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Design and assessment of a surgical instrument for passing the Gigli saw during pelvic osteotomies.

Dissertation presented by
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Abstract

The goal of this master thesis is to design, manufacture and test a new orthopaedic surgical instrument which will be used during pelvic osteotomies. The concerned osteotomy is the Salter osteotomy which consists of a reorientation of the pelvis thanks to a bone cutting. The bone cutting is performed along the innominate line. This surgery increases the covering of the femoral head and in this way decreases the risks of hip dislocation and degenerative diseases such as osteoarthritis.

The patients are most of the time children aged between 18 months and six years with acetubular dysplasia. The acetabulum is the part of the pelvis in which the femoral head is positioned.

The thesis begins with a clinical context in which the acetabular dysplasia is described with its different treatments. The challenges of these treatments are presented. The main challenge of the Salter osteotomy is the passage of the Gigli saw through the greater sciatic notch; that means the passage of the saw around the bone of the pelvis which has to be sawed. When the iliac fossa is well cleared and the Rang retractors are correctly placed, the passage of the guidewire can take only a few minutes. However when the iliac fossa is not cleared enough, or the Rang retractors are not correctly placed or if the dysplasia is acute, the passage of the Gigli saw through the greater sciatic notch can take up to thirty minutes. In this case, the child is under longer anaesthesia which is not good for his health.

The request of the surgeon is thus clear: **designing and testing a surgical instrument which assists the surgeon to pass the Gigli saw through the greater sciatic notch during Salter osteotomy**. Following the clarification of this request, a first functional analysis and the list of specification are realized. After that, based on the list of specifications, a second functional analysis specific to the instrument is established. Afterwards, the concept variants responding to the list of specifications are designed following a classical design method. The retained solutions are prototyped.

The last step is a feasibility test of the retained solutions. A first test was performed on an experimental setup which reproduces the surgical cavity with the pelvis and the Rang retractors. A second test was executed on a cadaver in the laboratory of anatomy from UCL. An additional test consisting of an analysis of the resistance of magnet to a steam sterilization process was performed. Following these tests, the feasibility of the final solution, consisting of a set of magnetic instruments, was approved. Research can therefore continue !

Résumé

Le but de ce mémoire est de concevoir, fabriquer et tester un intrument d'aide chirugicale pour les ostéotomies du bassin. L'ostéotomie concernée est l'ostéotomie de Salter qui consiste en une réorientation du bassin par découpe osseuse. La découpe du bassin est réalisée le long de la ligne innominée. Cette chirugie permet d'augmenter le recouvrement de la tête fémorale et ainsi de diminuer les risques de luxation de la hanche ainsi que de maladies dégénératives telles que l'arthrose.

Les patients concernés sont généralement des enfants ayant entre 18 mois et 6 ans présentant une dysplasie de l'acetabulum. L'acetabulum est la partie du bassin dans laquelle la tête du fémur vient se positionner.

Le travail commence par une mise en contexte dans laquelle la dysplasie de l'acetabulum est détaillée avec ses différents traitements possibles. Les défis rencontrés durant ces traitements sont présentés. Le principal défi de l'ostéotomie de Salter est le passage de la scie de Gigli au travers de la grande échancrure sciatique c'est-à-dire le passage de la scie autour de l'os du bassin devant être découpé. Lorsque la fosse iliaque est bien dégagée et que les écarteurs de Rang sont correctement placés, cette étape peut prendre quelques petites minutes mais lorsque ce n'est pas le cas ou que la dysplasie est aiguë, cette étape peut prendre jusqu'à trente minutes. L'enfant est alors sous anesthésie plus longtemps que prévu ce qui est néfaste pour sa santé.

La demande du chirugien est donc claire: **concevoir un intrument chirurgical permettant de l'assister lors du passage de la scie de Gigli au travers de la grande échancrure sciatique durant une ostéotomie innominée**. Suite à la clarification de cette demande, une première analyse fonctionnelle ainsi que le cahier des charges peuvent être réalisés. Ensuite, sur base de ce cahier des charges, une analyse fonctionnelle propre à l'instrument est élaborée. A partir de ces différents éléments, les variantes de concepts répondant au cahier des charges sont identifiées en suivant une méthode classique de conception. Les solutions retenues suite à cette étape de conception sont ensuite prototypées.

La dernière étape est un test de faisabilité des solutions. Un premier test a été réalisé sur un banc d'essai. Celui-ci représentait l'ouverture chirugicale avec l'os du bassin et les écarteurs de Rang. Un deuxième test a été réalisé sur cadavre au laboratoire d'anatomie de l'UCL. Un test supplémentaire consistant à analyser la résitance d'aimants à la stérilisation par vapeur a été réalisé. A l'issue de ces tests, la faisabilité de la solution finale consistant en un set d'instruments magnétiques a été approuvée. Les recherches peuvent donc continuer !

Contents

Glossary

Abduction is the action of certain muscles in pulling a leg, arm, etc away from the median axis of the body [1].

Acetabulum is the cup-shaped cavity on the lateral surface of the hip bone in which the head of the femur articulates [1].

Attractive force is the force by which one object attracts another. The magnetic attractive force corresponds the the attraction for iron [1].

Ball-and-socket joint is a multiaxial synovial joint in which a more or less extensive sphere on the head of one bone fits into a rounded cavity in the other bone, as in the hip joint [1].

Biocompatibility is the property of being biologically compatible by not producing a toxic, injurious, or immunologic response in living tissue [1].

Cartilage is a specialized, fibrous connective tissue present in adults, and forming most of the temporary skeleton in the embryo, providing a model in which most of the bones develop, and constituting an important part of the organism's growth mechanism [1].

Central nervous system is the part of the nervous system consisting of the brain and spinal cord [1].

Congruence is the functionally normal bone orientation within a normal joint [1].

Degenerative disease is the result of a continuous process based on degenerative cell changes, affecting tissues or organs, which will increasingly deteriorate over time, whether due to normal bodily wear or lifestyle choices such as exercise or eating habits [1].

Dislocation is a displacement of a bone from a joint [1].

Dysplasia is an abnormality of development; in pathology, alteration in size, shape, and organization of adult cells [1].

Extension is the act of straightening or extending an arm or leg [1].

F5 corresponds to the cylindrical ferrite magnet. Its diameter and its height are equal to 5 millimetres.

Ferrite is a ferromagnetic ceramic iron oxide based.

Flexion is the act of bending a joint or limb in the body by the action of flexors [1].

Gigli saw is a flexible wire saw used by surgeons for bone cutting [1].

Greater sciatic notch is the deep indentation in the posterior border of the hip bone at the point of union of the ilium and ischium [1].

Groin is the junctional region between the abdomen and thigh [1].

Iliac fossa is a concave area occupying much of the inner surface of the ilium, especially anteriorly; from it arises the iliac muscle [1].

Innominate line is an anatomic line which begins from the greater sciatic notch and ends in the anterior inferior iliac spine. This line is the cutting line of Salter osteotomy.

Ischial tuberosity is the rough bony projection at the junction of the lower end of the body of the ischium and its ramus [1].

Joint capsule is a sac enclosing the articulating ends of the bones participating in a synovial joint, formed by an outer fibrous layer and an inner synovial membrane [1].

Kirsnher pin is a steel wire for skeletal transfixing of fractured bones and for obtaining skeletal traction in fractures. It is inserted through the soft parts and the bone and is held tight in a clamp [1].

Myelin sheat is the insulating envelope of myelin that surrounds the core of a nerve fibre or axon and facilitates the transmission of nerve impulses [1].

N3 corresponds to the cylindrical neodymium magnet. Its diameter and its height are equal to 3 millimetres.

N5 corresponds to the cubic neodymium magnet. The length of the edges is equal to 5 millimetres.

Neodymium is metal from rare earth metal part. Combined with iron and boron, it can be used to produce permanent magnets.

Neuromuscular system is the muscles of the body collectively and the nerves supplying them [1].

Osteotomy incision or transection of a bone [1].

Ostheoarthritis is a progressive disorder of the joints caused by gradual loss of cartilage and resulting in the development of bony spurs and cysts at the margins of the joints [1].

Periosteum is a specialized connective tissue covering all bones of the body, and possessing bone-forming potentialities. Periosteum also serves as a point of attachment for certain muscles. The connective tissues of the muscle fuse with the fibrous layers of periosteum [1].

Rang retractor is a metallic and rigid retractor used to bare out the greater sciatic notch. It is a chevron-shaped lever. [31].

Rugine is a surgical instrument used to scrape the bone in order to removed the periosteum from it.

Salter osteotomy is an osteotomy of the pelvis performed along the innominate line.

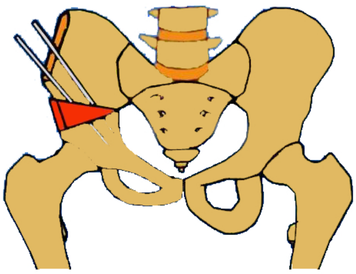
List of Figures

List of Tables

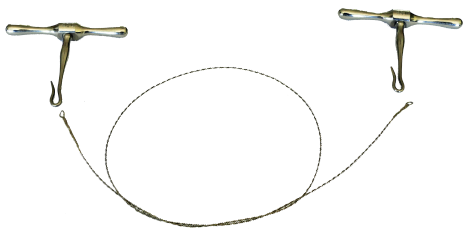
Introduction

Acetabular dysplasia is a pathology which affects 5% of the population in Europe and in America. This pathology causes a deformation of the socket of the hip joint. The socket is the part of the pelvis where the femoral head is positioned. A patient affected by acetabular dysplasia has its socket either not deep enough or not well oriented. This induces an insufficient covering of the femoral head rendering the hip unstable and conducive to early wear. If the child is not treated, the risk of dislocation or osteoarthritis of the hip increases when he grows.

To treat the children affected by pathology, a Salter osteotomy can be performed. This treatment consists of a reconstructive surgery of the pelvis. The surgeon executes a cut above the socket of the hip joint in order to lower the bone resulting in a better covering of the femoral head. However, the challenging manipulation of this surgery is the passage of the saw (hereafter, the "Gigli saw") around a bone of the pelvis. Indeed, in addition to the small body size of a child, some other issues can appear such as a too large pelvic bone or a too acute deformation. In these cases, this manipulation can take up to thirty minutes instead of a few minutes.



Salter osteotomy



Gigli saw

The goal of this Master's thesis is designing, manufacturing, and testing a new orthopedic surgical instrument which will be used to assist the surgeon during Salter osteotomy on children. This instrument will help the surgeon to pass the wire around a bone of the pelvis. The manipulation is not only difficult but is also dangerous due to the presence of some major structures around the surgical working environment (e.g. sciatic nerve, femoral artery, reproductive organs, etc.). The main objective of this thesis is reducing the duration of this manipulation to a few minutes.

The thesis is separated in six main steps. The first step is understanding the request of the surgeon concerning the surgery, the surgical environment, the critical steps, etc. Based on these informations, a list of specifications is established. Several solutions are then identified and compared to bring out the more promising ones. The retained solutions are prototyped to be tested on an experimental setup, which reproduces the surgical environment, and on a cadaver. Finally, an analysis of the results is performed and some recommendations for the future are given.

Chapter 1

Clinical context

The main concern of this project is the pediatric orthopedic surgery of the pelvis. The pelvis is the bone present between the abdomen and the thighs. It is composed of two pelvic bones on both lateral sides and of the sacrum and the coccyx on the dorsal side (see figure 1.1). The cavity created by this bone is called the pelvic cavity. It encloses the organs of the reproductive system, the rectum and the bladder. The pelvis joins the vertebral column and the lower limbs. The pelvic articulation is the hip which has a major motor function. It corresponds to the joint present between the acetabulum and the femur. It is a triaxial ball-and-socket joint which allows movements in all spatial planes and in rotation and supports the body weight [37].

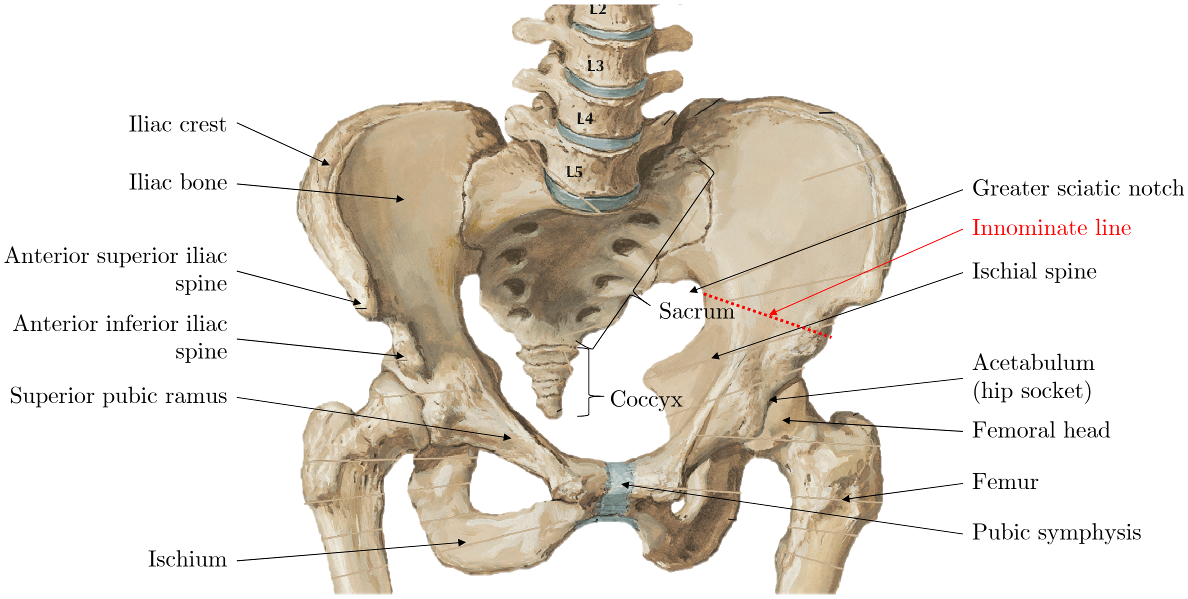


Figure 1.1: Captioned pelvis, adapted from [5].

1.1 Development of the pelvis

During the development of a newborn, the pelvis which is mainly cartilaginous transforms: the femoral head inflates and the bony kernel grows until the femoral head is almost entirely covered. The acetabulum deeps and growths [12].
The pelvic bone is composed of three main parts separated by the triradiate cartilage (see figure 1.2). These three bones fuse between 13 and 16 years for girls and two years later for boys [37]. The expansion and enlargement of the acetabulum are due to the growth of the triradiate cartilage. Moreover, the acetabular contour grows and tends to close the socket. Due to the pressure exerted by the femoral head on the acetabulum, it inflates and its spherical contour develops largely. It is essential that the pressure is centralized in the acetabulum to induce its normal growth [37].

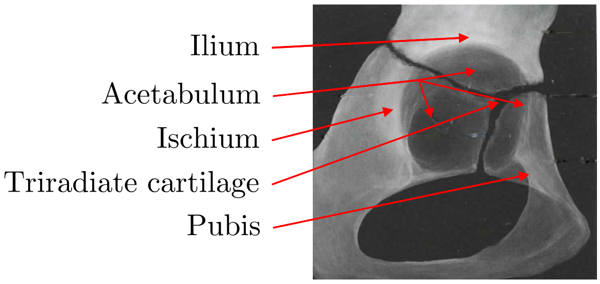


Figure 1.2: Ischium, ilium and pubis separated by the triradiate cartilage during child development, adapted from [2].

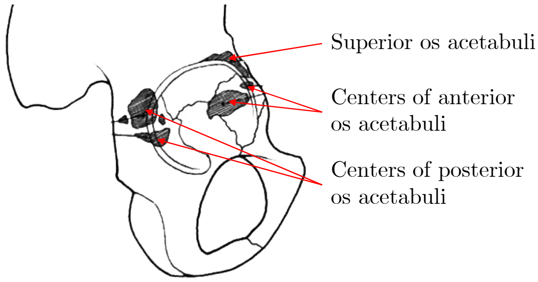


Figure 1.3: The three main ossification areas present during the development of the pelvis, adapted from [37].

In addition to this cartilaginous line, there are three main ossification areas: the superior, anterior and posterior os acetabuli (see figure 1.3) [37]. If one of these ossification areas fails to develop, deformations appear which can result in a deficiency of femoral head coverage [37].
Three things are essential for the good development of the hip:

- a correct genetic programming,
- a good in utero congruence with free articular movements,
- and a normal neuromuscular system [28].

1.2 Position of the acetabulum

The position and orientation of the acetabulum are characterized inter alia by (see figure 1.4):

- the center-edge (CE),
- the neck-shaft angle (NSA),
- and the acetabular index (AI)

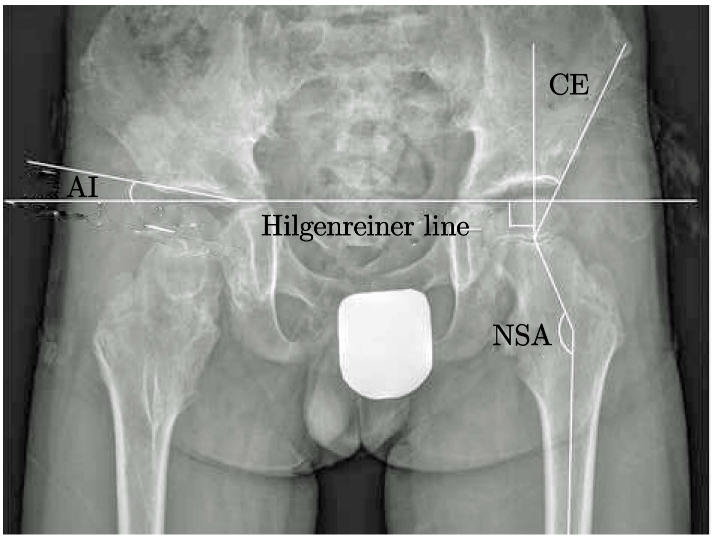


Figure 1.4: Acetabular index (AI), center-edge (CE) and neck-shaft angle (NSA) presented on a radiography of a pelvis, adapted from [45].

The **center-edge** is defined by the longitudinal body axis and the line passing through the center of the femoral head and the lateral margin of the acetabular roof. For children, this angle is approximatively equal to 31 degrees. The **neck-shaft angle** is the angle of inclination of the femoral neck. This angle is approximatively comprised between 135 and 145 degrees for newborns and decreases to 125 degrees for adults. The **acetabular index** is the angle formed with the Hilgenreiner line and the tangential line to the roof of the acetabulum. For newborns, this index is about 28 degrees and progressively decreases to 22 degrees for a one-year-old to finally reaches 12 degrees for a six-year-old. Finally, in the case of a sound child, the center of the femoral head coincides with the center of the acetabulum and the acetabulum covers more than 50 % of the femoral head [13, 37, 23, 20].

1.3 Pathology: acetabular dysplasia

Acetabular dysplasia is a malformation of the acetabulum resulting of a problem during the development of the pelvis. The acetabulum is either not well oriented or not enough deep causing an insufficient covering of the femoral head [3]. In the figure 1.5, a normal hip on the left (red contour) is compared to a dysplasic hip on the right (orange contour). In the pathological case, the femoral head is not sufficiently covered by the acetabulum resulting in an unstable hip. This kind of deformation can induce a dislocation of the hip and early degenerative disease. From a physics point of view, the load is not equally distributed inducing an excessive load along the rim of the acetabulum.

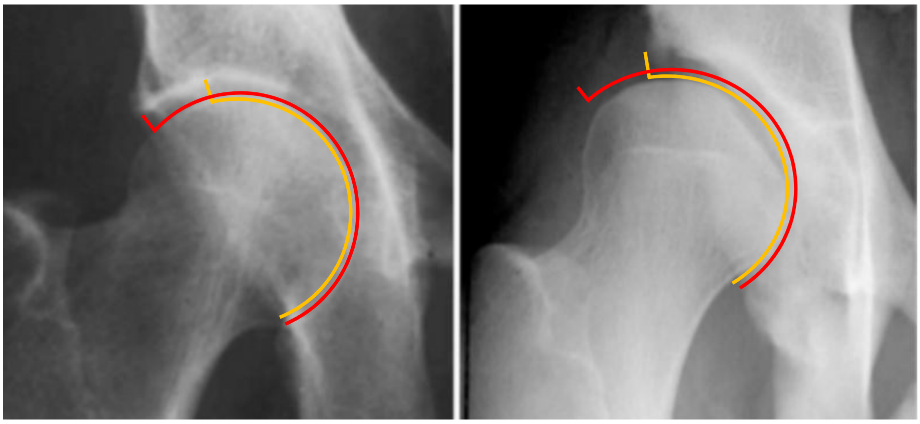


Figure 1.5: Radiography of a normal and dysplasic hip. On the left, it is a normal hip with the contour of the acetabulum in red and on the right, it is a dysplasic hip with the contour of the acetabulum in orange, adapted from [19].

At first, the dysplasia induces pain in the groin but when the acetabular labrum and the adjacent articular cartilage begins to wear out, the pain increases and a hip replacement at young age is necessary [3].

The earlier the dysplasia is detected, the better because the changes are not permanent and the child continues to grow and to adapt his shape. Furthermore, the younger the patient, the less the dysplasia is advanced, and the higher his remodelling capacities. This is why Salter osteotomies are mostly performed on children having between 18 months and 6 years. When the patient is too old, a hip replacement is needed.

1.3.1 Detection of an acetabular dysplasia

One can detect acetabular dysplasia from a detailed history and physical examination of the patient but, as explained in [20], the diagnostic has to be confirmed with a radiography. The doctor measures the CE, AI and/or NSA. The patient has acetabular dysplasia if one of these criteria is true:

- CE $< 20°$ [8]
- AI $> 40°$ [4]
- NSA increases during development instead of decreasing [32].

1.4 Treatments

The main treatments for acetabular dysplasia are osteotomies of the pelvis. An osteotomy is a surgical cutting of the bone performed to modify the shape or the orientation of it.
Two classes of pelvic osteotomies exist: the reconstructive class and the salvage class. Here the class of interest is the reconstructive osteotomy. The salvage osteotomy concerns the deformed femoral head and not a deformed acetabulum. The reconstructive class is divided in two categories: redirectionnal and reshaping one. A redirectionnal osteotomy changes the orientation of the acetabulum and a reshaping osteotomy reduces the size and the shape of the acetabulum. In each category, there are different treatment [8] (see figure 1.6):

- **Redirectional osteotomy**
  - Salter osteotomy: single osteotomy
  - Sutherland osteotomy: double osteotomy
  - Steele osteotomy: triple osteotomy
  - Periacetabular osteotomy (PAO): triple osteotomy
- **Reshaping osteotomy**
  - Pemberton osteotomy: incomplete single osteotomy
  - Dega osteotomy: incomplete single osteotomy

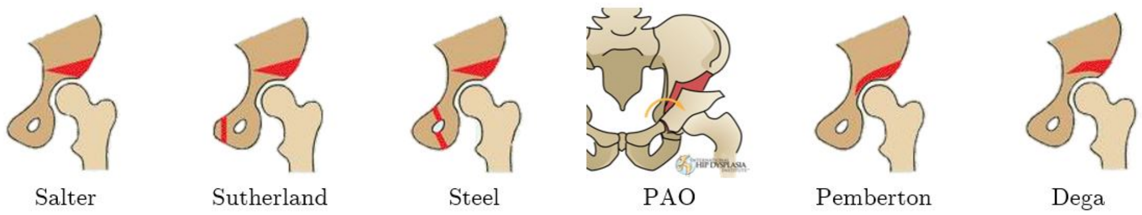


Figure 1.6: Comparison between different types of pelvic osteotomies. The bone grafts inserted in the spaces created by the osteotomies are represented in red. Left side of the pelvis, coronal section except for PAO where it is a front view. Adapted from [33, 18].

Single, double and triple osteotomies correspond respectively to one, two and tree bone cutting locations. There are many other procedure like Chiari, San Diego, Lace, Shelf, etc.
Salter, Dega and Pemberton osteotomies are performed to treat developmental hip dysplasia and residual dysplasia before maturity. The other one are performed to treat residual dysplasia after

maturity. [8]

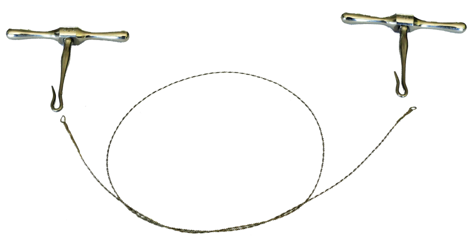
To allow for these surgeries to be realized, some conditions have to be complied with:

- good congruity between the hip joint surfaces,
- good mobility and range of motions because the surgery does not improve the mobility of the patient,
- the patient's age is between 18 months and 6 years,
- the femoral head must be able to be contained in the acetabulum,
- the femoral head is spherical,
- CE $< 20°$,
- AI $> 40°$,
- and an arc of flexion and extension of the thigh of minimum 70° [10, 25, 8].

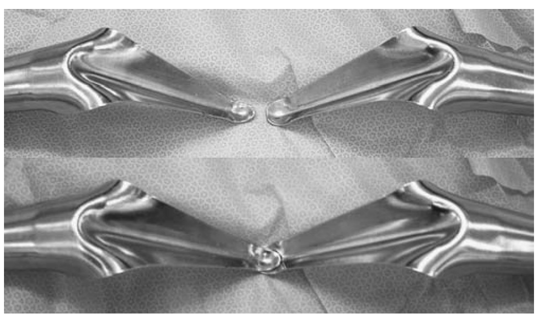
The goal of the treatments is to correct an acetabular deficiency, improving the femoral head covering and inducing normal growth and development in order to reduce the malformation by reorienting of the hip socket so that the femoral head fits more deeply in the acetabulum. Moreover, the difference between the two sides of the pelvis will decrease with the surgery. All of these consequences decrease the pain, restores the pressure distribution and establishes normal biomechanical forces around the hip joint [3].

1.4.1 Surgical instruments used during most of the presented osteotomies

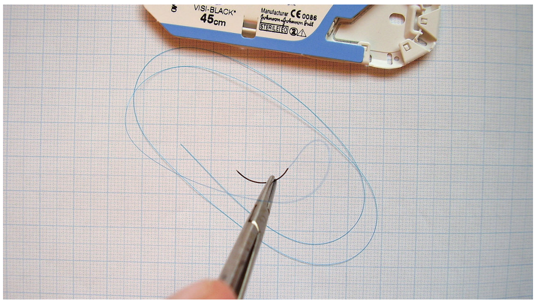
Before detailing the different surgeries, the main surgical instruments used for most of these osteotomies are presented.



The Gigli saw is a twisted, metallic and flexible saw. It is used to cut bones. The surgeon passes the saw around the bone, then places a handle at each extremity of the saw and by a reciprocating motion while pulling on the saw, the bone is cut.



The Rang retractors are metallic and rigid retractors used to bare the greater sciatic notch. The two retractors are chevron-shaped levers. They are placed on either side of the pelvic bone by inserting first the smaller one and then the largest one. They overlap them in the greater sciatic notch with the smaller retractor above the largest one [31].



The guidewire used to pass the Gigli saw through the greater sciatic notch is a suture thread. It is a resistant wire. The needle present at its extremity is removed when used as guidewire. (Figure from JOHNSON & JOHNSON)

A Kirshner pin is a metallic wire which is used to hold fragments of bone together. It exist in different sizes. (Figure from ORTHOSINTHESE)

During osteotomies, the curved clamp is mostly used to manipulate the suture thread used as guidewire or to manipulate compresses (e.g. to spread Isobetadine on the patient). (Figure from PLATTS & NISBETT)

A rugine is a surgical instrument used to scrape the bone in order to removed the periosteum from it. (Figure from TEAMALEX, MEDICAL TECHNOLOGIES)

1.4.2 Redirectional osteotomies

Salter osteotomy

The Salter osteotomy is a single complete pelvic osteotomy which reorients the acetabulum (see figure 1.7). The goal of this surgery is to improve the anterior and lateral covering of the femoral head in order to avoid a dislocation and a degenerative disease of the hip joint [10].

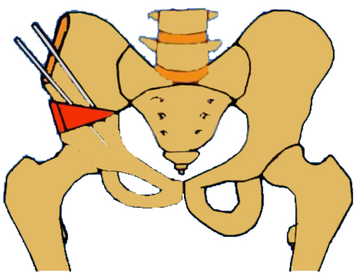


Figure 1.7: Illustration of a Salter osteotomy: the graft taken from the iliac crest is represented in red and fixed with Kirschner pins, front view, adapted from [17].

During the surgery, the patient is placed in dorsal recumbency (see figure 1.8) with a rolled tissue under his thorax. A Smith Peterson incision is performed (see figure 1.9). It begins just below the middle of the iliac crest and passes obliquely forwards distal to the anterior superior iliac spine. After the incision, the muscles are retracted to uncover the iliac crest and then an incision of the apophysis is carried out between the anterior superior and anterior inferior iliac spine (see figure 1.10). Thanks to this incision, the perisoteum could be easily retracted from the bone citeArticle1, Article14.

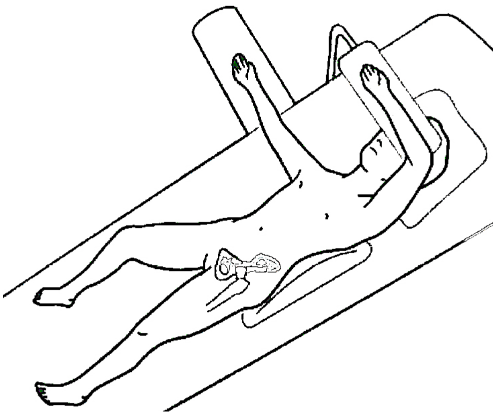


Figure 1.8: Position of the patient during the Salter osteotomy: dorsal recumbency [10].

Figure 1.9: Course of the Smith Peterson incision.

The periosteum is a membrane present on long bones and flat bones which is about 2-3 millimetres thick in children. It ensure a good growth and the vascularization of the bones. The next step is to take off the periosteum from the pelvis with a rugine (see figure 1.11). This manipulation is delicate because the periosteum cannot be drilled or broken. Indeed it protects some important structures present around as the sciatic nerve and gluteal arteries. This step allows to clear the way to the greater sciatic notch because the tissues around the bone are removed with the periosteum.

Figure 1.10: Incision of the apophysis of the iliac crest.

Figure 1.11: Detachment of the periosteum with a rugine.

The next important step is to place the Rang retractors in the greater sciatic notch by sliding these between the iliac bone and the periosteum and pass the Gigli saw through the greater sciatic notch (see figure 1.12). The Rang retractors overlap each other, spread the surrounding soft tissues and allow the passage of the Gigli saw. Moreover, these retractors protect the tissues present around the bone. The passage of the Gigli saw is achieved in two steps: first the surgeon passes a guidewire through the greater sciatic notch thanks to two curved clamps (see figure 1.13). Next this guidewire is fixed to the Gigli saw and by pulling the guidewire outside the greater sciatic notch, the Gigli saw is placed through it (see figure 1.14). This step can be fulfilled in a few minutes if the way is unobstructed. In case of some patient (e.g. patients with acute deformation), this step can take up to thirty minutes.

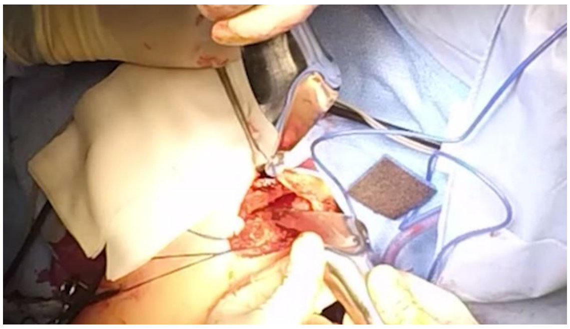


Figure 1.12: Positioning of the Rang retractors through the greater sciatic notch.

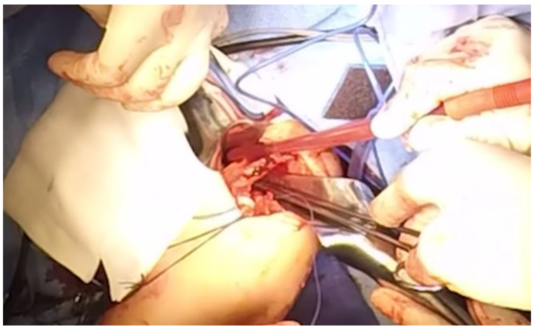


Figure 1.13: Passage of the guidewire through the greater sciatic notch with curved clamps.

Before starting the osteotomy, a bone graft is withdrawn from the ipsi-lateral iliac crest with an oscillatory saw (see figure 1.15).

Figure 1.14: Passage of the Gigli saw through the greater sciatic notch thanks to the guidewire.

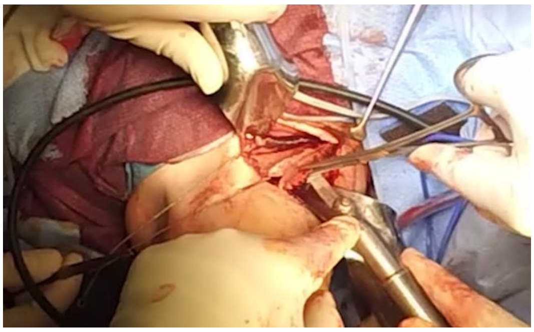


Figure 1.15: Bone graft withdrawn from the iliac crest thanks to an oscillatory saw.

After the passage of the Gili saw and the graft removal, the osteotomy can be performed (see figure 1.16). The cutting line is perpendicular to the iliac bone and follows the innonimate line. More precisely, it begins from the greater sciatic notch and ends at the anterior inferior iliac spine [10, 25].

After having cut the bone along the innonimate line, the surgeon carves the bone graft in a triangular shape (see figure 1.17). Next he separates the two parts of the bone: the upper part is maintained in position while the lower part is shifted downwards with an external rotation [25]. To assist this separation, the surgeon bends the leg of the patient. Doing so creates a gap between the two bones which is filled with the reshaped triangular bone graft (see figure 1.18). Finally, the graft is fixed on the bone with Kirschner pins (see figure 1.19). Then a second surgery is necessary to remove the pins.

Most of the time, the Salter osteotomy is a success [26, 24].

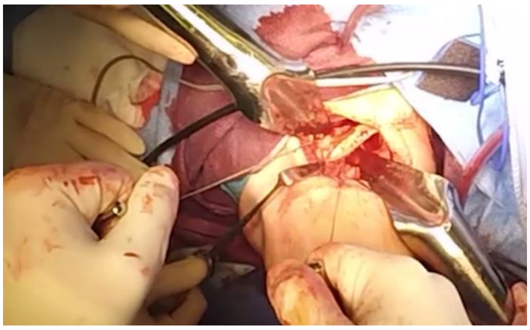


Figure 1.16: Innominate osteotomy performed with a Gigli saw.

Figure 1.17: The bone graft carved in a triangular shape.

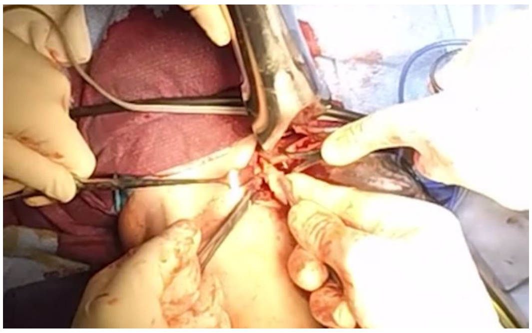


Figure 1.18: Insertion of the bone graft in the space created by the innominate osteotomy.

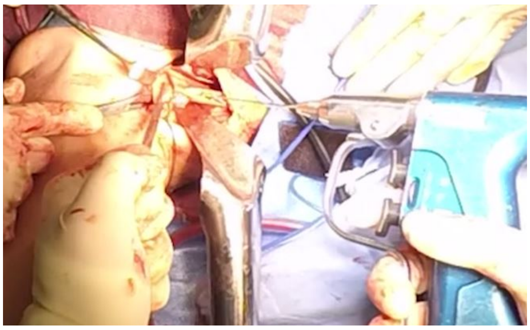


Figure 1.19: Fixation of the bone graft with Kirshner pins.

Sutherland osteotomy

The Sutherland osteotomy is a double complete osteotomy. One cut is performed along the innominate line as for the Salter osteotomy and an other one is performed near the pubis. This added cut increases degrees of freedom for rotation [26].

Steele osteotomy

The Steele osteotomy is a triple complete osteotomy which lateralises the hip and shortens the abductors. Thanks to the three osteotomies, this treatment allows a greater correction range compared to the Salter osteotomy, but it requires two separated incisions [24, 26].
One of the osteotomies is carried out along the innominate line as for the Salter osteotomy. An other one is conducted on the superior ramus and the last one on the ischial tuberosity (see figure 1.1) [26].

Periacetabular osteotomy

The PAO is a triple osteotomy which cuts the pelvic bone around the acetabulum to reorient it. This redistributes the pressure around the rim of the acetabulum [6]. The three osteotomies are performed through the pubis, ilium and ischium [24]. This treatment presents some advantages like preserving the superior gluteal artery and the acetabular blood supply. Moreover, the posterior column of the acetabulum remains intact and it protects the sciatic nerve during the surgery. Finally, the dimensions of the pelvis remain unchanged [24]. On the other hand, some complications as nerve dysfunction, interruption of the blood supply which induces acetabular osteonecrosis, destabilisation of the pelvic ring, etc., can appear [26].

1.4.3 Reshaping osteotomies

The Dega and Pemberton osteotomies are quite similar but the pattern of the cuts are different as such, they induce a different final orientation of the acetabulum [17].

Pemberton osteotomy

The Pemberton osteotomy is an incomplete pericapsular osteotomy. The osteotomy takes place around the triradiate cartilage. After cutting the bone, the surgeon pushes down the acetabulum to better cover the femoral head. The wedge above the acetabulum is subsequently filled with a graft taken from the ilium. The graft is impacted without any fixations thanks to the pressure exerted on it [25, 17].
Compared to the Salter osteotomy, the Pemberton osteotomy is not as through and does not disturb the integrity of the posterior column. The Salter osteotomy can induce an elongation of the ipsilateral leg. Moreover, the Salter osteotomy needs Kirshner pins to fix the graft, which is not the case here. This implies that a second surgery is not necessary [25].

Dega osteotomy

The Dega osteotomy is an incomplete osteotomy which is carried out when the acetabulum is too wide or too shallow. The acetabulum is pushed down over the head of the femur to better cover it. The bone cutting is performed along the innominate line but does not reach the greater sciatic notch. A graft taken, from the iliac crest, is added to fill the created space [25, 17]. As for the Pemberton osteotomy, compared to the Salter one, this osteotomy is incomplete then avoids any disturbances of the integrity of the posterior column. Again, no Kirshner pins are needed to maintain the graft in place.

1.5 Challenges during pelvic osteotomies

The first challenge is the passage of the Gigli saw around the bone when necessary. For example, during the Salter osteotomy, the surgeon uses curved clamp to pass the Gigli saw through the greater sciatic notch. Because the working space is really limited, this step is difficult and can take up to thirty minutes in the worst cases. This is not good for the patient, because he will be under longer anaesthesia. Moreover the surgeon could become nervous and then increases the risks of harming the patient.
The second one is that during all of the previously presented surgeries the surgeon is faced with a limited working space and must be extremely conscious not to harm the surrounding major structures. An example of such a structure is the sciatic nerve which passes through the pelvic cavity, just next to the greater sciatic notch. It conveys motor and sensitive informations between the lower limbs and the central nervous system.
As explained above, the Salter osteotomy consists of cutting the pelvis along the innominate line. In the following sections the structures in the direct environment of this line are presented. The following anatomical informations are not exhaustive.

1.5.1 Muscles

The muscles present around the innominate line are (see figures 1.20 and 1.21):

- The piriformis muscle which provides a motor function on the hip and leg.
- The coccygeus muscle which supports all the organs present in the pelvis and close the back of the pelvis cavity.

- The psoas major muscle which contributes to the flexion of the hip joint. This muscle links the upper and lower parts of the body.
- The iliac muscle contributes to (with other muscles) the flexion and rotation of the thigh.
- The gluteal muscles (medius and minimus) permits the abduction, extension, internal and external rotation of the hip joint [44, 42, 43].

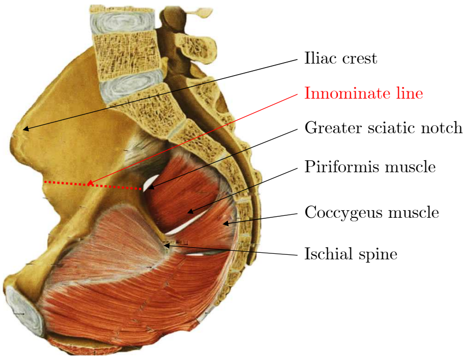


Figure 1.20: Muscles present around the innonimate line (in red), medial view of the right hemipelvis, adapted from [2].

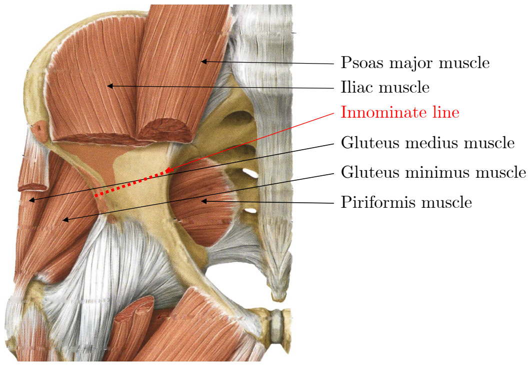


Figure 1.21: Muscles present around the innonimate line (in red), anterior view of the right hemipelvis, adapted from [2].

1.5.2 Ligaments

Four main ligaments are present around the innominate line (see figure 1.22):

- The sacrospinal ligaments stabilize the ischium with respect to the sacrum and help to maintain the sacrum in a neutral position during locomotion to prevent the pelvis from turning too much.
- The tuberal ligaments keep the sacrum and the coxal bone together.
- The anterior sacroiliac ligaments maintain the sacrum and the iliac bone.
- The inguinal ligament form with other structures the inguinal canal. The inguinal canal allows the passage of the spermatic cord for men and the round ligament for women [30, 29].

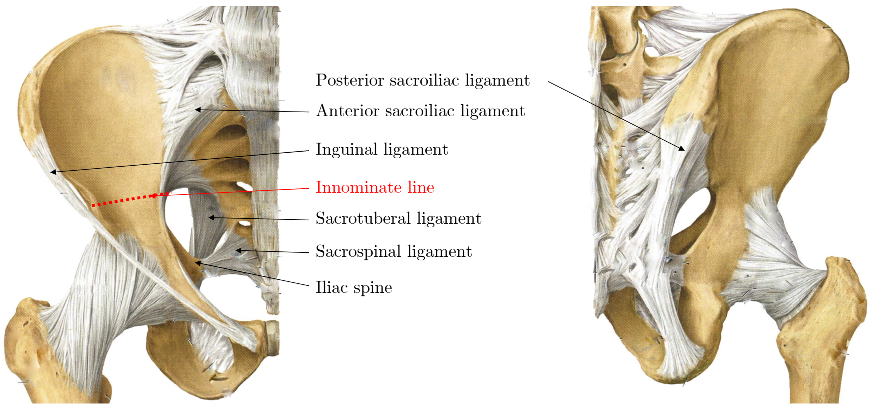


Figure 1.22: Ligaments present around the innominate line, left: anterior view, right: posterior view, innominate line in red, adapted from [2].

1.5.3 Nerves

Four main nerves are present around the innominate line (see figure 1.23):

- The obturator nerve allows abduction and lateral rotation of the thigh and conveys sensitive information from the lateral part of the thigh .
- The femoral nerve commands flexion of the thigh and extension of the leg. It also conveys sensitive informations from the anterior part of the thigh, from anterior medial part of the knee, from the leg and the ankle.
- The sciatic nerve is the longest and the largest nerve of the organism. It conveys the motor and sensitive informations to and from the lower limbs. It commands the flexion movement of the lower limb and the flexion and extension of the foot.
- The lateral femoral cutaneous nerve innervates the lateral part of the thigh and it conveys sensitive information of it [11] [41].

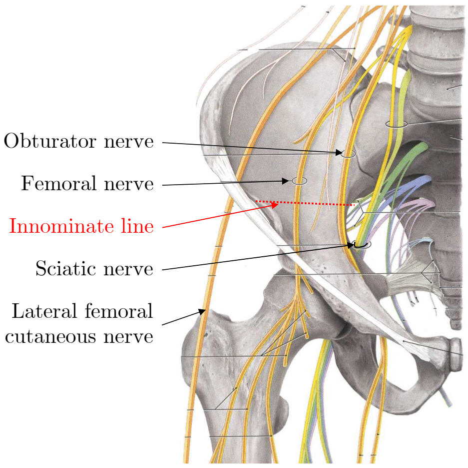


Figure 1.23: Nerves around the innominate line, anterior view, innominate line in red, adapted from [2].

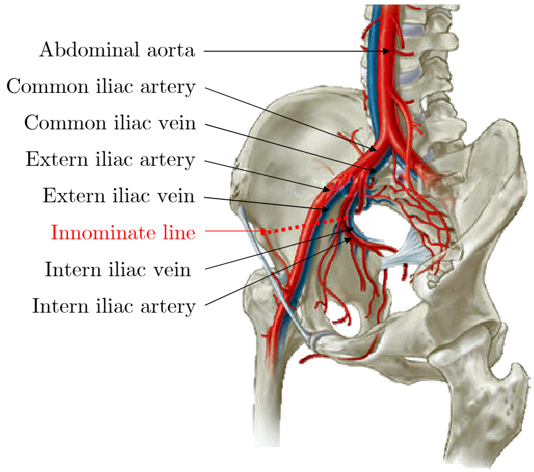


Figure 1.24: Vessels present around the innominate line, innominate line in red, adapted from [27].

1.5.4 Vessels

The main vessels present around the innominate line are presented in figure 1.24. The most important ones are the abdominal aorta, the common iliac artery and vein, the extern iliac artery and vein, and the intern iliac artery and vein. The internal and external iliac arteries supply the lower limbs. These are supply by the common iliac artery which is supplied by the abdominal aorta.

Chapter 2

List of specifications

In this chapter, we start from the request of the surgeon to arrive to the list of specifications. The design methodology used in this thesis follows several steps:

1. Reformulation of the **surgeon's request**.
2. Construction of the **objective tree** which is based on some basic questions about the instrument as "What?", "Where?", etc. This step brings out the main information from the surgeon's request.
3. Next, the **functional analysis of the need** is carried out based on the main functions required for the instrument in terms of the surgeon's request.
4. Based on the objective tree and the functional analysis, the **list of specifications** can be defined. This list will contain all the informations needed to design the surgical instrument: the purpose of the instrument, the constraints to which it is submitted, etc.
5. Subsequently, a **functional analysis specific to the instrument** based on the list of specifications is realized.
6. Before thinking about any solutions, the **comparison criteria**, which will be used to find the best solution, are defined. These criteria are linked to the task and the environment. A weight factor is attributed to each criterion, depending on its relative significance. The higher the weight factor, the more important the criterion.
7. Then, the **search for solutions** can begin. Solutions which fulfill the function of the instrument are searched. All the solutions must be drawn and detailed. The solutions which are based on the same idea are considered as the same concept variant. Normally, a morphological graph has to be carried out but in the present case, the instrument has only one main function this is why it is useless because the morphological graph will have only one line. Indeed, the different solutions could not be combined because they assumes the same function.
8. Finally, all the solutions are **quoted on each comparison criterion** to find the best one.

2.1 Surgeon's request

The surgeon Pierre-Louis Docquier asks for an instrument which can be used during Salter osteotomy on children. The patients are between 18 months and 6 years old and have an acetabulum dysplasia. The instrument should help the surgeon to pass the Gigli saw trough the greater sciatic notch (see section 1.4.2). This manipulation is executed after that the Rang retractors are correctly placed to push aside the soft tissues from the pelvic bone. The instrument should enable to place the guidewire or directly the Gigli saw in the bottom of the surgical cavity in front of the greater sciatic notch, then to pass the guidewire or the Gigli saw through the greater sciatic notch and finally to bring it out from the surgical cavity. After that, if a guidewire is used, the Gigli saw is fixed to the guidewire and by pulling the guidewire outside the greater sciatic notch, it carries the saw through the greater sciatic notch.
Currently, the surgeon uses two curved clamps to pass the guidewire through the greater sciatic notch but this can take a long time, up to 30 minutes in the worst cases. The main goal of the instrument is decreasing the duration of the passage of the Gigli saw through the greater sciatic notch.
Because it is a surgical instrument, it must be sterile. It needs to be conceived so that it could not hurt the patient or the surgical staff. Moreover, it has to be biocompatible to avoid any adverse reactions with the tissues of the patient. The fact that the patient is a child cannot be neglected because the small size of the patient limits the access to the greater sciatic notch even more.

2.2 Note on the drawings

Figure 2.1 shows the color code used for all the drawings in this report. Figure 2.2 shows the sectional view, used for the representation of the steps of the functional analysis and the solutions, is located.

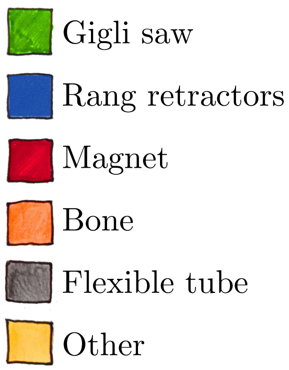


Figure 2.1: Color code used for all the drawings.

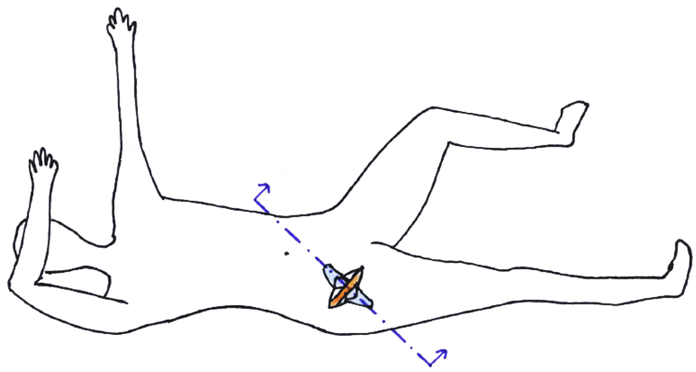


Figure 2.2: Position of the patient during the surgery (dorsal recumbency) and position of the sectional view (perpendicular to the Smith Peterson incision and parallel to the innominate line) used for the representations.

2.3 Objective tree

Based on the surgeon's request, the objective tree can be constructed (see figure 2.3).

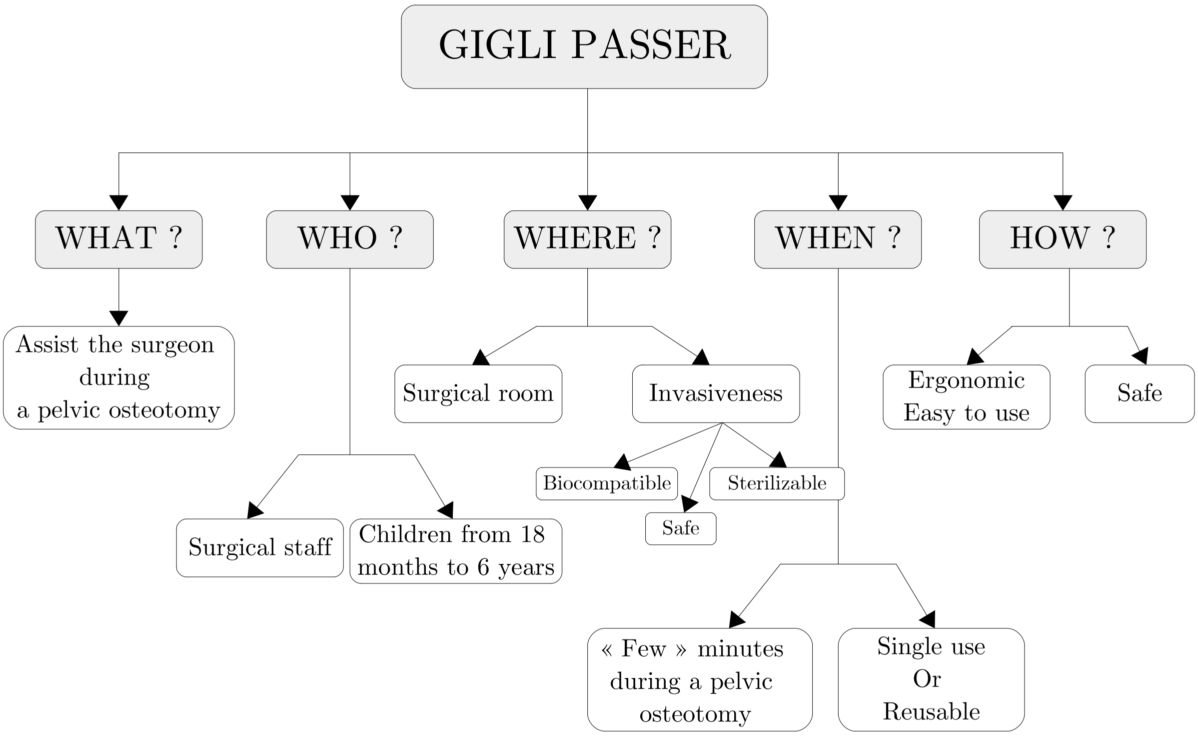


Figure 2.3: Objective tree.

2.4 Functional analysis arising from the surgeon's request

In figure 2.4, we can observe the functional analysis arising from the surgeon's request.
This functional analysis summarizes the request of the surgeon about the function of the instrument. In the present case, the function of the instrument is to place the Gigli saw through the greater sciatic notch. The functional analysis details all the main positions that the saw needs to reach to be correctly placed. This passage can be achieved in two steps: the first step is placing a guidewire through the greater sciatic notch. Next the Gigli saw is attached to the guidewire to pull it through the greater sciatic notch. The reason for this first step is that the Gigli saw is too rigid to be easily directly placed in the greater sciatic notch. In this case, the instrument will more precisely *assist the surgeon to pass the guidewire through the greater sciatic notch*. This guidewire is a suture thread from which the needle is removed.

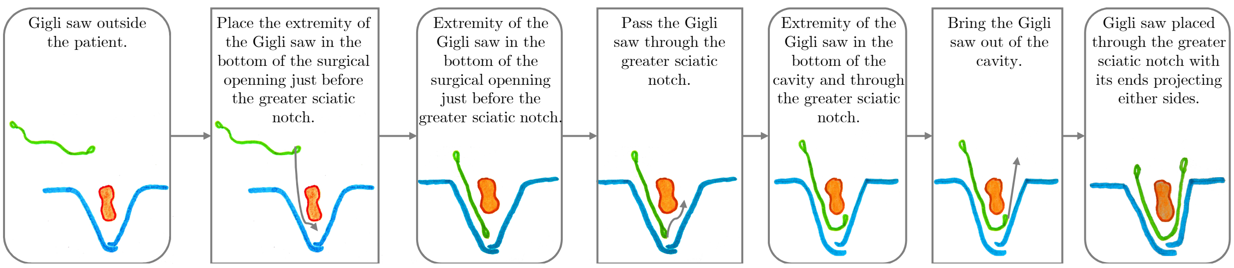


Figure 2.4: Functional analysis arising from the surgeon's request, sectional view from figure 2.2.

2.5 List of specifications

From the sections 2.1, 2.3 and 2.4, the specifications of the instrument can be defined. These are presented in the table 2.1.

Table 2.1: List of specifications.

Surgical instrument for Salter osteotomy			
Context: Children who are between 18 months and 6 years old and who present an acetabular dysplasia have to undergo a surgery to reorient the acetabulum. During it, the pelvis is sawed with a Gigli saw along the innominate line and a bone graft taken from the iliac crest is added. The passage of the Gigli saw through the greater sciatic notch is difficult due to the lack of space and the blood present. The objective of this work is to design a new surgical instrument which assists the surgeon to pass the Gigli saw through the greater sciatic notch during the Salter osteotomy in order to shorten the duration of surgery.			
Date	Source	**Main Function**	
25.08.16	Dr Docquier	**MF1**: Assist the surgeon to pass the Gigli saw through the greater sciatic notch during a pelvic osteotomy	
		Performance of the main function	
25.08.16	Dr Docquier	**1.1:** duration	less than 1 minute
		Constraint functions	
25.08.16	Dr Docquier	**CF2**: The instrument is used on children who are between 18 months and 6 years old.	
25.08.16	Dr Docquier	**CF3**: The instrument is used in a surgical medium during a Salter osteotomy, see section 1.4.2.	
26.08.16	Eléonore Nelis	**CF4**: The instrument is safe for the patient and the surgical staff.	
		Performance of the constraint functions	
28.02.17	Dr Docquier	**2.1:** Limited access	see section 2.5.2
28.02.17	Eléonore Nelis	**3.1:** Sterilizable	Steam sterilization or gaz sterilization.
28.02.17	Eléonore Nelis	**3.2:** Biocompatible	
28.02.17	Dr Docquier	**3.3:** Presence of the Rang retractors	see section 2.5.1
28.02.17	Eléonore Nelis	**3.4:** Material of the instrument	

2.5.1 Dimensions of the Rang retractors

The main dimensions of the Rang retractors are showed on the two sketches in figures 2.5 and 2.6. Because of the many curves, it is really difficult to get precise measurements.

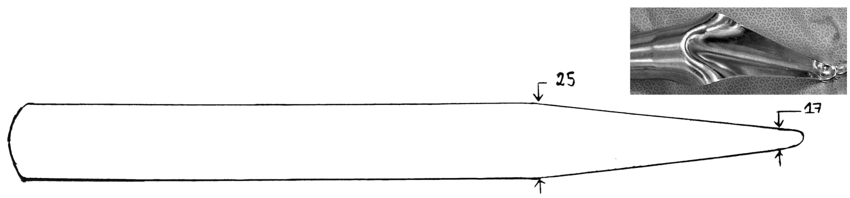


Figure 2.5: Approximation of the main dimensions of the Rang retractors, top view, [mm] [31].

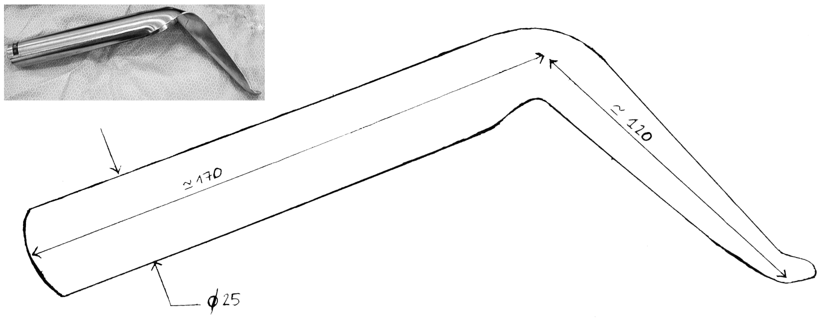


Figure 2.6: Approximation of the main dimensions of the Rang retractors, side view, , [mm] [31].

2.5.2 Dimensions of the surgical cavity

Based on informations obtained by Dr Pierre-Louis Docquier (see figures 2.7 and 2.8) and the dimensions of the Rang retractors (see figures 2.5 and 2.6), the bottom of the surgical cavity in the case of a child, around the greater sciatic notch, can be modelled as a hollow semi-cylinder (see figure 2.9). These dimensions are an approximation of reality. We are aware that each patient is different but this approximation is useful to decide the dimensions of the instruments. Especially that the bone grows after a surgery then this approximation of the surgical environment does not correspond to the reality for the patients who are re-operated.

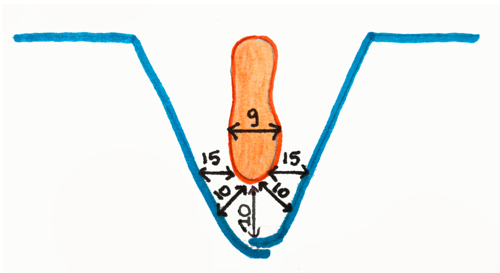


Figure 2.7: Estimation of the dimensions of the surgical cavity [mm], sectional view from figure 2.2.

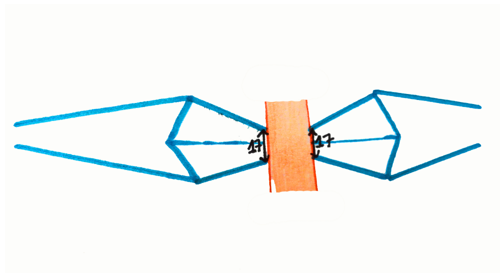


Figure 2.8: Estimation of the dimensions of the surgical cavity [mm], top view.

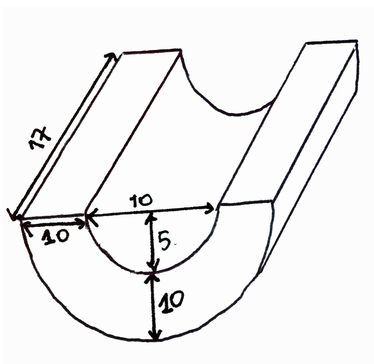


Figure 2.9: Modelling of the surgical cavity [mm]

2.6 Functional analysis arising from the list of specifications

From the list of specifications, the first functional analysis (see figure 2.4) can be slightly modified. This new functional analysis identifies the technical functions that the instrument has to fulfill to respect the list of specifications (see figure 2.10). Here the instrument has only one main function to fulfill: assist the surgeon to pass the Gigli saw through the greater sciatic notch. The instrument can manipulated directly the Gigli saw or, if it is easier, manipulated a guidewire which will be used after to pass the Gigli saw. The initial and final states of the Gigli saw are indicated in gray frames in the figure 2.10.

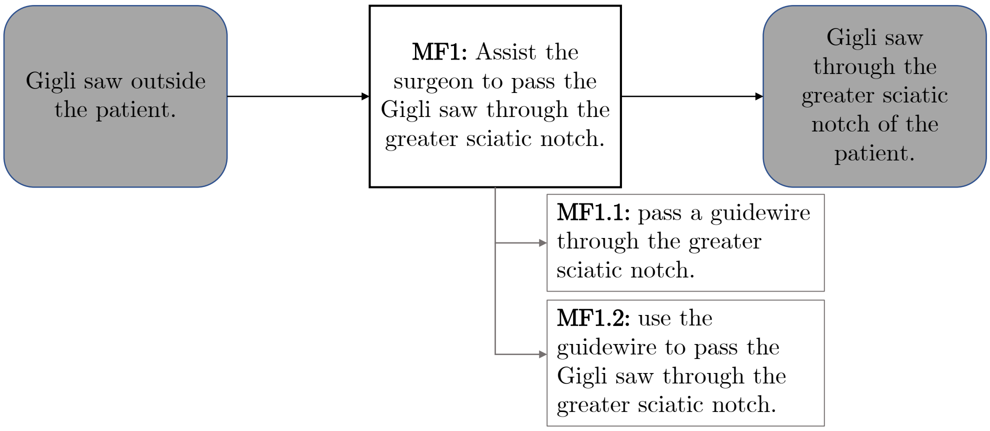


Figure 2.10: Functional analysis arising from the list of specifications. There are one main function (MF1) and two sub-functions (MF1.1 and MF1.2) which allow the passage of the Gigli saw from it initial state to its final state.

2.7 Comparison criteria

2.7.1 Criteria

Six criteria have been identified to compare the different solutions found. The relevance of the criteria was discussed with the research team.

Per-operative duration: This duration corresponds to the time needed to pass the Gigli saw through the greater sciatic notch. This includes all the needed manipulations (e.g. the positioning of the instruments, the passage of the guidewire, ...).

Safety: The instrument has to be as safe as possible for the patient but also for the surgical staff. This means amongst other things, that the different parts of the instrument must be safely held together, the surgeon cannot loose control of the instrument (e.g. a clamp blocked in a certain position). The instrument must be biocompatible and must not interact (if not desired) with the other instruments. Finally, it must prevent any harm to the biological tissues.

Obstruction: The obstruction corresponds to the volume the instrument occupies relative to the total available space in the surgical cavity. If it takes too much space, the surgeon will have to work blindly or enlarge the surgical cavity to be able to place the instrument correctly. Moreover, if the instrument is tool large, it could prevent an other instrument to work properly (e.g. a blood pump).

Ease of use: The ease of use of the instrument corresponds to the ease of the surgical staff to manipulate it. This ease of use concerns all the manipulations (which are executed with or without the new instrument) needed to position the Gigli saw through the greater sciatic notch. To define the ease of use of the instrument, the following questions can be useful: Are any training/instructions needed to understand how to use the device? Is the instruction manual enough to understand how to use the device ? After training/instructions, is it the device easy to use? Does the surgeon need to attach pieces of the instrument on the bone? Does the instrument lead to any modifications of the classical surgical procedure?

Ease of fabrication: The fabrication includes the fabrication procedure, the assembly of the different pieces of the instrument, the surface treatment and the certification processes.

Cost: The cost includes the cost of the instrument itself but also the cost of the people who have worked on it after its conception and its launch. This cost is highly dependent on the fact that the instrument is reusable or single use and if it is a made to measure instrument.

2.7.2 Comparison

The comparison between the different solutions is based on the comparison criteria and their weight. The weight factors are comprised between 1 and 4 depending on the relative importance of each criterion. The two most important criteria are the per-operative duration and the safety. The first one is directly linked to the purpose of the new instrument. The second one is fundamental for a surgical instrument because the patient and the surgical staff cannot be harmed. With a slightly lower weight factor come the ease of use and the obstruction which are important because the instrument may not increase the difficulty of the surgery or the risks. Finally the two less important criteria are the cost and the ease of fabrication. These criteria are of less importance because they do not directly concern the surgical medium. The weight factors for each criterion are indicated in table 2.2.
Moreover, in the table 2.2, an indication about the score that will be attributed to evaluate the instruments is given. For example, for the first criterion, if the passage of the Gigli saw takes ten minutes, the manipulation is considered as slow (bad) and then the score for the per-operative duration is equal to one. If, in opposition, it takes 30 seconds, then the passage is considered as fast (good) and then the score is equal to four.

Table 2.2: Criterion with their associated weight factor and the indication for the comparison between the different solutions.

Criterion	Weight	Score = 1	Score = 4
Per-operative duration	4	Slow	Fast
Safety	4	Dangerous	Safe
Ease of use	3	Difficult	Easy
Obstruction	3	Obstructive with increased risks	Not obstructive
Ease of fabrication	1	Difficult	Easy
Cost	1	Expensive	Cheap

Chapter 3

Design

In this chapter, different solutions are drawn and detailed. Then a comparison based on the comparison criteria between the six concept variants is performed.

3.1 Solutions

The solutions, including the existing ones, are classified in six concept variants:

1. Tube on the Rang retractors
2. Modular Rang retractors
3. Free tube
4. Simplified endoscope
5. 3D-guide
6. Magnetic instruments

Some concept variants include more than one solution but there are considered as the same solution with a different implementation.

Three of the proposed solutions from the third concept variant (3.4, 3.5 and 3.6) correspond to existing instruments which are currently used to pass the Gigli saw around bones in other part of the body. These three solutions can be compared to the solution 3.2. By modifying the shape of these instruments, they could be used for Salter osteotomy.

The colors used in the following drawings correspond to specific parts of the instrument, as detailed in section 2.2.

3.1.1 Concept variant 1: Tube on the Rang retractors

For the first concept variant, we use the Rang retractors to fix a flexible tube in which the guidewire is guided through the greater sciatic notch. Two implementations of this solution are presented.

Solution 1.1: Tube fixed on the Rang retractors

This solution uses the Rang retractors as support for flexible tubes which are magnetized at their extremities (see figure 3.1, red detail). The dimensions of the tubes are enough to pass the guidewire through them. Each tube is slided in two rings fixed on the retractor in order to maintain it. When the two retractors are well placed in the greater sciatic notch, the two extremities of the tubes join each other thanks to the magnets (yellow detail). Then the guidewire can be inserted inside the tubes. When the guidewire is correctly placed, the two flexible tubes are removed while maintaining the guidewire in position. Finally, the guidewire is used to pass the Gigli saw through the greater sciatic notch.

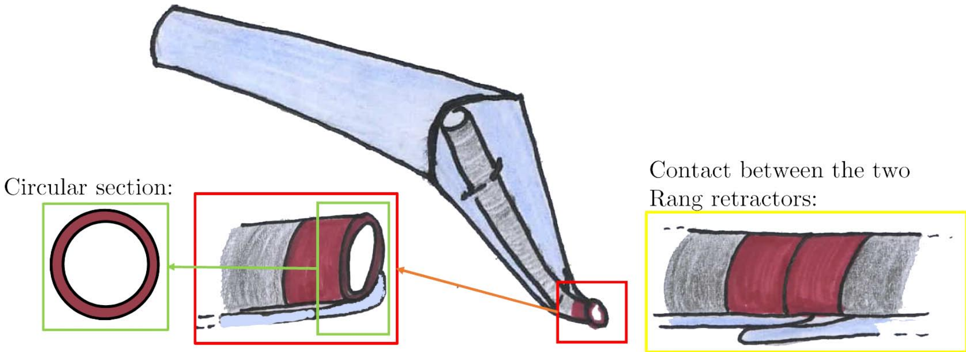


Figure 3.1: Drawing of solution 1.1: closed tube fixed on a Rang retractor. The extremity of the flexible tube is magnetized. Red detail: zoom on the magnetized extremity of one tube, yellow detail: contact between the two Rang retractors on which the two tubes are present, green detail: circular section of the tubes.

Solution 1.2: Open seam tube fixed on a Rang retractor

This solution is the same as the previous one except that the tubes present an open groove in the tube's length (see figure 3.2).
This tube is either flexible to allow the surgeon to remove it after having correctly placed the saw or rigid in which case it stays fixed to the Rang retractor during the surgery.
As in the previous solution, the contact between the two tubes in the greater sciatic notch is ensured by magnets (yellow details in figure 3.2).

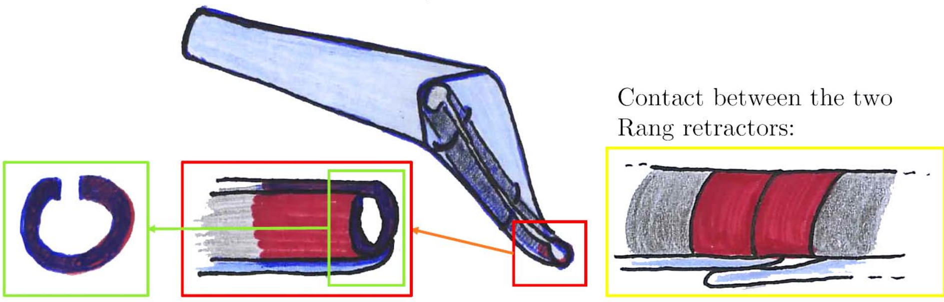


Figure 3.2: Drawing of solution 1.2: open seam tubes fixed on the Rang retractors with a magnetized extremity. Red detail: zoom on the magnetized extremity of one tube, yellow detail: contact between the two Rang retractors on which the two tubes are present, green detail: section of the tubes.

3.1.2 Concept variant 2: Modular Rang retractors

Solution 2.1: Modular Rang retractors

This solution uses the Rang retractors as support for two supplementary parts (see figure 3.3, red frame). The parts are added on the Rang retractors by sliding them in a groove (see figure 3.3, black frame). At the extremity of these additional parts, there is a semi-cylinder which covers the extremity of the Rang retractors.

The seven different steps of the passage of the guidewire through the greater sciatic notch are detailed in figure 3.4:

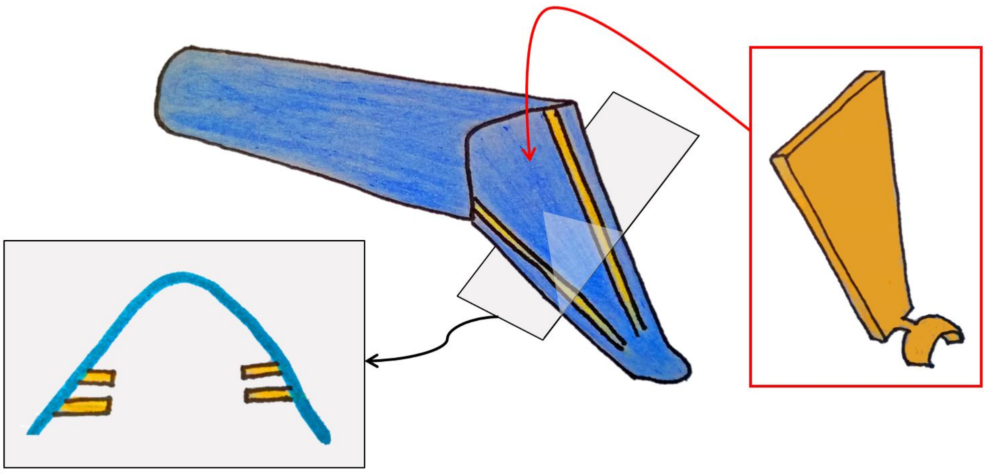


Figure 3.3: Drawing of solution 2.1: modular Rang retractors. The yellow additional part is added on the Rang retractor by sliding it in the grooves of the Rang retractor.

- Step 1: The Rang retractors are placed in the greater sciatic notch.
- Step 2: The first additional part is added on a Rang retractors
- Step 3: The second additional part is added such that the two additional parts overlap.
- Step 4: Thanks to the channel created between the retractors and the additional parts, the guidewire is inserted.
- Step 5: The additional parts are removed.
- Step 6: The Gigli saw is then attached to the guidewire.
- Step 7: The guidewire is used to pass the Gigli saw through the greater sciatic notch.

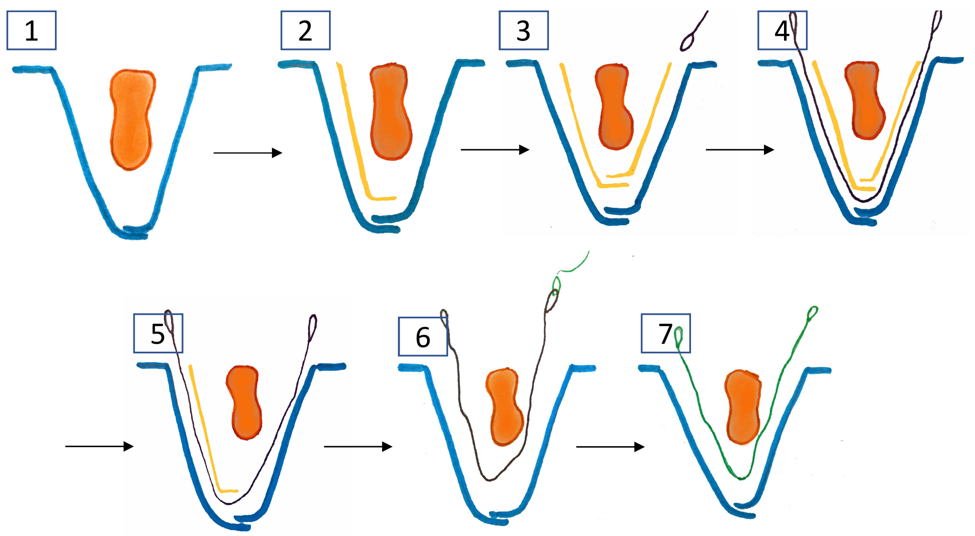


Figure 3.4: Graphic representation in seven steps of the passage of the Gigli saw through the greater sciatic notch with the solution 2.1: the modular Rang retractors, sectional view from figure 2.2.

3.1.3 Concept variant 3: Free tubes

Solution 3.1: Free tubes magnetized at their extremities

This solution consists of two tubes of which the two extremities are magnetized (see figures 3.5. This will ensure the connection in the greater sciatic notch.
To account for the fact that all the patients are different, the extremity of the instrument is removable and comes in different sizes (red and orange details in figure 3.5).

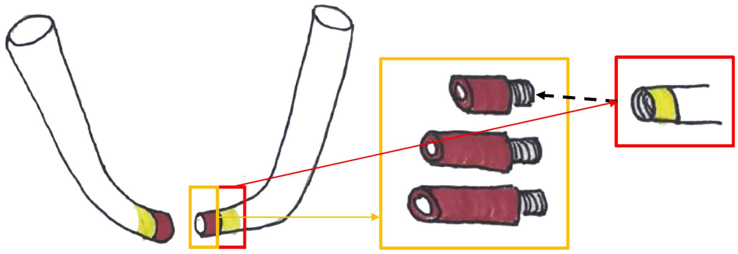


Figure 3.5: Drawing of solution 3.1: two free tubes magnetized at their extremities. The extremities are modular thanks to screw-on pieces of different sizes.

The passage of the Gigli saw through the greater sciatic notch with this instrument in six steps is detailed in figure 3.6:

- Step 1: The Rang retractors are placed in the greater sciatic notch.
- Step 2: The two tubes are placed in the greater sciatic notch by sliding them along the Rang retractors on both sides of the bone until they join in the greater sciatic notch.
- Step 3: The guidewire is introduced in the channel created by the two instruments.
- Step 4: One tube is removed while holding the guidewire in position.
- Step 5: The second tube is removed and the Gigli saw is attached to the guidewire.
- Step 6: The guidewire is used to pass the Gigli saw through the greater sciatic notch.

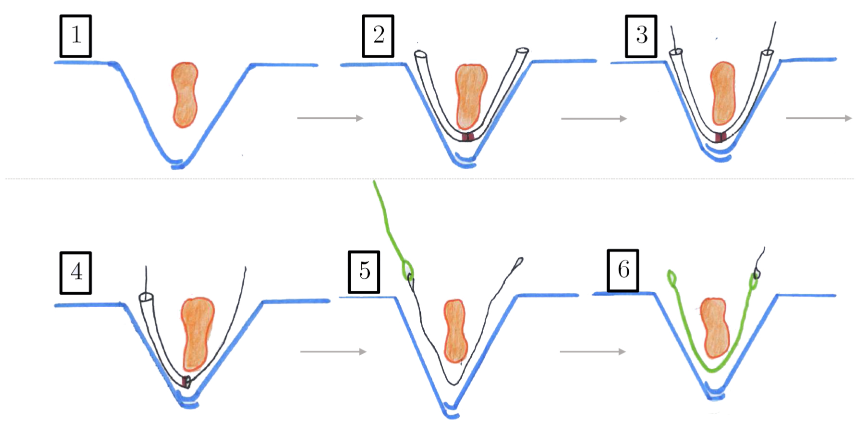


Figure 3.6: Graphic representation in six steps of the passage of the Gigli saw through the greater sciatic notch with the solution 3.1: two free tubes magnetized at the end, sectional view from figure 2.2.

Solution 3.2: Bended free tube

This solution consists of a set of hollow instruments curved at one extremity. Depending of the patient, the instrument which fits at best is used.

The nine main steps required for the passage of the Gigli saw through the greater sciatic notch with the bended tube are detailed in figure 3.7:

- Step 1: The bended tube is outside the patient.
- Steps 2 and 3: When the Rang retractors are placed in the greater sciatic notch the instrument is inserted in parallel to the iliac bone until the bottom of the cavity is reached.
- Step 4: The instrument is twisted 90 degrees to position the extremity of the instrument on the other side of the bone.
- Step 5: The instrument is lifted until the curved part molds the bone and the guidewire is inserted inside the instrument.
- Steps 6 and 7: The instrument is removed while keeping the guidewire in position.
- Step 8: The Gigli saw is attached to the guidewire.
- Step 9: The guidewire is used to pass the Gigli saw through the greater sciatic notch.

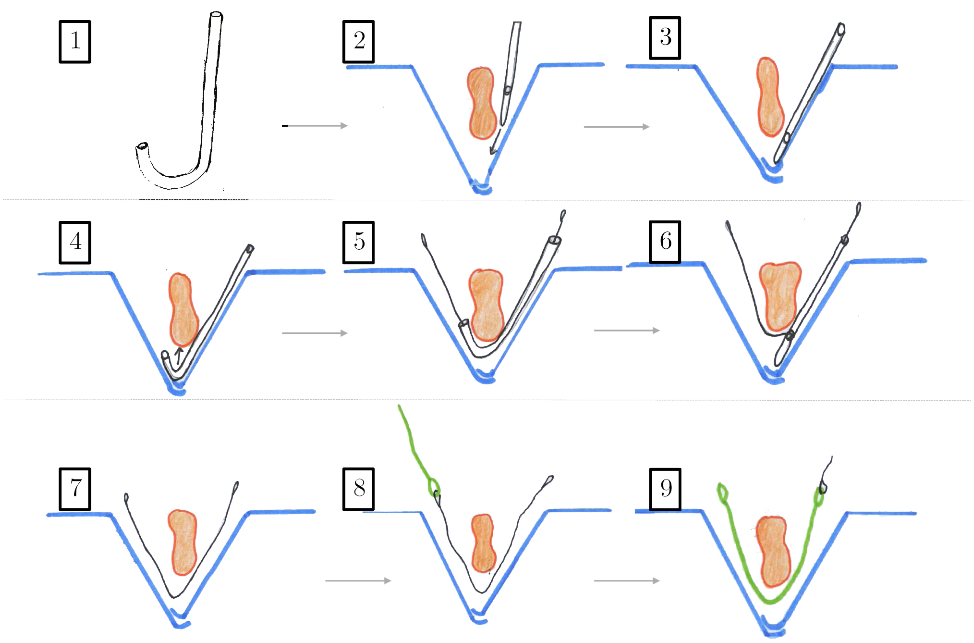


Figure 3.7: Graphic representation in nine steps of the passage of the Gigli saw through the greater sciatic notch with the solution 3.2: a bended free tube, sectional view from figure 2.2.

Solution 3.3: Open seam free tube

This solution corresponds to the solution 3.2 with a slight modification. The tube is grooved in order to be able to remove the guidewire from the instrument while keeping it in position through the greater sciatic notch (see figure 3.8).

The eight steps required for the passage of the Gigli saw through the greater sciatic notch with the open seam free tube are detailed in figure 3.8:

- Step 1: The open seam tube is outside the patient.
- Steps 2 and 3: When the Rang retractors are placed in the greater sciatic notch the instrument is inserted in parallel to the iliac bone until the bottom of the cavity is reached.
- Step 4: The instrument is twisted 90 degrees to position the extremity of the instrument on the other side of the bone and lifted until the curved part molds the bone.
- Step 5: The guidewire is inserted inside the instrument.
- Step 6: The guidewire is removed from the instrument while keeping it in position.
- Step 7: The instrument is removed from the surgical cavity and the Gigli saw is attached to the guidewire.
- Step 8: The guidewire is used to pass the Gigli saw through the greater sciatic notch.

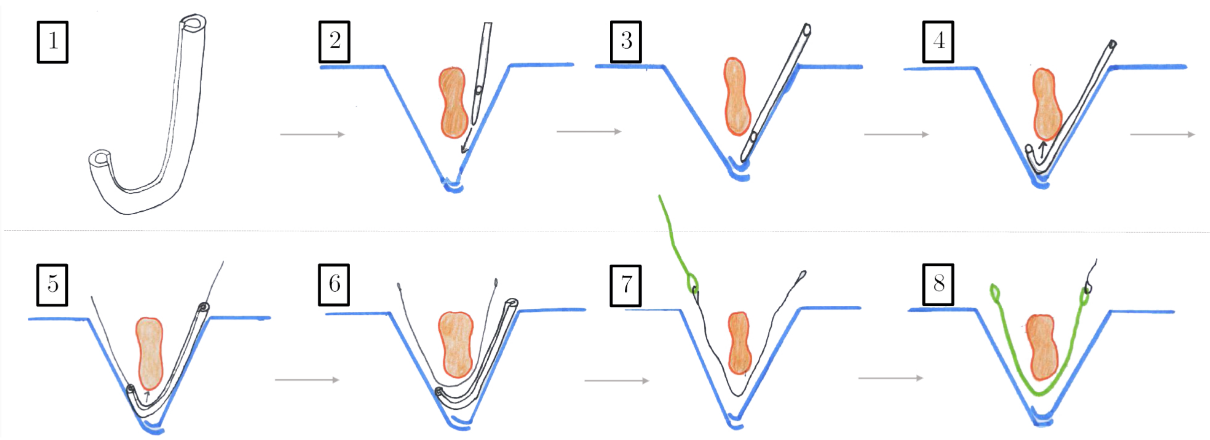


Figure 3.8: Graphic representation in eight steps of the passage of the Gigli saw through the greater sciatic notch with the solution 3.3: open seam free tube, sectional view from figure 2.2.

Solution 3.4: Existing solution for osteotomy of the greater trochanter

This instrument produced by Zimmer (see figure 3.9) is used to facilitate the passage of the Gigli saw during the osteotomy of the greater trochanter (see figure 3.10) [46]. It is composed of a tube at the extremity of a handle. It is used to pass the guidewire or directly the Gigli saw.

Figure 3.9: Solution 3.4: Zimmer 2807-01 Gigli Saw Passer [46].

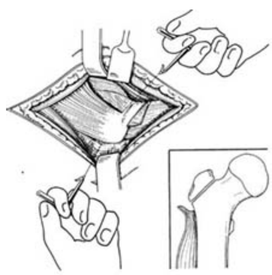


Figure 3.10: Osteotomy of the greater trochanter [9].

Solution 3.5: Existing solution for osteotomy of the ischium

This instrument (see figure 3.11) was developed by Nick Vanvooren and is used for pelvic osteotomy to ease the passage of the Gigli saw around the ischium (see figure 1.1).

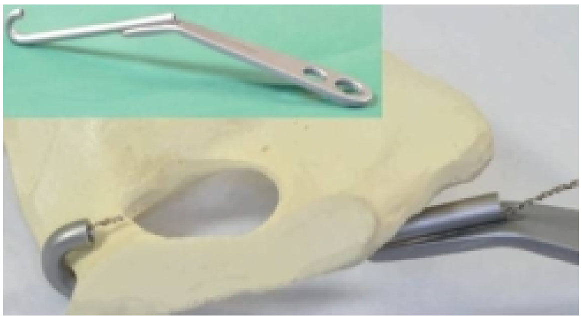


Figure 3.11: Solution 3.5: Gigli saw passer used to pass the Gigli saw around the ischium during an ischium osteotomy [40].

Solution 3.6: Existing solution: veterinary instrument

This instrument is used in the veterinary medium (see figure 3.12). It is a wire passer which is double ended cannulated. The two curved extremities have different curve radius.

Figure 3.12: Solution 3.6: Veterinary instrument: wire passer double ended cannulated [21].

3.1.4 Concept variant 4: Angulation system

Solution 4.1: Angulation system

This solution can be compared to a simplified endoscope (angulation system) (see figure 3.13). The instrument is composed of two regions: a immobile one and a mobile one. The mobile region is itself composed of a series of parts connected to each other. Their position relative to one another is controlled by two cables inside the instrument (in green in figure 3.13). By rotating the wheel present at the extremity of the immobile part of the instrument, the position of the cable changes causing a modification of the position of the mobile parts. This creates a curvature in the mobile part of the instrument.
Practically, the instrument is inserted in a straight position in the surgical cavity until reaching the greater sciatic notch. Then simultaneously, the surgeon turns the wheel and continues to lower the instrument in the cavity. The instrument progressively wraps round the bottom of the bone. When the instrument is completely curved (as in figure 3.13, right), the guidewire can be introduced inside the instrument. After that, the instrument is removed by manipulating it in a reverse way, while maintaining the guidewire in position through the greater sciatic notch.

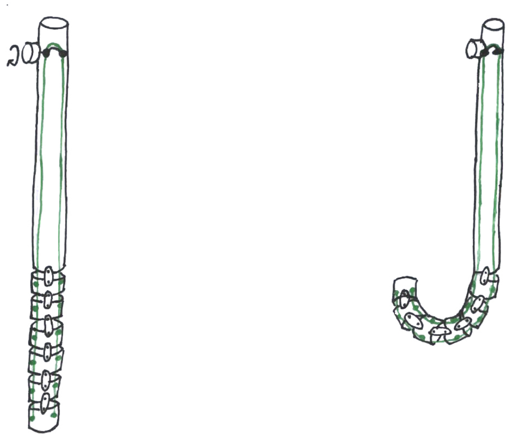


Figure 3.13: Drawing of solution 4.1: angulation system made up of one immobile and mobile region. The mobile region is composed of several mobile parts. The mobile region of the instrument can be curved by rotating the wheel from the rigid part what will lead to a modification of the position of the cables (green).

3.1.5 Concept variant 5: 3D-guide

Solution 5.1: 3D-guide

This 3D-guide has two main functions:

- guide the Gigli saw through the greater sciatic notch
- guide the cut along the innominate line

The second function is not required by the list of specifications but can be helpful for the surgeon. Starting from a CT-scan of the pelvis of the patient, a 3D-model of the patient's pelvis is created. Using this model, a 3D-guide is drawn and then printed. The guide is fixed with Kirschner pins on the bone of the patient. A groove in the 3D-guide along the innonimate line allows the surgeon to pass the Gigli saw through the greater sciatic notch. As such, this 3D-guide helps the surgeon to cut the bone exactly along the innonimate line and at the same time protects all the noble structures present around the cutting line.

On figure 3.14, an example of a 3D-cutting guide used to remove a tumor on the pelvis developed by 3D-Side is shown. The guide is personalized and constrains the surgeon to cut along the specific line to remove the tumor [7].

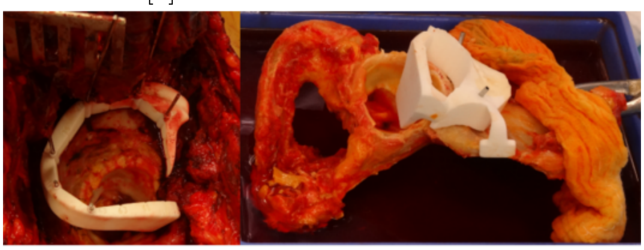


Figure 3.14: Example of a 3D-guide: 3D-guide to remove a tumor on the pelvis from 3D-Side [7].

3.1.6 Concept variant 6: Magnetic instruments

Solution 6.1: The magnetic stick and the magnetic part attached to the guidewire

This solution uses a stick which has a magnet fixed at its extremity to retrieve a magnetic part fixed on a wire (see figure 3.15).

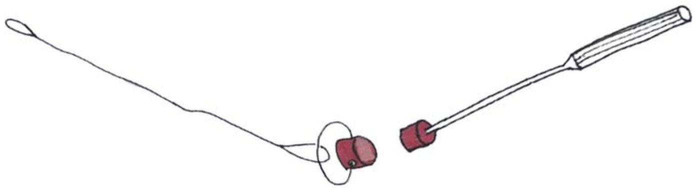


Figure 3.15: Drawing of solution 6.1: magnetic instruments: a magnetic part attached to a guidewire (left) and a magnetic stick (right).

This solution is the idea of a group of students who have worked on this project as a part of the course: LMECA2355, Mechanical design in biomedical engineering.

The seven steps required for the passage of the Gigli saw through the greater sciatic notch with the magnetic instruments are detailed in figure 3.16:

- Step 1: The Rang retractors are placed in the greater sciatic notch.
- Step 2: The magnetic part is first fixed on a guidewire and introduced in the greater sciatic notch.
- Step 3: The stick is introduced on the other side of the greater sciatic notch.
- Step 4: Thanks to the magnetic attractive force between the magnet of the stick and the magnetic part, the guidewire is attached to the stick.
- Step 5: By pulling the stick outside the surgical cavity, the guidewire passes through the greater sciatic notch.
- Step 6: The Gigli saw is attached to the guidewire.
- Step 7: The guidewire is used to pass the Gigli saw through the greater sciatic notch.

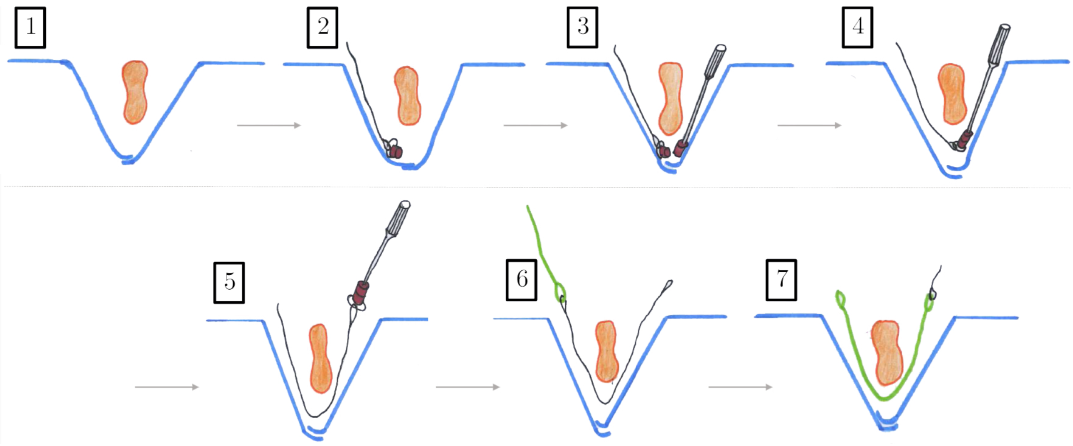


Figure 3.16: Graphic representation in seven steps of the passage of the Gigli saw through the greater sciatic notch with the solution 6.1: the magnetic instruments, sectional view from figure 2.2.

3.2 Comparison of the solutions

In this section, the criteria are evaluated for each concept variant. As said before, the score is comprised between 1 (bad) and 4 (good) (see table 2.2). To ensure that the comparison is not biased by less important criteria, the concept variants are first quoted based on the four main criteria (see table 3.1). Then a complete quotation on all the criteria is performed (see table 3.2). When both comparison are executed, one can verify that both comparisons yield close results.

The weighted total is equal to the sum of the products between the scores (x_i) and the weights (w_i) of each criteria (i) about one concept variant divided by the number of criteria (N):

$$\text{Weigthed total} = \frac{\Sigma_{i=1}^{\text{N}} x_i \cdot w_i}{\text{N}}$$

The maximal weighted total is calculated considering that each criterion obtains a maximal score (= 4). They are then equal to:

- 56 when the comparison is performed on the basis of the four main criteria.
- 64 when the comparison is performed on the basis of the six criteria.

The standard deviation is calculated to see if there is no too big difference between the different criteria for each concept variant. Indeed, the bigger the standard deviation, the more different are the scores of each criterion. It is calculated as follows:

$$\text{Standard deviation} = \sqrt{\Sigma_{i=1}^{N} \frac{1}{N}(x_i - \overline{x})}$$

Table 3.1: Score of the six concept variants (CV) based on the four main weighted criteria. The weights of the criteria are given in table 2.2.

Solutions	CV 1	CV 2	CV 3	CV 4	CV 5	CV 6
Per-operative duration	3	2	2	2	1	4
Safety	3	4	4	2	3	3
Ease of use	3	2	3	3	1	4
Obstruction	1	1	3	1	3	4
Weighted total	36	33	42	28	28	52
Standard deviation	0.866	1.2	0.7	0.7	1	0.43

When the solutions are compared on the basis of the four main criteria (see table 3.1), the best solution is the concept variant number 6 (both in terms of weighted mean and standard deviation). It comprised a single solution, solution 6.1: magnetic instruments. The solution which has the second best score is the concept variant number 3: the free tubes. The other concept variants are quite similar, except the sixth one which has at the same time a low weighted total and a high standard deviation.

As the first comparison, we can observe that the concept variant number 6 is the best when we compare the solution on the basis of the six criteria (see table 3.2). The second best one is the concept variant number 3 already.

Table 3.2: Score of the six concept variants (CV) based on the six weighted criteria. The weights of the criteria are given in table 2.2.

Solutions	CV 1	CV 2	CV 3	CV 4	CV 5	CV 6
Per-operative duration	3	2	2	2	1	4
Safety	3	4	4	2	3	3
Ease of use	3	2	3	3	1	4
Obstruction	1	1	3	1	3	4
Ease of fabrication	2	2	4	1	4	4
Cost	2	2	4	2	1	4
Weighted total	40	37	50	31	33	60
Standard deviation	0.745	0.9575	0.745	0.687	1.213	0.373

On an agreement of the whole research team, two solutions are retained for testing: concept variants number 6 and 3. Indeed, it is at this point difficult to distinguish the most promising solution.

Chapter 4

Retained solutions

The two retained solutions are the magnetic instruments and the free tube. In this chapter, these solutions are described and dimensioned. Furthermore, the resistance of the magnets, used for the magnetic instruments, to a steam sterilization process in autoclave is tested.

4.1 The free tube

This concept variant contains more than one solution. Given that the bended free tube solution (solution 3.2) is the easiest to produce as prototype, this solution was chosen for the further testing.

4.1.1 Description

The free tube is used as described in figure 3.7. Two tubes in stainless steel with an external diameter of 2.5 mm and 3 mm were used to produce the prototype. These tubes were bended to a curvature of 180 degrees at their extremities (see figures 4.1 and 4.2). The dimensions of the instrument are defined such as it can be inserted in the surgical cavity which has limited dimensions (see section 2.5 and figure 2.9).
The use of a 3D-printer to print a prototype of this instrument is impossible because the dimensions of the instrument cannot be reached with this technology.

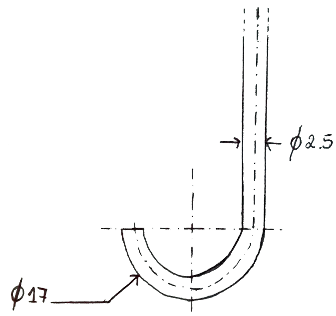


Figure 4.1: Dimensions of the free tube made with a stainless steel tube of 2.5 mm of external diameter, [mm].

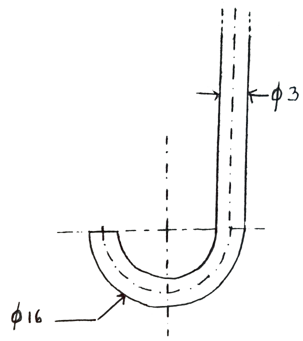


Figure 4.2: Dimensions of the free tube made with a stainless steel tube of 3 mm of external diameter, [mm].

4.1.2 Bending failure

Unfortunately, this solution cannot be prototyped because the bending of the tubes turned out to be impossible without wrinkling it with the available technologies at university. Even with the

help of the members of the machining laboratory, the tubes kept collapsing instead of bending (see figure 4.3).
The first try was executed by hand around a rigid rod. The second one was performed with two types of 3D-printed benders. These two benders allow the bending of rod in the required dimensions but not the bending of tubes. Other attempts were performed during which the tubes were filled with a flexible stem or with sand to prevent the cylinder from collapsing but the tubes broke again. On the last try, the tube was filled with sand and heated before bending it with one of the 3D-printed benders. The bending was almost well realized but the sand had melted and then hardened (see figure 4.4). The transformed sand could not be removed from the bended tube.

Figure 4.3: Bending failure with wrinkling.

Figure 4.4: Tube bended in the right shape with a 3D-printed bender but obstructed with melted sand.

4.2 Magnetic instruments

As described in section 3.1.6, this instrument is composed in two main parts: a stick on which a magnet is fixed and a magnetic part fixed to the guidewire.

4.2.1 Description

The magnetic instruments are used to pass the guidewire through the greater sciatic notch as described in figure 3.16.

Magnets

To find the most efficient solution, three different magnets were tested:

- **F5**: Magnetic disk (diameter: 5mm and height: 5mm) made from ferrite. The attractive force is approximatively equal to 100 g. The maximal operating temperature is 250°C (see appendix A.1) [34]
- **N3**: Magnetic disk (diameter: 3mm and heigth: 3mm) made from neodymium. The magnet is coated with a nickel-copper-nickel layer. The attractive force is approximatively equal to 290 g. The maximal operating temperature is 80° C and the Curie temperature is 310°C (see appendix A.2) [34]
- **N5**: Magnetic cube (of 5mm of side) made from neodymium. This magnet is also coated with a nickel-copper-nickel layer. The attractive force is approximatively equal to 1100 g. The maximal operating temperature is 80° C and the Curie temperature is 310°C (see appendix A.3) [34]

The maximal operating temperature determines from which temperature a magnet begins to loose attractive force. If the temperature of a magnet reaches its Curie temperature, it becomes fully demagnetized.

The advantage of ferrite magnets is that they resist to higher temperatures compared to neodymium magnets. But on the other hand, the neodymium magnets are more attractive than the ferrite ones. The neodymium magnets have a maximal operating temperature of 80°C, which means they would need to be sterilize with gas to avoid any loss of attractive force during the sterilization. The ferrite magnets however can be sterilized by steam in autoclave.

Magnets are already used in the surgical medium. For example some magnetized instruments are used to retrieve small magnetic pieces in the eyes. Another example is a device showed by Ms Sandrine Frederic, the head nurse in central sterilization at St-Luc Hospital, which is a magnetic screw driver from Zimmer. Ms Sandrine Frederic explains that this instrument was already sterilized hundreds of time and is still magnetic.

Sticks

The stick is composed of a handle, a central part and a socket (see figure 4.5). The handle and the central part are ten centimetres long each with a respective diameter of two centimetres and four millimetres. The socket is dimensioned to fit perfectly with each sort of magnet as showed on figures 4.6, 4.7 and 4.8. The thickness of the sides of the sockets is equal to one millimetre.

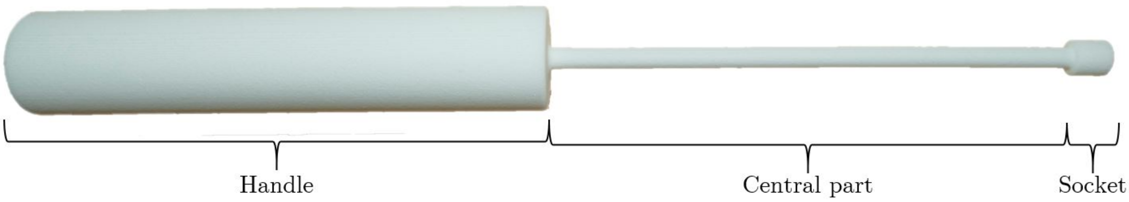


Figure 4.5: Magnetic stick composed in three main part: the handle, the central part and the socket. The handle and the central part are 10 cm long and the socket fit perfectly with the magnet associated to the stick.

The sticks were designed to fit with the three different types of magnets. The sticks were printed at 3D-Side. In figure 4.6, the three different sticks are presented.
The material of which they are made is biocompatible and sterilizable in autoclave. Due to the small dimensions of the instrument the central part of the stick is flexible. The magnets are inserted and glued in the socket of the stick (see figures 4.7 and 4.8). The glue used at the moment is not sterilized and a priori not biocompatible. For the future experiment, an other glue has to be used.

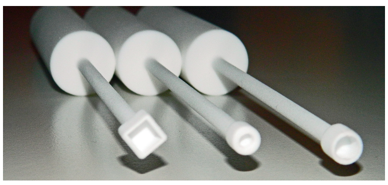


Figure 4.6: The three kinds of sticks which are compatible with the three types of magnets. From left to right: stick compatible with N5, N3 and F5.

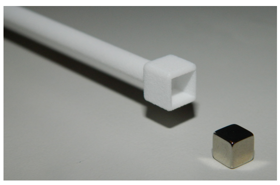


Figure 4.7: Insertion of a N5 magnet in the corresponding stick.

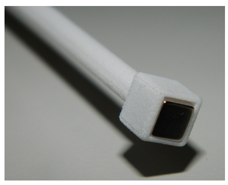


Figure 4.8: N5 magnet inserted and glued in the socket of the stick.

Magnetic hexagonal part

The magnetic hexagonal part is the piece of the instrument which is attached to the guidewire (see figure 4.9). It corresponds to a little regular hexagonal prism enclosed in a circle of 6 millimetres in diameter in stainless steel AISI 430. This material is magnetic and biocompatible. Three different hexagonal parts with thickness equal to 3, 4 and 5 millimetres were machined at the machining laboratory of UCL. Thanks to a hole of 2 millimetres in diameter in the middle of the prism, the guidewire can be fixed with a reef knot. The hexagonal shape was chosen to find a compromise between the number of surfaces the magnet can stick to and the area of each of these surfaces.

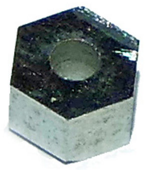


Figure 4.9: Magnetic hexagonal part. The hexagonal prism is enclosed in a circle of 6 millimetres in diameter and has a thikness equal to 3, 4 or 5 millimetres. The central hole has a diameter of 2 millimetres.

4.2.2 Test of the resistance of the magnet to a steam sterilization process in an autoclave

Steam sterilization process

Because no information about the resistance of the magnet used for the instrument to the sterilisation processes is available, a test was performed. The three types of magnets were sterilized once or twice by the sterilisation department of Saint-Luc with Ms. Sandrine Fréderic. They are sterilized by steam in an autoclave after having been washed:

- The washing follows several steps [39]:
    1. The first step consists of **three pre-washings** of approximatively 2 minutes each and is performed with soft water. The temperature is less than 40°C.
    2. **The washing** takes 5 minutes and is performed with an alkaline detergent and hot soft water. The temperature depends on the type of detergent and can reach 80°C.
    3. **Four rinsings** of approximatively 2 minutes each are performed. The first one is executed with soft water to remove any traces of suspended stains and detergent. Then a neutralisation by acid allows the neutralisation of the detergent and removes the limestone. Next a rinsing with soft water is performed before the final rinsing in purified hot water with demineralized or osmosis water.
    4. The **disinfection** performed with osmosis water decreases the microbial load. It is a thermal disinfection which reaches 90°C and the duration depends on the type of detergent.
    5. The last step is the **drying** which takes between 15 and 20 minutes at temperatures above 70-110°C. It is performed with filtered air.
- The steam sterilization process follows three main steps which are executed in an autoclave during approximatively one hour [15, 14, 22]:
    1. The **preprocessing** consists of removing the air, making the water steam permeate the environment perfectly and homogeneously; and a preheating.

2. **The sterilization** is the step during which the material is sterilized by an extended contact between the instrument and hot saturated steam. An example of sterilization tray is the Prion cycle which is defined by a constant temperature of 135 degrees during 18 minutes.
3. **The drying** is the last step which consists of drying the material to ensure a perfect sterility until its use.

Due to the high temperature, high pressure and the various products used to wash and sterilize the magnets, it can be supposed that they will lose their attractive force partially or entirely.

Protocol of the traction test

The attractive force of the magnets before and after the sterilization process is measured thanks to a traction test performed at the mechanical testing laboratory of UCL with Marc Sinnaeve. The test is executed on an INSTRON 5566 machine. A 100 Newton cell force is used for the experiment. The test is performed with a magnetic hexagonal part and the three kinds of magnets (non-sterilized, sterilized once and sterilized twice). On the lower plate of the machine, the magnetic hexagonal part is glued and on the upper plate, the magnet is glued (see figure 4.10). At the beginning, the magnet and the magnetic hexagonal part are in contact. When the test starts, they detach from each other. The upper plate moves at a pace of 1 [mm/min] upwards. The axial force (corresponding to the magnetic attractive force) and the axial displacement are recorded with a precision of 0.01 [N].

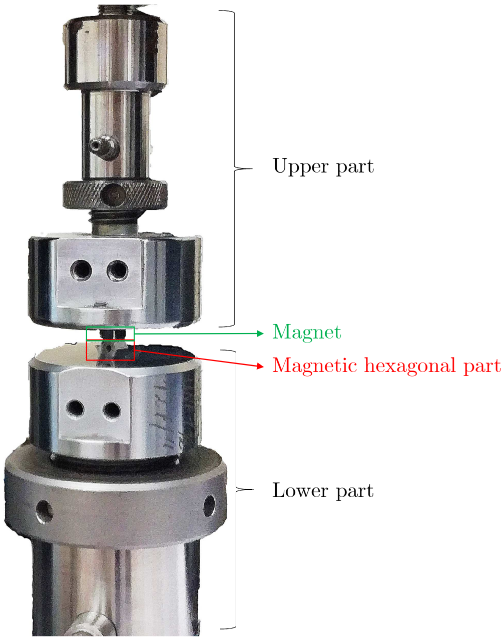


Figure 4.10: Traction test between the magnetic hexagonal part and a magnet on the INSTRON 5566 machine.

Results of the traction test

The graphs showing the magnetic attractive force depending on the distance between the magnetic hexagonal part and the three types of magnets are presented in figures 4.11, 4.12 and 4.13. The N3 magnet sterilized twice was lost during the sterilization process.

A first observation is that the magnetic attractive force exerted by the magnet on the magnetic hexagonal part is inversely proportional to the distance separating the two elements.

As predicted, the ferrite magnets resist to the sterilisation process and the neodymium magnets do not resist. The N5 magnets loose approximately 75% of their maximal attractive force after sterilization. The N3 magnets loose 25% of their maximal attractive force (see table 4.1). No notable difference was observed between magnets of the same type that underwent either one or two sterilization processes.

The results obtained with the non-sterilized magnets coincide approximatively with the information about the attractive force given by SUPERMAGNET (see table 4.1). This validates the protocol.

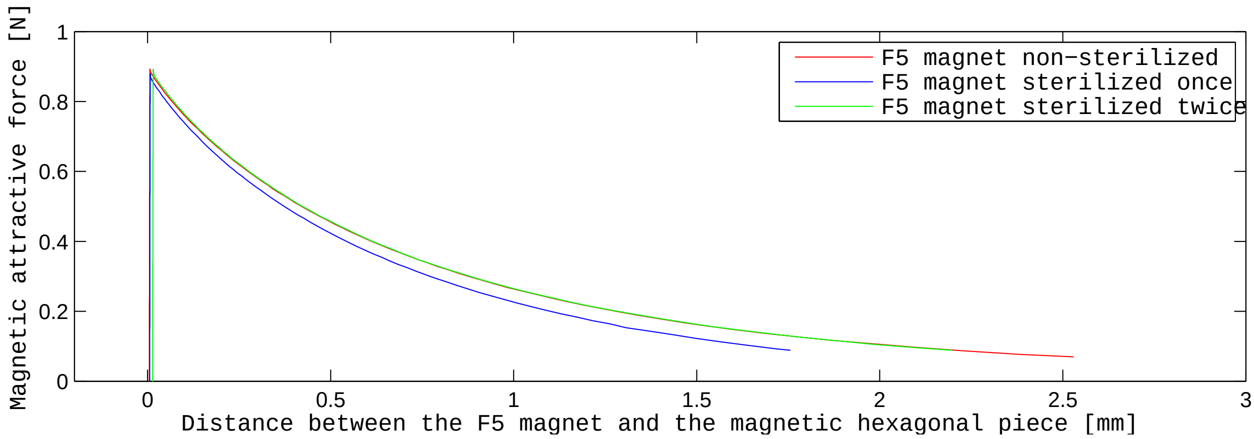


Figure 4.11: Comparison of the attractive force depending on the distance between the magnetic hexagonal part and a F5 magnet before sterilization and after one and two sterilization processes.

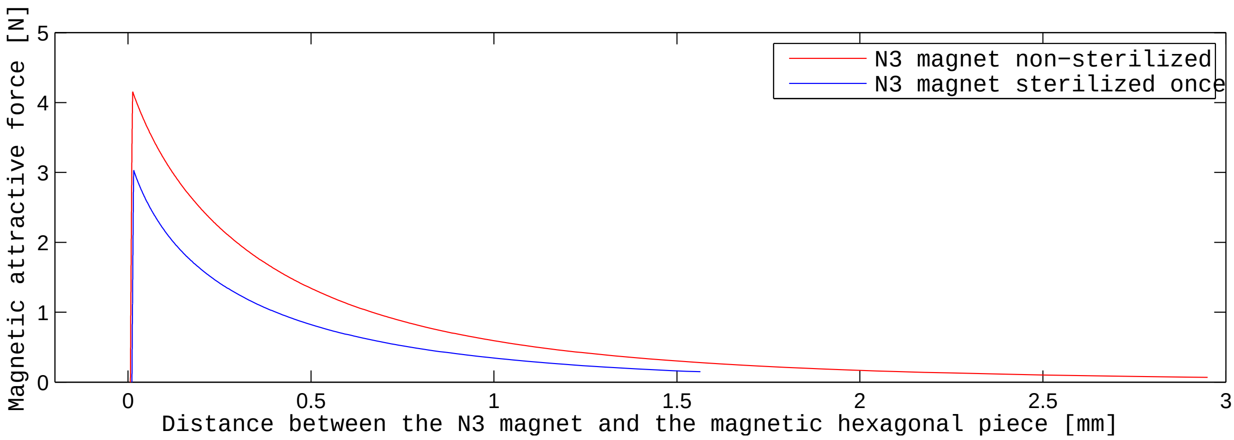


Figure 4.12: Comparison of the attractive force depending on the distance between the magnetic hexagonal part and a N3 magnet before sterilization and after a sterilization process.

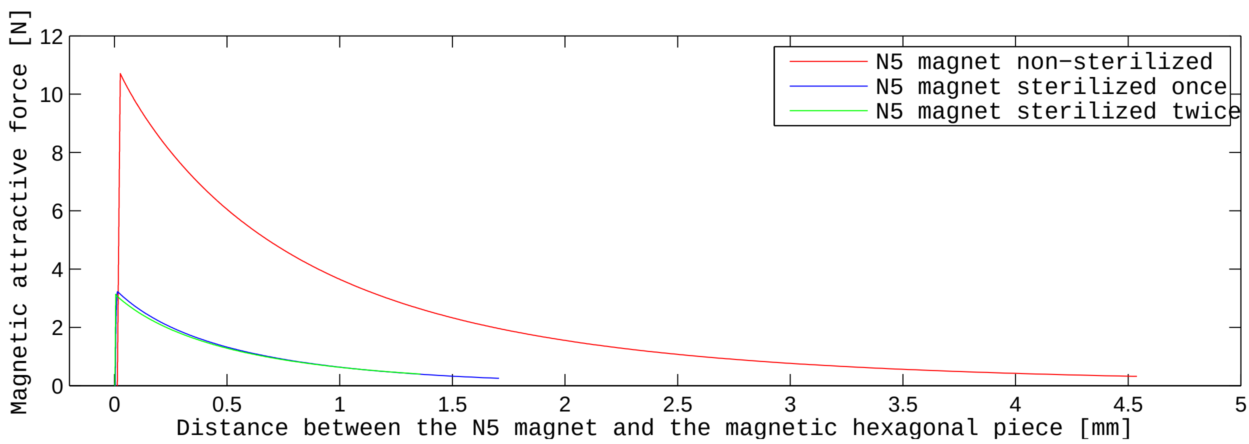


Figure 4.13: Comparison of the attractive force depending on the distance between the magnetic hexagonal part and a N5 magnet before sterilization and after one and two sterilization processes.

Table 4.1: Maximal attractive force of the non-sterilized magnets according to SUPERMAGNET and of the non-sterilized and sterilized magnets resulting from the traction test [N].

	SUPERMAGNET	Before sterilization	After one sterilization process	After two sterilization processes
F5 magnet	1	0.8929	0.8796	0.8918
N3 magnet	2.84	4.15	3.03	/
N5 magnet	10.8	10.7	3.14	3.22

Chapter 5

Feasibility study on the two retained solutions

The tests of the feasibility study are first performed on an experimental setup which artificially represents the surgical environment then on a cadaver.

5.1 On an experimental setup

Based on the modelling of the surgical environment presented in section 2.5.2 and with a CT-scan of an adult pelvis, a 3D-model representing the surgical environment was developed (see figure 5.1). The model of the pelvis was scaled to the size of a child's pelvis. This experimental setup is based on the experimental setup of the group of students who have worked on this project as a part of the course: LMECA2355, mechanical design in biomedical engineering.

During the surgery, a small quantity of blood is present in the surgical cavity and then obstructs the view of the surgeon to the greater sciatic notch. A blood pump partially resolves the problem but the very bottom of the cavity still contains a small amount of blood. This is why a cloudy liquid may be added in the 3D-printed model to increase its accuracy. The viscosity of the blood is equal to $3 \sim 4 \cdot 10^{-3}[Pa \cdot s]$. As grape juice ($2 \sim 5 \cdot 10^{-3}[Pa \cdot s]$) or milk ($3 \cdot 10^{-3}[Pa \cdot s]$) have similar viscosity, they can be used as substitute. They can be colored in red with a food dye.

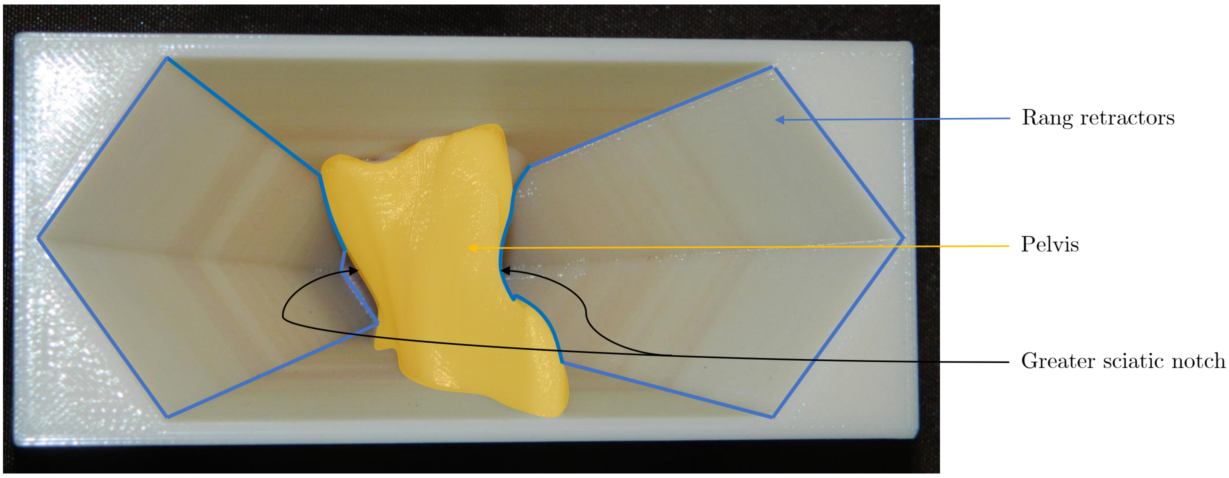


Figure 5.1: 3D-printed demonstrator of the surgical environment. In blue, there are the Rang retractors and in yellow the pelvic bone. In the bottom of the model, there is the greater sciatic notch.

5.1.1 Protocol

The aim of this experiment is to familiarize the surgeon with the instruments. It will also reveal major flaws if any are present. First the experimental setup is prepared by filling it with some (colored) milk. Then the surgeon will try the two retained solutions.

Free tubes

The surgeon uses the free tube as explained in figure 3.7. As reported in section 4.1.2, the tubes could only be put in shape when they are heated and filled with sand, resulting in an obstructed tube. The goal of the experiment is thus reoriented to assessing the correct and efficient placement of the tube.

Magnetic instruments

The surgeon manipulates the sticks as detailed on figure 3.16. He tries the three different sticks (associated to the three kinds of magnets) and ranks them with respect to the ease of use.

5.1.2 Results

Free tube

Dr Docquier was not very enthusiast about this instrument because a wide set of instruments is required to cover for the differences between patients. For future prospects, he proposes to investigate the use of a rod instead of a tube. The curved extremity of the rod would be provided with an eye of a needle for inserting the guidewire. He also mentions that it might be interesting to use a flexible material for the rod such that it can be reshaped to fit for every patient.

Magnetic instruments

Dr. Docquier is **enthusiast** about the magnetic instruments. All trials were successful. The manipulations executed by the surgeon lead to a classification of the three kinds of magnets from the most efficient to the least efficient:

1. N5 magnet
2. F5 magnet
3. N3 magnet

Dr. Docquier proposes to **use the instruments in different manner as planned** (see figure 5.2):

- Step 1: The Rang retractors are placed in the greater sciatic notch and the magnetic hexagonal part is fixed to the guidewire.
- Steps 2 and 3: A low-attractive magnetic stick (hereafter, the "positioning stick"; e.g. the stick with the F5 magnet) is used to pull the guidewire to the greater sciatic notch by means of the magnetic hexagonal part on the side where the smaller Rang retractor is placed.
- Steps 4 and 5: A high-attractive magnetic stick (hereafter, the "retrieving stick"; e.g. the stick with the N5 magnet) is inserted in the greater sciatic notch from the other side of the bone.
- Step 6: Because of the higher attractive force of the retrieving stick, the magnetic hexagonal part will pass from the positioning stick to the retrieving stick in the greater sciatic notch.

- Step 7: The retrieving stick is used to get the guidewire out of the cavity.
- Step 8: The Gigli saw is attached to the guidewire.
- Step 9: The guidewire is used to pass the Gigli saw through the greater sciatic notch

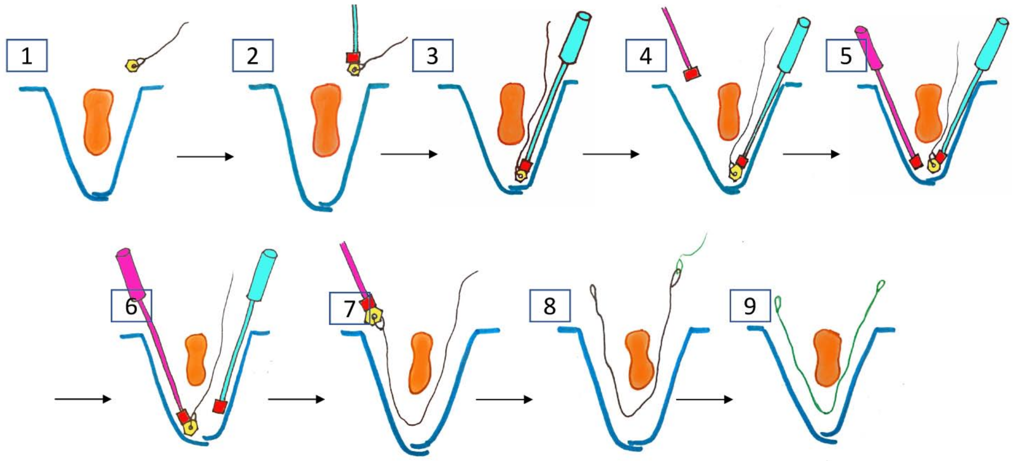


Figure 5.2: Modified manipulation of the magnetic instruments to pass the Gigli saw through the greater sciatic notch which includes a positioning stick (drawn in turquoise) and a retrieving stick (drawn in pink), sectional view from figure 2.2.

The **flexibility** of the central part of the sticks proved to be essential to allow for the surgeon to slide the instrument along modelled Rang retractors of the experimental setup. Moreover this flexibility eases the passage of the magnetic hexagonal part from the positioning stick to the retrieving stick in the greater sciatic notch (see figure 5.3)

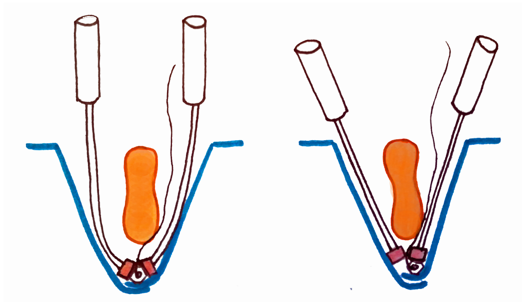


Figure 5.3: Importance of the flexibility of the sticks, left: flexible sticks, right: rigid sticks, sectional view from figure 2.2.

The instrument turned out to be **very versatile** regarding their reduced obstructiveness. They are adapted to a wide range of patients and to the patients having an inflated bone.

5.1.3 Conclusions on the experimental setup test

The experimental setup represents correctly the reality and the milk is a good liquid to mimic the blood. However, the manipulations on this experimental setup are too easy due to the absence of smooth tissues and because the modeled Rang retractors are perfectly positioned which is not always the case in a real situation.
Moreover, the magnetic instruments are the most promising solution. The positive points of this solution are the ease of manipulation and the flexibility of the sticks.
Finally, the tube is set aside because the tests were not convincing. Indeed it does not work on the experimental setup.

5.2 On cadaver

The experiment was performed in the laboratory of anatomy from UCL. The fresh cadaver was a little old woman. Dr. Docquier and his assistant were present to perform the test.

5.2.1 Protocol

The test is organized in four main tasks:

1. preparation of the surgical cavity,
2. positioning of the Rang retractors,
3. passage of the guidewire,
4. and the osteotomy with the best combination of magnetic sticks according to the surgeon.

Preparation of the surgical cavity

The surgeon incises the patient until he reaches the iliac bone and the greater sciatic notch (see figure 5.4). The way is then cleared by decommiting of the iliac crest, sectioning the muscles of the abdomen which are attached on the iliac crest and removing all the structures inserted on the bone. To clear the iliac fossa, the surgeon uses a rugine. The iliac fossa is cleared until the hip joint capsule is reached.

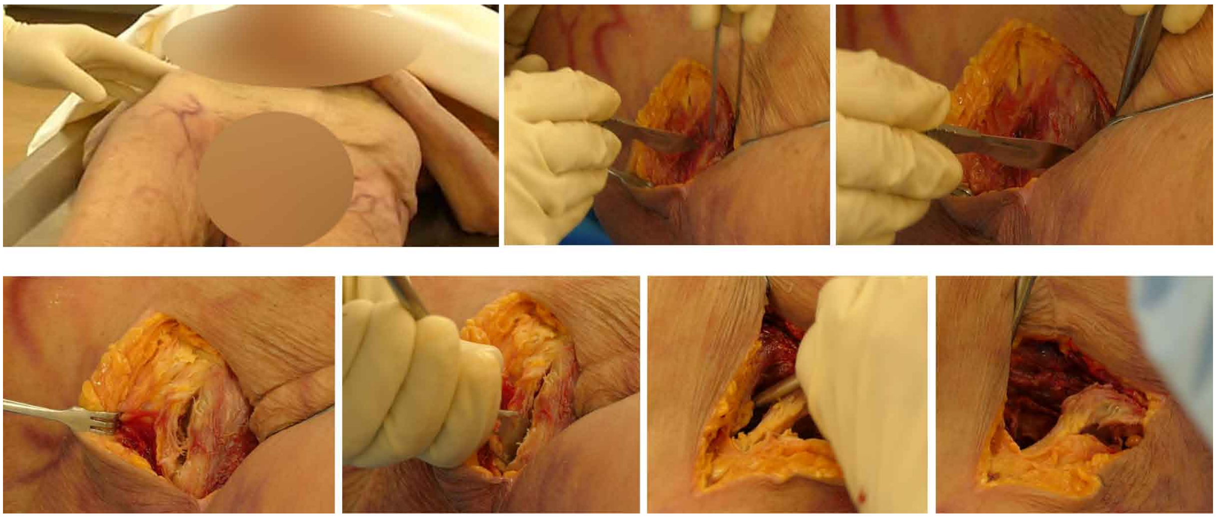


Figure 5.4: Chronological preparation of the surgical cavity during the experiment on cadaver: from the Pemberton incision to the cleared access to the greater sciatic notch.

Positioning the Rang retractors

To push aside soft tissues from the bone, the surgeon places the Rang retractors in the greater sciatic notch (see figure 5.5). The smaller retractor is inserted in first then the larger one. The larger retractor comes below the smaller one. Finally, the surgeon estimates the distance existing between the extremities of the two Rang retractors in the greater sciatic notch. Ideally, the extremities of the two Rang retractors overlap each other.

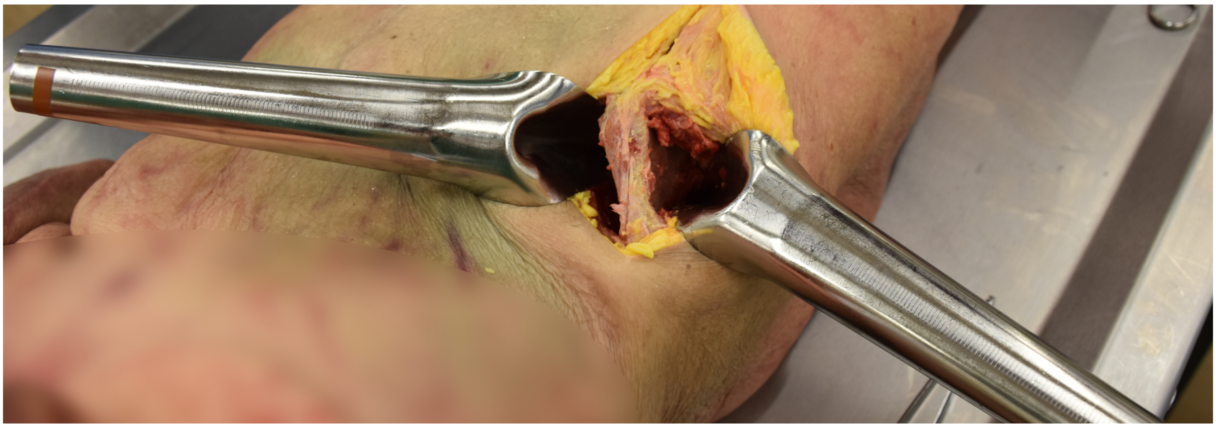


Figure 5.5: Positioning of the Rang retractors in the greater sciatic notch of the cadaver.

Passage of the guidewire

The passage of the guidewire through the greater sciatic notch is performed as detailed in figure 5.2. This task is the step of interest for the thesis.
First, the magnetic hexagonal part is fixed to the guidewire with a reef knot.
Then, the surgeon starts testing the different magnetic sticks. Six sticks are presented to him:

- a stick with the N5 non-sterilized magnet,
- a stick with the N3 non-sterilized magnet,
- a stick with the F5 non-sterilized magnet,
- a stick with the N5 sterilized twice magnet,
- a stick with the N3 sterilized twice magnet,
- and a stick with the F5 sterilized twice magnet.

Then the operator chooses the sticks that he will use at random: one stick is used to position the magnetic hexagonal part in the greater sciatic notch on the side where the smaller Rang retractor is placed (see figure 5.6). Another stick is used to retrieve the magnetic hexagonal part (see figure 5.7). As many sticks combination as possible are tested.

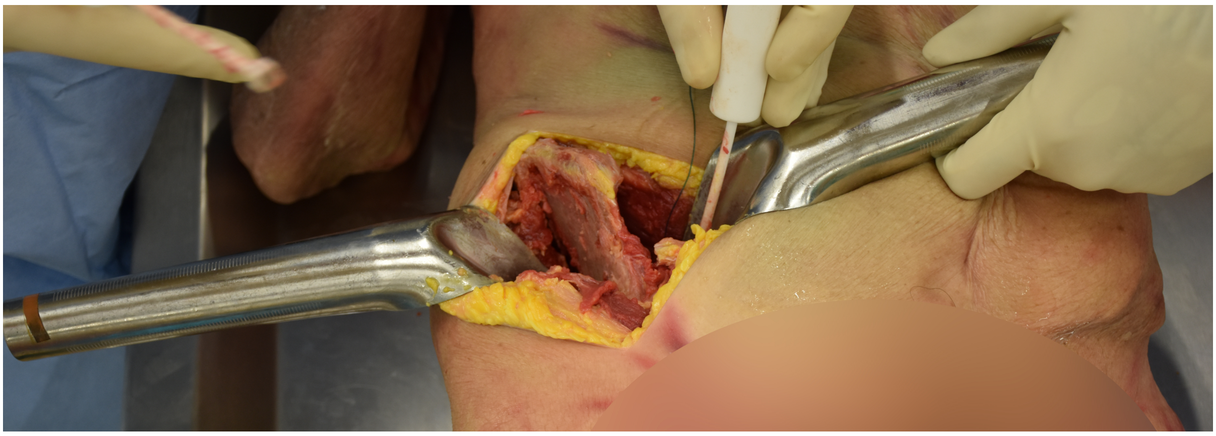


Figure 5.6: Positioning of the magnetic hexagonal part in the greater sciatic notch of the cadaver thanks to the low-attractive magnetic stick.

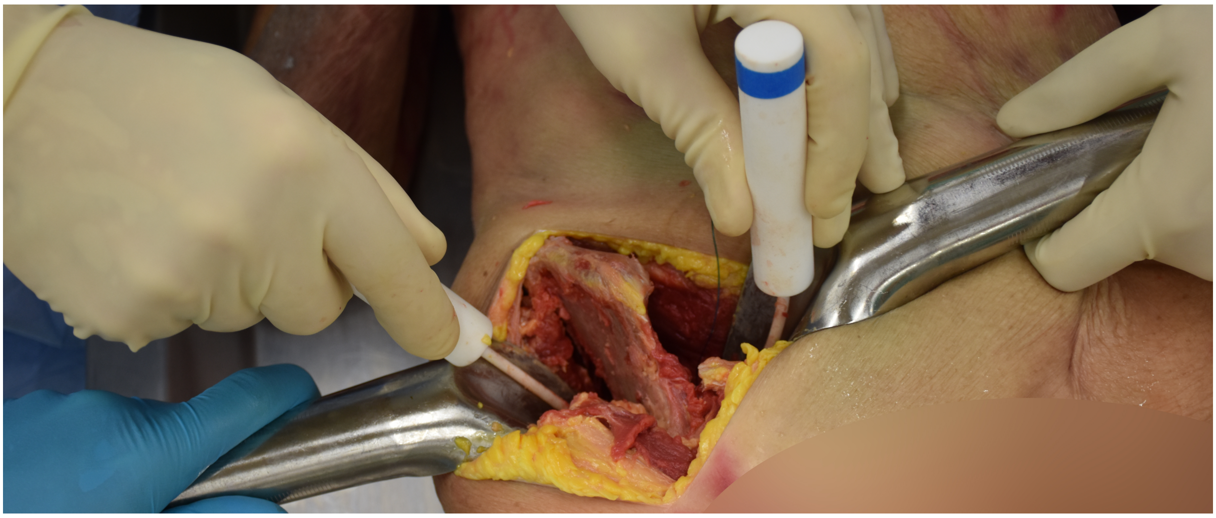


Figure 5.7: Retrieving of the magnetic hexagonal part in the greater sciatic notch of the cadaver thanks to the high-attractive magnetic stick.

The duration of each passage of the guidewire through the greater sciatic notch is timed. When all the sticks combinations are tested, the operator passes the guidewire with the two curved clamps. This last manipulation is performed in order to compare the passage executed with the magnetic instruments and the one executed with the curved clamps.

Dr. Docquier performs first the manipulations described previously on one side of the cadaver. When he is finished the surgeon's assistant repeats the manipulations.
Afterwards, the surgeon and the assistant execute the surgery on the other side of the pelvis of the patient. When the Rang retractors are correctly placed, the surgeon passes first the guidewire with the two curved clamps. Then he passes the guidewire with the best combination of the magnetic instruments.

Osteotomy with the best magnetic sticks combination according to the surgeon

The surgeon passes the guidewire with the sticks combination he felt most comfortable with. Next, he passes the Gigli saw with the guidewire and he saws the bone along the innominate line.

Figure 5.8: Surgeon saws the pelvic bone of the cadaver along the innominate line with the Gigli saw.

Remarks

Initially it was planned to sterilize the magnets used for the experiment once but they were accidentally sterilized twice.

In addition, as explained in section 5.1.2, the magnetic instruments were not used as initially planned. This is why the initial protocol was modified. Indeed in addition to find the best instrument to retrieve the magnetic hexagonal part from the greater sciatic notch, the best combination of instruments to position and retrieve the magnetic hexagonal piece has to be found. A clamp could also be used to position the magnetic hexagonal part in the greater sciatic notch.

5.2.2 Results

In table B.1 from annex B, the 32 trials performed during the test on the cadaver are presented. It details information about each test: the sticks that are used to position and retrieve the magnetic hexagonal part, the side of the pelvis where the test is performed, the operator (the surgeon or the surgeon's assistant), the duration of the passage of the guidewire and the comments given by the operator on the trials.

Right side

The first trials to pass the guidewire with the magnetic instruments were not convincing. This was caused by an inaccurate positioning of the Rang retractors. The surgeon repositioned them and after this, it was possible to pass the guidewire with the sticks: it took approximatively 15 seconds to pass the guidewire through the greater sciatic notch.

Some additional tests were performed with an additional magnet attached at the extremity of the retrieving stick to highlight the **negative effect of the socket** of the stick (see figure 5.9). Indeed, the side of the socket, in which the magnet is glued, imposes a minimal distance of one millimetre between the magnet and the magnetic hexagonal part. However, as shown in figures 4.11, 4.12 and 4.13, the force of the magnet with which it attracts the magnetic hexagonal part depends directly to the distance which separates the two components. The attractive force at a distance of one millimetre is significantly lower (see table 5.1). Moreover in the case of the distance of one millimetre imposed by the socket, it is a polymer and not air that separated the magnet and the magnetic hexagonal part. This can change the values of the attractive force measured at a distance of one millimetre.

Figure 5.9: Additional F5 magnet attached to the F5 magnet of a stick.

Table 5.1: Attractive force of the magnet (non-sterilized, sterilized once and sterilized twice) measured during the traction test for the distance separating the magnet and the magnetic hexagonal part equal to 0 and 1 millimetre.

	Non-sterilized		Sterilized once		Sterilized twice	
Distance	0 mm	1 mm	0 mm	1 mm	0 mm	1 mm
F5 magnet	0.8929	0.26	0.8796	0.224	0.8918	0.224
N3 magnet	4.15	0.583	3.03	0.34		
N5 magnet	10.7	3.65	3.14	0.63	3.22	0.63

From the experiment on the right side of the cadaver, **functional sticks combinations** are coming out (see table 5.2). During the experiment, the surgeon and his assistant did not always use two sticks to pass the guidewire through the greater sciatic notch as planned. Indeed instead of using a stick to position the magnetic hexagonal part, they sometimes used a clamp (see details of all the tests in table B.1). This is why the last efficient combination presented in table 5.2 contains a clamp.

Table 5.2: Combinations of sticks resulting from the experiment on cadaver.

Positioning stick or clamp	Retrieving stick
N3 sterilized	N5 sterilized
F5 non-sterilized	N5 sterilized
F5 non-sterilized	N5 non-sterilized
N5 non-sterilized	F5 sterilized
F5 sterilized	N5 sterilized + N5 additional magnet non-sterilized
F5 non-sterilized	F5 sterilized + additional N5 magnet non-sterilized
F5 non-sterilized	F5 sterilized + additional N3 magnet non-sterilized
Clamp	N3 sterilized + additional N5 sterilized magnet

The passage of the guidewire with the two curved clamps on the right side takes less than 20 seconds but this trial was biased as a result of the passage of all previous tests: *Now we have done the way so well that it will maybe be easy too.*, Pierre-Louis Docquier.

Left side

On the left side, the passage of the guidewire with the two curved clamps took more than one minute. Without modifying the position of the Rang retractors or clearing the iliac fossa more, the passage of the guidewire with the magnetic instruments took less than 20 seconds. These two trials can be compared because they were executed in the same conditions.

General

In table 5.3, the **duration of the four main tasks** of the experiment are presented. The difference of the duration between the left and right side to prepare the surgical cavity can be justified by the fact that the surgeon did not clear the iliac fossa enough on the right side. The duration for this step on the left side is more representative. The total duration of the surgery until the end of the innominate osteotomy is approximatively equal to 20 minutes. The passage of the guidewire with the magnetic instrument is then negligible when it takes approximatively 15 seconds.
During the surgery, the half of the time is spent for the preparation of the surgical cavity, one quarter for the positioning of the Rang retractors and a last quarter of the time for the innominate osteotomy.

Table 5.3: Approximative duration of the four main tasks of the surgery during the cadaver test.

Task	Duration on the right side	Duration on the left side
Preparation of the surgical cavity	2′45”	10′24”
Positioning of the Rang Retractors	5′50”	5′30”
Passage of the guidewire		
- with the magnetic instruments	∼ 15”	15”
- with the magnetic instruments and an additional magnet	∼ 10”	/
- with the curved clamps	∼ 17”	1′15”
Complete osteotomy	/	5′

5.2.3 Conclusions on the cadaver test

Based on these results, the magnetic instruments induce **a reduction of the duration of the passage of the guidewire**. However the efficiency is directly correlated to the position of the Rang retractors. If they are not well placed, the passage of the guidewire through the greater sciatic notch is difficult or impossible. On the other hand, when the Rang retractors are well placed, the manipulation is really easy and fast: *I think that when the Rang retractors are well placed, in my opinion, it will work on the first try with the magnetic instruments*, Pierre-Louis Docquier.

To avoid the negative effect of the sticks socket, part or the totality of the **socket can be removed**.

According to the surgeon and his assistant, the **risks to damage the sciatic nerve are decreased** using the magnetic instruments instead of the curved clamps to pass the guidewire through the greater sciatic notch: *I dare more going retrieving the guidewire. There are less risks of touching the sciatic nerve.*, assistant of Pierre-Louis Docquier. The sciatic nerve can be discarded with clamps but not be pinched because the myelin sheath of the sciatic nerve could be damaged: *If the myelin sheath is damaged, a temporary paralysis could occur.*, Pierre-Louis Docquier. However if the sciatic nerve is damage, a definitive paralysis can appear. With the curved clamps, the surgeon works almost blindly to pass the guidewire through the greater sciatic notch then the risks to pinch the nerve in the clamp cannot be neglected: *If I pinch the sciatic nerve, it is certain that the patient will be paralysed.*, Pierre-Louis Docquier. Indeed, instead of catching the guidewire, he could catch the sciatic nerve. With the magnetic instruments, this incident could a priori not appear.

Moreover, the surgeon thinks that the **dimensions** of the instruments are adapted to paediatric surgery.

Furthermore, as explained in section 5.1.2 and shown on figure 5.3, the **flexibility** of the sticks is crucial: *Yes, the fact that it is flexible allow us to slide the instrument along the Rang retractors. If it was rigid, a curve should be made in the instrument.*, Pierre-Louis Docquier.

Finally, the **cadaver is different from a child**: : *A priori it is a little bit easier in children because it is less large and the Rang retractors are better placed.*, Pierre-Louis Docquier. In comparison with the cadaver, the child has:

- smaller iliac bone: therefore the Rang retractors are normally in contact in the greater sciatic notch that is not always the case in adults.
- less rigid tissues.
- smother bone: this facilitates the sawing of the bone.
- a larger periosteum: The periosteum of the children is about 2-3 millimeters large and it is only a thin layer in adults. That makes a big difference because for the children, after having cutted the apophysis, the periosteum can be easily detached from the bone removing the surrounding tissues with it. In adults, the periosteum tears directly thus the surgeon must detach the tissues which are fixed to the bone.
- blood in the greater sciatic notch during the passage of the guidewire and the Gigli saw.

5.3 Conclusion

Based on the tests performed, the feasibility of the free tube is compromised. For this reason, the free tube is set aside. On the other hand, the magnetic instruments seem promising and work on the experimental setup and on the cadaver.

Moreover, as required in the list of specifications (see table 2.1), the magnetic instruments assist the surgeon to pass the Gigli saw through the greater sciatic notch by means of a guidewire. From the results of cadaver test, it is shown that the duration of the passage is reduced with the magnetic instruments compared to the duration of the passage with the curved clamps: *It could be really faster because sometimes we try with the curved clamp but we never see the end of it. Sometimes it goes fast but sometimes it takes a really long time.*, Pierre-Louis Docquier.

Chapter 6

Final solution: magnetic instruments

As a result of the tests performed on the experimental setup and on the cadaver, the magnetic instruments are chosen as final solution. In this chapter, the magnetic instruments are briefly described reflecting the actual results of the experiments. Then the final dimensions and the final surgical workflow are presented. In addition some details about the sterilization are provided. Next, a non-exhaustive list of the risks is realized to highlight some future challenges of this research. Finally, the classification of the magnetic instrument based on the guidance document is performed.

6.1 Description of the device

On the basis of current research finding, the first sticks combination presented in table 5.2 will be chosen as final solution: the positioning stick uses a N3 magnet and the retrieving stick uses a N5 magnet. It is an efficient stick combination: less than 10 seconds where required to pass the guidewire through the greater sciatic notch during the cadaver test. Moreover, it is the only sterilized combination and the two magnets keep enough attractive force after two sterilization processes to be used to pass the guidewire through the greater sciatic notch.

The material used for the sticks can be replaced (even if the material which is currently used responds to the requirements), but it has to be flexible between the handle and the socket.

The depth of the sticks' socket is reduced to 1 mm instead of the totality of the magnet's height (see figures 6.1 and 6.2). Currently, the magnet is fixed with glue in the socket of the stick. But this glue a priori does not resist to the reached temperatures of the sterilization process and is not biocompatible. An other glue or another fixation system has to be found.

The magnetic hexagonal part described in figure 4.9 with a thickness equal to three millimetres is chosen for the final set of instruments.

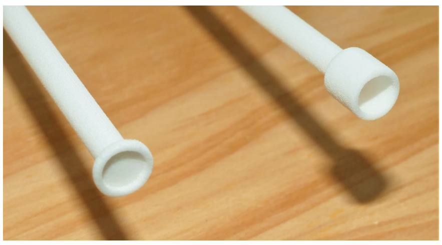


Figure 6.1: Sticks socket for a F5 magnet before and after modification of its dimensions: the initial stick had a socket of 5 mm in depth (right) and it was reduced to 1 mm in depth (left).

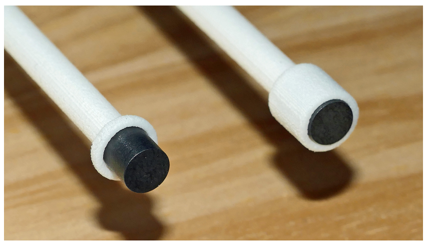


Figure 6.2: Sticks socket with a F5 magnet before and after modification of its dimensions: the initial stick had a socket of 5 mm in depth (right) and it was reduced to 1 mm in depth (left).

6.2 Surgical workflow

The magnetic instruments are used as detailed in figure 5.2. The manipulation of the instruments begins when the Rang retractors are placed trough the greater sciatic notch and it ends when the Gigli saw is in position.

6.3 Sterilization

The sterilization of the instruments can be performed by steam in an autoclave (see details in section 4.2.2). Some investigations about the long term effect of the repetitive steam sterilization on the magnets have to be performed. If the effect on the attractive force of the magnet is the same after one and hundreds sterilization processes, the actual instrument could be reusable if an other fixation system for the magnet is found and if an other material for the sticks is used. To avoid the loss of magnetization due to the high temperature reached, a gas sterilization can be considered. For example, a sterilization by ethylene oxide could be a good solution. This kind of sterilization is used for approximatively 80 % of the medical devices and is used for temperature-sensitive medical devices. This process consists of four main steps [36]:

1. **Preconditioning**: humidification of the instruments at a given temperature comprised between 30 and 60 degrees. This temperature depends on the material of the device.
2. **Sterilization:** exposure of the instruments to a fast injection of ethylene oxide. This step takes about 20 minutes at a temperature comprised between 30 and 60 degrees.
3. **Evacuation and rinsing**: evacuation of the ethylene oxide and rinsing of the instruments.
4. **Aeration**: process whereby the pressure returns to a value equal to the atmospheric pressure.

With this kind of sterilization process, the temperature does not reach the maximal operating temperature of the neodymium magnet (80°C) such that they normally do not loose attractive force.

6.4 Risk analysis

The risk analysis is based on the questions provided by the ISO14971 standard.

The main risk for a medical device is the lack of sterilization. This can be due to the sterilization itself, the washing steps or a bad packaging. This can induce infections, inflammations, transmission of virus or bacteria, etc.

A second risk is the failure of the instrument. This can come from the guidewire which can induce a loss of the magnetic hexagonal part in the patient's body or from the failure of a stick making the instrument unusable. If the magnet comes off from the socket of the stick and falls inside the patient, the surgeon will have to retrieve it. This could hurt the patient and increases the surgery duration.

Interactions between the instruments and the tissues can occur such as allergies. Moreover, coagulation of blood on the instruments can decrease the efficiency of the magnets.

There exists a small risk that the instrument harms the patient or the surgical staff (e.g. if tissues are pinched between the stick and the magnetic hexagonal part).

The magnetic instruments become unusable if the surgical space is smaller than expected. In this case, the instruments cannot be inserted in the greater sciatic notch.

More specific to magnets, some risks have to be considered:

- The demagnetization of the magnet due the temperature as detailed in section 4.2.2.
- The demagnetization of the magnets can also be caused by other medical devices present in the hospital.
- In addition to the risks of demagnetisation, the magnets could be damaged as a consequence of the high temperatures and the high pressures during the washing and sterilization processes or as a consequence of shocks during manipulations. E.g. the neodymium magnets are coated with a nickel-copper-nickel layer and shocks, high pressure, etc. can induce a flaking of this coating or break the magnet.
- Interactions between the magnet and the body, the implanted devices, the other surgical instruments or devices can occur (e.g. clamp attracted by a stick because some of clamps are magnetic).

The least controlled risk is the demagnetization of the magnet during sterilization. The risk was explored and some findings were realized (see section 4.2.2).
The risk related to the lack of sterilization is normally managed and limited by the sterilization department of the hospital.
The risk of failure of the stick and the guidewire and also the resistance of the fixation of the magnet in the stick's socket would still need to be investigated with mechanical tests.

6.5 Classification

Thanks to the guidance document related to the medical devices [16], the classification of the magnetic instruments can be achieved. Because it is a medical device, it must satisfy to the general requirements and be CE marked to be used.
The medical devices are classified in four main classes depending on the risks induced [16] [38]:

- **Class I**: lowest risk level: reusable surgical scalpel, bandage, wheelchair, glasses, etc.
- **Class IIa**: low risk level: contact lens, pregnancy tests kits, surgical gloves, etc.
- **Class IIb**: moderate risk level: orthopaedic implants, glucose monitors, dental implants, etc.
- **Class III**: high risk level: pacemakers, angioplasty catheters, spinal needles, neuro-endoscopes, etc.

To classify the device correctly, some definitions taken from the guidance document are useful:

- **Surgically invasive device:** An invasive device which penetrates inside the body through the surface of the body, with the aid of or in the context of surgical operation.
- **Transient use:** Normally intended for continuous use for less than 60 minutes.

- **Reusable surgical instrument:** Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.
- **Active medical devices:** Any medical device operation of which depends any source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active devices. [16]

The final solution uses magnetic energy but does not convert this energy or transmit it to the patient. The instrument is thus a passive device which is a surgically invasive instrument and is used less than 60 minutes during the surgery. The rule to follow from the guidance document is the sixth one (see figure 6.3). If the instrument is single use, it is a class IIa medical device but if it is reusable, it is a class I medical device.

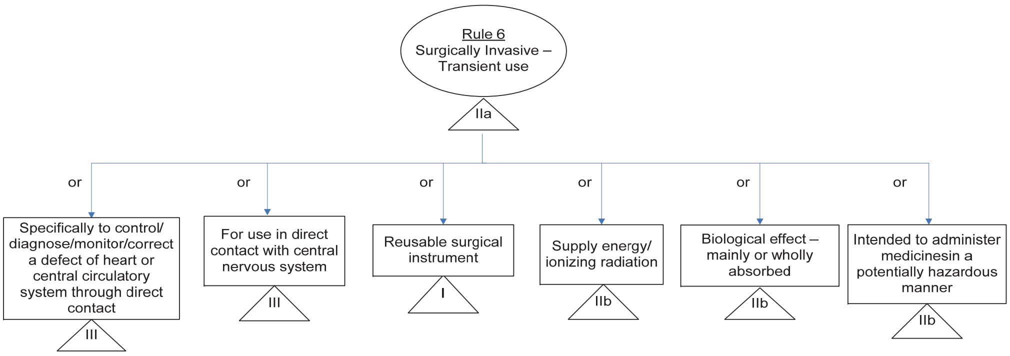


Figure 6.3: Rule 6 of the guidance: Classification of surgically invasive medical devices - transient use [16].

6.6 Other uses

In addition to being used during innominate osteotomy, the use of this instrument can be enlarged and applied to every situation where a wire has to be passed around the bone. For example, this instrument can be used to pass the guidewire around the pubis during a Sutherland osteotomy or around the ischium during a Steele osteotomy (see section 1.4). It can also be used for orthopaedic cerclage (see figures 6.4 and 6.5).

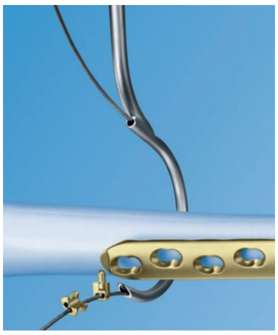


Figure 6.4: Orthopaedic cerclage: passage of a wire around the femur thanks to a wire passer. [35]

Figure 6.5: Orthopaedic cerclage of the femur in order to maintain a hip prosthesis. [35]

Conclusion

The research was successful. Indeed, an instrument to assist the surgeon to pass the Gigli saw through the greater sciatic notch during a Salter osteotomy was designed and tested. The instrument reaches the third technology readiness level. This means that the concept is proved and the first laboratory tests were performed. Six additional levels have to be reached before hoping to see this device on the market. At the moment, the instrument is defined as a single use passive surgical invasive medical device of class IIa.

This instrument is composed of three main parts: a magnetized positioning stick, a magnetized retrieving stick and a magnetic hexagonal part fixed to a guidewire. The magnets used for the sticks are made in neodymium. The magnet used for the positioning stick is less attractive than the magnet used for the retrieving stick in order to get a difference of magnetic attractive force between the two sticks. The positioning stick is used to position a guidewire in the greater sciatic notch by means of the magnetic hexagonal part. The retrieving stick is used to get the guidewire out of the surgical cavity. Afterwards, the guidewire is used to pass the Gigli saw through the greater sciatic notch. The instruments are sterilized by steam in an autoclave under a Prion cycle. However, due to the loss of attractive force of the magnet induced during the sterilization process, the device has to be single use. Nevertheless, the tests performed have shown that the resulting attractive force after one and two sterilization processes is enough to ensure the efficiency of the instrument.

From the tests performed on the experimental setup and on a cadaver, it can be concluded that the instrument responds to the list of specifications and eases the passage of the Gigli saw through the greater sciatic notch.

The test on cadaver has allowed to use the instruments in an almost real situation. Indeed the presence of the smooth tissues which were not modelled in the experimental setup shows the difficulty of the passage of the guidewire through the greater sciatic notch.

During the experiments, the position of the Rang retractors influenced directly the efficiency of the instruments: if the Rang retractors are not correctly placed, the passage of the guidewire is really difficult if not impossible. An additional research aimed to improve the Rang retractors (e.g. their shape, their dimensions) could be considered.

For the future researches, the effect of the repetitive steam sterilization on the attractive force of the magnet has to be investigated but also the effect of the gas sterilization. In addition, the instruments' ergonomics has to be improved and another fixation system for the magnets on the sticks has to be found.

To conclude, sometimes *the simplest things are the best.*

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Appendix A

Data sheet of the magnets

A.1 Cylindrical ferrite (F5) magnet

Fiche de données article FE-S-05-05

Données techniques et sécurité d'utilisation

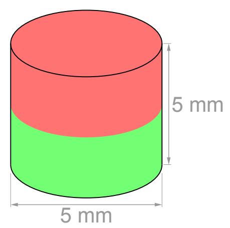
Webcraft GmbH
Industriepark 206
78244 Gottmadingen, Allemagne

Téléphone: +49 7731 939 839 3
Fax: +49 7731 939 839 9

www.supermagnete.be
support@supermagnete.be

1. Informations techniques

ID article	FE-S-05-05
Matériau	Ferrite
Forme	Disque
Diamètre	5 mm(+/- 0,1 mm)
Hauteur	5 mm(+/- 0,1 mm)
Revêtement	sans placage
Magnétisation	Y35
force d'adhérence	~ 100 g
Température max. d'utilisation	250°C
Poids	0,48 g



A.2 Cylindrical neodymium (N3) magnet

Fiche de données article S-03-03-N

Données techniques et sécurité d'utilisation

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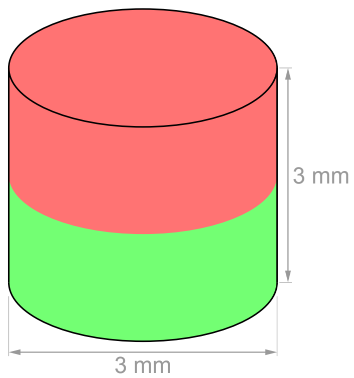
support@supermagnete.be

1. Informations techniques

Article	S-03-03-N	
Forme	Disque	
Diamètre	3 mm	
Hauteur	3 mm	
Tolérance des dimensions	+/- 0,1 mm	
Sens de magnétisation	axial (parallèle à la hauteur)	
Matériau	NdFeB (Néodyme-Fer-Bore)	
Type de placage	Nickel (Ni-Cu-Ni)	
Force d'adhérence	~ 290 g	~ 2,84 N
Poids	0,1612 g	
Méthode de fabrication	par frittage	
Magnétisation (Qualité)	N45	
Température max. d'utilisation	80°C	
Température de Curie	310 °C	
Rémanence Br	13200-13700 G	1.32-1.37 T
Champ coercitif bHc	10.8-12.5 kOe	860-995 kA/m
Champ coercitif iHc	≥12 kOe	≥955 kA/m
Produit énergétique (BxH)max	43-45 MGOe	342-358 kJ/m^3



A.3 Cubic neodymium (N5) magnet

Fiche de données article W-05-N

Données techniques et sécurité d'utilisation

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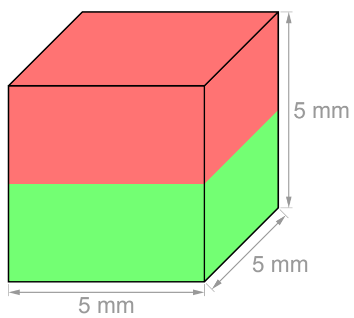
support@supermagnete.be

1. Informations techniques

Article	W-05-N	
Forme	Cube	
Longueur des côtés	5 mm	
Tolérance des dimensions	+/- 0,1 mm	
Matériau	NdFeB (Néodyme-Fer-Bore)	
Type de placage	Nickel (Ni-Cu-Ni)	
Force d'adhérence	~ 1,1 kg	~ 10,8 N
Poids	0,95 g	
Méthode de fabrication	par frittage	
Magnétisation (Qualité)	N42	
Température max. d'utilisation	80°C	
Température de Curie	310 °C	
Rémanence Br	12900-13200 G	1.29-1.32 T
Champ coercitif bHc	10.8-12.0 kOe	860-955 kA/m
Champ coercitif iHc	≥12 kOe	≥955 kA/m
Produit énergétique (BxH)max	40-42 MGOe	318-334 kJ/m^3



Appendix B

Results of the experiment on cadaver

Table B.1: Results of the tests on cadaver: Number of the trial, positioning and retrieving sticks, side (left (L) or right (R)) of the patient on which the operator (surgeon (S) or assistant (A)) works, duration and a specific remark of the trial.

	Positioning stick or clamp	Retrieving stick	Side	Operator	Duration	Remarks
The magnetic hexagonal part of 5 mm thick is used.						
1	/	F5 non-sterilized	R	S	/	Retractors not well placed because the surgeon did not enough clear the intern iliac fossa
2	/	N5 sterilized	R	S	/	Retractors not well placed because the surgeon did not enough clear the intern iliac fossa.
3	F5 non-sterilized	N5 sterilized	R	S	/	Retractors not well placed because the surgeon did not enough clear the intern iliac fossa and there is not enough place to use the cubic magnetic stick.
4	Clamp	N3 non-sterilized	R	S	/	Retractors not well placed because the surgeon did not enough clear the intern iliac fossa and there is not enough place to use the cubic magnetic stick. And the surgeon notices that there is periosteum yet.
5	Clamp	F5 non-sterilized	R	S	/	Retractors not well placed because the surgeon did not enough clear the intern iliac fossa and there is not enough place to use the cubic magnetic stick. And the surgeon notices that there is periosteum yet. But he feels that he attracts something.
6	F5 non-sterilized	N5 sterilized	R	S	/	/

Change of hexagonal magnetic piece from the 5 mm thick to the 3 mm thick one.						
7	F5 non-sterilized	N5 sterilized	R	S	/	/
8	Clamp	N5 sterilized	R	S	16"	Internal Rang retractor too low compared to the other one then the magnetic hexagonal part is blocked somewhere.
9	F5 non-sterilized	N5 sterilized	R	S	18"	Internal Rang retractor too low compared to the other one then the hexagonal piece is blocked somewhere. The intern iliac fossa is not enough clear. Usually, the surgeon detaches more the tissues attached to the bone. The surgeon has to be careful to do not go to low with the retractors to do not touch the sciatic nerve.
10	F5 non-sterilized	N5 sterilized	R	S	< 10"	/
11	F5 non-sterilized	N5 sterilized	R	S	15"	/
12	F5 non-sterilized	N3 sterilized	R	S	/	The N3 sterilized stick seems really low-attractive.
13	/	F5 sterilized	R	S	/	/
14	F5 non-sterilized	N5 non-sterilized	R	S	5"	This is easy.
15	F5 non-sterilized	N5 sterilized	R	S	5"	This is easy. When the Rang retractors are well places in the greater sciatic notch, the guidewire pass the first trial.
16	F5 sterilized	N5 sterilized	R	S	/	F5 sterilized stick is too attractive . The F5 sterilized stick is more attractive than the N5 sterilized.
17	F5 non-sterilized	N5 sterilized	R	S	33"	The Rang retractors were not correctly placed.
18	F5 non-sterilized	N5 non-sterilized	R	S	25"	The position of the Rang retractors has to be improved.
19	**N3 sterilized**	**N5 sterilized**	R	S	**9"**	**Good sticks combination because successful and both sticks are sterilized.**
20	Clamp and F5 sterilized	N5 sterilized and an additional N5 non-sterilized magnet	R	S	46"	
21	F5 sterilized	N5 sterilized and an additional N5 non-sterilized magnet	R	S	5"	

22	F5 non-sterilized	F5 sterilized and an additional N5 non-sterilized magnet	R	S	5"	
23	F5 non-sterilized	F5 sterilized and an additional N5 non-sterilized magnet	R	S	4"	
24	Clamp	N5 sterilized	R	A	/	
25	Clamp	F5 sterilized and an additional N5 non-sterilized magnet	R	A	10"	
26	F5 non-sterilized	F5 sterilized and an additional N3 non-sterilized magnet	R	A	7"	
27	Hand and clamp	F5 sterilized and an additional N5 non-sterilized magnet	R	A	/	Rang retractors not well placed then hexagonal piece is blocked between the two retractors.
28	Clamp	N3 sterilized and an additional N5 sterilized magnet	R	A	14"	
29	Clamp	N3 sterilized and an additional N5 sterilized magnet	R	S	14"	Really fast and easy.
30	Curved clamp	Curved clamp	R	S	17"	The trial is biased because the way is perfectly clean due to the number of passages already performed with the magnetic sticks. Then really easy.
31	Curved clamp	Curved clamp	L	S	1'15"	First trial on the left side then the way is not too clean as during the trial 30.
32	N5 non-sterilized	F5 sterilized	L	S	15"	The environment is the same as for the trial 31 then they could be compared.

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