wire would be modified in order to include a strong magnet (made of Neodymium), and to allow bending. The bending would be obtained with a special design that combines lateral flexibility with axial stiffness. An external magnetic device (a solenoid) would generate an axial magnetic field large enough to guide the magnetic tip (Figure 9). This device would be easily placed and adjusted on the leg of the patient, over the fracture site and can be selectively turned on and off by the surgeon. When on, the external device would generate a pulsed magnetic field, so the guidance is done in a step-by-step manner. The strength of the magnetic field (i.e. strength of the guiding force) would be also adjustable. Thanks to the added flexibility at the tip of the wire, large misalignments fracture can be overcame.

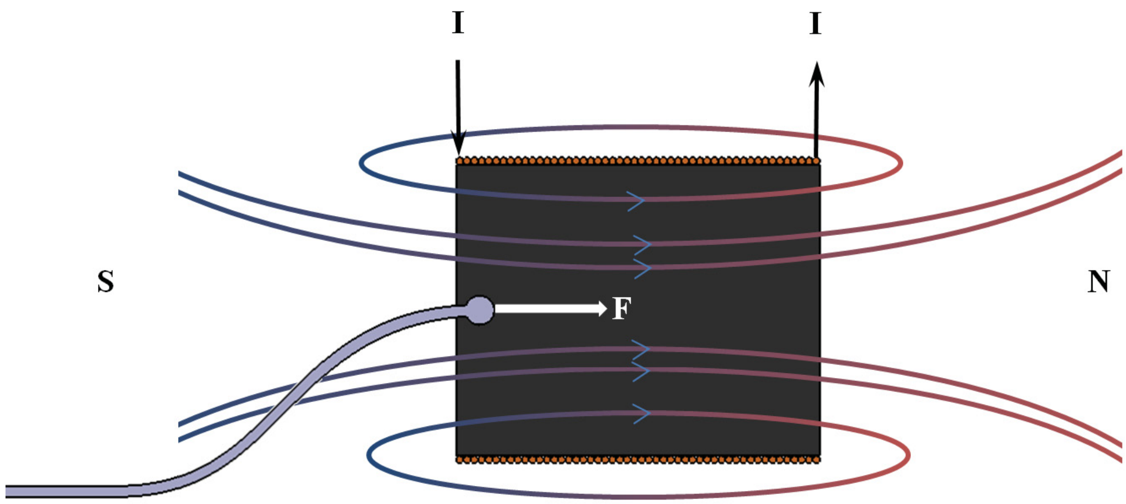


Figure 9 - Guidance by the external magnetic device

The working principle for this device was tested with a simple montage: a solenoid was built and the attraction on a neodymium magnet was tested on air (which has lower magnetic susceptibility than human tissues). With a small current, the test device was able to exert enough force on the magnet to deviate it from the resting position.

Based on Health Canada's guide for the Risk-based Classification System, the wire would constitute a short-term (30 days) surgically invasive device and since it is not intended for the use on the cardio-vascular or central nervous systems, neither it is intended to be absorbed by the body, it would be a class II device (rule 1). On the other hand, the external device does not emit ionizing radiation, but since it is connected to a class II device, it would be at least a device of the same class (rule 7). None of the other rules apply to this device.

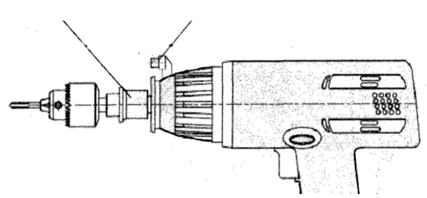
Novel Bone Drill

One common medical device orthopaedic surgeons employ to stabilize fractures and reconstruct the musculoskeletal system are bone-drills. Drilling is used to create channels for the screws and orthopaedic devices to fix the bone and it is one of the fundamental orthopaedic skills learned by the professionals in the field.

However, the bone drills commonly used in practice can be substantially improved through innovation to further aid the orthopaedic procedures. Currently there are no safe guard mechanisms to prevent plunging from the drilling process when fixing screws. The amount that the drill projects past the cortex of the distal surface is called the plunge depth. In non-ideal conditions, when surgeons use dull drill bits, they have reported plunge-depths of up to 21 mm [55]. Plunging becomes a clinical complication during surgical practice because it can result in soft tissue damage and damage to vessels, nerves and tendons in the affected area. Furthermore, bone drilling causes an increase in bone temperature and above the critical temperature of 47°C can actually cause bone necrosis [59,60]. This causes further patient morbidity and prolongs patient recovery. Lastly, measurement of bone depth is necessary for screw insertion during tibial fixation [55]. Currently a depth gauge is implemented for measurement, which is a time consuming and inefficient process.

Existing Technologies/ Patents

Smart Medical Devices is a company specialized in controlled drilling and depth measurement applied to the medical field. They have the technology SMARTdrill (US8821493B2) [57] that automatically stops and allows for measuring the depth.



This intelligent bone drill patented in China (CN201384531Y) [58] has speed, pressure and torque sensors, which was created to prevent plunging.

The aim was to innovate a novel bone drill that addresses these insufficiencies stated above. The innovation team would add sensors on the drill so that it stops when it reaches the desired depth without causing damage to the soft tissues. It would also come with disposable drill bits to prevent reusability. It should also give the depth of the screw required. Lastly, a temperature sensor would be added on the tip of the drill to let the surgeons know if it reaches a critical temperature during drilling or reaming and a built in cooling system to prevent necrosis of bone tissue.

Must – have	**Nice – to – Have**
• Temperature measurement • Disposable drill bit • Self-stopping	• Depth measurement

Mini C-arm

Currently, the retrieval of positional information about the intramedullary nail procedure in order to place the distal screws is currently mainly based on X-Rays and physical guides (jigs). These techniques can be cumbersome, time-consuming and, in the case of X-Rays, represent a risk for the safety of the medical staff, which requires taking additional security measures.

Existing Technologies/ Patents

The existing US patent (US6234672B1) [59] for a mini C-arm apparatus, used for X-ray fluoroscopic imaging. The innovation team proposed a device (Figure 10) that will easily help locate the distal holes of the nail based on RF magnetic signals. These signals are known to be able to traverse the human tissues but to be blocked up to 53% by titanium implants [60, 61]. This will allow determining whether the device is aligned with a hole or not. In addition, this could help determining whether the reamer has reached the endpoint or not. The device will be small and easy to use and will have an indication when the device is properly aligned with the axis of a hole in the nail. A hole in the device will allow the drill to perforate perfectly aligned with this axis. Three configurations will be possible: hand held use, attached to the drill and attached to the operating bed.

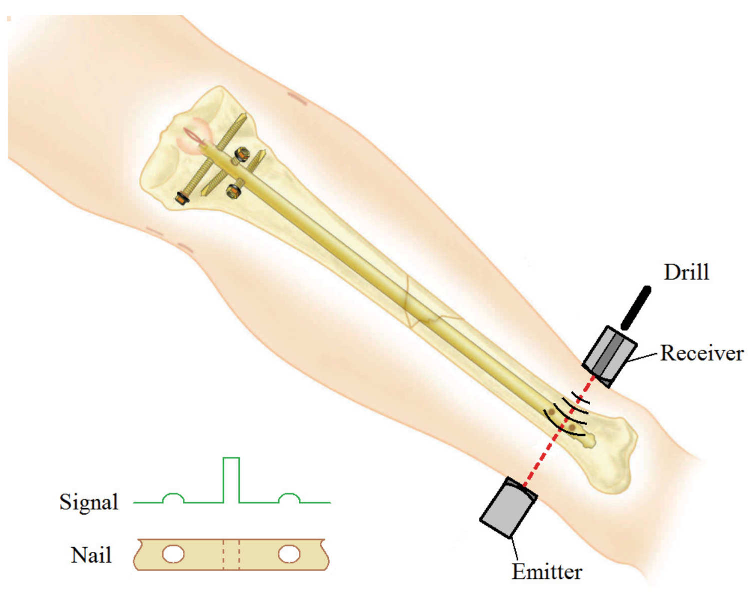


Figure 10 - Proposed mini C-arm concept

A surgical devices company, Smith & Nephew, proposed a similar concept through their Trigen Sureshot [61]. However, the device is product specific and only compatible with their nails because it requires a magnetic gauge placed inside their specialised nail. In addition, it is cumbersome to use in the operating room since it requires an external monitor to show the position of the nails.

Based on Health Canada's guide for the Risk-based Classification System, this device does not emit ionizing radiation, but may come in contact with injured skin, which converts it in a class II device (Rule 4).

Nail stress sensors

Immediately after surgical procedure, the intramedullary nail carries most of the external load. With progression of fracture healing, the amount of load carried by the implant decreases, while the portion carried by the bone increases. Current methods for assessing the fracture healing process provide limited information about the progress of healing. The most commonly used method, X-ray images, only show callus geometry and doesn't provide information about its mechanical properties [62]. Therefore, it complicated to determine when the callus is resistant enough to resist the external loads and can be thus fully loaded.

The proposed device is an intramedullary nail that integrates stress sensors (strain gages) and the necessary electronic components to transmit the data via RFID to an external reader. The circuit on the nail will be powered by the RFID signal, similarly to the device proposed by Bergmann (2012) [62]. The adequate calibration of this device, would allow determining when the callus has enough strength to be fully loaded.

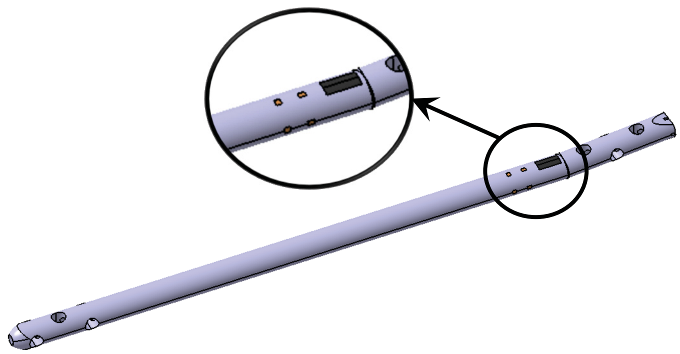


Figure 11 - Proposed nail sensing concept

To this point, no commercial system that provides this information has been found. However, several patents and research projects to measure mechanical loads inside the body exist. Bergmann (2012) [62] successfully implanted hip implants having strain gages and RFID system to measure the hip contact forces and transmit them to a reader outside the body. Smith & Nephew has patented (US8486070) [63] an intramedullary nail that integrates sensors and a RFID system to measure the mechanical load across the implant and read it wirelessly. More recently, Seide (2006) [64] have instrumented the fixation plates in the same way.

Based on Health Canada's guide for the Risk-based Classification System, the transponder would constitute a long-term (≥30 days) surgically invasive device and would be a class III device. The reader (external device) does not emit ionizing radiation, but since it is connected to a class III device, it would be a class II device (rule 7).

11. Final concept selection

In order to choose from the four previously proposed concepts, consideration was given to the existing interest of clinical stakeholders, the regulatory environment, financial forecasts, and competition (i.e. patents and products).

Stakeholder Survey

Finally, a survey was prepared and presented to two surgeons to take into account their expertise with regards to the final choice. The survey consisted of four questions to be scored from one being the least to five, as the best, in regards to the novelty of the device, the surgeon's general reaction to the concept, interest, and probability of adoption in the medical practice. In addition, a multiple-choice question was also included to let the surgeon choose the outcomes of the device: whether it will improve outcomes, save operation time, and/or facilitate surgeons' work progress. The average scores from two surgeons are showed below. From the survey, the best-validated concept was the mini C-arm, while a new nail with strain sensors followed closely behind. The least validated solution by the surgeons was the drill.

Table 4: Survey results

	Guide wire	Drill	Nail	Mini C-arm
General reaction	4	3,5	5	4,5
Interest	3,5	3,5	5	4,5
Novelty	4	4	3,5	4
Probability of adoption	3	2,5	3	4

Facilitate the work	0,5	0,5	0,5	1
Save time	0,5	0,5	0	1
Improve outcomes	0	0,5	1	0
Total	15,5	15	18	19

Regulatory considerations

The regulatory environment for each concept was assessed according to Health Canada Medical Device Bureau classification, and compliance with Canadian Medical Devices Regulations (SOR/98-282) and FDA (21CFR part 820). In all cases, manufacturing using an ISO-13485 certified service provider would be needed for compliance. However, the team rationalized that extensive validation and clinical trials would be required to demonstrate safety for the approval and adoption of the nail concept. In contrast, the mini C-Arm, drill and guide wire concepts would not require such extensive study for safety, but rather place emphasis on performance.

Financial Forecasting

The financials surrounding the development and commercialization of two of the top stakeholder selected concepts was assessed. Regarding the nail concept, the team rationalized that due to the extensive clinical validation attesting to its safety, and the associated monetary investment in said trials, financial forecasting was found to be unfavourable. Hence, the team presented the financial assumptions surrounding the commercialization of the guide-wire and the mini C-arm. Preliminary sales and revenue forecasts were performed with several reasonable assumptions. Preliminary forecasts were performed for the next 10 years and are assumed to commence in 2016.

For the guide-wire, total sales were calculated by first calculating the total number of relevant surgeries employing the use of guide wires. This was based on 64,110 reported annual cases of femur/tibia/fibula fractures in the US (Agency for Healthcare Research and Quality, 2015) [24]. A year-on-year growth rate of 0.76% (The World Bank, Data Bank 2014) [65] was used to coincide with the reported US population growth rate. Next, adoption of this product by stakeholders is expected to be high, due to its self-explanatory nature and expected ability to be integrated into current technologies and procedures.

Table 5 - Projected sales and revenues for the guide wire concept

	Year										
Annual Revenues	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Total**
Incident Pop. (US/Can)	64,110	64,597	65,088	65,583	66,081	66,583	67,090	67,599	68,113	68,631	
Growth Rate	1.0076	1.0076	1.0076	1.0076	1.0076	1.0076	1.0076	1.0076	1.0076	1.0076	
Penetration	0	0.001	0.01	0.05	0.1	0.2	0.3	0.5	0.7	1	
Estimated Surgeries	0	65	651	3,279	6,608	13,317	20,127	33,800	47,679	68,631	
Total Sales	**0**	**71**	**716**	**3,607**	**7,269**	**14,648**	**22,140**	**37,180**	**52,447**	**75,494**	**$213,572**
Retail Price	$100	$100	$100	$100	$100	$100	$100	$100	$100	$100	
Total Revenue	**$0**	**$7,106**	**$71,597**	**$360,706**	**$726,894**	**$1,464,837**	**$2,213,954**	**$3,717,967**	**$5,244,714**	**$7,549,391**	**$21,357,165**
Initial Investments	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Total**
Prototyping	-$5,000										
Development	-$250,000	-$500,000									
Regulatory	-$50,000										
IP	-$20,000	-$20,000	-$50,000								
Promotion	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	
Total Investment	**-$425,000**	**-$620,000**	**-$150,000**	**-$100,000**	**-$100,000**	**-$100,000**	**-$100,000**	**-$100,000**	**-$100,000**	**-$100,000**	**-$1,895,000**

Therefore, a feasible North American penetration of 10% (6,608 surgeries) was estimated by year 5, and 100% penetration (68,631 surgeries) by year 10. Due to the fact that a a number of surgeons use up to two guide wires per procedure, it is assumed that additional sales of 10% over the total number of surgeries would occur, generating total units sold of 7,269 (year 5) and 75,494 (year 10). Current guide wires are for one-time use and retail for approximately $100 per unit. At this price point, the analysis forecasts total revenues of ~$730,000 by year 5, $7.5M by year 10, and total aggregated revenues of $21M by year 10. Assuming a variable cost of $10 per unit, and an initial investment of $1.9M for prototyping, development, IP protection, regulatory approval, and promotion, forecast an ROI of 914% after 10 years under these assumptions. Assuming a present value discount factor/hurdle rate of 50%, the projections return a 10 year NPV of +$174,929 suggesting the potential for a profit generating investment.

In contrast to the disposable nature of the guide wire, the mini C-arm is expected to be reusable product with a multi-year shelf life prior to obsolescence. For this reason, total unit sales of the mini C-arm were calculated based upon the number of registered hospitals. In the US 5,686 hospitals are registered (American Hospital Association 2015) [66], while in Canada, 493 medical/surgical hospitals (with >100 employees) are reported (Statistics Canada, Canadian Business Patterns Database December 2014) [67]. It is assumed that on average, each hospital will be equipped with 10 units. Unlike the guide wire, the rate of adoption of the mini C-arm will not be as straightforward and is expected to be lower due to the training and familiarity expected from a change in technology. Moreover, a change in standard care protocols will need to be pushed by clinician communities of practice. Nonetheless, a product launch by year 5 is anticipated with an initial penetration of 0.1%, growing to 30% by year 10 or presence in 1,870 hospitals across North America. Factoring in a 10% annual repurchase rate by previously sold hospitals, annual sales of ~6,000 units is anticipated. It is speculated that a product of this nature would retail for ~$2,000, generating total revenues of $124,000 by year 5 and $12.7M by year 10, for total accumulated revenues of $39M. Assuming a variable profit margin of 50%, and an initial investment of $3.2M for prototyping, development, IP protection, regulatory approval, and promotion, an ROI of 1011% after 10 years is forecasted under these assumptions. Assuming a present value discount factor/hurdle rate of 50%, the projections return a 10 year NPV of +$7,465 suggesting that the potential for profit from this investment exists under this optimistic assumptions.

Table 6 - Decision criteria matrix

Annual Revenues	Year 1	2	3	4	5	6	7	8	9	10	Total
# Hospitals	6,179	6,185	6,191	6,198	6,204	6,210	6,216	6,222	6,229	6,235	
Growth Rate	1.001	1.001	1.001	1.001	1.001	1.001	1.001	1.001	1.001	1.001	
# Units per hospital	10	10	10	10	10	10	10	10	10	10	
# Potential total units	61,790	61,852	61,914	61,976	62,038	62,100	62,162	62,224	62,286	62,348	
Penetration	0	0	0	0	0.001	0.01	0.05	0.1	0.2	0.3	
# Hospitals sold	0	0	0	0	6	62	311	622	1,246	1,870	
# New hospitals over previous year	0	0	0	0	6	56	249	311	623	625	
New hospital sales	0	0	0	0	62	559	2,487	3,114	6,235	6,247	
Repurchase rate	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	
Sales from repurchase	0.0	0.0	0.0	0	0	1	6	31	62	125	
Total sales	**0**	**0**	**0**	**0**	**62**	**560**	**2,493**	**3,145**	**6,297**	**6,372**	**18,929**
Retail price	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	
Total Revenue	**$0**	**$0**	**$0**	**$0**	**$124,075**	**$1,119,157**	**$4,986,595**	**$6,290,761**	**$12,594,103**	**$12,743,727**	**$37,858,418**
Initial Investments	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Total**
Prototype	-$50,000										
Development	-$500,000	-$500,000	-$500,000	-$500,000							
Regulatory	-$100,000										
IP	-$20,000	-$20,000	-$50,000								
Promotion	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	-$100,000	
Total Investment	**-$770,000**	**-$620,000**	**-$650,000**	**-$600,000**	**-$100,000**	**-$100,000**	**-$100,000**	**-$100,000**	**-$100,000**	**-$100,000**	**-$3,240,000**

Conclusion of Concept Generation

A matrix was utilized to help with the final concept selection. All the aforementioned fields were taken into account. As it can be seen in Table 7, when all factors are combined, the "winning" concept is the mini C-arm, while the guide wire came close in second position.

Table 7 - Decision criteria matrix

		Drill	Guide wire	Nail	mini C-arm
Regulatory (Class)		2	2	3	2
Solution for innovation field	**1**	1	0	1	1
	2	0	1	0	0
	3	0	1	1	1
	4	1	0	1	1
	5	1	1	1	0

	6	1	1	0	1
Surgeon's choice		4	3	2	1
Existing competition		2	0	1	0
Market / Economical		1	0	0	1
Total score (less best)		13	9	10	8

From these two concepts, the final selection was rationalized by considering the advantages and disadvantages of each concept in relation to one another (Table 8).

Table 8 - Advantages and Disadvantages for Final Concept Selection

	Advantages	**Disadvantages**
Guide wire	• Easier/cheaper to develop (faster to launch) • Intuitive design, integrates with existing tech = easier adoption • Surgeons receptive to idea • More accurate form of measure than current tech	• Simple concept, marginal innovation • Marginal time/X-Ray savings • Easily replicable replicated by competition
Mini C-Arm	• Greater potential to innovate • Most interesting innovation to surgeons • Higher potential saves in time and X-Rays	• Higher development costs, barriers to entry expected to slow adoption • Prove of concept more complicated

Therefore, based upon this evaluation it is clear that the guide wire has the potential to produce the quickest returns, while the mini C-Arm has the greatest potential for innovation. Based on a long-term view of inventing a product that may have a greater impact on the intramedullary nail procedure, and coupled with the fact that the surgical stakeholders were most receptive to the concept, the mini C-arm was chosen as this project's final concept.

12. Final Concept Description: Mini C-arm

The idea for helping the distal holes positioning in the intramedullary nailing (mini C-arm) was the preferred concept by the surgeons and it is the concept that obtained the best overall score, according to the choice matrix. This device is intended to reduce, but not completely eliminate the X-Rays, since they are the gold standard in trans-bone imaging and provide the surgeons with a confidence that is hard to match with any other aiming device. In this way, although jigs exist for the proximal fixation, X-Rays continue to be employed, mostly for verification purposes. In any case, a reduction in the amount of X-Rays, combined with the expected time reduction attributable to an easier detection and aiming, would result in a not negligible improvement for the current surgery technique, as it was recognized by the medical experts that were contacted.

The proposed device will be small, easy to operate, and based in non-ionizing radiation (magnetic fields), which are not harmful to the patient or the medical staff. Moreover, it can be potentially used for other applications different to locating the distal holes, such as determining whether the reamer has reached the end position. In addition, the device is conceived such as it can be easily combined with the currently used devices, such as jigs, X-Rays and drills. In this way, it will have radio-opaque markers to verify the alignment by X-Rays, if needed. It will be provided with different modes of use: the free-hand method, attached to the operating table or attached to the drill.

Compared to the closest competitor, the Trigen Sureshot by Smith and Nephew (Nephew), the proposed device shows two major advantages: first, it will have a small integrated screen, so that the surgeon can directly see if a hole has been detected and doesn't take necessary space in the already crowded operating room. Second, it is intended to be universal, this is, it will be conceived so that it can be used with any kind of nail, from any manufacturer, having holes for fixation. It can be equally used for tibia and femur intramedullary nailing procedures.

Working principle

The materials, depending on the signal frequency and the material properties, absorb electromagnetic signals. In this way, while low-frequency signals are known to be moderately absorbed by titanium (Ti6Al4V) implants, higher frequencies signals (i.e. 10 KHz) can be reduced up to 53% [62]. On the other hand, these signals are able to traverse the living tissues (such as bone, muscle and marrow), making possible the data transmission to the outside of the body for a variety of implanted medical devices, such as pacemakers and instrumented implants [62]. The proposed device will take advantage of this principle; in the way that strong signals will be detected whenever the device is aligned with the axis of a nail's hole is present.

General description

The proposed device (Figure 12) would have a magnetic coil emitter that generates a pulsed (radio frequency, RF) magnetic signal, and a Giant Magneto-Resistive field sensor (GMR) acting as receiver. An emitter and a receiver will be placed 180 degrees apart, so the axis of the hole can be detected. A display will provide the doctor with information about the detection, such as: indicator of hole detection or alignment with the nail axis.

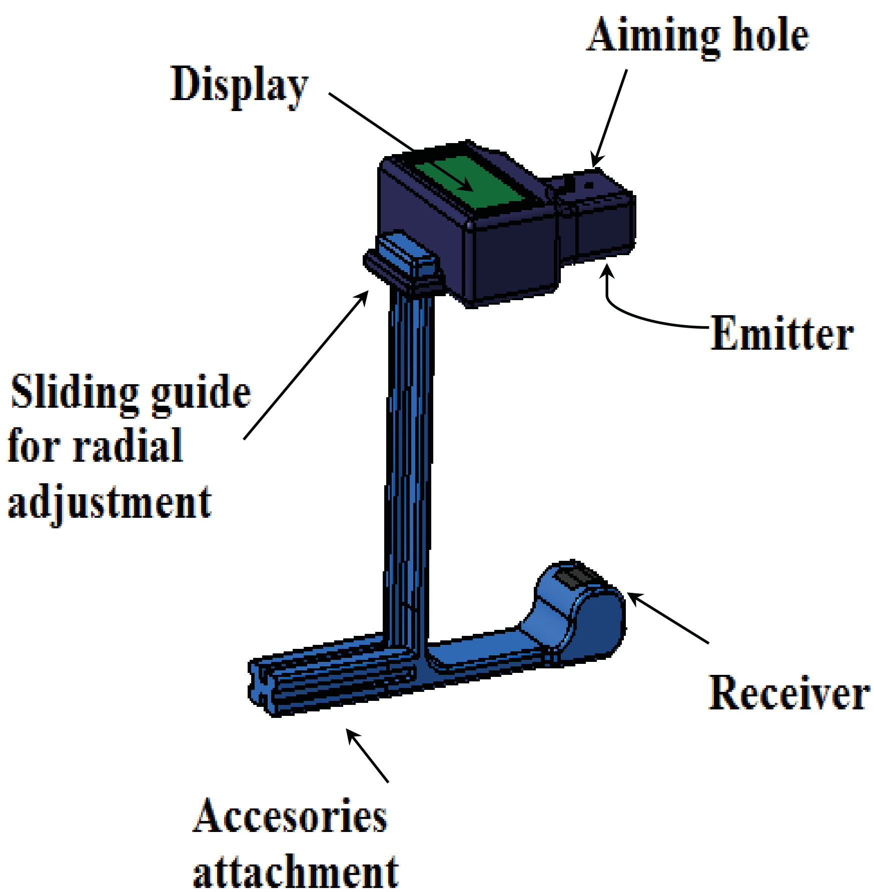


Figure 12 - Mini C-arm concept

The device will have an adjustable C-shape with the adequate dimensions to fit the distal part of the lower limb. The surgeons using the free-hand method can operate this device and it can also be connected to a support fixed on the operating table or attached to the drill. For this purpose a universal attachment will be conceived. As an example, the accessory for attaching the device to the operating table is shown in Figure 13.

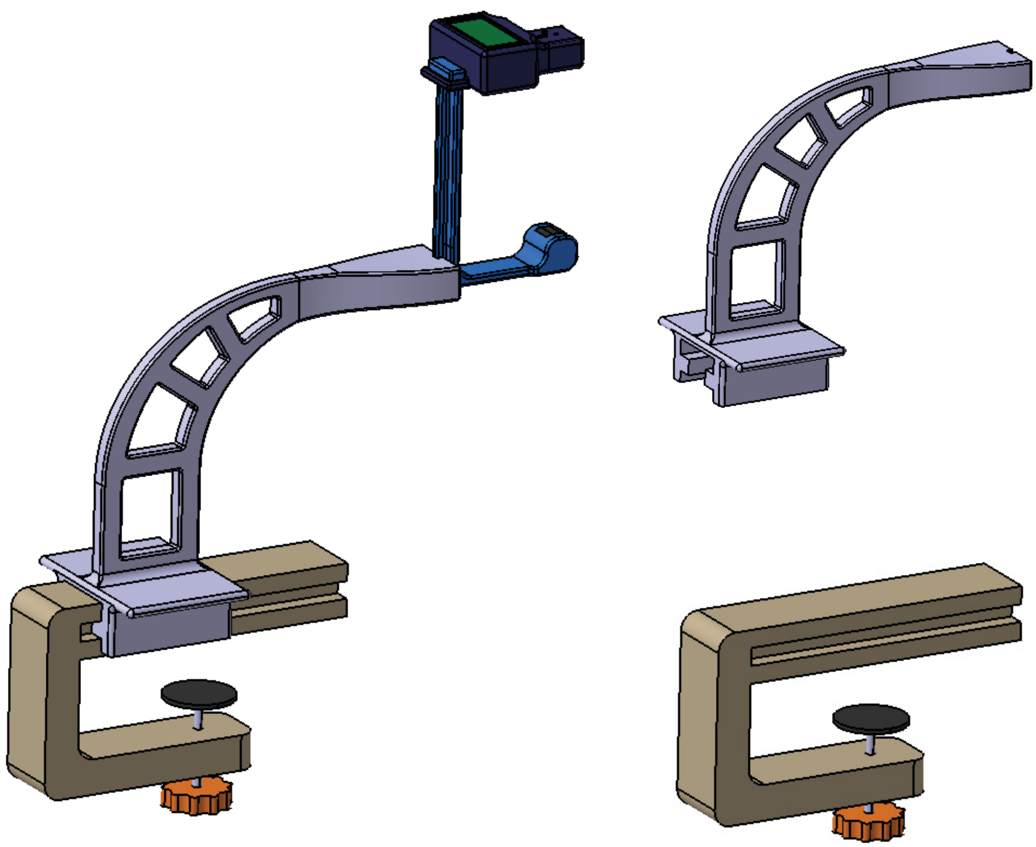


Figure 13 – Accessory for fixation to operating bed for Mini C-arm concept

Pre-dimensioning

Apart from the mechanical parts, two separated electronic circuits mainly compose the device: a magnetic RF generator circuit, and a magnetic RF receiver circuit. Magnetic RF generator circuit

In its simplest form, the RF generator circuit would consist on a pulse generator and a magnetic coil, connected to a battery. A simple pulse generator circuit based on a 555 timer will be constructed, as shown below.

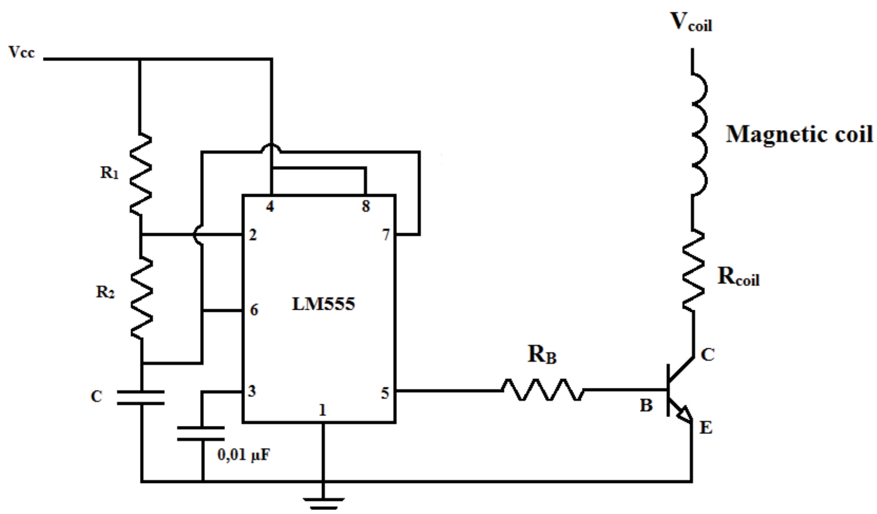


Figure 14 - Emitter electronic circuit

In this circuit *C*, R_1 and R_2 control the frequency of the signal according to

$$f = \frac{1.44}{(R_1 + 2 \cdot R_2) \cdot C}$$

As recommended in the LM555 datasheet, for a frequency of 10kHz, and a combination of $R_1 + 2 \cdot R_2 = 10\ k\Omega$, C must be approximately 0.015 μF. Then, if $R_1 = R_2$ is assumed, the required resistance value is $R_1 = R_2 = 3.2\ k\Omega$.

On the other hand, the output signal would vary between 1/3 and 2/3 of the supplied voltage Vcc (typically 5V). In this case, the maximum output value of 2/3 of Vcc is likely too small to generate a magnetic pulse with the adequate intensity. Therefore, the output signal of the LM555 will be connected, through the resistance R_B, to a transistor operating as an electronic switch. This will act as a trigger for the magnetic coil, connected to an adequate voltage supply. In a first time, the coil will be custom-made in order to limit the costs related to a possible change in its characteristics if different magnetic field intensity is needed.

Magnetic RF reader circuit

This circuit will read the signal that passes through the patient and will provide information to the surgeon on a LCD screen. In order to detect the magnetic field, the starting point will be the Giant Magnetoresistive (GMR) field sensor (AA002-02), as proposed by Bergmann et al, 2012 [62]. This sensor can detect magnetic fields with intensities within 1.5 and 10.5 Gauss. Special care would be taken to isolate the interest signal from the all other possible sources of magnetic radiation. The received signal will be amplified, filtered and processed to extract the information of interest (see **Appendix E**).

As previously stated, the proposed medical design is a class II device, which requires a license from Health Canada in order to be commercialized or advertised (section 26 and 27). A medical device license for this class requires: the name class and identifier of the device, the name and address of the manufacturer, a description of the medical intended use, a list of the standards of safety and effectiveness, an attestation of safety and effectiveness, an attestation of investigational testing on human subjects and a copy of the quality management system under which the device is manufactured.

13. Invention: Concept Screening & Validation

In order to proceed to the final step of the invention phase, the team needed to further screen the concepts and validate the hypothesis. In conjunction with District3 Innovation Centre at Concordia University, the team initiated the business model canvas, where the team aimed to bring forth this innovation concept into a real prototype. However, throughout the Surgical Innovation class at District 3, this innovation team was expected to continuously validate the group’s ideas and learn much more about the specific field [1]. To do so, the team arranged interviews with numerous medical staff at the Montreal General Hospital, representatives from medical technology companies and innovators in orthopaedic surgeries. The team scheduled a couple of interviews per week from January to April 2016 to validate the team’s assumptions, understand orthopaedic innovations from their perspective, discover more about current needs, the solutions and gaps, and finally necessities for the devices and its value propositions [1]. From the raw data amongst the sixty-three private interviews conducted, the group was able to identify and validate the team’s concept and its necessary features (see **Appendix F**). Our main goal for the interviews was to identify the key value propositions of the medical device, the mini C- arm. The team aimed for the device to offer these value propositions: reduce radiation exposure for surgeons, increase efficacy of the distal-locking procedure, be cost – effective, reduce total surgery time and by doing so, increase the number of surgeries per day, increase patient safety, reduce co-morbidities and lastly, offer peace of mind for surgeons. Amongst the eight value propositions, the team wanted to know which ones would be validated my surgeons working in the field and performing the intra-medullary nailing procedure. The team interviewed twelve surgeons working in Montreal hospitals and asked them which value proposition would be a necessity for the device, a nice-to-have and whether any of the value propositions were insignificant. The results are summarized in Table 9 and it illustrates the variety of opinions from surgeons.

Table 9: Value Proposition Feedback from Surgeons.
M = Must-have, N = Nice-to-have, D = does not matter, N/A = no opinion

Surgeons	Peace of mind	Reduce X-ray exposure	Increase efficacy of procedure	Increase patient safety	Cost effective	Reduce surgery time	Increase # of surgeries per day	Reduction of co-morbidities
Surgeon 1	M	D	M	M	N/A	N	D	N
Surgeon 2	M	M	M	D	M	N	D	D
Surgeon 3	M	M	M	M	N	D	D	D
Surgeon 4	D	N	M	D	N/A	N	N	D
Surgeon 5	D	D	N	D	D	D	D	D
Surgeon 6	M	D	M	M	N	N	D	N/A
Surgeon 7	N/A	D	N	N	M	N/A	D	N/A
Surgeon 8	N/A	N	N/A	N	M	M	N	N/A
Surgeon 9	N	N	N/A	N/A	N	M	N	N/A
Surgeon 10	N	N	N/A	N/A	N/A	N	N	N/A
Surgeon 11	M	N	N/A	N/A	N	N	N/A	N/A
Surgeon 12	N/A	D	N	M	M	D	D	N/A

When the group meetings were held to analyze the surgeons' responses, the team concluded that the product would receive mixed feedback from orthopaedic surgeons. Most surgeons felt that the device would not need to reduce comorbidities for its adoption because surgical complications are not only dependent on the distal-locking part of the procedure. However, the majority of surgeons felt that the reduction of radiation exposure during distal-locking was a significant value proposition. Furthermore, the surgeons at the teaching hospitals described their enthusiasm for a device that increases the efficiency of the procedure. Currently, the distal-interlocking is mainly performed with the free-hand technique [67]. However, in teaching hospitals, the surgeons and the orthopaedic residents described this procedure as "cumbersome and archaic". The orthopaedic residents specifically expressed interests in devices or "gadgets" that could enhance this procedure. Lastly, the surgeons did not express interest in reducing surgery time or increasing the number of surgeries per day. Upon deeper inspection with the OR schedules and management, the team discovered that there are pre-set number of procedures per day in the Montreal General Hospital and thus, even if surgeries were completed faster, another surgery would not be booked. This example highlights why a global perspective on the market is necessary. While, in Canada the number of surgeries per day in limited, in America, they encourage faster and efficient procedures to perform more surgeries in a day [69].

This device has been specifically tailored to the clinical needs investigated in the department of orthopaedic surgery at the Montreal General Hospital. However, the procedure the team selected to optimize – intra-medullary nailing- is the gold standard for long bone fractures [75], which has a global market for device sales. With the feedback from surgeons, medical technology companies, and innovators, the innovation team successfully completed the concept-screening step of the invention phase. The team decided to innovate a fracture fixation-targeting device called Hawk-eye.

14. Hawk-eye: Fracture Fixation Targeting Device

The innovation team's solution is a handheld targeting device that can be used to locate the precise location of the distal holes on the intra-medullary nails that stabilizes long bone fractures. Studies have shown that electromagnetic signals go through human tissues but get shielded up to 53% by Ti implants [76]. Using this principle, the innovation team can build the device with a strong electro-magnetic emitter on top and an array of receivers at the bottom to detect the signal variations. It would need an intelligent algorithm to analyze the values read from the receivers, and analyze the variations in the signal.

From analyzing the procedure, the team wanted the device to be attached to an external fixture once the distal hole has been detected. It will also need to continuously detect the hole, so that it can display warnings if misalignment occurs during the distal-locking. Other key features of the Hawk-eye are its ability to be combined with any drill or any nail for universal use, user-friendly set-up and manoeuvrability, both precise and radiation free, virtual nail image and drilling guidance and finally its affordability.

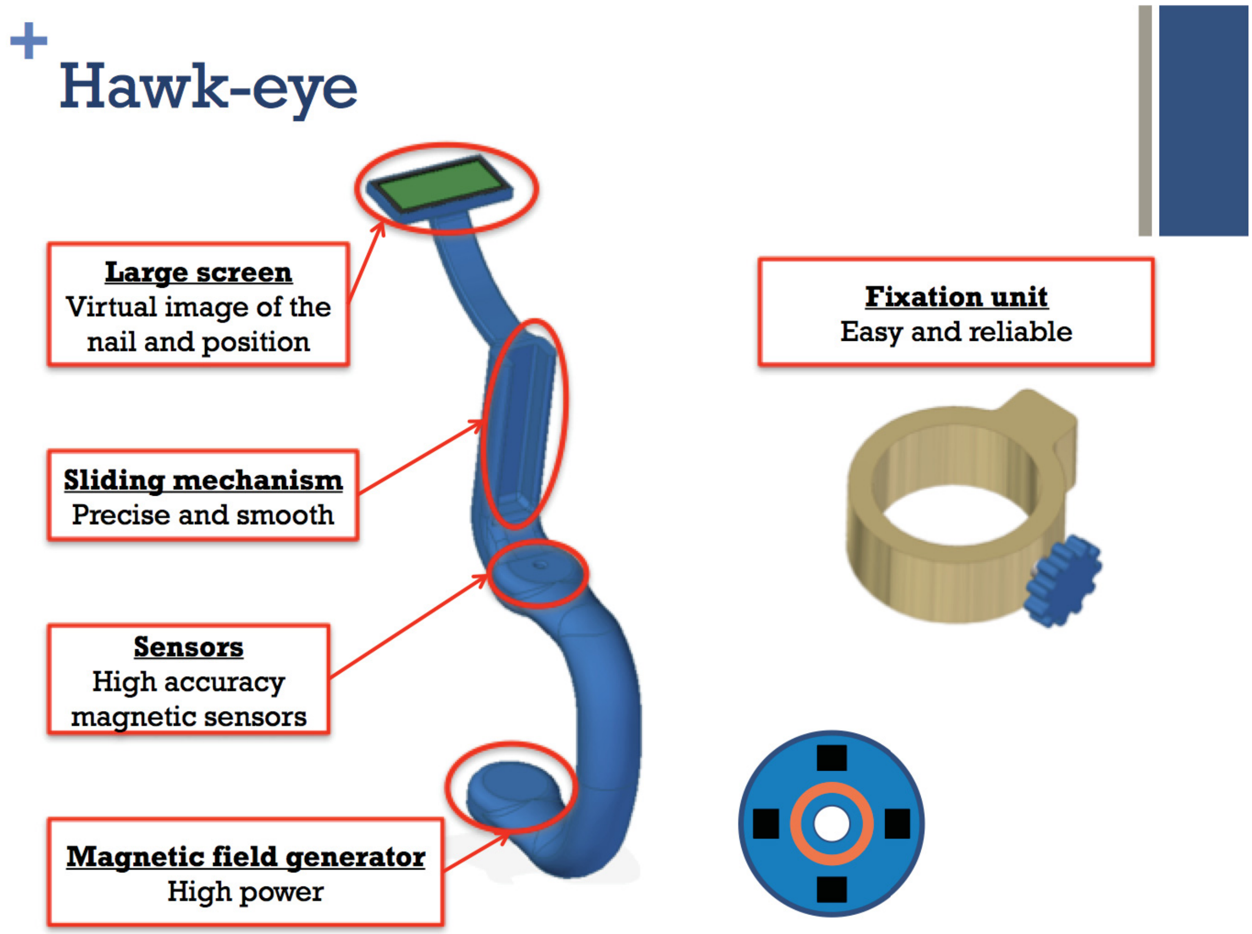


Figure 15: Design and features of Hawk-eye fracture fixation targeting device

The main components of the device:

1. High power magnetic field emitter at the bottom

2. An array of high accuracy magnetic sensors

3. A large screen to show the virtual representation of the nail and the hole

4. A fixation unit for the drill, and attachable to the device.

Additionally, the team is designing flexible mechanism to be able to attach and secure the device to the bed, while still being able to position the device to locate the distal holes.

15. Current Challenges

It is encouraging to know that the technology for this device does exist. Smith & Nephew's Trigen Sureshot and RFID (radio-frequency identification) implants are both commercially available and being used in orthopaedic surgeries [62-64]. Since the competitors are successful and established medical technology companies, the team would need to address all gaps or clinical needs that current targeting technologies have failed to address. It is important to make the Hawk-Eye medical device universal with the ability to be used with any IM nails and bone-drills for seamless adoption into current orthopaedic practice. For example, virtual real-time feedback of distal hole targeting and alignment from the Hawk-eye device is necessary for surgeons to gain confidence on the device. The team would also need to address the problem of sterilization, a crucial practice in the operating room. The team's business would need to offer sterilized covering disposables for the targeting device. Moreover, the team would need to make this device affordable, but also offer disposables as a source of revenue for the business.

Since targeting device patents currently exists, the team would need to contact patent holders with similar patents to negotiate patent licencing agreements to make the products. Contrastingly, the innovation team could also work with a patent officer to ensure that this invention does not infringe of current patents and file for a new patent.

16. Conclusions and Future Work

The Surgical Innovation program offered a different approach to the realm of research. As opposed to the top down process in traditional basic science research, the innovation group were able to explore clinical needs in the field of orthopaedic surgery without a predetermined project of hypothesis. The process through which the team narrowed down the scope, screened out numerous clinical needs, identified the final need, completed the invention phase through concept generation, screening and exploration resulted in the completion of the innovation project. From the original need *"A way to improve the accuracy in the positioning of distal interlocking screws during intramedullary nail fixation, in order to reduce the operation time and the X-Ray dose received by the medical staff"* the team broadened the scope to optimize the entire IM nailing procedure; *"A way to improve the intramedullary nail fixation procedure in order to reduce the operation time and the X-Ray dose received by the medical staff".* From the four possible solutions generated, the fracture-fixation targeting device was chosen as the innovation concept to further develop.

Orthopaedic surgeons and innovators gave constructive feedback for the ideas, which allowed the team to further explore the concept and characterize the Hawk- Eye targeting device. If the innovation group is to continue this project and become a start-up with the medical device, the next steps include incorporation of the business and further research into patents and intellectual properties (IPs). The team would need licencing agreements with similar patent holders or the team's patent for the Hawk-eye device. Furthermore, the team needs to prototype the device with the engineers from the team and outside resources. Simultaneously, the team would start testing the device in cadaver models to optimize the device for surgical use. Lastly, the team needs to build the business model canvas, provide proof-of-concept and obtain funding to become a start-up company.

References

1. Zenios, S., Makower, J., & Yock, P. (2010). *Biodesign: The Process of Innovating Medical Technologies*: Cambridge University Press.

2. Heikens, J. T., Gooszen, H. G., Rovers, M. M., & van Laarhoven, C. J. (2013). Stages and evaluation of surgical innovation: a clinical example of the ileo neorectal anastomosis after ulcerative colitis and familial adenomatous polyposis. *Surg Innov, 20*(5), 459-465. doi:10.1177/1553350612468959
3. Regens, J. L., Schultheiss, A., & Mould, N. (2015). Regional Variation in Causes of Injuries among Terrorism Victims for Mass Casualty Events. *Frontiers in Public Health*, *3*, 198. http://doi.org/10.3389/fpubh.2015.00198

4. Kalra, S., Kelkar, D., Galwankar, S. C., Papadimos, T. J., Stawicki, S. P., Arquilla, B., … Jahre, J. A. (2014). The Emergence of Ebola as a Global Health Security Threat: From "Lessons Learned" to Coordinated Multilateral Containment Efforts. *Journal of Global Infectious Diseases*, *6*(4), 164–177. http://doi.org/10.4103/0974-777X.145247

5. Bernard, E., & Titov, V. (2015). Evolution of tsunami warning systems and products. *Philosophical Transactions. Series A, Mathematical, Physical, and Engineering Sciences*, *373*(2053), 20140371.

6. Park, J. O., Shin, S. D., Song, K. J., Hong, K. J., & Kim, J. (2016). Epidemiology of Emergency Medical Services-Assessed Mass Casualty Incidents according to Causes. *Journal of Korean Medical Science*, *31*(3), 449–456. http://doi.org/10.3346/jkms.2016.31.3.449

7. Lerner, E. B., McKee, C. H., Cady, C. E., Cone, D. C., Colella, M. R., Cooper, A., … Swienton, R. E. (2015). A Consensus-Based Gold Standard for the Evaluation of Mass Casualty Triage Systems. *Prehospital Emergency Care : Official Journal of the National Association of EMS Physicians and the National Association of State EMS Directors*, *19*(2), 267–271. http://doi.org/10.3109/10903127.2014.959222

8. Culley, J. M., & Effken, J. A. (2010). Development and Validation of a Mass Casualty Conceptual Model. *Journal of Nursing Scholarship : An Official Publication of Sigma Theta Tau International Honor Society of Nursing / Sigma Theta Tau*, *42*(1), 66–75. http://doi.org/10.1111/j.1547-5069.2009.01320.x

9. Gomez, D., Haas, B., Ahmed, N., Tien, H., & Nathens, A. (2011). Disaster preparedness of Canadian trauma centres: the perspective of medical directors of trauma. *Canadian Journal of Surgery*, *54*(1), 9–15. http://doi.org/10.1503/cjs.022909

10. Lampi, M., Vikström, T., & Jonson, C.-O. (2013). Triage performance of Swedish physicians using the ATLS algorithm in a simulated mass casualty incident: a prospective cross-sectional survey. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine*, *21*, 90. http://doi.org/10.1186/1757-7241-21-90

11. Ricci, W. M., Gallagher, B., & Haidukewych, G. J. (2009). Intramedullary nailing of femoral shaft fractures: current concepts. *Journal of the American Academy of Orthopedic Surgeons, 17*(5), 296-305.

12. Rommens, P. M., & Hessmann, M. H. (2015). *Intramedullary Nailing. A comprehensive guide.* London: Springer.

13. Grewal, I., & Carter, P. (2012). *Focus on distal locking of intramedullary nails.* Récupéré sur http://www.boneandjoint.org.uk/content/focus/distal-locking-intramedullary-nails.

14. Chan, D., Burris, R., Erdogan, M., & Sagi, H. (2013). The insertion of intramedullary nail locking screws without fluoroscopy: a faster and safer technique. *Journal of Orthopaedic Trauma, 27*(7), 363-366.

15. Yiannakopoulos, C. K., Kanellopoulos, A. D., & Apostolou, C. (2005). Distal Intramedullary Nail Interlocking. *Journal of Orthopaedic Trauma, 19*, 410-414.

16. Kreb, D. L., Blokhuis, T. J., van Wessem, J.P., K., Bemelman, M., Lansink, K. W., & Leenen, L. P. (2013). Intramedullary nailing without interlocking screws for femoral and tibial shaft fractures. *Archives of Orthopaedic and Trauma Surgery, 133*(8).

17. FDA, U. F. (2015, 10 13). *White Paper: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging.* Récupéré sur http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199994.htm

18. Anastopoulos, G. (2006). Distal Locking with Mechanical Jig (Author's Own Technique). Dans K.-S. Leung, G. Taglang, R. Schnettler, V. Alt, H. Haarman, H. Seidel, & I. Kempf, *Practice of Intramedullary Locked Nails. New Development in Techniques and Applications* (pp. 271-274). Heidelberg: Springer Berlin.

19. Langfitt, M. K., Halvorson, J. J., Scott, A. T., Beth, S. P., Russel, G. B., Jinnah, R. H., . . . Carroll, E. A. (2013). Distal locking using an electromagnetic field-guided computer-based real-time system for orthopaedic trauma patients. *Journal of Orthopaedic Trauma, 27*(7), 367-373.

20. Stryker, «Tibial Nail Compression. Operative Technique,» 13 10 2015. [En ligne]. Available: http://www.osteosynthesis.stryker.com/medias/pdf/s2tibiacomp_optech_b1000016 d3709.pdf.

21. Reynders, P., Schonken, P., & Hoogmartens, M. (1990). Interlocking nail: a practical aiming device for distal screw insertion. *Acta Orthopaedica Belgica, 56*(3-4), 605-608.

22. Narain, S., Dave, P. K., Shah, S. N., Ganai, M., Singh, S., & Singh, A. (2011). A Comparative Study of Intramedullary Expandable Nail and Interlocking Nail in Tibial, Femoral & Humeral Shaft Fractures: A Prospective and Retrospective Study. *Journal of the International Medical Sciences Academy, 24*(1), 15-16.

23. Blomquist, J., Lundberg, O. J., Gjerdet, N. R., & Molster, A. (2008). Are inflatable nails an alternative to interlocked nails in tibial fractures? *Clinical Orthopaedic and Related Research, 466*(5), 1225-1231.

24. Agency for Healthcare Research and Quality, U. D. (2015, 10 13). http://hcupnet.ahrq.gov/HCUPnet.jsp?Id=AAFAF85EE53ECFEC&Form=DispTab&JS=Y&Action=%3E%3ENext%3E%3E&GoTo=MAINSEL

25. Simonet, F., Wilkins, R., Labranche, E., Smylie, J., Heaman, M., Martens, P., … Luo, Z.-C. (2009). Primary birthing attendants and birth outcomes in remote Inuit communities—a natural “experiment” in Nunavik, Canada. *Journal of Epidemiology and Community Health*, *63*(7), 546–551. http://doi.org/10.1136/jech.2008.080598

26. Simonet, F., Wilkins, R., Heaman, M., Smylie, J., Martens, P., Mchugh, N. G. L., … Luo, Z.-C. (2010). Urban Living is Not Associated with Better Birth and Infant Outcomes among Inuit and First Nations in Quebec. *The Open Women’s Health Journal*, *4*, 25–31.

27. Parkinson, A. J., & Evengård, B. (2009). Climate change, its impact on human health in the Arctic and the public health response to threats of emerging infectious diseases. *Global Health Action*, *2*, 10.3402/gha.v2i0.2075. http://doi.org/10.3402/gha.v2i0.2075

28. Reid, J. G., McGowan, J. J., Ricci, M. A., & McFarlane, G. (1997). Desktop teleradiology in support of rural orthopedic trauma care. *Proceedings of the AMIA Annual Fall Symposium*, 403–407.

29. Zanaboni, P., Knarvik, U., & Wootton, R. (2014). Adoption of routine telemedicine in Norway: the current picture. *Global Health Action*, *7*, 10.3402/gha.v7.22801. http://doi.org/10.3402/gha.v7.22801

30. Wootton, R., Vladzymyrskyy, A., Zolfo, M., & Bonnardot, L. (2011). Experience with low-cost telemedicine in three different settings. Recommendations based on a proposed framework for network performance evaluation. *Global Health Action*, *4*, 10.3402/gha.v4i0.7214. http://doi.org/10.3402/gha.v4i0.7214

31. Wootton, R., Geissbuhler, A., Jethwani, K., Kovarik, C., Person, D. A., Vladzymyrskyy, A., … Zolfo, M. (2012). Long-running telemedicine networks delivering humanitarian services: experience, performance and scientific output. *Bulletin of the World Health Organization*, *90*(5), 341–347D. http://doi.org/10.2471/BLT.11.099143

32. Hassan R1, Siregar JA1, A Rahman Mohd NA1. The implementation of teleneurosurgery in the management of referrals to a neurosurgical department in hospital sultanah amninah johor bahru. Malays J Med Sci. 2014 Mar;21(2):54-62.

33. Dario C1, Scannapieco G, Scienza R, Carraro MG, Saccavini C, Vio E, Valongo S. The neurosurgical telecounseling network in the Veneto Region: 4 years of experience of HEALTH OPTIMUM. Telemed J E Health. 2014 Nov;20(11):1009-14. doi: 10.1089/tmj.2013.0351. Epub 2014 Oct 1.

34. Shenai MB1, Tubbs RS, Guthrie BL, Cohen-Gadol AA. Virtual interactive presence for real-time, long-distance surgical collaboration during complex microsurgical procedures. J Neurosurg. 2014 Aug;121(2):277-84. doi: 10.3171/2014.4.JNS131805. Epub 2014 Jun 6.

35. Davis MC, Can DD, Pindrik J, Rocque BG, Johnston JM. Virtual Interactive Presence in Global Surgical Education: International Collaboration through Augmented Reality. World Neurosurg. 2015 Sep 2. pii: S1878-8750(15)01069-4. doi: 10.1016/j.wneu.2015.08.053. [Epub ahead of print]

36. Ponce BA, Menendez ME, Oladeji LO, Fryberger CT, Dantuluri PK.Emerging technology in surgical education: combining real-time augmented reality and wearable computing devices. Orthopedics. 2014 Nov;37(11):751-7. doi: 10.3928/01477447-20141023-05.

37. Kirkpatrick AW, Tien H, LaPorta AT, Lavell K, Keillor J, Wright Beatty HE, McKee JL, Brien S, Roberts DJ, Wong J, Ball CG, Beckett A. The marriage of surgical simulation and telementoring for damage-control surgical training of operational first responders: A pilot study. J Trauma Acute Care Surg. 2015 Sep 29.

38. Daruwalla ZJ1, Wong KL, Thambiah J. The application of telemedicine in orthopedic surgery in singapore: a pilot study on a secure, mobile telehealth application and messaging platform. JMIR Mhealth Uhealth. 2014 Jun 5;2(2):e28. doi: 10.2196/mhealth.3303.

39. Cota A, Tarchala M, Parent-Harvey C, Harvey EJ A review of 5.5 years' experience using email-based telemedicine to deliver orthopaedic care to remote communities. AAOS 2015

40. Kühnisch, J., Seto, J., Lange, C., Schrof, S., Stumpp, S., Kobus, K., … Kolanczyk, M. (2014). Multiscale, Converging Defects of Macro-Porosity, Microstructure and Matrix Mineralization Impact Long Bone Fragility in NF1. *PLoS ONE*, *9*(1), e86115. http://doi.org/10.1371/journal.pone.0086115

41. Bauer, J. M., Callan, A. K., & Jahangir, A. A. (2015). Length-Preserving Intramedullary Femoral Fixation for Traumatic Leg Amputation. *A Case Report, 5*(2), e38. doi:10.2106/jbjs.cc.n.00169

42. Praamsma, M., Carnahan, H., Backstein, D., Veillette, C. J. H., Gonzalez, D., & Dubrowski, A. (2008). Drilling sounds are used by surgeons and intermediate residents, but not novice orthopedic trainees, to guide drilling motions. *Canadian Journal of Surgery*, *51*(6), 442–446.

43. Alajmo, G., Schlegel, U., Gueorguiev, B., Matthys, R., & Gautier, E. (2012). Plunging when drilling: effect of using blunt drill bits. *J Orthop Trauma, 26*(8), 482-487. doi: 10.1097/BOT.0b013e3182336ec3

44. Bi, X., Sterling, J. A., Merkel, A. R., Perrien, D. S., Nyman, J., & Mahadevan-Jansen, A. (2013). Prostate Cancer Metastases Alter Bone Mineral and Matrix Composition Independent of Effects on Bone Architecture in Mice A Quantitative Study Using microCT and Raman Spectroscopy. *Bone*, *56*(2), 454–460. http://doi.org/10.1016/j.bone.2013.07.006

45. Khokhotva, Mykola, David Backstein, and Adam Dubrowski. “Outcome Errors Are Not Necessary for Learning Orthopedic Bone Drilling.” *Canadian Journal of Surgery* 52.2 (2009): 98–102. Print.

46. Praamsma, Monate et al. “Drilling Sounds Are Used by Surgeons and Intermediate Residents, but Not Novice Orthopedic Trainees, to Guide Drilling Motions.” *Canadian Journal of Surgery* 51.6 (2008): 442–446. Print.

47. Giordano, V., Gomes, A. F., Amaral, N. P., Albuquerque, R. P., & Pires, R. E. (2011). Preventing surgical complications: A survey on surgeons’ perception of intra-articular malleolar screw misplacement in a cadaveric study. *Patient Safety in Surgery*, *5*, 24. http://doi.org/10.1186/1754-9493-5-24

48. L. Bessette, S. Jean, M. Lapointe-Garant, E. Belzile, K. Davison, L. Ste-Marie et J. Brown, «Direct medical costs attributable to peripheral fractures in Canadian post- menopausal women,» *Osteoporosis international,* vol. 23, n° %16, pp. 1557-1768, 2012.

49. A. f. H. R. a. Q. (. D. o. H. &. H. Services), «H-CUPnet: A tool for identifying , tracking, and analyzing national hospital statistics,» 13 10 2015. [En ligne]. Available: http://hcupnet.ahrq.gov/HCUPnet.jsp?Id=AAFAF85EE53ECFEC&Form=DispTab &JS=Y&Action=%3E%3ENext%3E%3E&GoTo=MAINSEL.

50. W. Ricci, B. Gallagher et G. Haidukewych, «Intramedullary nailing of femoral shaft fractures: current concepts,» *Journal of the American Academy of Orthopedic Surgeons,* vol. 17, n° %15, pp. 296-305, 2009.

51. SPRINT, E. Schemitsch, M. Bhandari, G. Guyatt, D. Sanders, M. Swiontkowski, P. Tornetta, S. Walter, R. Zdero, J. Goslings, D. Teague, K. Jeray et M. McKee, «Study to prospectively evaluate reamed intramedually nails in patients with tibial fractures (S.P.R.I.N.T.): study rationale and design,» *BMC Musculoskeletal Disorders,* vol. 9, p. 91, 2008.

52. T. Russel et R. Sanders, «TRIGEN IM Nail System Surgical Technique,» Smith and Nephew.

53. M. Hessmann, S. Nork, C. Sommer et B. Twaddle, «Distal tibia - Intramedullary Nailing - AO Surgical Reference,» AO Foundation, 03 12 2008. [En ligne]. Available: https://www2.aofoundation.org/wps/portal/!ut/p/a1/04_Sj9CPykssy0xPLMnMz0v MAfGjzOKN_A0M3D2DDbz9_UMMDRyDXQ3dw9wMDAwCTYEKIvEocDQn Tr8BDuBoQEi_l35Uek5- EtipkY55ScYW6fpRRalpqUWpRXqlRUDhjJKSgmIrVQNVg_Lycr30_Pz0nFS95 ERs6jPyi0v0I1CVFeSGRlT5pIYDAPKRp0U!/dl5/d5/L2dJQ. [Accès le 10 12 2015].

54. M. Hafez, R. Smith, S. Matthews, G. Kalap et S. KP, «Radiation exposure to the hands of orthopaedic surgeons: are we underestimating the risk?,» *Acta of Orthopaedic and Trauma Surgery,* vol. 125, n° %15, pp. 330-335, 2005.

55. Steel wire guider used in orthopedics department». China Brevet CN202105018U, 11 January 2012.

56. G. Alajmo, U. Schlegel, B. Gueorguiev, R. Matthys et E. Gautier, «Plunging when drilling: effect of using blunt drill bits,» *Journal of Orthopaedic Trauma,* vol. 26, n° %18, pp. 482-487, 2012.

57. W. Anderson, «Depth controllable and measurable medical driver devices and methods of use». US Brevet US8821493B2, 2 September 2014.

58. «Intelligent bone drill». China Brevet CN201384531Y, 20 January 2010.

59. US6234672B1 *1998-03-182001-05-22Fluoroscan Imaging Systems, Inc.Miniature C-arm apparatus with C-arm mounted controls

60. S. Hollstien, D. Hollstien, B. Hollstien et R. Hollstien, «Method and apparatus for distal targeting of locking screws in intramedullary nails». Brevet US5411503A, 2 May 1995.

61. S. a. Nephew, «Trigen Sureshot,» [En ligne]. Available: http://www.smith-nephew.com/professional/products/all-products/trigen-sureshot/. [Accès le 10 12 2015].

62. G. Bergmann, F. Graichen, J. Dymke, A. Rohlmann, G. N. Duda et P. Damm, «High-tech hip implant for wireless temperature measurements in vivo,» *PLOS one,* vol. 7, n° %18, p. e43489, 2012.

63. R. Morgan, M. Wickham, P. Brady, S. Janna, G. Austin et D. Wilson, «Telemetric orthopaedic implant». US Brevet US8486070B2, 16 July 2013.

64. K. Seide, M. Faschingbauer, N. Weinrich, M. Wurm, G. Mehrtens, H. Erhard, C. Jürgens et J. Müller, «An intelligent internal fixator system for long bones,» chez *52th Orthopaedic Research Society Meeting*, Chicago, 2006.

65. T. W. Bank, «Data Bank 2014,» 2014. [En ligne]. Available: http://data.worldbank.org/.

66. A. H. Association, 2015. [En ligne]. Available: http://www.aha.org.

67. S. Canada, «Canadian Business Patterns Database,» December 2014. [En ligne]. Available: http://www5.statcan.gc.ca/cansim/a26?lang=eng&id=5510006

68. Brumback RJ, Virkus WW: Intramedullary nailing of the femur: Reamed versus nonreamed. *J Am Acad Orthop Surg* 2000;8:83-90.

69. Lewallen, Eric Alexander et al. "Biological Strategies for Improved Osseointegration and Osteoinduction of Porous Metal Orthopedic Implants." *Tissue Engineering. Part B, Reviews* 21.2 (2015): 218–230. *PMC*. Web. 6 Nov. 2016.

70. Sejdić, Ervin et al. "Innovation and Translation Efforts in Wireless Medical Connectivity, Telemedicine and eMedicine: A Story from the RFID Center of Excellence at the University of Pittsburgh." *Annals of biomedical engineering*41.9 (2013): 1913–1925. *PMC*. Web. 7 Nov. 2016.

71. Lee, C. B. (2016). Surgical innovation and safety: femoroacetabular impingement and the IDEAL collaborative framework. *J Hip Preserv Surg, 3*(2), 89-96. doi:10.1093/jhps/hnv074

72. Pucher, P. H., Sodergren, M. H., Lord, A. C., Teare, J., Yang, G. Z., & Darzi, A. (2015). Consumer demand for surgical innovation: a systematic review of public perception of NOTES. *Surg Endosc, 29*(4), 774-780.

73. Brinker, MR. Nonunions: Evaluation and Treatment. In: Browner, BD.; Jupiter, JB.; Levine, AM.; Trafton, PG.; Green, NE.; Swiontkowski, MF., editors. Skeletal Trauma: Basic Science, Management, and Reconstruction. New York: Saunders; 2003. p. 507

74. Busse, J. W., Morton, E., Lacchetti, C., Guyatt, G. H., & Bhandari, M. (2008). Current management of tibial shaft fractures. A survey of 450 Canadian orthopedic trauma surgeons. *Acta Orthopaedica, 79*(5), 689–694.

75. Code Orange Simulation. Retrieved from MUHC: https://muhc.ca/newsroom/article/code-orange-simulation.

76. Faccioli, G., & Stefano, R. (1997, 03 05). *Brevet n° US 5766179 A.* US.

77. Hannink G, Chris Arts JJ (2011) Bioresorbability, porosity and mechanical strength of bone substitutes: what is optimal for bone regeneration? Inj-Int J Care Inj 42:522–525

78. Helge Giersch, K. D. (2006, 08 10). *Brevet n° EP 2049025 B1.* Europe.

79. Levi, L., Bregman, D., Geva, H., & Revach, M. (1998). Hospital disaster management simulation system. Prehospital and disaster medicine, 13(01), 22-27. (MUHC)

80. Malek, S., Phillips, R., Mohsen, A., Viant, W., Bielby, M., & Sherman, K. (2006). Computer assisted orthopaedic surgical system for insertion of distal locking screws in intra-medullary nails: a valid and reliable navigation system. *The International Journal of Medical Robotics and Computer Assisted Surgery, 1*(4), 34-45.

81. Mehta M, Schmidt-Bleek K, Duda GN, Mooney DJ (2012) Biomaterial delivery of morphogens to mimic the natural healing cascade in bone. Adv Drug Deliv Rev. doi:10.1016/j.addr.2012.05.006

82. Ponce BA1, Jennings JK1, Clay TB1, May MB1, Huisingh C1, Sheppard ED1.

83. Rahman, M. M., Taha, W. S., & Shaheen, M. M. (1998). A simple technique for distal locking of tibial nails. *Injury, 29*(10), 789-790.

84. Schmitz JP, Hollinger JO. The critical size defect as an experimental model for craniomandibulofacial nonunions. Clin Orthop 1986:299–308. [PubMed: 3084153]

85. Telementoring: use of augmented reality in orthopaedic education: AAOS exhibit selection. J Bone Joint Surg Am. 2014 May 21;96(10):e84. doi: 10.2106/JBJS.M.00928.

86. Wilkerson, W., Avstreih, D., Gruppen, L., Beier, K. P., & Woolliscroft, J. (2008). Using immersive simulation for training first responders for mass casualty incidents. Academic emergency medicine, 15(11), 1152-1159.

87. Willie BM, Petersen A, Schmidt-Bleek K, Cipitria A, Mehta M, Strube P, Lienau J, Wildemann B, Fratzl P, Duda G (2010) Designing biomimetic scaffolds for bone regeneration: why aim for a copy of mature tissue properties if nature uses a different approach? Soft Matter 6:4976– 4987

88. Wilkerson, W., Avstreih, D., Gruppen, L., Beier, K. P., & Woolliscroft, J. (2008). Using immersive simulation for training first responders for mass casualty incidents. Academic emergency medicine, 15(11), 1152-1159.

89. Levi, L., Bregman, D., Geva, H., & Revach, M. (1998). Hospital disaster management simulation system. Prehospital and disaster medicine, 13(01), 22-27. (MUHC)

90. Code Orange Simulation. Retrieved from MUHC: https://muhc.ca/newsroom/article/code-orange-simulation

91. Pak N, Siegle JH, Kinney JP, Denman DJ, Blanche TJ, Boyden ES. Closed-loop, ultraprecise, automated craniotomies. *Journal of Neurophysiology*. 2015;113(10):3943-3953. doi:10.1152/jn.01055.2014.

Appendix A: Summary of Initial Needs Finding (Identification Phase)

1	18-Sep-15	Fracture Clinic	Fracture x-rays examined on a low resolution screen
2	18-Sep-15	Fracture Clinic	Scrolling/examination through CT scans relies on mouse scroll wheel, digital button presses on keyboard (cumbersome)
3	18-Sep-15	Fracture Clinic	Critical bone deficit (>4cm) relies on auto/allograft (mentioned by Dr. Berry as a particular outstanding need) **Some fractures have segmented bone defects which need bone grafting**
4	18-Sep-15	Fracture Clinic	Guy getting his arm set into a cast has to hold his arm above his head as it dries (~10 min)
5	18-Sep-15	Fracture Clinic	Uncomfortable chairs for reduced mobility patients to manoeuvre into/out of
6	18-Sep-15	Fracture Clinic	Limited/no access to x-rays/CT in patient rooms
7	18-Sep-15	Fracture Clinic	Line up for plaster clinic is long, blocks flow of traffic
8	18-Sep-15	Fracture Clinic	Nurse tech has to walk out, verbally call patients, orient them to a observation room
9	18-Sep-15	Fracture Clinic	Patient follow-up (proper contact info) can be difficult from young, deliquent patients
10	18-Sep-15	Fracture Clinic	General disorganization with placement/discharge of patients (Lack of prioritization with placement, plaster, x-rays)
11	18-Sep-15	Fracture Clinic	Patients standing around/waiting around in observation rooms wondering what the fuck is going on
12	18-Sep-15	Fracture Clinic	Liaison/greeter (dude in red robe) is pretty rude to patients
13	18-Sep-15	Fracture Clinic	Not enough space for incoming patients
14	18-Sep-15	Fracture Clinic	No specific space/zone for inmobilized patients (e.g. in wheelchairs)
15	18-Sep-15	Fracture Clinic	Patient calls are difficult to hear and understand (names)
16	18-Sep-15	Fracture Clinic	A doctor (?) directly explains to patient where to go and what to do
17	18-Sep-15	Fracture Clinic	Xray/Patient data only present in doctors' room and in clasting room (not in the other rooms)
18	18-Sep-15	Fracture Clinic	Doctor suggestion: regeneration of critical bone defects
19	18-Sep-15	Fracture Clinic	Doctors talk about 3D printing for preoperative planning
20	18-Sep-15	Fracture Clinic	Lack of communication emergency-ortho-Xrays
21	18-Sep-15	Fracture Clinic	Cast clinic: long queue
22	18-Sep-15	Fracture Clinic	Cast of a patient seemed tight (didn't ask the patient though)
23	18-Sep-15	Fracture Clinic	People (patients) don't know what's going on, for how long they have still to wait
24	18-Sep-15	Fracture Clinic	Some calls to patients are made eventhough the Xrays are not loaded yet
25	18-Sep-15	Fracture Clinic	A guy was already sitting on a room waiting for the doctor for a while, when he was pulled off (without seeing the doctor) to get another patient in who also waits
26	18-Sep-15	Fracture Clinic	Doctors (?) didn't know who was a patient on the room (why he was there, name...)
27	18-Sep-15	Fracture Clinic	A piece of "casting sheet" was thrown to the bin
28	18-Sep-15	Fracture Clinic	Scissors didn't cut very well (casting)
29	18-Sep-15	Fracture Clinic	People just walk in the casting room without knowing what to do or where to go
30	18-Sep-15	Fracture Clinic	Max's observation: patients with ambulatory fractures have great delays in surgery (3-4 weeks) without much info

31	18-Sep-15	Fracture Clinic	A nurse (?) doesn't know who preoperated a patient
32	25-Sep-15	Fracture Clinic	Dr. had to request patients from nurse tech ("Can I see some patients? ...I'd like to see some patients please")
33	25-Sep-15	Fracture Clinic	Syringes left out in the hallway allow for easy access to theft
34	25-Sep-15	Fracture Clinic	Guy has to hold leg up while waiting for a cast (eventually got tired and had to rest leg in painful position on top of wound/stiches
35	25-Sep-15	Fracture Clinic	Patient broke ankles some time ago, cartilage has degraded following loss of chondrocytes to impact; 1. ankle to be fused together reducing mobility, 2. use of osteotome to chisel off bone surface and allow for fusing/healing... Dr. has to judge/follow architecture of bone by eye
36	18-Sep-15	Fracture Clinic	Gurney in front of the door, access through the door is limited
37	25-Sep-15	Fracture Clinic	Ability for smaller clinics/developing nation hospitals to house large inventory of implants/nails of numerous sizes
38	18-Sep-15	Fracture Clinic	Allocation of rooms to patients is manual and chaotic, lack of co-ordination among stuff about which patient should come in and when and who will see them
39	25-Sep-15	Fracture Clinic	Discussed again critical bone deficit with Max; relayed ideas for 3D printing of collagen-coated biopolymers
40	18-Sep-15	Fracture Clinic	Monitors in the doctors' room are small, low resolution
41	18-Sep-15	Fracture Clinic	Patient rooms are small
42	25-Sep-15	Fracture Clinic	Fluorescece x-rays in OR present issues for Drs (constant exposure to low-dose radiation); may be better to use ultrasound
43	18-Sep-15	Fracture Clinic	No access for the doctor to any computer in the patient room
44	18-Sep-15	Fracture Clinic	Not much privacy in the plaster room
45	25-Sep-15	Fracture Clinic	Patient allocation confusion yet again... (where is paiteint, where to send patient, sending patient to x-ray, etc.)
46	18-Sep-15	Fracture Clinic	Dr. Berry: we should investigate if we can do anything for critical bone mass regeneration
47	18-Sep-15	Fracture Clinic	Plaster room is a bottleneck sometimes
48	18-Sep-15	Fracture Clinic	Difficulty for patients with limited movements to get on the bed in the plaster room
49	18-Sep-15	Fracture Clinic	Not much support for patient when doctor asks her to walk, it could be risky for the patient, she has nothing to hold on to if she can't walk properly
50	18-Sep-15	Fracture Clinic	Dr. Talbot: Time for a patient to get ambulatory surgery might be long, but the patient does not get much feedback
51	18-Sep-15	Fracture Clinic	Residents need consult, it can be chaotic for the doctors, not clear where they are needed
52	18-Sep-15	Fracture Clinic	Dr. Talbot: some app for keeping track of things to be done or follow up would be useful
53	18-Sep-15	Fracture Clinic	The waiting area is very full around noon, patients are in the dark about how long it'll take at each step
54	18-Sep-15	Fracture Clinic	patients are usually received/scheduled on first-come-first-serve basis, which causes problems such as a complex case may be assigned in the afternoon, for which xrays/ct scans etc. might take long, which would have been better if that patient was scheduled in the morning
55	18-Sep-15	Fracture Clinic	Lack of synchronization/communication among xray/ct techs, nurses, doctors, patients
56	18-Sep-15	Fracture Clinic	Xray/CT images are available in the 'raw' format, no option for enhancements
57	25-Sep-15	Fracture Clinic	A patient had to wait 5 min to see a receptionist because he was not sure if he could go home after seeing doctor
58	25-Sep-15	Fracture Clinic	Few patients had to wait in the hallway for plaster room, for patient room
59	25-Sep-15	Fracture Clinic	Residents waiting for consults everywhere
60	25-Sep-15	Fracture Clinic	Plaster room nurses can't cope up with the flow of patients
61	25-Sep-15	Fracture Clinic	Not enough computers in the doctors' office, sometimes the room is crowded
62	25-Sep-15	Fracture Clinic	Dr. Talbot: 3D printing of custom shaped screws/implants

63	25-Sep-15	Fracture Clinic	Doctor saw a patient, had to get back to the doctor's office to see another xray since he didn't have access to the xray
64	25-Sep-15	Fracture Clinic	Repeated paperwork like CSST
65	25-Sep-15	Fracture Clinic	Patient was in the plaster room for a long time (more than 1 hour)
66	25-Sep-15	Fracture Clinic	Doctor was taking patient notes in the hallway
67	25-Sep-15	Fracture Clinic	Patient gets called inside, then had to go out again to get x-rays
68	25-Sep-15	Fracture Clinic	Patient gets frustrated waiting outside the plaster room
69	25-Sep-15	Fracture Clinic	No one seems to know where a patient is when called inside
70	28-Sept-15	OR - Glen site	Hours of standing for staff members (without proper posture) hurtful to surgeons
71	28-Sept-15	OR - Glen site	Perfusionist could not clearly hear instructions from the head surgeon
72	28-Sept-15	OR - Glen site	Aortic valves were not a perfect fit - the perfect fit was in b/w 2 sizes
73	28-Sept-15	OR - Glen site	Osteosarcoma - the tumour was two thirds of the patients face, faster treatment before it gets this severe/ better treatment options to tackle a severe disease
74	15-10-06	OR - MGH	X-rays necessitate need for surgeons to wear heavy lead aprons and skirts for entire procedure; cumbersome, can become taxing over the course of a long procedure
75	15-10-06	OR - MGH	Big, open "window" above anaesthesiology team (on wall)... can be space for giant monitor, displaying patient vitals, x-rays, hockey game
76	15-10-06	OR - MGH	C-ARM (x-ray) is very large, bulky, and is separated into two parts (screen + monitor)
77	15-10-06	OR - MGH	anaesthesiology team gathered around smallish ~13" monitor looking at vitals
78	15-10-06	OR - MGH	Surgeons have to look at C-ARM monitor across the room and out of the line of sight of the patient on which they are operating and need to manipulate
79	15-10-06	OR - MGH	Over 30 x-rays were taken in one procedure (the transverse tibial fracture) for a total of 70.2 cumulative seconds, 5.02 mGy... this repeated exposure cannot be good for the surgeons
80	15-10-06	OR - MGH	In both procedures, the battery died on the drill/reamer during use
81	15-10-06	OR - MGH	Large inventory and store room required for nails and implants ($900-1000 estimated per nail)... according to Fernando an implant can be 3D printed in titanium in about 4-8 hr, so not immediate but if a procedure was planned a day or two in advance..
82	15-10-06	OR - MGH	Difficulty in determining length of limiting screws by residents; residents used screw that was a bit too long, close to pressing onto fibula
83	15-10-06	OR-MGH	Patients waiting in the hallway before taken to OR
84	15-10-06	OR-MGH	Garbage bin gets full quickly
85	15-10-06	OR-MGH	Surgeons do not see the vital signs of the patients
86	15-10-06	OR-MGH	Anesthesiologists see a small monitor for vitals
87	15-10-06	OR-MGH	lead aprons are heavy and had to be worn for the whole duration by the OR team
88	15-10-06	OR-MGH	door to protect anesthesiologists from xray looks inadequate
89	15-10-06	OR-MGH	The determination of length and width of nails and implants is manual
90	15-10-06	OR-MGH	putting in the nails near the ankles is time consuming and requires a lot of xray images while surgeons hold instruments to guess the correct location
91	15-10-06	OR-MGH	Drill does not indicate the battery level
92	15-10-06	OR-MGH	Takes about an hour to clean up the room after a surgery
93	15-10-06	OR-MGH	C-Arm is huge and difficult to move, takes time to line up to the correct location and angle, also often gets in the way of the surgeons
94	15-10-06	OR-MGH	The screens for xray is at an awkward position, it seems fixed, surgeons often have to look to the side or behind to see the screens

95	15-10-06	OR-MGH	The set up is not optimal for students, there is no screen showing the surgery, often it's not possible to see anything
96	15-10-18	Fracture Clinic	PM.1st visit to the clinic.Dr Talbot present to part of the non-medical staff.Ethnography(feel,think,like) with clinic nurses and coordinator.
97	15-10-29	Fracture Clinic	Shadowing-Interview nurse staff(8-15:30 h).This let me to understand how clinic function and interact with other organisations and the process management issues at the clinic(Report done.Will be provided under request).
98	15-10-02	Fracture Clinic	CT scans shows that bone infection caused by an open fracture can be difficult to eliminate.
99	15-10-05	OR-MGH	When operating a tibia fracture,doctor choose an initial intramedullary nail size(46 or 43 cm),positionated and realized that a shorter one will be necessary.He asked for a 36 cm.
100	15-10-05	OR-MGH	Tibia suport(operationg tibia fracture) is rudimentary and leg has free movement.One doctor must immobilize the leg while the other one drills.
101	15-10-05	OR-MGH	The individual protection against X-ray equipement used by the medical staff and the observers is heavy.After one hour and a half I experienced low-back pain!
102	15-10-14	OR-MGH	During THR surgeon use different sizes(increasing size) of surgical broaches when preparing the femur for the implant.
103	15-10-14	OR-MGH	Plonging is a problem when drilling the bone (Max)
104	15-10-14	OR-MGH	Everything was placed on the bed base and felt down to the floor
105	15-10-14	OR-MGH	Patient's supports are complex to mount and position (3 or 4 pieces)
106	15-10-14	OR-MGH	Distractor grips are slippery for the doctor, doctor used a dressing to pull it
107	15-10-14	OR-MGH	Extracting the femoral head is hard, there is no handle on the tool
108	15-10-11	Fracture Clinic	Max: a patient has been waiting 36 days for surgery --> need of alert!
109	15-10-11	Fracture Clinic	Scafoid fractures are difficult to diagnose
110	15-10-11	Fracture Clinic	Casting on inexperienced people may result in too tight or bad positionned casts
111	15-10-11	Fracture Clinic	Orthopedic boot is comfortable but sole is much higher than the other foot --> uncomfortable
112	15-10-11	Fracture Clinic	Once residents have seen a patient, they wait (sometimes longtime) for the doctor that re-analyzes the case and decides
113	15-10-11	Fracture Clinic	Patients have to go to CT or X-Ray but they don't know the way
114	15-10-11	Fracture Clinic	Undisplaced fractures diagnostic is complicated
115	15-10-05	OR-MGH	A doctor lifted the patient's leg before the anesthesia did effect
116	15-10-05	OR-MGH	Eyes are covered with a scotch tape
117	15-10-05	OR-MGH	Changing from operation table to the hospital bed is complicated: 5 people lift the patient by hand
118	15-10-05	OR-MGH	Nothing other than the X-rays indicates propper direction of the drill
119	15-10-05	OR-MGH	Doctor didn't ream far enough. They stop based on their feeling
120	15-10-05	OR-MGH	Distal interlocks needed lots of X-Rays. Experienced based

Appendix B: Detailed Observation – Problem – Need Statements

(**O** = Observations, **P** = Problem, **N** = Needs Statement)

1. Clinical Data Access for Doctors

O: Doctors do not have access to patients' x-rays during their room visits. Doctors at the MGH trauma clinic walk several time between the patients' rooms and the doctor's lounge to access patients' health records (OACIS) and the X-Ray/CT scans.

P: Not being able to have immediate and transportable access to patients' records is a burden to the doctors and staff. It is a time-consuming process and the residents have to wait longer to get the reviews from doctors and thus the workflow is slowed significantly.

N: A way to provide doctors at the MGH with the patients' necessary health records and up to date scans that is portable in order to reduce the time needed to evaluate the patients.

2. Clinic/Patient management

O: The trauma clinic is not optimally organized. Patients are not prioritized and organized and therefore some patients who have not had their imaging are sent to the waiting room. The staffs do not know where patients are inside the clinic.

P: This is an inefficient process that is time-consuming and frustrating for all parties involved.

N: A way to improve patient management processes in the clinics in order to increase their efficiency, time management and patient satisfaction.

3. **Paperwork assistance**

O: There are numerous forms and paperwork that needs to be completed by physicians after each patient visit in the trauma clinic.

P: The process in time-consuming; it limits the rate at which the patients are seen by their physicians.

N: A way to improve how medical staff completes their paperwork in order to increase the efficiency of this task.

4. **Mass Casualty Incidents Management Training Software**

O: Hospitals regularly exercises mass casualty simulations to increase disaster preparedness.

P: Large-scale simulations are time consuming and expensive which makes it difficult to play out all possible scenarios.

N: A way to increase medical staff preparedness in mass-casualty incidents in order to improve the handling of critical situations.

5. **Post-operative Infection**

O: Low-grade infection following internal fixation is difficult to diagnose. The clinical signs and symptoms are non-specific, laboratory tests are overly sensitive, and current imaging rarely provides useful information.

P: The diagnosis of infection is often made late in the disease process. The consequences are that long-standing infection often leads to complications (ex.: non-union) and is more difficult to eradicate.

N: In patients with orthopaedic implants, a technique to monitor the surgical site for infection which allows the surgeon to take early action with surgery and/or antibiotics.

6. **Telemedicine**

O: MUHC's catchment area comprises a vast area of Northern Quebec that extends 1700 km north of Montreal.

P: Trauma patients in this isolated location are at least 6-24 hours from a trauma center. Consequently, family physicians and nurses with limited resources are called on to manage complex trauma patients until evacuation by fixed-wing aircraft.
N: A robust and interactive capacity that integrates all aspects of trauma care between the MUHC and remote areas in its catchment area to improve trauma outcomes.

7. **Intra-operative Situational Awareness**

O: Orthopaedic surgeons have limited real-time awareness of various physiological events during surgery notably blood loss; fat embolism load; oxygen saturation; and coagulation parameters.
P: There is often a delay between an event being noticed by anesthesia and the communication of this finding to the surgeon. In many cases, significant events are not communicated at all to the surgeon. This may result in inappropriate decision-making.
N: A system to promote total surgeon awareness of intra-operative physiology to improve intra-operative decision-making.

8. **External Fixation in Damage-control Surgery**

O: In damage-control surgery, swift and coordinated actions by the general surgeon, vascular surgeon, orthopaedic surgeon and anesthetist are required to ensure patient survival. External fixation is often required in these cases.
P: The radiology equipment required for external fixation emits radiation; is cumbersome; heavy; and difficult to maneuver around the operating table. This slows the procedure and limits the mobility of all team members.
N: A technique to apply external fixators safely and quickly while minimizing obstruction of the operating room.

9. **Intramedullary Nail Fixation**

O: When a patient is being operated for a tibia femur fracture, an intramedullary nail is used to reduce and stabilize the fracture. The nail is fixated both distally and proximally with 2 screws on each side. Large amount of fluroscopic images are taken to insert the locking screws for the intramedullary nail fixation, especially for the distal screws.
Problem: During this trial-error procedure, the patient receives too much irradiation. Operation time is increased and often inaccurate screw placement, resulting in patient morbidity.
Need: A way to improve the accuracy of insertion of distal interlocking screws during intramedullary nail fixation, in order to reduce the operation time and to decrease the amount of radiation exposure.

10. **Cast Application**

O: In the Orthopaedic Clinic, a patient needs his full-arm cast to be replaced. The patient needs to hold up his arm during a minimum of 15 minutes for the cast to dry.
P: Fatigue and pain for the patient, especially in vulnerable populations such as the elderly.
N: A way to improve casting procedure in order to avoid uncomfortable posture and positioning of the patients and to reduce the fatigue they experience.

11. **Pre-op Skin Preparation**

O: For pre-op skin preparation, the nurses sterilize the skin with iodine. The nurse has to hold a patient’s limb up while they apply the iodine. Once the iodine application is finished, the nurse has to hold up the limb for an additional ten minutes.

P: The task is induced fatigue for the staff performing the procedure and it can be complicated to perform. For example, the positioning of the limb not always ideal, which can harm the patient. Furthermore, it may be hard for other medical staff to get around the individual holding up the limb, decreasing OR space available.
N: A way to simplify the skin preparation in surgical procedures, in order to decrease the fatigue of the medical staff and to improve the efficiency of the pre-op procedure.

12. **Patient Transfer**

Observation: After the operation, when a patient is transferred from the operation table to the hospital bed, a minimum of five people are needed to lift the patient and transfer them. This is done in a very uncomfortable position and the patient can be under significant mechanical stress.
Problem: Moving patients in this manner may harm the patient or the staff performing the transfer. This increases the chances of iatrogenic injuries.
Need: A way to improve patient transfer between the surgical table and the hospital bed, in order to avoid injuries to the patient and medical staff.

13. **Undisplaced Fracture Diagnosis**

O: Undisplaced fractures are difficult to diagnose and they often go unnoticed.
P: This particular clinical case can be misdiagnosed and have delays in treatment.
N: A way to improve the diagnostic of undisplaced fractures that will allow the surgeon to identify the fracture and select the adequate treatments in its early stages.

14. **Plunging with dril bit**

O: When drilling through the cortices of long bones to place screws, doctors have to rely on their experience and intuition to guide their drilling procedure. They pierce through the cortex and sometimes plunge into the surrounding soft tissues
P: Plunging can result in damage to soft tissues, nerves and vessels.
N: A way to reduce plunging with drill bits in order to prevent soft tissue damage and patient morbidity.

15. **Peripheral Nerve Damage**

O: Some surgical procedures can result in damage to the peripheral nerves
P: This secondary complication from surgery results in patient morbidity – including muscle paralysis, hypoesthesia and neurogenic pain
N: A way to visualize peripheral superficial and deep nerves in trauma patients that decreases accidental nerve damage due to surgery.

16. **Nerve Grafting**

O: Nerve grafting for peripheral nerve injury is less successful when longer nerve grafts required.
P: This often results in unsuccessful grafting procedure and has less predictable outcomes with an increased risk of nerve atrophy.
N: A different methodology for repairing peripheral nerve damage in patients requiring long nerve grafts (>7 cm) that increases success of the surgical intervention.

17. **Articular Cartilage Repair**

O: High-energy trauma and/or articular incongruity can result in chondrocyte apoptosis and a loss in articular cartilage turnover.

P: Cartilage damage can result in decreased range of motion, joint pain, and may progress to osteoarthritis.

N: A method that can facilitate cartilage regeneration in patients with permanent joint damage.

18. **Producing Implants**

O: Implants, nails, and screws are available in numerous standardized sizes and require the physical space to house a large, diverse inventory.

P: The ability to maintain an inventory requires space considerations, which can be a luxury to rural/developing nation/mobile clinics.

N: The ability for rural/developing nation/mobile clinics to request and acquire necessary implants while circumventing the requirement of housing an extensive inventory.

19. **Encouraging Bone Union in Arthrodesis**

O: Ankle fusion entails bone union between the distal tibia and the talus. This requires the removal of the articular cartilage with an osteotome.

P: Removal of the articular cartilage is a meticulous, time consuming procedure subject to significant variability.

N: An automated means for surgeons to remove articular cartilage to obtain perfectly matching arthrodesis surfaces.

20. **Critical Bone Deficit**

O: Fractures that have large segmented bone defects present a situation where intervention (e.g. bone grafting) may be required to avoid delayed healing or non-union.

P: Bone grafting is associated with inherent problems such as limited availability, donor site pain, prolonged surgery time, and thus increased risk of infection.

N: A suitable means that promotes proper bone union in patients with a critical-size bone defect, which avoids bone-graft associated morbidity

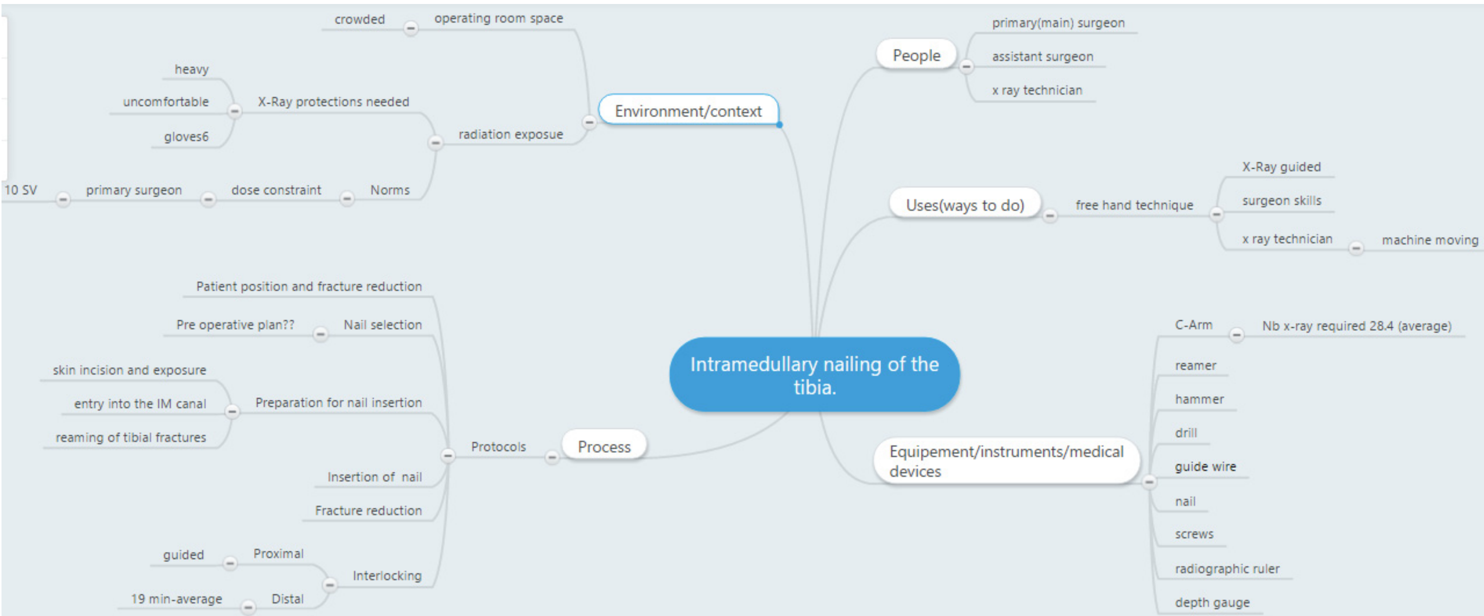
19. Appendix C: Needs Selection

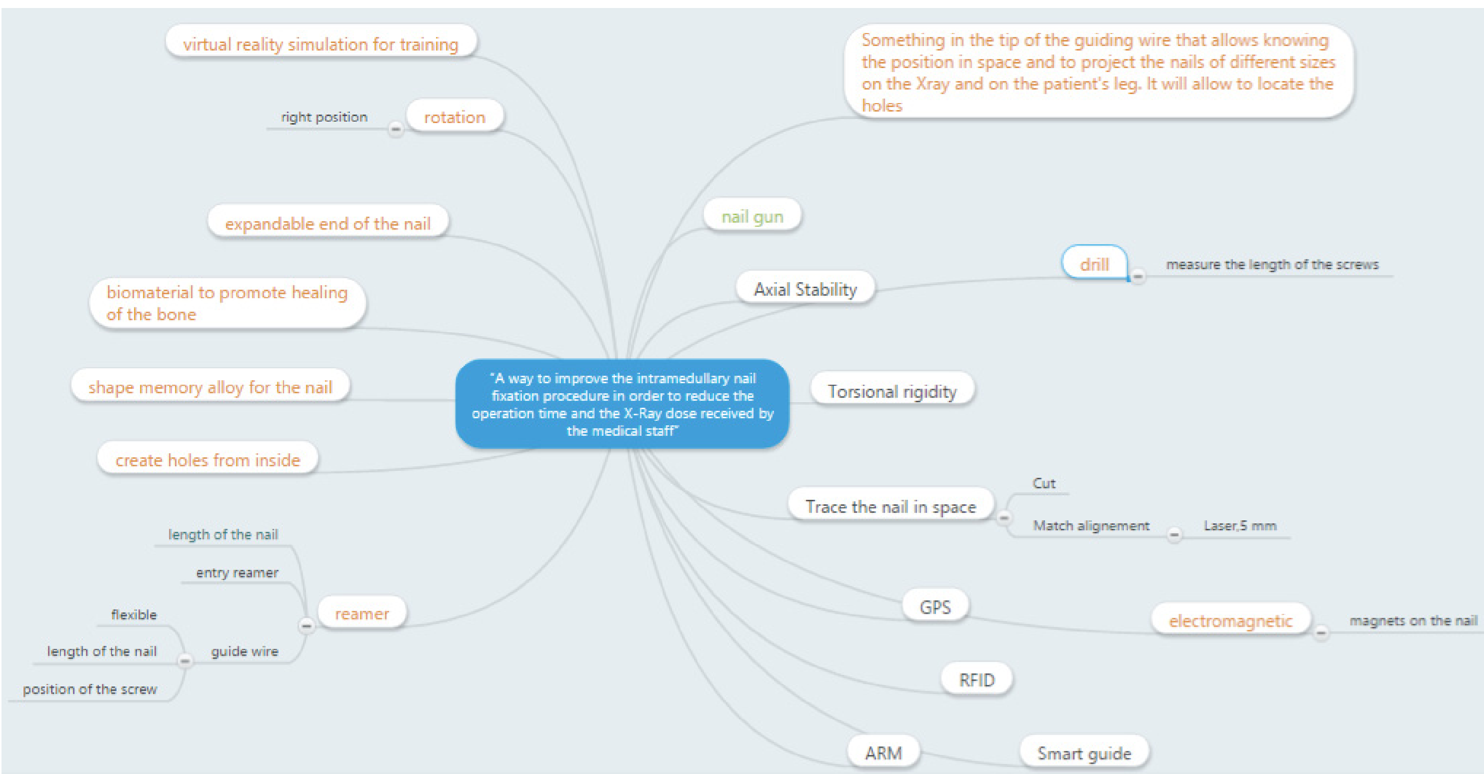
Top Needs Selection

Need	Need statement	Near term feasibility (within a year)	Within team's expertise	Market Size (Assumptions)	Unserved Market	Short-term impact on Surgical Field	Marketable	Group Interest	Weighted Rank
Plunging with drill bit	**A way to reduce plunging with drill bits in order to prevent soft tissue damage and patient morbidity.**	8	8	6	4	7	7	8	206.00
Mass Casualty Incidents Management Training Software	**A way to increase medical staff preparedness in mass-casualty incidents in order to improve the handling of critical situations.**	8	8	7	6	2	6	8	193.67
Intramedullary Nail Fixation	**A way to improve the accuracy of insertion of distal interlocking screws during intramedullary nail fixation, in order to reduce the operation time and to decrease the amount of medical staff radiation exposure.**	9	7	6	2	5	6	6	180.50
Cast Application	A way to improve casting procedure in order to avoid uncomfortable posture and positioning of the patients and to reduce the fatigue they experience.	8	8	6	6	2	7	5	179.50
Pre-op Skin Preparation	A way to simplify the skin preparation in surgical procedures, in order to decrease the fatigue of the medical staff and to improve the efficiency of the pre-op procedure.	8	8	4	4	5	7	5	178.33
Patient Transfer	A way to improve patient transfer between the surgical table and the hospital bed, in order to avoid injuries to the patient and medical staff.	4	7	7	3	5	6	7	160.67
Intra-operative Situational Awareness	A system to promote total surgeon awareness of intra-operative physiology to improve intra-operative decision-making.	4	6	6	8	6	6	4	159.00
Remote care	**A robust and interactive capacity that integrates all aspects of trauma care between the MUHC and remote areas in its catchment area to improve trauma outcomes.**	7	7	6	4	1	5	6	156.67
External Fixation in Damage-control Surgery	A technique to apply external fixators safely and quickly while minimizing obstruction of the operating room.	8	6	4	3	5	2	4	145.83
Critical Bone Deficit	**A suitable means that promotes proper bone union in patients with a critical-size bone defect, which avoids bone-graft associated morbidity.**	2	8	4	2	2	8	7	135.33
Paperwork assistance	A way to improve how medical staff complete their paperwork in order to increase the efficiency of this task.	5	7	6	5	2	4	3	134.67
Clinical Data Access for Doctors	A way to provide doctors at the MGH with the patients' necessary health records and up to date scans that is portable in order to reduce the time needed to evaluate the patients	8	7	2	3	2	1	1	116.67
Producing Implants	The ability for rural/developing nation/mobile clinics to request and acquire necessary implants while circumventing the requirement of housing an extensive inventory.	1	5	5	5	1	5	6	109.67
Articular Cartilage Repair	A method that can facilitate cartilage regeneration in patients with permanent joint damage.	1	5	8	3	1	10	2	107.50
Post-operative Infection	In patients with orthopaedic implants, a technique to monitor the surgical site for infection which allows the surgeon to take early action with surgery and/or antibiotics	1	1	10	10	1	6	2	104.83
Clinic/Patient management	A way to improve patient management processes in the clinics in order to increase their efficiency, time management and patient satisfaction.	1	7	6	3	2	1	2	90.17
Nerve Grafting	A different methodology for repairing peripheral nerve damage in patients requiring long nerve grafts (>7 cm) that increases success of the surgical intervention.	1	4	5	4	1	6	2	85.33
Encouraging Bone Union in Arthrodesis	An automated means for surgeons to remove articular cartilage to obtain perfectly matching arthrodesis surfaces.	2	5	1	1	1	1	5	74.50

Peripheral Nerve Damage	A way to visualize peripheral superficial and deep nerves in trauma patients that decreases accidental nerve damage due to surgery.	2	5	1	1	3	3	2	73.83
Undisplaced Fracture Diagnosis	A way to improve the diagnostic of undisplaced fractures that will allow the surgeon to identify the fracture and select the adequate treatments in its early stages.	2	2	2	2	2	5	3	71.17

Appendix D: Mind – Map Concept Generation





Appendix E: Test of Magnetic Guidance

The objective of this test is to prove that a magnetic element can be guided by a solenoid. For this purpose, we got a cubic Neodymium magnet, each side being 3.175 mm in length. Then we built an electromagnetic coil, wrapping magnet wire around a plastic cylinder. The coil had 208 turns, a length of 60 mm, and a diameter of 34.5 mm. This solenoid will produce a force (F) proportional to its surface (A), the number of turns (n) and the intensity (i), and inversely proportional to the gap with the magnet (g).

$$F = \frac{\mu_0 \cdot (n \cdot i)^2 \cdot A}{2g^2}$$

In the previous equation, $\mu_0 = 4 \cdot \pi \cdot 10^{-7}$ is the magnetic permeability of vacuum. A simple electric circuit (RL) was then built, by connecting a group of 5 parallel resistances in series with the coil. The total resistance was 5.8 . The circuit was connected to a power source and an intensity of 0.4 A was applied. First, a confinement test was performed, where the magnet was deposed over the coil and forced outside, in such situation, the magnet tried to remain within the coil. An additional test was done where the magnet was hanging from a wire and the intensity was varied from 0 to 0.5 A. This successfully attired the magnet to the center of the coil.

Montage for the test (left) and confinement test (right)

As a conclusion, the concept of guiding the guide wire from outside the body by magnetic forces seems possible. Further tests would be needed in order to determine the guiding magnet characteristics for this purpose.

Appendix F: Concept Screening Interviews

DATE	TITLE	KEY INSIGHTS	TRANSCRIPT
16-04-02	Service Contracts		
16-04-02	Disposables		
16-04-02	Device Sales		
16-03-31	In Person Meeting with Dr Louis-Philippe Amiot, CEO, Zimmer Cas	"Find technology that's fun, and figure out why sureshot is not fun.. Even if do not gain time, we could get companies that will distribute our product"	Dr Amiot's CV :Engineering degree in electronics and telecommunications (1988).Bell Northern Research (image transmission systems in real time (MPEG protocol)1988-1990.Medical studies at the University of Montreal 1995-2000.Master of Biomedical Sciences (MSc-MD) in 1997.Began working in computer-assisted surgery during an internship at the hospital Ste-Justine in Montreal in 1993. In 1995 he founded ORTHOsoft.Orthopedic surgery specialisation from 1995 to 2000(UdeM).Subspecialty in reconstruction techniques of the spine at Johns Hopkins University in Baltimore, (under the direction of Professor John Kostuik 2000-2001)Orthopedic surgeon at Maisonneuve-Rosemont Hospital (spine oncology patients).Author of numerous articles and speaker at several conferences about computer assisted orthopedic surgery.Best SMEs prize of the National Bank(2002)Arista Prize for young entrepreneur small and medium business (2004).Genesis Entrepreneurship prize in Health Sciences (2005).Faculty of Medicine of the University of Montreal, awarded him with a goal medal highlighting its achievements of the past 10 years(2005) http://hmrortho.ca/index.php?option=com_content&view=article&id=35&Itemid=66 Zimmer Cas(Orthosoft)-develops :surgical navigation systems(knee and hip replacement) Technology :Accelerometers and gyroscopes that provide accurate measurments about theorientation of the surgeon instruments to make a successful joint replacement. assistedsurgery(mentionned the name of his director-didn't catch dit) V notes: During undergrad, he had the opportunity to build spine navigation tech and that's how his journey started into both innovation and medicine « People don't know what they want till they have it inhis hands » Depends on your business model : direct sales vsdistribution via a partner.Is it difficult to approach a distributor when youare not known enough?LPA : don't think so. V notes: Question about Learning curve for our product and innovations in general: There is always a question of trust, especially for surgeons because they need to go to court if something goes wrong. Advice: We need to accompany people with our machines and install trust is our innovation
16-03-30	Distribution/GPOs		
16-03-30	Clinical trial design (FDA IDE application)		
16-03-30	Engage distributors/GPOs (Novation, MedAssets, Amerinet, Premier, HealthTrust, MAGNET)		
16-03-30	Engage manufacturing partners		
16-03-30	Prototype Development (Establish sensitivity of RF detection)		
16-03-30	Dr. William Krause (Entrepreneur, owner of patent, has working prototype/algorithms)		

16-03-29	Phone Call with William R Krause, Ph.D mechanical engineering, President-Flex Technology		Dr Krause is the inventor (improvement)of the targeting device for an implant(US6074394) that can be used with all kind ofnails.He developped a magnetic targetingsystem where the first receiver or internal sensor unit is embedded in a unitor handle to which the implanted device is attached or can bepositionned within a probe inserted in the intramedullary nail. After finishing his PhD inmechanical engineering at Clemson University at Vermont he worked 5 years as an assistent professor at Montreal Generalhospital! I started my interview validatingmy findings concerning his IP summary :18 US applications filed.14 US patents issued.1 FDA registered product : the « Flex shaft reamer » IP it's essential for him to keephis ideas away from competitors.
16-03-25	Phone Call with Warren West, CEO, Littleton Regional Hospital		Surgeons operate on pay-per-service, but do receive basic salary from hospital. Slowly moving more toward salary support system from hospitals. Hospital has four staff orthopedic surgeons, who specialize in knee, shoulder joint replacement. Also perform trauma (fracture fixation) if brought into the ER. Calls Orthopedic surgeons "Orthopods". Hilarious. Capital acquisitions go in front of capital procurement committee once per fiscal year. At year end, look though revenues and decide total amount to spend on capital equipment and also in which areas their priority might lie. Limited budget and determine what equipment to procure based on clinical utility and cost-effectiveness. Just bought two c-arms last year. Personally, prefers outright purchasing of capital vs. leasing since "you always pay more when you lease something". But reality of the situation will dictate whether to buy outright or to finance a purchase. Typically, will depreciate capital assets over 5 years (straight line).
16-03-18	In Person Meeting with Dr. Gregory Berry, Orthopaedic Surgeon, Montreal General Hospital		Radiation is a big concern and anything that eliminates or decreases it for orthopaedic surgeons would be extremely welcomed. Especially with academic hospitals, any device that could help junior residents with the distal locking would be appreciated. Finally, the c-arm can be extremely difficult/ frustrating to operate.
16-03-18	In Person Meeting with Dr. (Egypt), Orthopaedic Surgical Fellow, Montreal General Hospital		IM nailing is the best procedural option for patients however lack of imaging technology available in the middle east and elsewhere in the world prevents surgeons from doing this procedure. He personally would be very happy circumventing the need to c-arm entirely and do the whole procedure with ultrasound and our proposed device.
16-03-17	In Person Meeting with Mary, OR Head Nurse, Montreal General Hospital		Limited number of C-arms and technicians available to operate it. A clerk has to look through requests to schedule operations with the available resources. We realized that this scheduling clerk would be a great customer to contact! N - No

16-03-19	Phone Call with Peter Wright, CEO, Valley Regional Hospital, NH	For small hospitals, partnerships with medical device companies that incentivize increases in numbers of sales/surgeries, work in the favour for both companies.	Biggest difficulty facing regional hospital is finance. Reduced payments eating into margins. Bottom line takes a beating by Medicaid; reduced payments for services. Example of orthopedics: Need high volume of orthopedic surgeries in order to reach financial goals for hospital. Need about 100 surgeries or so; orthopedic surgeries are one of the tops in terms of profitability therefore assumed that this income stream subsidizes cost of other revenue negative or breakeven streams. Difficult to fill in necessary volume with low population density and local competition with other hospitals. Biggest problems with orthopedic surgeries are the cost of the equipment. Implants and devices are inherently expensive and the major cost driver for these surgeries. Capital costs are also considered but these are amortized over several years/numerous procedures. Joint replacement is going to be much less profitable than carpel tunnel surgery due to the sheer cost of the implant.
16-03-18	Phone Call with Sue Zemany, Director, Materials Management, Adirondack Medical Center, Saranac Lake, NY	Time savings is tough to quantify. Time savings only give positive ROI if more surgeries can be booked in a day	Adirondack Medical Center is a regional hospital in upstate NY. Has an Orthopedics unit focusing primarily on hip/joint replacement but also do fractures. Hospital has 4 ORs and 4 c-arms. Role of Director of Materials Management is multi-faceted, involved in ordering, stocking, procurement of supplies and capital purchases for the hospital. Oversees the budget and allocation of funds for specific buckets: capital expenses vs. consumables/supplies Capital budget purchases are conducted in the following manner: 1. Directors from each department submit proposals for equipment to the capital procurement committee based on needs/wants of doctors and other staff 2. Each list prioritizes the expected capital needs for the next 3 years 3. Committee evaluates the proposal lists from each director and prioritizes based on urgency (i.e. if request is to fulfill a change in standard of care, or to address a code violation, then it will be prioritized) 4. Committee will evaluate each capital request according to an internal algorithm in conjunction with value analysis committee. 5. Value analysis committee looks for savings in time, associated costs for consumables over the life of the device, and lifetime ROI 6. Capital committee meets every quarter; upcoming meeting they have $1.2M is requests with only $420K to spend (majority of requests will be triaged)

16-03-04	Phone Call with Luc Péloquin, Consultant/Advisor, Concierge		Concierge is a single access point to funding, expertise, facilities, and global opportunities for small- and medium-sized enterprises (SMEs) seeking to grow through innovation. The only service of its kind in Canada, it offers free, one-on-one assistance from expert advisors who provide customized guidance in selecting the most relevant programs and services to help grow our startup Concierge for business innovation is delivered by the National Research Council of Canada Industrial Research Assistance Program (NRC-IRAP) in collaboration with federal and provincial partners. Many government grants, loans, and tax credits available to help fund and grow the business. Many startups or medium sized enterprises do not know that these programs or incentives are available; concierge advisors will work to link us up with these programs. Concierge advisors will help us raise funds but can also provide advice on business plan creation and use their connections to put us in contact witht he right people. Free consultation service sponsored by Government of Canada (National Research Council)
16-03-09	Educational workshops		
16-03-06	Phone Call with Ian Swanson, Business Development Associate, Synaptive Medical	If the tech is mind-blowingly good; the surgeons will want it. Canadian academic tech advances are largely untapped by US counterparts	Synaptive Medical is a small (250 employees) medical device company that specializes in the manufacturing and sales of an innovative imaging technology for neurosurgeries. Based out of Toronto their main product offering is called Brightmatter. They "manufacture" their product themselves, i.e assembly, work with multiple vendors to design and spec out the components, build the betas/testers, and then find a manufacturer for the component. Often it is the vendor that helps build the prototypes. Assemble the components in house, in Toronto. "Our long term vision is that as production volumes increase we are going to own more of our supply chain, allowing us to tweak designs rapidly and thus respond to customer needs quicker." Direct sales. As a big capital equipment maker who is early in the sales cycle they dont see the benefit of distributors. Limited geographic (NA) launch allows direct sales. Distributors may come into play for a more diverse geographic mix where the sales process essentially runs through distributors, e.g. in parts of Asia where each hospital has specific sales channels and only go through a limited number of vendors (distributors).
16-03-09	Pega Medical (Engineering team, resources for prototyping, R&D)		
16-03-08	Circumvent need for C-arm		
16-03-03	Video Chat with Dr.Guillermo Sanchez MD, Msc,		You cannot pay for everything and at any price.We need safety, effective and cost-effective technologies. Health ressources are limited and we have to develop the « capacity of discernment » PHD, Director, THE COLOMBIAN HEALTH TECHNOLOGY ASSESSMENT INSTITUTE
16-02-28	In Person Meeting with Dr. Michel Malo, Head of orthopaedic, Hôpital du Sacré-Coeur de Montreal		Difficulties when distal locking : it's notat all a problem for him. What about residents? : Residents receiveintructions(how to position the limb, etc) If the resident takes too much time,he takes the lead because the patientis under the main surgeon resposability.The resident will have the chance topractice again, he mentionned.He doesn't let the resident take 30 minutes to distal locking!
16-02-17	Business/Financing Advisory Board (Can we get Guillaume Hervé on board?)		
16-02-17	Surgical Advisory Board (Drs. Ed Harvey, François Fassier, Venitolli)		

16-02-15	In Person Meeting with Dr. Pascal-André Venditolli, ? Research Director, Orthopedics Division, University of Montreal ? Assistant Clinical Professor, University of Montreal, Hôpital Maissoneuve-Rosemont	Key attraction of the concept should be : « the surgeon feels confident when using the device »	Difficulties when distal locking :Distal locking : the more difficult step of the surgery, less experiment surgeons can take 20-30 minutes to accomplish this step. Position the tibia on the surgical table and position the C-Arm. Risk of contamination for the patient (when rotating the C-Arm).Femur reductions are more frequent than tibia reductions : « leg is caught in a traction »,don't have access to both sides of the limb. Surgeons want to do it right the first time, every time, safely .It depends on the skills : capacity of 3D vision and triangulation of the surgeon.
16-02-15	In Person Meeting with Dr.Julio Fernandes, ? Regular Researcher, Research Center of Sacred Heart Hospital of Montreal ? Orthopedist, Sacred Heart Hospital ? Holder, Orthopedics Research Chair at (the University of Montreal) Sacred Heart Hospital ?	« The solution should not be more complicated than the problem to solve »	We started talking about the aim of the cursus (surgicalinnovation) and about product development. He's familiar with some tools usedto develop the concept of a new product. One of his students used QFDmethod/house of quality for one special project.He has a good understanding aboutthe fact that a concept must be developed on the basis of customer needs. Wecontinue to discuss about his concerns/difficulties when reducing a fracture,about the concept and his feedback/hypothesis validation. About fracture reduction (his concerns) :Complex cases : Tibial plateau fractures,proximal distal, « minimalist fixation » : when lockingwith 2 screws are not enough to stabilize the fracture.How to reduce the fracture when the surgeon has to manipulate 6 degrees offreedom! Rotation is difficult to control when you move the leg even theslightest. (
16-02-15	In Person Meeting with Dr. Charles Turcotte, Resident(R5), Residents coordinator, Hôpital du Sacré-Coeur de Montreal		Regarding the concept : Could be useful to increase efficacy of the procedure fornew residents.Is it cumbersome? Peace of mind is not a concerm for him. (temporary problemfor less experienced residents) Reduce radiation exposure : not concerned about it. Increase patient safety : don't think so.The wound won'tbe open until reaching the perfect circle. Reduction in comorbidities : don't really thinkso.Obese patient could be at risk but it's not related to the procedure..it'smore related to patient condition. He knows about existing technologies-devices like SureShot(neverused it) He showed me(web) the Zimmer antegrade femoral surgicaltechnique(pdf attached-see page 16PDF/14Document) and a device for distal targeting?.hesupposed that this can be used also intibial fractures.
16-02-05	In Person Meeting with Dr. Mohammed Alzarami, Resident, R4, MGH		He talked about bone cement/bone foam for defect filling. Problem is it's not absorbed and stays in bone which is not good. His opinion is that the learning curve is not big for IM nailing procedure. The residents have to follow the techniques properly and only then they can avoid any potential problem. Usually the surgery takes longer when rushing through the steps and not following the techniques. For him it usually takes only 3 xray shots to get the position correct. He is not much concerned with radiation and does not think we can save significant time in distal interlocking. But he sees our concept/device being useful in military and emergency damage control situations.
16-02-05	In Person Meeting with Dr. Rudy Reindl, Surgeon, MGH		His main concern is patient care. He agrees that any innovation in the distal interlocking process that can save time would be useful. Implant budgets are too small for hospitals, that may be an area worth further exploration.
16-02-04	In Person Meeting with Monika Paape		We started by discussing US patent 7,060,075 which describes an invention for distal interlocking that includes a probe inside the nail. We subsequently found multiple other patents that include a probe inside the nail. There are lots of patents covering distal interlocking. One patent- without a probe inside the canal- is highly problematic for us.
16-02-05	In Person Meeting with Dr. Khalid Alkhelaifi, Resident (R5), MUHC		Needs/Problems:Systematic problems; patient changeover (1 hr to clean/sterile room is too long)Logistical problemsPatient positioning for surgeries; includes positioning for C-arm (e.g. for shoulder surgery)Hard to position in good position, move them around, sometimes can take 30 min to move them into position.

16-02-05	In Person Meeting with Dr. Andrew Chase Crasper, Resident (R5), MUHC		Needs/ProblemsLead is uncomfortable; sweats all the timeC-arm is "a nuisance" and "barbaric"; have to keep it sterile, everyone has to move out of the way, radiation exposure is a concernMentioned something about increase likelihood of thyroid cancer in orthopedic surgeons (NEED TO CHECK LITERATURE)Mentioned that pregnant surgeons can't operate/be in OR when C-arm is flashingSays that radiation is a problem for him (a concern) however, when probed admitted it's about a 6.5/10 Mentioned that they have to manipulate/rotate the limb and c-arm to get perfect alignment ("perfect circles").
16-02-05	Cost-effective		
16-02-05	In Person Meeting with Dr. Asim Makhdom, Resident (R5), MUHC		Surgeon values everything going smoothly; smooth = good not great; mistakes/problems = NOT kind of bad but fucking awful/stressful
16-02-05	Creating branded Co (100% in-house)		
16-02-05	Commissioning manufacturing and selling wholesale to Med Dev Co		
16-02-05	IP Play (Licensing, Selling)		
16-02-04	In Person Meeting with Dr. Vincent Dubé, Resident(R3), Hôpital du Sacré-Coeur de Montreal		When I asked him about the issues experienced when distal locking: He clarified that he hasn't done enough distal locking but he thinks that the main problems are finding the « truehole » and make sure to screw properly. He also mentioned that distal locking is more difficult when patient is obese (to do x-ray, to move the leg).
16-02-04	In Person Meeting with Dr. Qin(Chin) Du, Resident(R4), Hôpital du Sacré-Coeur de Montreal		X-ray technologist must be effective and comfortable when finding the « truehole ».Her worst experiences : during weekends and when the radiolgist « on call » hassome difficulties to position the C-Arm. Too many shots....communication issues between surgeon and technologist. Feelings of frustration and angry comes when is difficult for the trainee to reach the static hole but she mentioned that the trainee/surgeon has the possibility to use the distal oval hole instead when « dynamisation »is possible (Zimmer-Recon the suppliers of IM nails). Her comments :distal licking is a matter of practise
16-02-03	In Person Meeting with Alain Readman Valiquette		Notes from 03-Feb-2016 PresentationPrefers VP "Peace of Mind"Think we should really explore VP and how it relates to CS Surgeons and/or Residents/Remote TraumaExplore Channels (e.g. IP play, licensing, distribution, etc.)Would like us to explore some of these channels for next week's presentation
16-02-02	Peace of Mind		
16-02-02	Orthopedic Residents/Remote Trauma		
16-02-02	In Person Meeting with Julie Simard		If our tech is obvious (not necessarily identical) to claims of another tech, then it may not be patentable Mercier, Intellectual Property Analyst, Université de Montreal
16-02-02	Human (R&D)		
16-02-02	Intellectual		
16-02-02	Manufacturing		
16-02-02	Finance (Start-up capital)		

15-12-28	In Person Meeting with Dr.François Fassier, Chief of Staff Emeritus, Shriners	When Dr Fassier mentionned that our concept was interesting. He told us that we had a "great challenge to solve" and he encouraged us to integrate the idea within a drill." La tête chercheuse " it's a dream he said.	Interviewers: Fernando and Mariana. We started by asking him general questions about the greatest problems hi has found in his practice. Then we ask him how he felt about the problems we identified (in particular high X-Ray dosis). We then presented our prototype and ask him for his opinion. Finally we ask him about how could it impact (to look for additional stakeholders). In total we had about 30 minutes interview. Overall he seemed to like the idea and found the problem "a great challenge to solve". The take-home-message we took was: 1) He doesn'tthink that reducing x-ray is a priorty.In his opinion the harm to medical staff by to x-rayexposure hasn't been proved.(He told us that his exposition to X-Ray was never checked..and he's in good shape :-) 2) If our conceptcan reduce the time variability during distal interlocking (5-35 minutesdepending on surgeons skills) then the risk of infection for the patient can bereduced. 3) Our conceptcould improve the distal interlocking in a "standard way" speciallyfor trainees, reducing insecurities,fears and frustrations while looking for thehole."Peace of mind for the primary surgeon" regarding the work of his resident..Dr Fassier mentionnedthat he leaves the OR only when the wound is closed. 4) We have to think in going towards integrating the idea within a drill (he called it "tête chercheuse"). After the conference: I feel extremelly confident about continue validating our concept.Mariana
16-01-27	Customer advisory board		
16-01-27	Sales force		
16-01-27	Trade shows, conferences		
16-01-27	Increase # surgeries per day		
16-01-27	Healthcare Management (Profit)		
16-01-25	Reduction in co-morbidities		
16-01-25	Hospital purchasing dept (Budget)		
16-01-25	Increase efficacy of procedure		
16-01-25	Increase patient safety		
16-01-25	Reduce radiation exposure		
16-01-25	Patients		
16-01-25	OR nurses		
16-01-21	Reduce surgery time		
16-01-21	Orthopedic Surgeons (Staff)		