Correcting sagittal balance: Design and validation of a novel pelvic osteotomy concept with a patient-specific fixation system

Master thesis – Medical Device Design track
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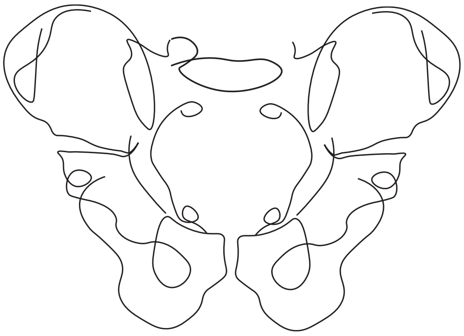

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~ *Emmy Ezendam*

Abstract

Introduction: Loss of lumbar lordosis (LL) disrupts sagittal balance, causing chronic back pain and reduced mobility. To address limitations of current surgical options, this thesis introduces the Y-osteotomy, a novel approach aimed at improving stability and reducing posterior fracture risks, combined with a patient-specific fixation system.

Methods: The Y-osteotomy was designed by combining an open- and closed wedge osteotomy techniques. A fixation system, involving a patient-specific plate and lag screw, was developed to stabilize the osteotomy. Biomechanical analysis, including free body diagrams and finite element analysis, were used to assess the system's performance under load. The concept was validated and tested on practical feasibility through a saw bone test simulating surgical conditions as closely as possible.

Results: The biomechanical analysis demonstrated that the fixation system withstood the calculated forces in extreme loading conditions, providing the necessary stability for the Y-osteotomy. The saw bone test confirmed improved posterior bone contact and, consequently, greater stability compared to previous methods. Additionally, the saw bone test further confirmed the feasibility of the surgical procedure, although some technical challenges remain, particularly in guiding tool precision.

Conclusion: The Y-osteotomy offers a promising alternative for the BEPO concept to correct sagittal balance by improving stability and reducing the risk of fractures. However, further clinical testing and refinement of the guiding tools are necessary. Additionally, the stability of the complete construct should be further tested.

Keywords: Sagittal imbalance; Pelvic osteotomy; Biomechanical analysis; Internal fixation system; Patient-specific; Loss of lumbar lordosis.

Contents

List of Abbreviations

APP	Anterior pelvic plane
ASIS	Anterior Superior Iliac Spine
AIIS	Anterior Inferior Iliac Spine
BEPO	Bilateral Extended Pelvic Osteotomy
DPO	Dome Pelvic Osteotomy
FBD	Free Body Diagram
FBSS	Failed Back Surgery Syndrome
FEA	Finite Element Analysis
IIA	Ischio-iliac angle
K-wire	Kirscher Wire
LL	Lumbar Lordosis
LP	Locking plate
L1	First lumbar vertebrae
L5	The fifth and last lumbar vertebrae
PI	Pelvic Incidence
PS	Patient-Specific
PSO	Pedicle Subtraction Osteotomy
N/A	Not assessed, not applicable, not available, no answer
SI	Sacroiliac
STL	Stereolithography or Standard Triangle Language
SVA	Sagittal vertical axis
SW	SolidWorks
S1	Sacral endplate
TFL	Tensor fascia latea
UMCU	University Medical Center Utrecht
2D	Two dimensional
3D	Three dimensional

Introduction

The loss of lumbar lordosis (LL) is an adult spinal deformity characterized by the flattening of the lower spine (L1-L5), leading to sagittal and spinal malalignment (sagittal imbalance), causing chronic back pain and limited functional mobility which can severely decrease the quality of life. The Pelvic Incidence (PI), a spinopelvic parameter, is a measurement for the sagittal balance. With the loss of LL, a PI-LL mismatch occurs. [1] [2]

The natural human posture, allowing us to stand upright, is evolutionarily created and involves fully extended hip and knees with the body's centre of mass directly above the hips. The spine plays an essential role in the biomechanics of the human body in maintaining balance, posture, and a horizontal gaze. The flattening of the LL and the PI-LL mismatch disrupts these biomechanics requiring the body to compensate by muscular effort to tilt the pelvis, bending of knees and upper body to attain an upright posture and a horizontal gaze. [2] [3]

For severe loss of lumbar lordosis surgical treatment is needed. A current surgical procedure is the pedicle subtraction osteotomy (PSO). While PSO can yield positive results, it is also associated with major complications, and has a high complication rate of 62.5%. Complications include high blood loss, deep wound infections, and neurological deficits. [4] [5] [6]

An alternative method to restore the sagittal balance instead of PSO is wanted. Therefore, the University Medical Centre Utrecht (UMCU) proposed an alternative surgical treatment which targets the pelvis rather than the spine. The pelvis will be cut bilaterally, creating an open wedge to extend it, aiming to decrease the PI-LL mismatch. Previous research has been conducted on the location and type of osteotomy, in which two osteotomy concepts have been developed and researched. [7] [8] As an outcome, the bilateral extended pelvis osteotomy (BEPO) method, in which a hinge will be created at the posterior side of the bone leaving 1 cm of bone intact is created. [7]

The pelvis is fundamental for the human posture. It converts the loads from the upper body to the lower body. [9] Therefore, it is essential that the osteotomy is fixated stable after the surgery. Previous research showed that stability is not guaranteed with the BEPO method due to the unpredictable fractures that occur in the hinge. Currently, these risks are not tackled, and a specific fixation system does not exist. Therefor, the goal of this master thesis is to improve the BEPO method and develop a new fixation system for the surgical osteotomy procedure in the pelvis.

This thesis will propose an improved concept for the osteotomy together with a fixation system. Chapter 1 will cover some basic understanding of the pelvis, the previous research, and the state of the art of fixation systems. This will lead to the problem definition with boundary condition which will be stated in chapter 2. Based on chapter 1 and 2 requirements are formed in chapter 3. Chapter 4 and 5 will cover additional research needed to specify some of the requirements. Chapter 6 will describe the design of the fixation system. In chapter 7 and 8 testing and validation will be performed. At the end, a general discussion on the complete concept and thesis will be given together with some limitations and recommendations.

1. Background and state of the art

1.1. Anatomy and physiology of the spine and pelvis

The human spine or spinal column extends from the skull to the pelvis, transmitting load from the trunk to the lower limbs. The lumbar spine is the lower spine consisting of five vertebrae, L1-L5, with L5 connecting to the endplate of the sacrum. The sacrum is connected to the pelvis through the sacroiliac (SI) joints. The hip joints link the pelvis to the lower joints. [10]

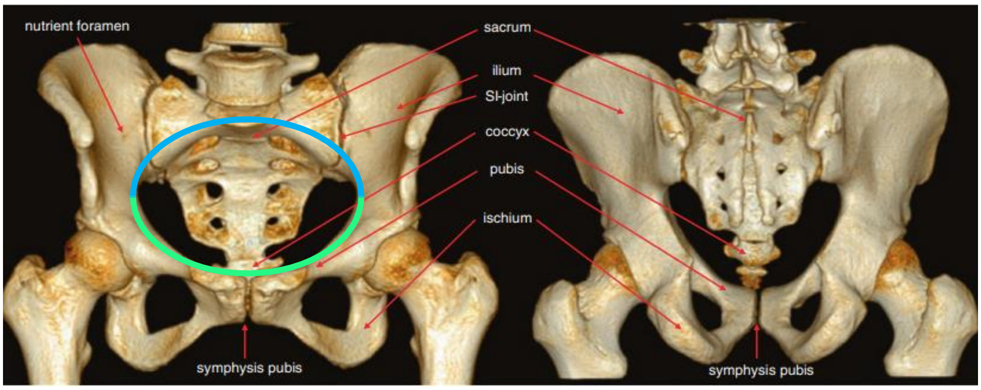

Figure 1: Anatomy of the pelvis. The ilium, ischium and pubis form a hemipelvis. [10] The pelvic ring is represented with the blue/green circle. The blue, upper line is the posterior pelvic ring. The green part the anterior pelvic ring. [11]

The pelvis is a critical structure that connects the upper to the lower body, supports weight, protects internal organs, and facilitates movement. It consists of the pelvic spine (sacrum and coccyx) and the pelvic girdle (two hemipelves, each made up of the ilium, ischium, and pubis). Together, these structures form the pelvic ring, which is essential for stability and support. [10] Figure 1 illustrates the pelvis and pelvic ring. The pelvic ring can be divided in the posterior pelvic ring and anterior pelvic ring.

The pelvis is divided into the true (lesser) and false (greater) pelvis. The true pelvis forms the bony framework for the pelvic cavity, while the false pelvis supports abdominal organs. The sciatic notch located posterior-medially to the ilium, provides passage for the sciatic nerves, which are crucial for lower body function

1.1.1. Structure and strength of the pelvic bones

The pelvis is a flat bone with a thin, slightly curved shape, comprising an inner spongy (cancellous) bone layer between two outer layers of compact (cortical) bone. The periosteum, a membrane rich in nerves and blood vessels, covers the bones, providing essential nutrients and sensory functions. The density of bone decreases with age, potentially leading to osteoporosis. According to Wolff's law, bones adapt to mechanical stresses by increasing in density and thickness, such as at muscle insertion points. [10]

1.1.2. Biomechanics of the pelvic ring

The adult pelvic ring is a rigid structure with limited movement due to the strong ligaments connecting the sacrum to the hemipelves at the SI joint. The left and right hemipelves are connected anteriorly by the pubic symphysis. The stability of the pelvic ring depends on static stabilizers (bony structure) and dynamic stabilizers (ligaments, muscles, tendons). Mechanical forces are primarily transferred through the cortical bone, while the cancellous bone distributes shear and pressure forces. [9]

1.1.3. Load distribution

Figure 2 illustrates the load distribution on the pelvic ring. The sacrum acts as the "keystone" of the pelvic ring, and transfers 67% of the load through the posterior pelvis and 21% through the lumbosacral facet joint. The posterior pelvic structure functions like a suspension bridge, where the posterior iliac spines serve as pillars, the sacrum as the bridge, and the sacroiliac ligaments as the suspension bars. It bears the most loading. The anterior pelvic ring serves as a pull bar, prevent lateral spreading and enhance stability. Pelvic stability refers to the pelvis's ability to withstand physiological loads. [9]

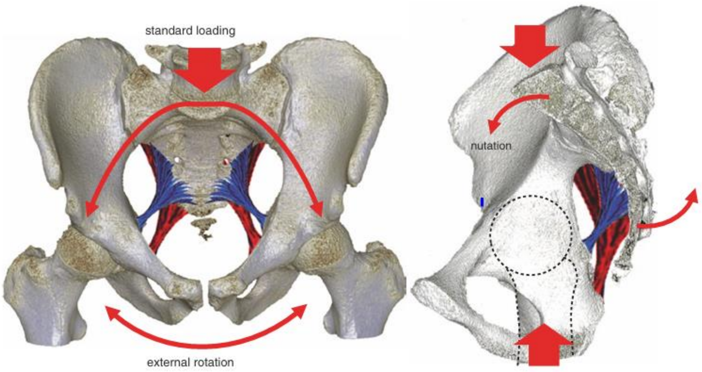

Figure 2: Load bearing of the pelvis. The posterior ring primarily bears the body's weight, while the anterior pelvic ring acts against external rotation during axial loading. [9][11]

1.1.4. Muscles and landmarks

Several key muscles attach to distinct landmarks on the pelvis and play crucial roles in movement and stability. Identifying some of these points is essential for accessing the area, protecting the muscles, and ensuring correct placement of the fixation system.

Figure 3 illustrates the important landmarks: the anterior inferior iliac spine (AIIS), superior iliac spine (ASIS), and the iliac crest. Due to their superficial laying, the ASIS and the AIIS are key reference points for surgical approaches and tool placement. The rectus femoris attaches at the AIIS while the sartorius muscle inserts at the ASIS. The tensor fascia latae (TFL) and the group of gluteus muscles (minimus, medius, and maximum) attach to the iliac crest and the ASIS. [10]

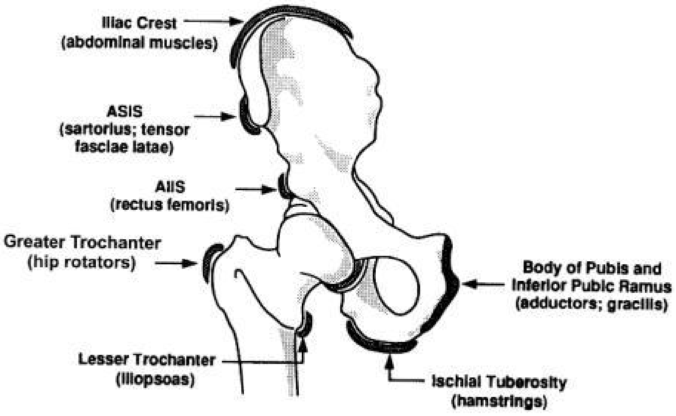

Figure 3: Right hemipelvis showing key landmarks and muscle insertion points. (muscles are indicated in brackets). [12]

1.2. Clinical context

Loss of Lumbar Lordosis can result from degenerative diseases (such as disk degeneration), trauma, or conditions like ankylosing spondylitis, and is affecting approximately 3.63% of the global population (266 million individuals). [13] The prevalence of spinal deformities is expected to rise with aging. LL loss can also occur after lumbar spinal fusion surgery, often leading to Failed Back Surgery Syndrome (FBSS), with a global incidence of 0.033%. [1] [14] The loss of LL and FBSS can significantly impact the quality of life, emphasizing the need for treatment to restore sagittal alignment and prevent complications obtained by the compensatory mechanisms of the body.

In Figure 4 the difference in postures between a normal sagittal balance and sagittal malalignment can be seen. The loss of LL can lead to severe sagittal and spinal malalignment, causing a forward-leaning posture, chronic back pain, and limited mobility. Patients compensate by tilting the pelvis anteriorly to maintain balance, using muscular effort. This can result in mechanical pain and neurological complications. [15]

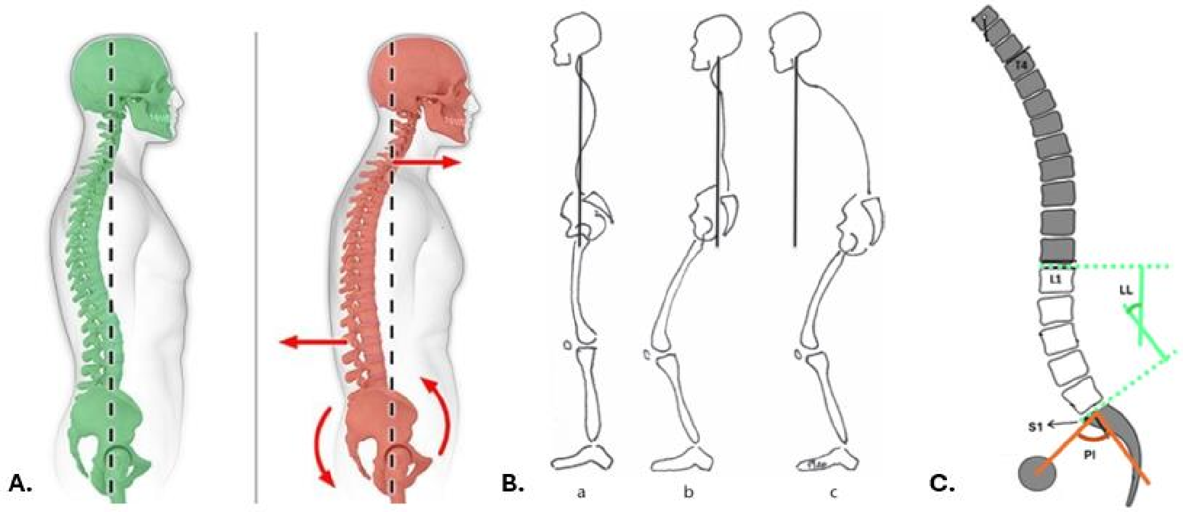

Figure 4: A. Shows a normal spine (green) and a spine with degenerative loss of lumbar lordosis (red). [16] B. Shows the progression of spinal malalignment with the coping mechanisms of the body. a) normal posture, b) pelvic tilt and bending of knees, c) using the upper body, potentially forming of kyphosis. [17] C. The lumbar lordosis (orange) and pelvic incidence (green) angles illustrated. [18]

Figure 4C shows the LL angle and Pelvic Incidence (PI). The LL is defined as the angle between the superior endplate of L1 and the superior plate of S1. The loss of LL reduces this angle. The LL is related to the PI, which is defined as the angle between the line perpendicular to the sacral endplate at the midpoint of the S1 and a line connecting this point to the centre of the femoral head. The PI is fixed by anatomy and provides insight into the pelvic orientation relative to the spine. In healthy individuals the PI has a value of 55° (SD 10°). [18] The LL is relatively small due to the evolutionary evolved human's upright position. [3] The optimal LL generally falls within the range of PI ± 9°. [7] The relationship between the PI and LL is crucial for the sagittal balance. A significant mismatch – where LL falls outside this range - can lead to malalignment and compensatory mechanisms. Correcting this mismatch is essential for restoring functional balance and reducing mechanical pain. [2] [7] [17] [18]

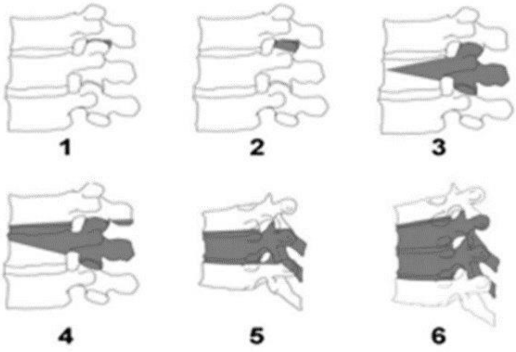

Figure 5: Pedicle spine osteotomies, with six osteotomy grades. [19]

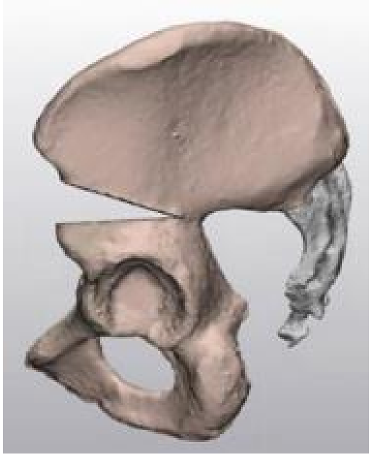

Figure 6: The Bilateral Extended Pelvic Osteotomy (BEPO). [7]

1.2.1. Current surgical and non-surgical treatment

Non-surgical treatments for LL loss include physical therapy and epidural steroid injections. For severe cases, pedicle subtraction osteotomy (PSO) is the current surgical standard, showed in Figure 5. PSO is used for more than 25 degrees of LL loss. It can correct the sagittal plane by 30-40 degrees, aiming to restore sagittal alignment by increasing the LL and so decrease the PI-LL mismatch. However, PSO has a high complication rate (62.5%) and heavily declining success rates with repeated surgeries. Complications include high blood loss, deep wound infections, and neurological deficits. [4] [5] [6]

1.2.2. New alternative method

The University Medical Centre Utrecht (UMCU) has developed a new surgical procedure to correct spinal sagittal alignment by targeting the pelvis rather than the spine. This method is based on the correlation between the PI and the Ischio-Iliac angle (IIA), which is the angle between the ischium and the ilium. [REF]. Hypothesized is that an osteotomy between the sacral endplate and femoral heads could reduce the PI.

Inspired by hip dysplasia correction techniques, like the Salter and Pemberton osteotomies, the Bilateral Extended Pelvis Osteotomy (BEPO) was proposed. [20] In this procedure, a bilateral open wedge is created, leaving one centimeter of the bone cortex intact posteriorly as a hinge, see Figure 6. Rotating the upper part posteriorly decreases the PI. An angle of 15 degree, previous identified by Ochtman, is used as the target for the angle of the open wedge. [7]

First studies on the BEPO have shown promising results in changing the pelvic incidence (PI). A cadaver study of the BEPO showed a mean correction of the PI of 10.4° with a 15° open wedge angle. [7] It showed a significant difference of PI change, but the results are less optimal compared to PSO where a correction of 25° is reached. Most importantly, unpredictable hinge fractures with instability occurred when performing the BEPO, challenging the method and questioning its safety and feasibility. These challenges started the exploration for alternative approaches. [7] A newly patient specific implant was designed with the aim to achieve sufficient stability and reduce the risk of fractures. However, a cadaver test, illustrated in Figure 8, showed that posterior hinge fractures continued to be problematic. [21]

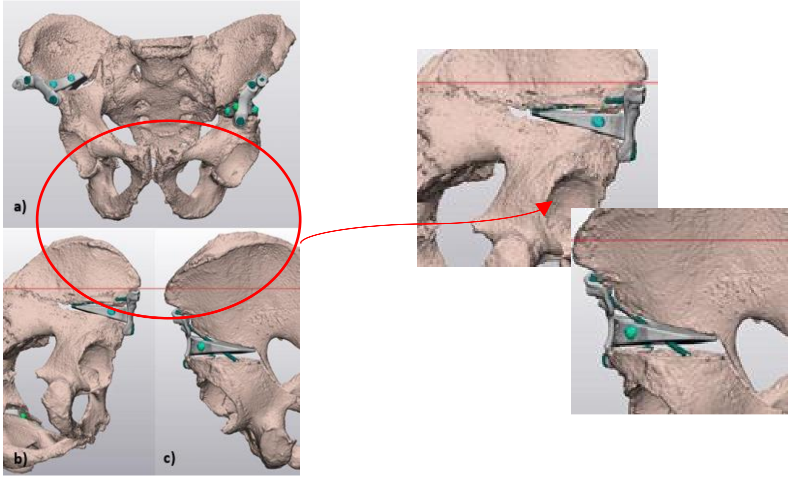

Figure 8: The result of the implementation of a fixation system in the BEPO method resulting in posterior hinge fractures. [21]

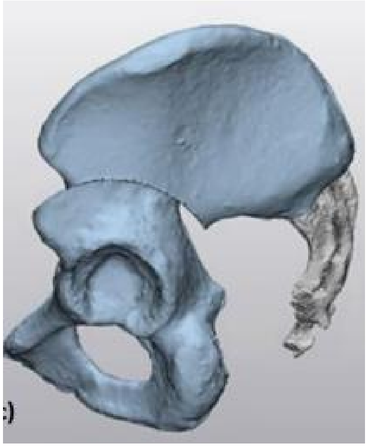

Figure 7: The Dome Pelvic Osteotomy (ADPO). [8]

To address these limitations, the Dome Pelvic Osteotomy (DPO), a dome-shaped osteotomy, was developed in a third study, see Figure 7. The DPO should offer greater stability and more predictable correction angles due to increased bone contact, which is ideally more than 25%. In-silico models demonstrated an improved outcome of 32% bone contact and a PI change of 20 degrees for a rotation of 20 degrees. The clinical feasibility of the DPO is limited by technical challenges such as the need for specialized equipment and more invasive surgical procedures, and thus not opted to be clinical possible. [8] [22]

Overall, research showed that both the DPO and BEPO obtain significant results in a change of PI. Were the BEPO seems clinical feasible, the concept comes with high risks of unpredictable fractures and instability. The DPO has a better stability but a low clinical feasibility.

1.3. Internal fixation of bones

When treating fractures and osteotomies, choosing the appropriate fixation method is crucial for achieving optimal outcome. Internal fixation is often preferred over external fixation for more complex and unstable fractures due to its advantages in restoring bony anatomy while minimizing soft tissue damage and complications. Internal fixation typically leads to better alignment, stability, and faster recovery and is associated with a decrease in mortality and adverse effects. This makes it the preferred method for most osteotomies and fractures. [9] [23]

1.3.1. Internal fixation principles

The AO foundation has formulated four basic principles for internal fixation of fractures [24] [25]:

1. **Anatomic Reduction:** Restore normal anatomy through fracture reduction and fixation.
2. **Stable Fixation:** Achieve fracture fixation with relative or absolute stability, depending on the injury and type of fracture.
3. **Preservation of Blood Supply:** Maintain vascularity with gentle reduction and careful handling.
4. **Early and Active Mobilization:** Promote rehabilitation through early, safe mobilization.

These principles aim to enhance healing and ensure optimal outcomes for patients undergoing internal fixation.

1.3.2. Types of healing

Bone healing can be classified into two main types: primary and secondary. Primary healing requires minimal motion and low strain at the fracture site. It facilitates direct bone healing through precise alignment and compression. Achieving perfect reduction and fixation is often ideal but can be challenging in practice. This approach demands absolute stability and is typically pursued when optimal conditions for healing are desired. [26] [27] [25] [28]

In contrast, secondary healing involves indirect reduction and relative stability. This process comprises four stages, with micromotion at the fracture site being beneficial for callus formation. Callus is the new tissue being formed around the fracture, that plays a crucial role in stabilizing the fracture over time. Secondary healing is common in scenarios where perfect reduction and fixation are difficult to achieve, allowing for more gradual recovery. [26] [27] [25, 28]

For closed wedge osteotomies, where precise alignment and stability are crucial, principles of primary healing are emphasized to strive for the best possible outcomes.

1.3.3. State of the art in internal fixation techniques

Fixation methods

Internal fixation methods are chosen based on the type of fixation required. Common techniques include the use of plate and screws. Screws are categorized into four main types based on their function: positional screws (have a neutral effect on fracture alignment), plate screws (locking or non-locking), poller or blocking screws (long rods), and lag screws (used for inter-fragmentary compression). [9] [29]

Plates serve multiple functions, including neutralizing forces, providing buttressing or anti-gliding support, creating a tension band, applying compression, and acting as a bridge across the fracture site. [28] [30]

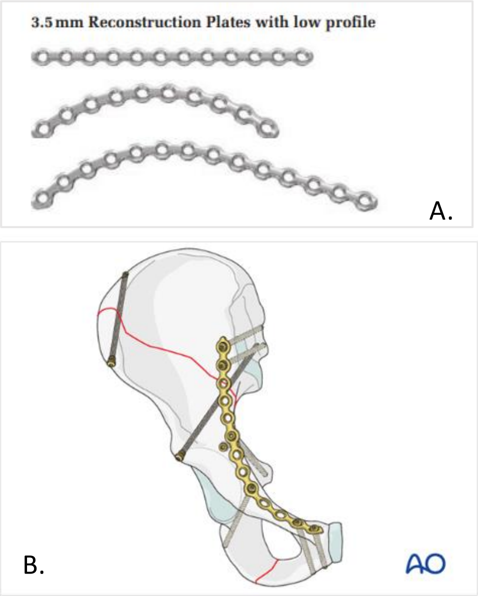

Figure 9: example of conventional pelvic ring plates. [24][31]

Pelvic ring fractures and other osteotomies

Pelvic ring fractures are categorized using the Young-Burgess classification, which reflects the degree of instability within the pelvic ring. [9] As the posterior pelvic ring bears the majority of the load transmitted through the pelvis, its stability is crucial for overall pelvic stability. Effective internal fixation requires stabilization of both the anterior and the posterior segments of the pelvic ring. [9] [32] Common approaches include using contoured reconstruction plates combined with lag screws to ensure proper alignment and mechanical stability, see Figure 9. This comprehensive fixation approach is vital for effective healing, minimizing complications, and improving recovery outcomes. [24]

In the context of osteotomies, the procedures are as stated often closed- or open-wedge. Both required a different stability as seen in the section above. The required absolute stability in closed wedge osteotomies is fixated with screws and plates. [33] Open wedge osteotomies maintain the desired angle using a fixation system, often stabilized with autografts, allografts, cages, or bone-stimulating materials.[34] [35]

Conventional vs Patient-specific fixation

Conventional plates and screws are not patient-specific, often resulting in poor fit, technical complications, decreased technical properties, and increased risk of soft tissue irritation. Patient-specific fixation systems, designed to match an individual's anatomy, address these issues and enhance accuracy and stability. Advanced techniques like computer-aided manufacturing and 3D printing facilitate the creation of patient-specific implants. [36] [37]

2. Problem definition and objectives

The previous chapter showed that using only a fixation system will not suffice to mitigate the risk of unpredictable posterior fractures and resulting instability. Despite the fixation system, the fractures still occurred. Since essentially the skeleton of a patient will be divided into two, the most controllable way of procedure is needed. The risks of uncontrolled fractures of the hinge, that are part of the BEPO ask for a new kind of procedure.

As seen in section 1.2.2, the concept of the BEPO showed a positive effect on the change of PI-LL mismatch and seems clinical feasible. The concept of the DPO also showed a positive effect on the change of the PI-mismatch and has a high advantage by introducing more stability due to the bone contact. However, the DPO is not clinical feasible. The advantages of the BEPO and the DPO, together with brainstorming and discussions leads to the introduction of a new concept: the Y-osteotomy, illustrated in Figure 10.

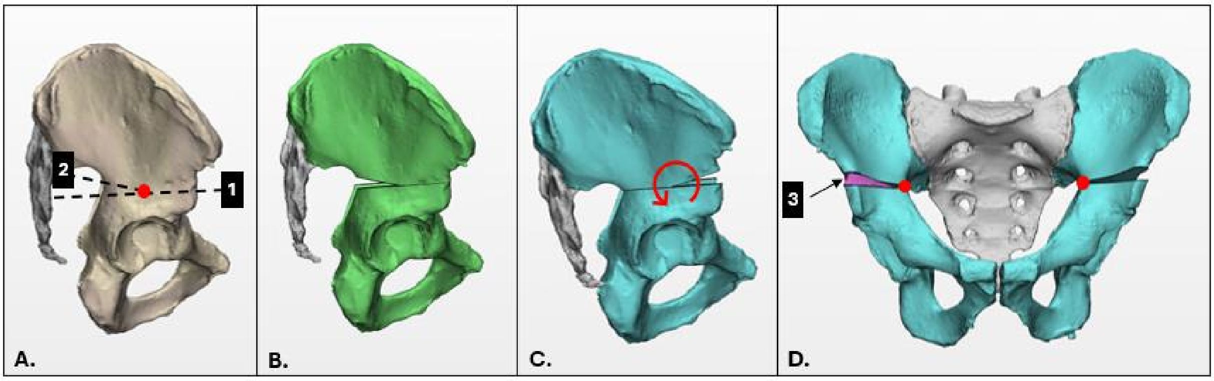

Figure 10: The Y-osteotomy. a) saw cut 1 (1) and sawcut 2 (2), with the red dot representing the point of rotation. b) Depicts the saw bone, illustrating the concept of the bone segment to be transferred. C) Demonstrates the rotation of the cranial and caudal bone segments. D) Frontal view showing the placement of the bone segment on the right side (3), and the point of rotation visible on the inner pelvic ring.

This concept, based on the combined wedge osteotomies in the knee, combines the open wedge of the BEPO with the bone contact of the DPO. [38] Instead of leaving a hinge, a complete cut through the bone will be made, completely eliminating the risk of uncontrolled fractures, see cut 1 in Figure 10. Additionally, a second saw cut will be made at a midpoint in the ilium towards the posterior side, see cut 2 in Figure 10. This will create a triangular section of bone that will be resected from the posterior side and transferred to the front. This section of bone, an autograft, is hypothesized to be strong enough to fill the gap and stimulate bone growth. [39]

A rotation point is created in the middle of the ilium by the second cut. This rotation point introduces a large area of bone contact at the posterior part of the pelvis. Believed is that this has a positive effect on the stability, as the loads are mostly transferred on the posterior part and on the healing. The Y-osteotomy is a realignment osteotomy that combines both open and closed wedge osteotomy techniques. [38] Since primary and secondary healing processes cannot be combined, internal fixation with absolute stability is chosen for the Y-osteotomy, as bone contact requires absolute stability, and a large amount of bone contact is aimed.

2.1. Problem definition

The aim of this master thesis is to develop and evaluate the Y-osteotomy with a corresponding fixation system. The goal is to ensure accurate execution of the osteotomy in the pelvis by assessing their feasibility, stability, and overall potential for clinical use.

2.2. Objectives

1) Develop an initial proof-of-concept for the Y-osteotomy, defining preliminary anatomical cuts and configurations. This step aims to establish a foundation of the concept, and basic specifications to guide the design of the fixation system.
2) Analyze the global forces acting on the osteotomy site in the ilium to determine the biomechanical requirements of the fixation system. The specific methods for the analysis will be selected based on the study's needs.
3) Development of a fixation system tailored for the Y-osteotomy. This design will be based on the proof-of-concept Y-osteotomy, biomechanical analysis, and identified requirements.
4) Conduct in-silico testing to evaluate the performance of the fixation system under the identified loads of objective two. The choice of testing methods will be detailed based on the requirements of the study and explained in Chapter 7.
5) Asses the clinical feasibility and usability of the Y-osteotomy and the fixation system. The evaluation will include testing the procedure's execution and system's performance with specific criteria and methods detailed in Chapter 8.

3. Requirements

Based on the previous chapters, a preliminary list of requirements has been developed. These requirements serve as the input for the design phase, defining the constraints and design space. While a fully developed and ready-to-use system would require many additional requirements, this project focuses on creating a proof-of-concept fixation method. Thus, the current requirements are specifically chosen to support this initial goal.

This chapter is divided into two lists. The first outlines the demands and wishes for the new osteotomy method. The second list details the general demands and wishes for the fixation system designed for this new osteotomy method.

3.1.1. The new osteotomy concept

#	**Demands**
Technical feasibility	
1.	The correction must be at least 15 degrees.[7]
2.	The bone contact must be at least 25% of the area. [8]
Anatomical feasibility	
3.	The sciatic nerve must not be compressed.
4.	A surgical approach must be feasible.
5.	The acetabulum must be preserved with a minimal margin of 15 mm from the cuts.
Wishes	
6.	Position the second saw cut on the inner pelvic ring.
7.	Minimize muscle damage.
8.	The transferred bone should fit the open wedge with minimal protrusion.
9.	Ensure precise anatomical alignment post-osteotomy, minimizing malalignment between the pelvic segments.

3.1.2. The fixation system

The requirements for the fixation system are categorized into five categories reflecting mechanical performance, anatomical and physiological considerations, clinical feasibility, design specifications and additional wishes. More specific requirements will be discussed in later chapters.

Overall demands:

#	***Requirements description***	***Details/ specifications***	***Testing/ validation methods***	***Sources***
1. Mechanical constraints and performance:				
1.1.	The fixation system must not interfere with the point of rotation.	To prevent fractures and uncontrolled rotation.	Simulation of rotational behavior.	
1.2.	The closed wedge should be fixed by compression.	To promote absolute fixation.	Literature, experts' opinion	
2. Mechanical stability and performance				
2.1.	The fixation system must ensure fixation of the anterior and posterior side of the hemipelvis.		Observation	[32]

2.2.	The fixation system must withstand the global forces and loads of an adult at the osteotomy site in a static position.	Specified in Chapter 5.	Simplified FEA.	
3. Anatomical and physiological requirements:				
3.1.	Placement of the components must not interfere with the SI joint.		Preoperative planning, post-op review.	[9, 10]
3.2.	Insertion points of the fixation system must not interfere with the osteotomy site.	Minimum distance of 10 mm.	Preoperative planning, post-op review.	
3.3.	The acetabulum must be protected.		Preoperative planning, post-op imaging, 3matic analysis.	
3.3.1.	No components must penetrate the acetabulum.		Observation	
3.3.2.	Maintain a minimum distance of 5 mm from the acetabulum edge.		Observation	
3.4.	The fixation system must assure an opening of 15 degrees in the open wedge.		3Matic measurement.	[7]
3.5.	The sciatic nerve must be protected during and after fixation.		Observations, experts' opinion, 3matic analysis.	
3.6.	Avoid gaps to reduce malunion/nonunion risks.		3matic evaluation, pre- and postoperative.	
4. Clinical feasibility and safety:				
4.1.	The fixation system must have accessible screw holes.	To be reached with tools during surgery.	Surgical simulation, surgeon feedback.	
4.2.	The fixation system must fit post-procedure alignment accurately.		Post-operative observation, expert's opinion.	
4.3.	Materials must be CE-approved.		Regulatory approval review.	
5. Design and user specifications:				
5.1.	The fixation system must be patient specific.		3d modelling,	

			patient-specific simulation.	
5.1.1.	The design must allow application across different patients.			
5.2.	Components that must be pre-formed to match the anatomy, should be formed within three adjustments.			[40] [37]
5.3.	Components must ensure intuitive use and placement.	Labeled for location, placement and rotation.		
5.4.	All the elements may not have any sharp edges.	Edges should be rounded.	Physical inspection, feedback surgeon.	
6. Wishes				
6.1.	Minimize the sacrifice of ligaments and muscles.	Protect: Rectus femoris, TFL, sartorius, gluteus muscles (at ASIS).	Feedback surgeon, pre-operative planning and observation.	
6.2.	Components should be as small as possible.			
6.3.	Limit soft tissue damage as much as possible.		Feedback surgeon.	
6.4.	Elements should be visible on X-ray during surgery.	For proper placement verification.	Imaging studies, surgeon feedback.	
6.5.	The fixation system's location and orientation must be visible on CT scans.	For post-operative review of the patient.		
6.6.	Ideally, the fixation system should be suitable for osteoporotic bones.			

4. Detailing of the Y-osteotomy

The Y-osteotomy consists of two saw cuts at the lateral-anterior ilium and the inner pelvic ring. The success of the osteotomy depends on the placement of the first cut, as it influences the bone contact, alignment, and fit of the bone segments. Identifying this point is also essential for designing the fixation system and surgical tools, that need to fit the locations precisely.

The goal of this chapter is to determine the best location for the first saw cut on the lateral-anterior ilium, ensuring maximal bone contact, minimal malalignment (overlap), and a proper fit of the triangular bone section (the bone wedge).

4.1. Methods

The osteotomy was modeled using Materialise 3-matic 16.0 (Materialise, Leuven, Belgium). Two CTA scans, including one male and one female pelvis, were selected from an anonymized database. The inclusion criteria were:

- Complete pelvis and sacrum.
- No history of pelvic or hip fractures or surgery.
- No significant height asymmetry between the right and left hemipelves.

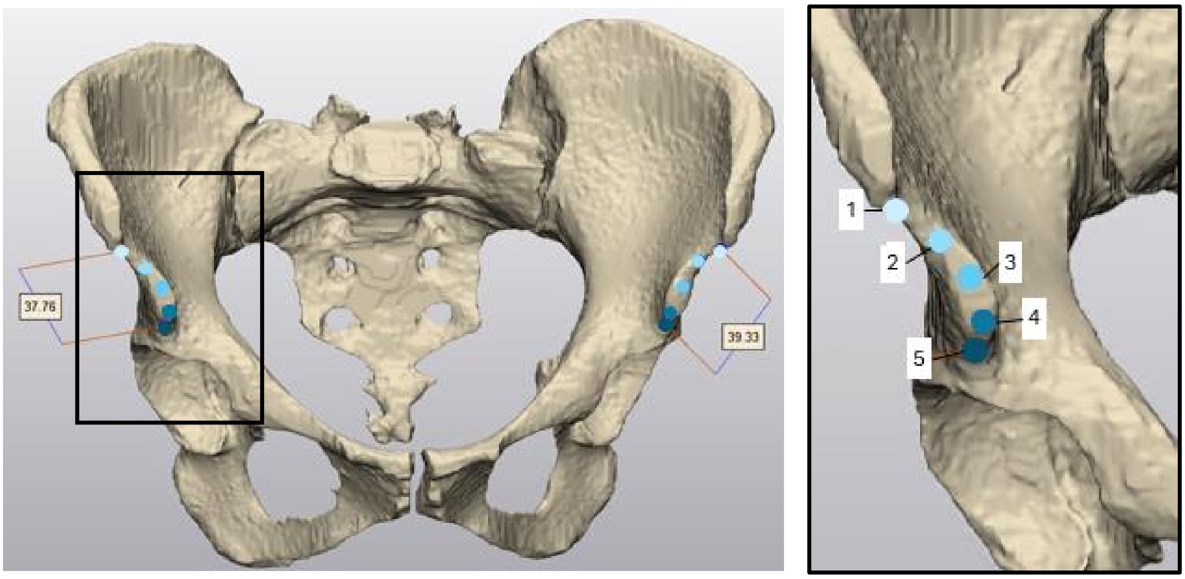

Figure 11: The five selected points on the iliac edge, visualized on the female pelvis. Due to the anatomy of the female pelvis, the points are positioned somewhat closer together.

Selection of five entry points

Five points were selected along the lateral-anterior ilium, these points can be seen in Figure 11. The points fall into the anatomically restricted range between the ASIS and the acetabulum. The range was determined in consultation with an orthopedic surgeon, with more than 15 years of experience, to ensure safety and feasibility. The points were spaced evenly across this range to provide a balanced evaluation of the different regions of the ilium. The endpoint of the first cut was consistently placed just below the sciatic notch on a flat area, as this location was hypothesized to reduce posterior overlap. According to this decision, the endpoint of the second cut ended below this first endpoint.

Y-osteotomy procedure

The saw cuts were aligned using the Anterior Posterior Plane (APP), a commonly used reference in pelvic surgery. [41] [42] The first cut was directed from the anterior ilium towards the sciatic notch, and the second cut was rotated 15 degrees downward from the inner pelvic ring.

Variables measured and observed

The following variables were measured and observed during the execution of the osteotomy:

- Bone contact surface area: the surface area of the contact between the bone segments post-execution was measured using the intersection tools in Materialise 3-Matic.
- Overlap: visual assessment of the overlap between the bone segments on the posterior and lateral-medial sides. The goal was to minimize misalignment.
- Fit of the bone wedge: observed by evaluating how well the bone segment fit into the open wedge and how much trimming would be required during surgery.
- Preservation of anatomical structures: special attention was paid to avoided damage to the rectus femoris muscle and ensuring the sciatic nerve was not at risk of compression.

4.2. Results

The osteotomy was performed for all five selected points on both female and male pelvises. Each point resulted in sufficient bone contact, exceeding the required minimum of 25%. Slight variations were observed, particularly in the female pelvis.

The following results were observed:

- The higher points on the ilium (points 1 and 2): these points provided less bone contact and a larger opening in the osteotomy wedge. They also resulted in greater overlap at the posterior and lateral sides and are located close to the ASIS.
- Middle points near the rectus femoris insertion (points 3 and 4): these points demonstrated more bone contact, and a better balance of bone contact and less posterior overlap. Anatomical structures, as the rectus femoris, are less likely to be affected.
- The lowest point (point 5): demonstrated less bone contact than points 3 and 4, and more deviation in overlap. Anatomical structures as the acetabulum and AIIS are likely to be affected.

4.3. Discussion

The final chosen point (3) located just above the rectus femoris insertion, consistently demonstrated the best bone contact, minimal overlap and should apply less damage to anatomical structures. Although the bone wedge was slightly larger than the opening at the sides, surgical trimming was deemed manageable based on expert consultation. The risk of sciatic nerve compression was considered low, as protective tools like the Hohmann retractor could be used during surgery.

While the entry point worked well for both male and female pelvis, anatomical differences between the sexes suggest that future research should validate these findings across a larger sample size. Additionally, ensuring that the sciatic nerve is not compressed during the osteotomy procedure needs to be validated. Testing nerve protection strategies, such as the use of a Hohmann retractor, will be critical for further refining the technique. Further, damage of the rectus femoris seems unavoidable, but can be limited hence the choice of the final point.

The goal of this study was to determine the optimal location for the first saw cut in the Y-osteotomy. The point just above the rectus femoris insertion was selected based on its ability to maximize bone contact, minimize overlap, and preserve muscle integrity. With this point chosen, a specific fixation system and surgical tools can be developed for the Y-osteotomy.

5. Calculation of the approximated forces

To estimate the forces acting on the pelvis and the Y-osteotomy and to estimate the required stiffness and strength of the implant, free body diagrams (FBDs) were created. These diagrams provide a basis for further analysis and help the design to meet the biomechanical demands. The aim of this chapter is to specify the mechanical requirement for the Y-osteotomy. (Requirement 2.2 (Chapter 3, section 3.1.2).)

5.1. Methods

The calculation procedure is as follows: a FBD of the Y-osteotomy is created, with a cut at the osteotomy side, to focus on the desired internal forces. To calculate the reaction forces on the pelvis, occurring forces need to be used. For this, the forces in the hip joint calculated by Bergmann are applied. Bergmann's study provides data on the forces acting on the femoral head, obtained from sensors implanted in hip replacements. [43] A key activity examined is the transition from a two-legged stance to a one-legged stance. The joint reaction forces (JRFs) recorded during the two-legged phase of this activity are used (Table 4 of Bergmann et al).[43]

5.2. Assumptions

Several assumptions were necessary for this analysis:

Equilibrium and weight distribution:

- The body is in a state of equilibrium.
- The weight of the upper body acts through the center of the pelvis in a two-legged stance.
- The weight is equally distributed between the legs in a two-legged stance.
- The weight of the lower extremities is neglected.

Pelvis and sacrum configuration:

- The sacrum and pelvis are rigidly connected.
- The pelvis is symmetrical.
- The upper part of the pelvis and sacrum is unconstrained, and "floating" in space.
- The pubic symphysis allows rotation but resists horizontal and vertical forces.

Muscle and joint forces:

- Net muscles forces and moments account for muscle activity at a joint, putting the antagonist against the agonist muscles. The abductor muscles act in a standing position and are assumed to be the main forces.
- The abductor muscles only act in tension, applying a force at the attachment sides of the pelvis and the femur.
- Joint reaction forces at the femur-acetabulum interface act at the center of the acetabulum.
- Horizontal forces on the feet are neglected assuming that they have a minimum impact on the equilibrium.
- Soft tissues and other muscle groups besides the abductor are neglected for simplicity.

Geometric and angle assumptions:

- The dimensions for the frontal plane are based on Schroeder et al. The dimensions of the sagittal plane on Dzupa et al. [44] [45]
- The abductor muscles are estimated at 20° in the frontal plane and 45 degrees in the sagittal plane. [46]
- The joint reaction force angle is set at 13°, derived from Bergmann's study and additional sources.

5.3. Free body diagrams

In the free body diagrams (FBDs) used for this master thesis, the pelvic girdle (section 1.1) is assumed as a rigid body. [47] A two-legged stance is chosen, as this scenario is relevant and suitable for early stages of recovery.

The analysis can be simplified to a two-dimensional problem in two planes (the frontal and sagittal plane), that are perpendicular to each other. Together they create a 3D overview. The two 2D planes, enables the use of three independent equilibrium equations for each plane: one for the moments and two for the forces along the axes (XZ and YZ). The created free body diagrams are showed in Figure 12 below:

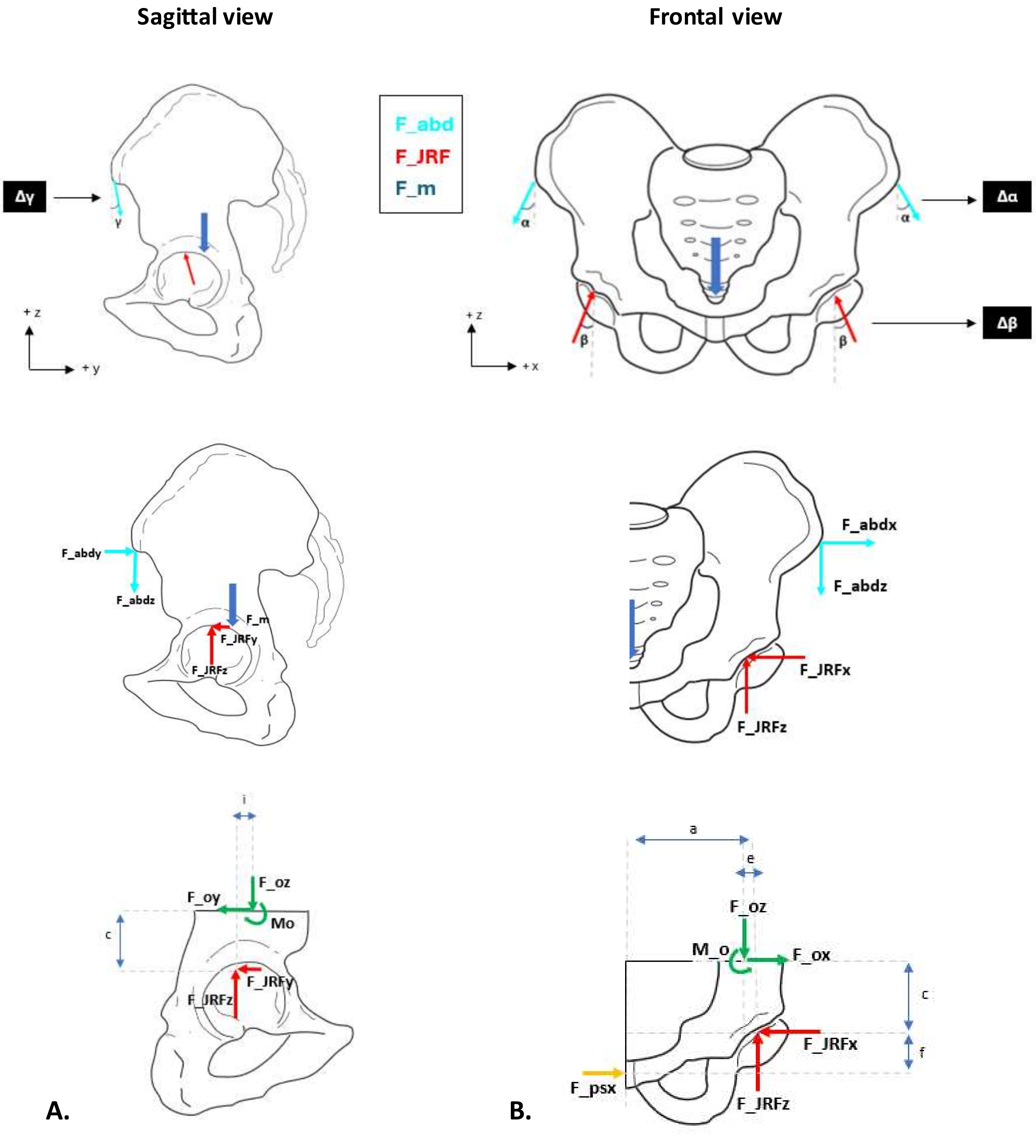

Figure 12: A. Free body diagrams in the sagittal plane. The FBD in the bottom left shows the osteotomy configuration. B. Free body diagrams in the frontal plane. The FBD in bottom right shows the osteotomy configuration.

5.4. Calculated forces

5.4.1. Joint reaction force and transformation

The measured joint reaction forces (JRFs) on the femoral head by Bergmann et al., are given in a reference frame connected to the femur (femoral coordinate system), where the femur is positioned vertically and viewed from behind (Z=vertically upward, x=lateral, y=anterior).[43] The forces are approximately:

$$F_{JRF} = \begin{vmatrix} F_x \\ F_y \\ F_z \end{vmatrix} = \begin{vmatrix} 347 \\ -50 \\ 1000 \end{vmatrix} \; Newton$$

The forces need to be transformed to the pelvic coordinate system to align before further calculations can be made.

Coordinate system and transformation/rotation of the forces

The transformation of the femur coordinate system to the pelvic coordinate system requires two steps, illustrated in Figure 13:

1) **180° rotation around the z-axis**. – This step aligns the femur coordinate system with the pelvis by flipping the orientation from front-to-back. This rotation changes the lateral and posterior axes, while the vertical axis remains unchanged.
2) **9° rotation around the y-axis** – after the first rotation, the femur axis is not aligned with the pelvic axis. An 9° angle is found between the femur and pelvic (vertical) axes, which accounts for the anatomical difference between the systems, θ = 9°. This rotation aims to bring the two in alignment. [48] [49, 50]

Lastly, Newton's third law (Action = -Reaction) is applied because the JRFs provided by Bergmann are measured on the femur. To determine the forces acting on the pelvis, the direction of the forces must be reversed, resulting in the following JRFs:

$$\begin{bmatrix} x''' \\ y''' \\ z''' \end{bmatrix} = \begin{bmatrix} F_x \\ F_y \\ F_z \end{bmatrix} = \begin{bmatrix} 397 \\ -50 \\ 832 \end{bmatrix} \; Newton$$

The calculations can be found in Appendix A .

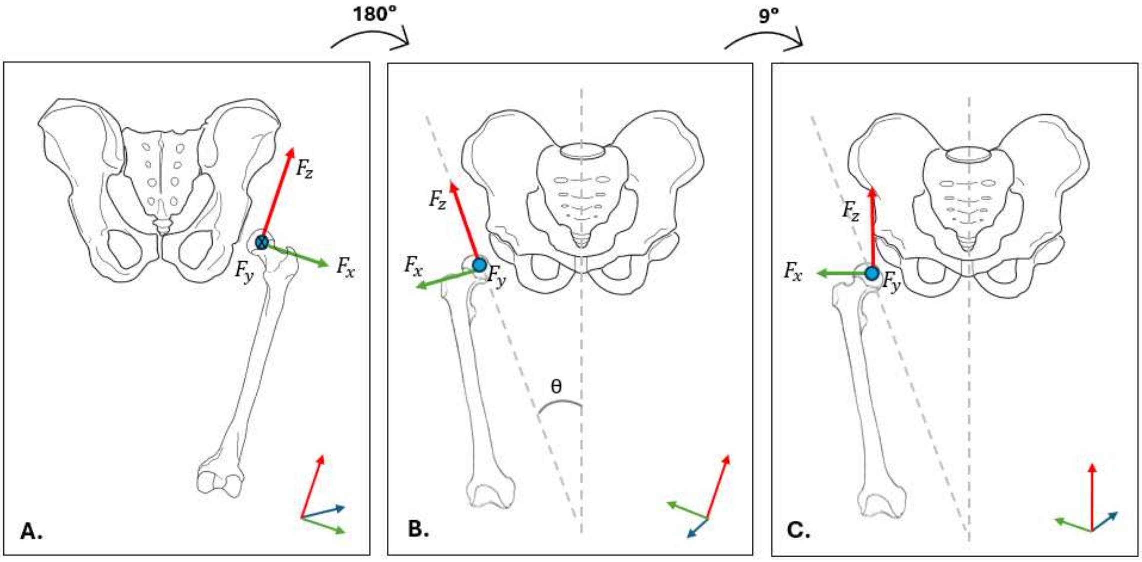

Figure 13: The transformation of JRFs from the femur coordinate system to the pelvic coordinate system. A. the initial orientation of the JRFs. B. The 180 ° rotation. C. Rotation of 9 ° to the vertical axis. [43]

5.4.2. Considerations for the fixation scenario

To calculate the forces at the osteotomy site, an assumption must be made for the forces at the pubic symphysis (yellow part in Figure 14). As this assumption matters towards the calculation, and the forces cannot be calculated without an assumption due to many unknown forces, two extreme cases are created. The fixation system is hereby assumed to be modelled as an implant.

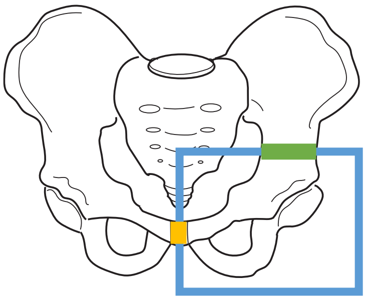

Figure 14: In blue the frame of the 'cut-through' FBD of the frontal pelvis. Green = the osteotomy site. Yellow = the pubic symphysis.

1) **Case 1 – stiff implant:** The pubic symphysis force in the x direction (defined by F_{psx}) is assumed to be zero. The moment at the implant (defined by M_o) must offer balance indicating that the implant must be very stiff.
2) **Case 2 – flexible implant:** The implant is assumed to be very flexible and thus $M_o = 0$. F_{psx} must offer the balance.

5.4.3. The equations

For the cut-through configurations, the following equations are created:

Frontal osteotomy FBD (Figure 12B):

$$\sum F_x = 0 \quad \rightarrow F_{ox} - F_{JRFx} + F_{psx} = 0$$
$$\sum F_z = 0 \quad \rightarrow F_{JRFz} - F_{oz} = 0$$
$$\sum M_{JRF} = 0 \quad \rightarrow M_o - F_{ox} * c + F_{oz} * e + F_{psx} * f = 0$$

Sagittal osteotomy FBD (Figure 12A):

$$\sum F_y = 0 \quad \rightarrow \sum F_y = -F_{oy} + F_{JRFy} = 0$$
$$\sum F_z = 0 \quad \rightarrow \sum F_z = -F_{oz} + F_{JRFz} = 0$$
$$\sum M_{JRF} = 0 \quad \rightarrow \sum M = -F_{oz} * i + F_{oy} * c - M_o = 0$$

5.4.4. The outcomes

The calculations can be found in Appendix B. The results from the equations are the following:

Frontal osteotomy configuration:

$$\text{Scenario one: } \begin{bmatrix} F_x \\ F_z \\ F\,px \\ M_O \end{bmatrix} = \begin{bmatrix} 397\ N \\ 832\ N \\ 0\ N \\ 18\ N * m \end{bmatrix} \text{ vs. Scenario two: } \begin{bmatrix} F_{ox} \\ F_z \\ F\,px \\ M_O \end{bmatrix} = \begin{bmatrix} 140\ N \\ 832\ N \\ 257\ N \\ 0\ N * m \end{bmatrix}$$

Sagittal osteotomy configuration:

$$\begin{bmatrix} F_{oy} \\ F_{oz} \\ M_o \end{bmatrix} = \begin{bmatrix} 50\ N \\ 832\ N \\ -6.4\ N * m \end{bmatrix}$$

5.5. Discussion

In this chapter, the loading conditions acting at the osteotomy site were approximated by a simplified 2D analysis in both frontal and sagittal view. An osteotomy configuration was created for both. For the frontal view two extreme scenarios are considered: a stiff implant (case one) and a flexible implant (case two), to estimate the range of forces acting on an assumed implant. In both cases the role of the pubic symphysis was assumed.

Force variability and implications

In case one, higher horizontal forces and moments suggests that the fixation system needs to resist rotational instability. This might reflect a situation in which the stabilizing effects of the surrounding muscles and soft tissues are not properly functioning. This case represents a more pessimistic case. In contrast, case two seems to be more optimistic. Lower horizontal forces and no moment demonstrate suggest a more stable configuration. Internal stabilizing elements, such as the pubic symphysis, contribute to balancing forces and minimizing the load on the fixation system.

Design implications for the fixation system

These findings are crucial for guiding the design of the fixation system. The system must be capable to withstand higher loads and moments in situations where soft tissue support is minimal, which could be in the early recovery phase, or where muscle support is diverging. It can be assumed that internal stabilization will improve during the recovery phase, which would reduce the mechanical load on the fixation system. However, variation in healing rate could impact the systems performance. To address this, the fixation system is tested under the highest forces identified in this analysis to ensure it can handle the maximum load conditions without failure. This test will be performed in Chapter 7. Further considerations, such as stress shielding, will be discussed in chapter 6 when designing the fixation system.

Other limitations

This study used a simplified model of the real physiological environment. Introducing more variables, such as the soft tissues and more muscles, can result in different forces. As internal forces create considerably larger forces compared to external forces, a more realistic understanding could be beneficial. However, this is difficult to achieve with a FBD and would require better tools such as FEA. One key simplification in this analysis is the pubic symphysis. In reality, the pubic symphysis is more complex and likely introduces additional constraints and stiffness to the pelvis. However, without the simplification the calculation could not been made.

Additionally, anatomical variability plays a significant role in force distribution. Difference in male and female pelvic anatomy can result in variations in moment arms and load distribution. Further research is required to fully account for these differences and ensure that the fixation system can meet the biomechanical requirements for different patients.

Lastly, posture and balance influence the biomechanical forces acting on the pelvis. In this study, the posture of a healthy individual was assumed. However, deviations in spinal alignment, such as the loss of lumbar lordosis, can alter the distribution of weight and the activity of muscles, pulling or pushing to maintain balance. These changes can affect force transmission and load distribution, particularly in the sagittal plane, and change the demands on the fixation system. Further studies should explore how these variations impact force transmission and fixation system requirements.

6. Design of the fixation system

6.1. Surgical approach

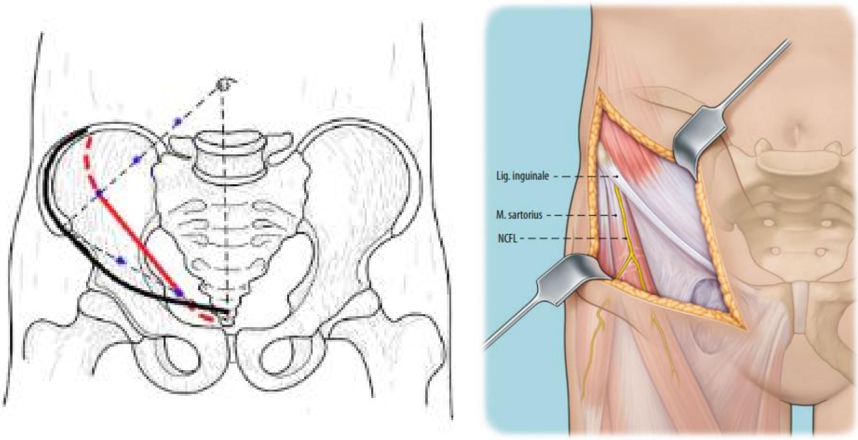

Figure 15: The anterior surgical approach, at the anterior/lateral side of the belly. The ASIS is used as landmark. [51] [52]

The surgical approach to perform the osteotomy defines the space for the fixation system. After consultation with two orthopedic surgeons and a 3dlab expert, an anterior approach was chosen over a posterior approach due to its reliability and familiarity in surgical procedures such as the Pemberton and Chiari osteotomies. This approach offers better access and is less invasive than posterior methods, which is critical for minimizing recovery time and complications. In Figure 15 the approach is illustrated. The patient will be in supine position, creating an incision along the medical iliac crest towards the pubic symphysis. Careful dissection through the periosteum at the AIIS will minimize ligament damage and clear the bone for the first cut. [51]

6.2. Fixation System design

6.2.1. Chosen design

Several fixation methods were evaluated, including plates, screws, and cages. [53] [54] Plates and screws commonly used in acetabular fractures were favoured due to their proven stability in load-bearing areas like the pelvis. [55] Standard techniques involve the use of long screws and pelvic plates and seems well-suited for the Y-osteotomy. Therefor, the combination of a lag-screw and patient-specific (PS) plate was chosen. This combination can be seen in Figure 16.

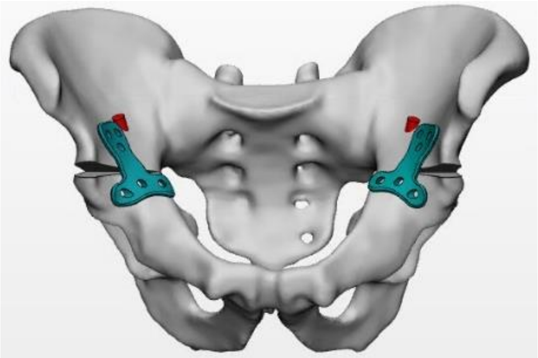

Figure 16: the chosen fixation system consisting of a patient specific plate at the open wedge, and a lag screw to apply compression on the closed wedge.

The lag screw ensure compression in the closed wedge of the osteotomy, while the PS plate provides stabilization in the open wedge. Hypothesized is that this combination provides the best balance of compression and stability, ensuring properly alignment of the bone fragments to improve healing, see section 1.3.1. Quang Huy le et al. showed that a posterior plate and screw versus an anterior plate and screw obtained the same result. [32] Therefore, with the anterior approach, an anterior plate design will be designed.

6.2.2. Final design specifications

Design parameter	**Chosen specification**	**Justification**	**[Ref.]**
Lag screw			
Thickness	Ø6.5 mm.	Commonly used in pelvic fracture fixation.	
Surface	Smooth + threaded	Only the part under the osteotomy site is threaded. (Cancellous bone screw)	
Plate			
Distance between screws	Minimum of 10 mm (centre-to-centre)	Literature and expert opinions.	[40]
Distance from screw to plate edge	Minimum of 6 mm (centre to edge)	Literature and dimensions measured on existing plates.	
Screw diameter	5.0 mm	Common for pelvic plates, balances strength and space.	[40, 56]
Screw type	Bi-cortical screws	Ensures fixation in the cortical layers, (cortical layer to cortical layer). Limits periosteum damage.	[40]
Plate thickness	3.0-3.5 mm	Balances stiffness and risk of stress shielding.	[36] [57] [58] [59] [40]
Screw placement	Triangular configuration in upper part, circular around acetabulum.	Triangular: enhances pullout strength and construct stability. Circular due to anatomical constraints.	[36]
Bridging span*	At least 25 mm	Literature suggests this to balance stiffness and non-union risk	[40]
Fixation type	LP, with angular fixation.	Ensure screws are held at fixed angles, providing stable fixation under load.	[36]
Plate material	Titanium	Complies with ISO 5832-3 standards for surgical implants. (mentioned in ISO 14602)	[60]

*The bridging span is the distance between the centers of the screws on either side of the osteotomy line.

6.2.3. Explanation of the design decisions

6.2.3.1. Plate design

The plate bridges the open wedge to maintain the correction angle. Three fixation systems evaluated: Locking Plate (LP), Dynamic Compression Plate (DCP), and Locking Compression Plate (LCP). [36] Given the high loads on the pelvis, a locking plate system using locking screws was selected for its superior mechanical stability and resistance to screw loosening. The locking plate ensures that the screws are fixed at specific angles allowing the plate and screws to function as a single unit. This offers a secure and stable fixation that is less likely to fail under high load conditions, which is needed for the pelvis. [36]

Design parameters of the plate:
The plate is designed to minimize stress concentrations while providing adequate stability (see discussion Chapter 5.5). Research showed that using more than three screws per fragment does not significantly increase stability. [36] [56] Therefore, three screws were chosen for both the upper and lower parts of the plate. In which the upper screws are arranged in a triangular configuration, with divergent and convergent directions to maximize pullout strenght, construct stability and reduce the risk of loosening. Due to anatomical constraints, the design around the acetabulum has a more circular pattern, optimizing screw placement, with similarly divergent and convergent directions. Bi-cortical screws (5.0 mm in diameter) are chosen for their strenght, with a minimum centre-to-centre of 10 mm to ensure strenght and minimize the risk of failure.

6.2.3.2. Placement

Plate placement
The plate is positioned on the anterior ilium, avoiding muscle attachment points. It is placed slightly toward the rotational point of the osteotomy to distribute load evenly. The screws are oriented with respect to the soft tissues, no screw intersection possibilities, in different directions, and maximizing working length for each screw.

Lag screw placement
A perpendicular direction of the screw on the closed wedge osteotomy site is preferred to achieve optimal compression. The goal is to maximize the contact area between screw and bone, which increases fixation strength. Furthermore, the placement must minimize muscle and tissue damage and be clinical feasible. Different options were investigated, and the placement of the lag screw was carefully considered in consultation with an orthopaedic surgeon with more than 15 years of experience. A location in the middle of the ilium just behind the plate was chosen for this concept, see Figure 17. [55] The lag screws run from the middle of the ilium towards the point of the Ischium, having a 120 mm length. Insertion is hypothesized to be surgical feasible considering the body space and using a 3d printed guiding tool.

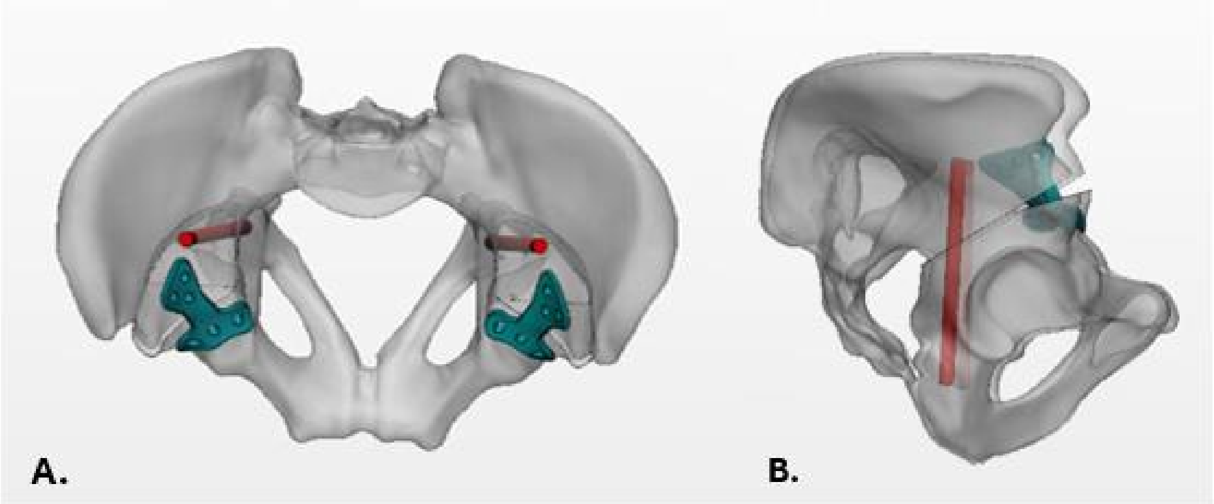

Figure 17: Transparent view of the pelvis showing the orientation of the lag screw. A) Top view of the pelvis. B) Side view, illustrating the path of the lag screw running from the center of the ilium towards the Ischium.

6.2.3.3. Surgical planning

K-wires, or Kirschner wires, which are thin, sharp pins commonly used for temporary fixation during orthopaedical procedures, will not be used in this design to minimize the number of holes in the plate. Instead, the existing screw holes can serve this purpose if wanted, with pre-drilling aiding in the process. Guiding, 3dprinted tools are designed for the clinical procedure in section 6.3 below.

6.2.4. Material and Manufacturing

Titanium is selected as the final material for the plate due to its excellent biocompatibility, strength, and suitability for 3D printing. [36] [61]

The design is initially created in Fusion 360 and refined in Materialise 3Matic 18.0 to ensure a precise fit with the patient’s anatomy. Unnecessary contours and angles should be reduced as these will compromise the mechanical properties of the material, leading to potential failure under load. [40] A basic symmetrical shape is created in Fusion 360, which is extruded to a solid, thick block. The aim of this basic shape is to establish a consistent design that can be easily adapted for multiple patients, streamlining the workflow for producing patient-specific plates.

6.2.4.1. Creation of the plate

For this thesis, a plate was created for a male pelvic saw bone [62], for the placement of the screws the male pelvis used in Chapter 4, was used as reference for identifying of the space in the bone. Segmentation in Materialise Mimics allowed visualization of the bone, focusing specifically on the cortical bone. This approach ensured that the space around and within the acetabulum was carefully considered when determining the plate's placement and its screws.

This saw bone was scanned using the RevoPoint Miraco 3D scanner to create a 3D model. The scan was then processed and exported to materialise 3-Matic 18.0, where the Y-osteotomy was performed. The final file was exported to Fusion 360, where the basic shape of the plate was designed and positioned correctly in the anatomical model. In Fusion 360, a STL file of the basic plate in block form, was created and exported back to Materialise 3-Matic. To ensure a proper fit without unnecessary curvature, the saw bone was smoothed, and the open wedge was filled and smoothed again. The block was then carefully positioned in 3Matic at the desired location.

A surface was generated from the contact area, with an offset of 0.5 mm towards the bone to prevent direct contact. An additional offset of 3.5 mm was used to create the plate's thickness, ensuring that all areas of the plate would be at least 3 mm thick. Screws were then placed according to the available space in the male pelvis model. Figure 18 illustrates a quick overview of the three main steps, Appendix C illustrates the dimensions.

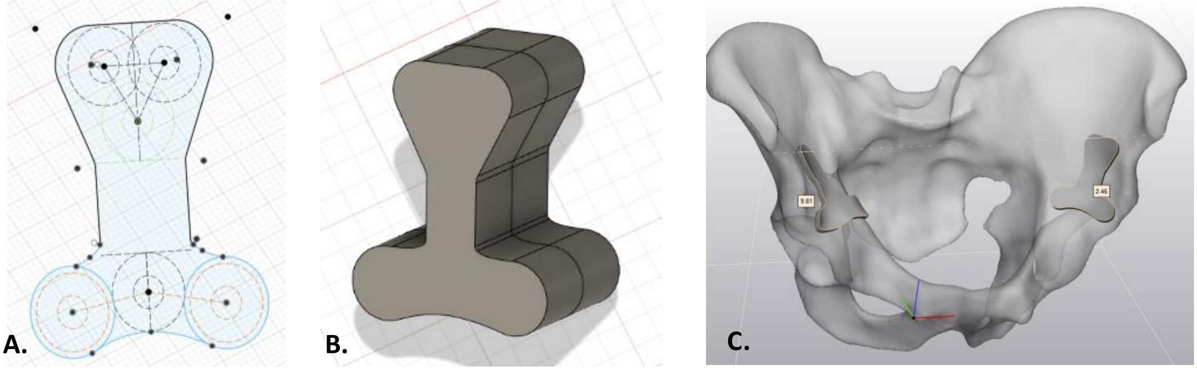

Figure 18: a) The sketch in Fusion 360 of the final design of the plate. B) the extrusion of the sketch to form a solid block. C) the creation of the plate in Materialise 3matic.

6.3. Guiding and drilling tools

To ensure a precise execution of the Y-osteotomy, accurate drilling of screw holes, and proper alignment of the fixation system, guiding tools were designed. This section outlines the key requirements for the tools and their design considerations.

6.3.1. Requirements for the guiding tools

The guiding tools were developed based on the following functional and safety requirements:

Part	Requirement
Saw guides	Guide one must facilitate sawing across the full bone width of the ilium.
	Guide two should enable sawing from the anterior to the posterior pelvis.
	The saw guides must accommodate a 1.2 mm oscillating saw blade, requiring a slot opening of 1.7 mm (including a 0.25 mm margin on each side) and a supporting block with a minimum thickness of 8 mm and a height of 15 mm.
Drill guides	Guidance tubes should be at least 15 ± 2 mm long for standard screws and 20 ± 2 mm for the lag screw.
	Drill guides must ensure unique placement on the ilium within one minute.
	Tubes should have an inner diameter of 5-6 mm to accommodate a 4.5 mm drill (including a 0.25 mm margin).
K-wire guides	At least two K-wires should be incorporated on each tool, with a preference for three.
	Holes must be 2.05 mm in diameter to accommodate a 1.8 mm K-wire, with a tolerance of 0.25 mm.
	The guide tube edges should be 2-4 mm thick, with a length of 15 ± 2 mm.
	K-wires must avoid intersecting with the osteotomy plane and saw paths.
	K-wires must avoid endangering the sciatic notch, ensuring an 8 mm margin from the end of the bone.
Rotation guide	Must facilitate caudal pelvis rotation around the cranial pelvis.
	Fixed securely to both cranial and caudal sides.
General design	Tools must be intuitive in use.
	Each guide should be placeable on the ilium within one minute.
	Thickness must range from 3 to 4.5 mm.
	Guides should not interfere with muscle attachments (gluteus maximus, gluteus medius, tensor fascia latae, sartorius, rectus femoris).
	Guides must be clearly labelled for side and orientation.
Safety	Smooth edges are essential to prevent tissue damage.
	K-wires must not intersect or penetrate the sciatic notch, acetabulum, or outer bone surfaces.

6.3.2. Design Considerations of the guiding tools

3D printed, patient-specific guiding tools were selected over external and existing surgical tools to maximize precision. While external tools require manual alignment through the layers of skin and tissue, 3D-printed tools are placed directly on the bone, providing more accurate control and guidance during the procedure.

Straight and well-aligned cuts are critical for the success of the Y-osteotomy, as they directly affect the fit and stability of the osteotomy. To ensure precision, a compelled saw guide was chosen. [63] This type of guide encloses the saw blade on two sides, ensuring a controlled path during cutting. By minimizing reliance on the surgeon's manual precision, the guide should significantly reduce the risk of error and should ensure better alignment and accuracy.

To further enhance precision and fit, separate guides were designed for the two osteotomy cuts. This to improve accuracy, minimize material usage, and allow for better placement on the ilium to achieve the desired sawing angles.

6.3.3. Overview of the guiding tools

Five distinct tools were developed, each designed to fulfill a specific function during the osteotomy and fixation process. Figure 19 below shows the placement and design of the saw guides.

1) **Saw guide 1 (Anterior lateral)** – positioned on the edge of the ilium at the AIIS, this guide directs the first cut. It needs to ensure the saw to follow a controlled, precise path, ensuring precise alignment.
2) **Saw guide 2 (Anterior medial)–** positioned on the inner pelvic ring with some extra material for support. This guide helps direct the second osteotomy cut, following the desired plane.
3) **Drilling guide plate** – Ensures pre-drilling of screw holes at the correct angles and positions for the fixation system.
4) **Lag screw drilling tool** – guides the lag screw placement to achieve the desired location (see section 6.2.3.2)
5) **Rotation guide** – facilitates rotation of the caudal pelvis around the cranial pelvis at the inner pelvic ring.

Each tool incorporates K-wires guides for proper fixation during surgery. Several dimensions, including those of the k-wires guides and saw guides, are illustrated in Appendix C.

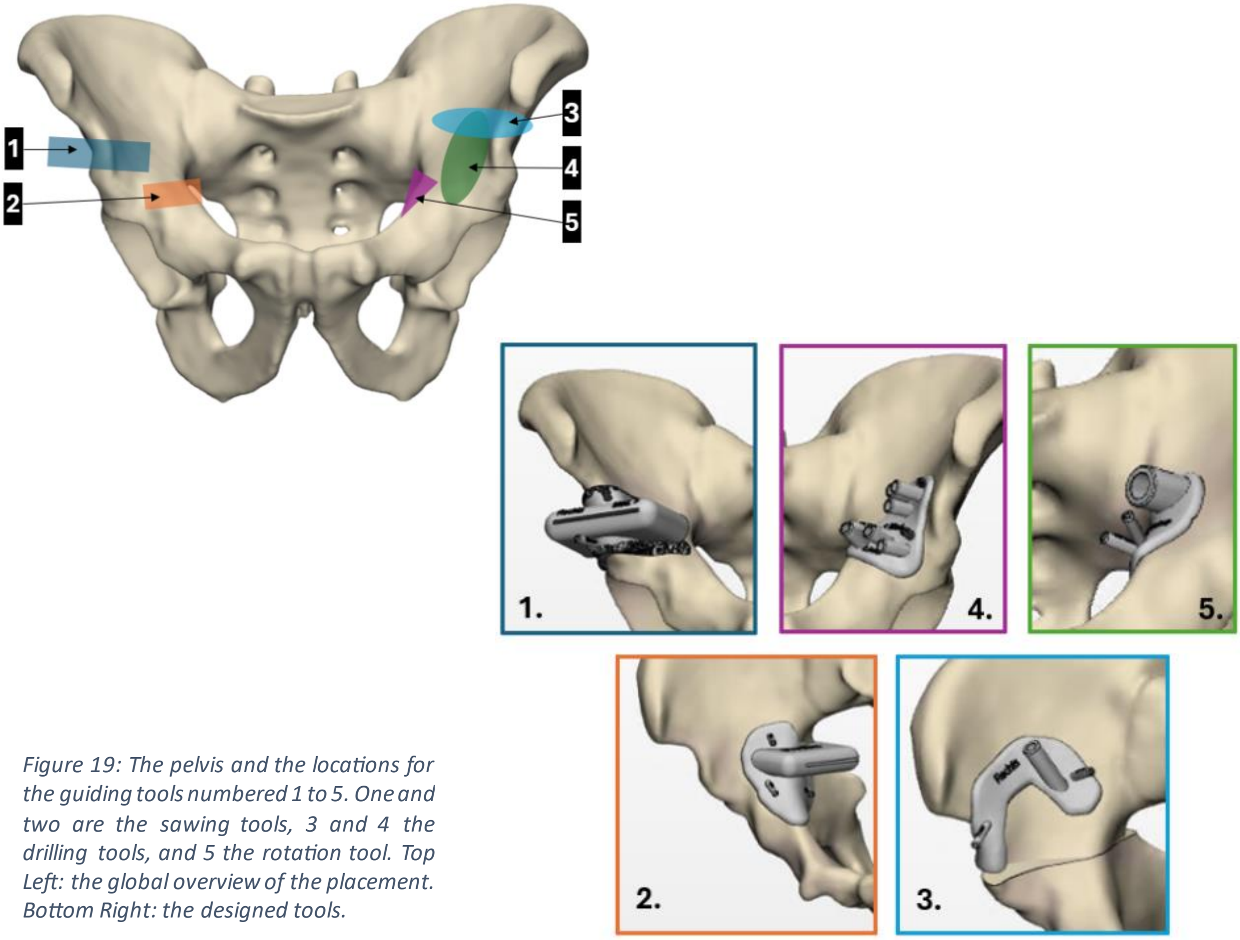

Figure 19: The pelvis and the locations for the guiding tools numbered 1 to 5. One and two are the sawing tools, 3 and 4 the drilling tools, and 5 the rotation tool. Top Left: the global overview of the placement. Bottom Right: the designed tools.

6.4. Discussion

6.4.1. Fixation system

The primary goal of this section was to develop a patient-specific fixation system that would enhance the stability and accuracy of the Y-osteotomy. The result is a patient-specific anterior plate with a thick lag-screw. While this design has clear advantages in terms of anatomical fit, several areas require further research and testing.

The design specifications have been explored to form a first concept. However, each design specifications or characteristics is a separate factor influencing the behavior of the fixation system. The influence of some of the specifications requires some extra research:

There is extensive research on both customized and standard plates. However, customized plates for the pelvis are less studied. Furthermore, the principles and potential improvements of standard plates have not been fully applied or studied in terms of their functionality and strenght in pelvic osteotomy procedures.

The plate-screw angles are not specified, as hypothesized was that a different direction of screws would be beneficial and was not depended on a specific angle. However, more research could be conducted towards this aspect.

The thickness and length are based on commonly used sizes. While literature proves the effectiveness of these sizes, it has not been mechanically tested for this application and the customized form. These dimensions should be validated to ensure they meet the specific requirements of the osteotomy.

In literature, the bone-plate distance is identified as an important variable affecting effectiveness, force distribution, strength, and stability. Currently, this factor has only been visually assessed and approximated using Materialise 3-Matic. Future research should investigate the impact of this variable in greater detail.

Additionally, stress shielding was not evaluated in this thesis. Stress shielding can result in bone resorption by taking over the bone’s function. The risk of stress shielding, as well as the acceptable level of risk and its performance applications, should be further investigated.

In Chapter 7, the plate will be tested against the approximated forces calculated in chapter 5. This testing may lead to design changes, particularly in areas like plate thickness or screw configuration, to optimized load distribution. However, further testing of the fixation system, such as stability, durability, and compliance with ISO standards, will be necessary to fully validate its performance.

6.4.2. Guiding tools

Five guiding tools were designed to ensure accurate cutting and drilling during the Y-osteotomy. These represent the first versions of the tools, and further testing is necessary to evaluate their performance in a surgical setting. This testing will be conducted in Chapter 8.

7. Validation of the mechanical safety

The mechanical behavior of the fixation system developed for the Y-osteotomy was evaluated using a simplified Finite Element Analysis (FEA). While the posterior bone contact and lag screw are assumed to handle most of the mechanical load, the patient-specific plate provides essential support in maintaining the alignment, distributing residual forces, and ensuring the overall integrity of the osteotomy site during the healing process. This analysis focuses solely on the performance of the PS-plate, assuming it bears the entire load to overestimate the stresses for a safer margin. FEA was chosen for its ability to model complex geometries and loading conditions, providing insight into the plate's structural performance. The aim of this test is to assess whether the PS-plate can withstand the biomechanical forces.

7.1. Methods

Patient-Specific Plate Design

The fixation plate was digitally modelled in Materialise 3matic 18.0, with a smooth surface and without screw threads to simplify the analysis. The material was set as threated and aged Ti6A14V in SolidWorks, chosen for its high yield strength, which is crucial for ensuring absolute fixation. The yield strength of the material is specified as 8,274 e^+08 MPa.

Mesh Generation

The quality of the mesh is essential for the accuracy of FEA. The surface mesh is built of triangular surface elements and a volume mesh with tetrahedral (Tet4) elements. The elements were optimized to resemble equilateral shapes, ensuring better accuracy. Tet4 elements are chosen since these are used for linear analyses, not expecting to have large deformations. A uniform mesh with an edge length of 1.000 mm was applied, and a volume mesh with a maximum edge length of 2.000 mm. Further refinement was done to ensure that the mesh quality met the necessary standards.

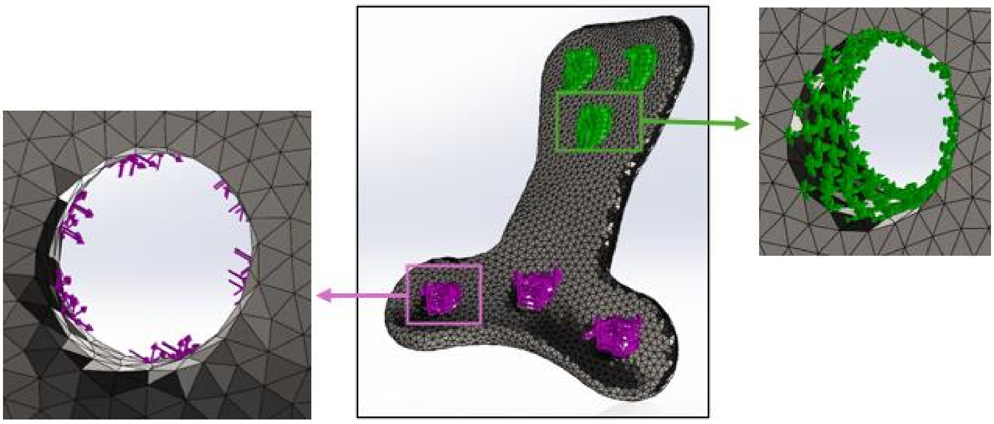

Figure 20: The loads applied to the plate in SolidWorks. The green indicates the rigid fixation at the cranial screw locations. The purple represents the applied load at 6 points in the caudal screw holes.

Coordinate System and Load Application

The coordinate system was aligned with the coordinate system of the free body diagrams (FBD's). The necessary transformations were applied to match SolidWorks conventions. The forces derived from the FBD (section 5.4.4) were evenly distributed across the three caudal screw holes. These loads were applied at six points within each hole, with each point receiving an equal portion of the total force on that hole, as shown in purple in Figure 20. The forces were applied in a fixed orientation to maintain consistent loading conditions. The cranial holes were rigidly fixated, as shown in green in Figure 20.

The load was applied in two cases:

1) **The highest loads of the extreme cases of the FBDs:** This was divided by three and rotated around the z-axis with 90° to match the SolidWorks coordinate system. This gave the following forces:

$$\begin{bmatrix} F_{ox} \\ F_{oy} \\ F_{oz} \end{bmatrix} = \begin{bmatrix} -17\ N \\ 133\ N \\ 278\ N \end{bmatrix}$$

2) **The highest loads combined with the highest moment derived from the FBD (18 Nm):** The moment was also divided by three and then applied on the same locations in the screws holes as the forces.

Von Mises stresses

The von Mises stress is used as parameter to assess the material's response to the applied forces. It measures the combined effect of stresses (both normal and shear) in three perpendicular directions. This measurement helps determine whether the stresses remain below the material's yield strenght (the maximum stress that can be applied before permanent deformation occurs). This provides insight into potential failure points.

7.2. Results

7.2.1. Initial Analysis – case 1

The FEA primarily highlighted the von mises stresses experienced in the PS plate. The initial results indicated that the highest stresses occurred on the bridge of the fixation plate, exceeding the material's yield strength, see Figure 21. The stress concentrations suggest that design changes may be necessary to enhance the plate's load distribution.

Deformation was observed in the lower part of the PS plate. However, since this area moves relative to the fixed notes, it does not provide sufficient insight into the material's overall performance.

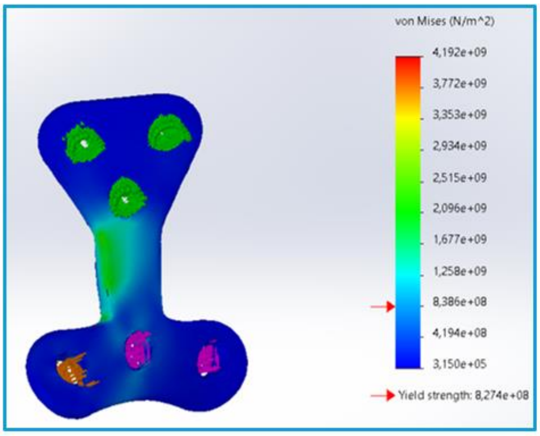

Figure 21: Initial analysis of the PS plate with a 10 mm bridge width. The von mises stress distribution is shown with a color scale, where the red arrow represents the material's yield strenght.

7.2.2. Subsequent design adjustments

To reduce the risk of failure at the point of highest stress, the bridge width of the fixation plate was increased from 10 mm to 15 mm. This adjustment was made based on the rationale that the plate is positioned deeper within the patient's body, therefore less superficial. This minimises irritation and would allow additional material to be added to increase strength without significantly increasing discomfort.

Figure 22 shows the von Mises stresses experienced by the plate. The absence of a red arrow in the colour bar indicates that the von Mises stresses do not exceed the material’s yield strength. The left figure represents case 1, and the right figure represent case 2.

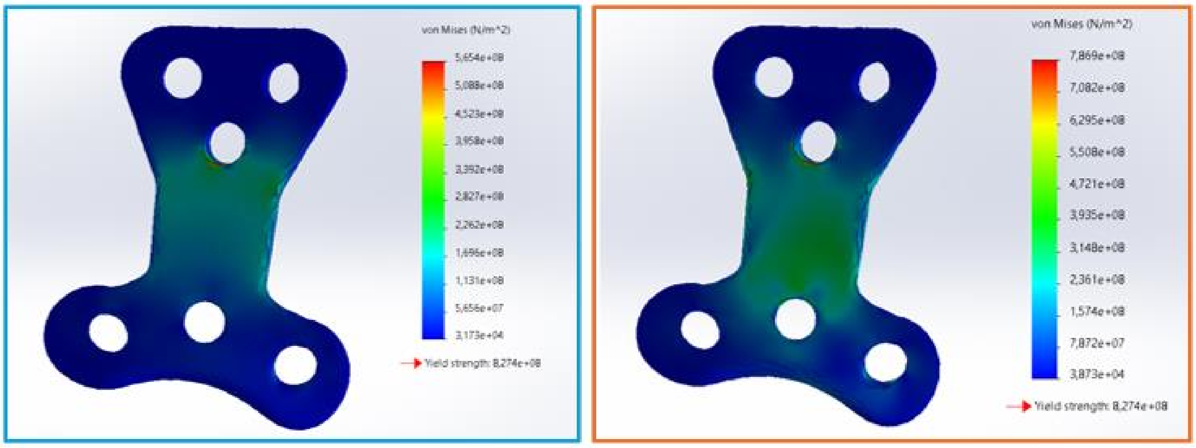

Figure 22: In both cases, the colored bar shows the highest forces present. Left (blue) – Simulation of case 1, with no forces exceeding the yield strength. Right (orange) – Simulation of case 2, similarly below the yield strength.

7.3. Discussion

The simplified FEA provides valuable insights into the stress distribution and potential failure points of the PS plate. By assuming the PS plate to bear all the load, this analysis offers an approach that likely overestimates the stresses on the PS plate. While this assumption simplifies the biomechanical environment, it serves as a robust validation method by identifying critical stress points and ensuring that the PS plate can withstand even the most demanding conditions.

However, it is essential to recognize the limitations of this approach, and the assumptions made. The assumption that the plate carries all the load does not fully reflect the actual biomechanical environment. Incorporating bone, and screw interactions and the load distribution between lag screw and the PS plate would provide more accurate representation of the system’s mechanical behaviour. Additionally, the current model does not account for non-linear material properties, which could further impact the plate’s performance under more realistic conditions.

Another limitation is the direction of the applied forces in SolidWorks. Although this was carefully considered, the direction may be incorrect or misaligned with actual loading conditions due to the use of a fixed force direction. If inaccurate, this can lead to unrealistic loading scenarios and misleading stress predictions.

Future work could focus on creating more detailed models, including bone and screw interactions, and non-linear material properties, to improve the accuracy of the predictions. Furthermore, in vitro testing will be necessary to validate these findings and guide further refinements in the plate design.

8. Saw bone test

The aim of this chapter is to evaluate the practical feasibility of the Y-osteotomy procedure, the developed fixation system, and the associated guiding tools through a saw bone test. It focuses on the clinical feasibility and usability, providing insights into effectiveness and potential areas of improvement of the designed system and procedure. Key aspects of the evaluation include the accuracy of alignment, the fit of the fixation system, and whether the planned surgical approach can be executed as intended.

8.1. Methods

8.1.1. Materials

To perform the test, the following materials were used:

- **One saw bone pelvis (**Sawbones, USA, product: pelvis, full male, foam cortical) [62]
- **One oscillating saw** (Skil)
- **One sawblade** of 1.2 mm by 20 mm by 88 mm.
- **10 Kirscher boring wires** with a diameter of 1.8 mm and length of 310 mm. (Braun)
- **One drill**, with drill set up of 4.5 mm.
- **Two glue clamps**
- **A ruler**
- **A marker**
- **The custom-designed guiding tools** (see chapter 6)
- **3d printed patient-specific plates** for left and right.
- **2 lag screws**, universal screws. Diameter: 6.0 mm, length: 120 mm. (Hornbach, Enschede, 2024)
- **12 shorter universal screws** with a diameter of 5.0 mm. 6 screws with a length of 35 mm for the cranial part. 2 screws with a length of 40 mm and 4 screws with a length of 45 mm for the caudal part. (Hornbach, Enschede,2024)

8.1.2. Prototyping

Additive manufacturing was used to prototype the patient-specific plate and guides. The guides and plate were modelled in Materialise 3-matic 16.0 (Materialise, Leuven) and exported as STL files. In-house printing was conducted using Fuse 1+ 30 W SLS printer (Formlabs, Sommerville, United States) in nylon, ensuring precise and reliable prototypes. The plate was designed with predefined holes to achieve the desired angles for the angular fixation.

8.1.3. Scenario and set-up:

The test set up simulated a surgical scenario using an anterior approach, with the saw bone pelvis positioned supine. The set-up can be seen in Figure 23. The goal was to replicate surgical conditions as closely as possible. The synthetic bone was pressed on a foam with tie wraps enabling a rigid connection. An extra piece of foam was placed under the sacrum to obtain a more realistic position of the pelvis. Extra foam could be added by the surgeon if needed.

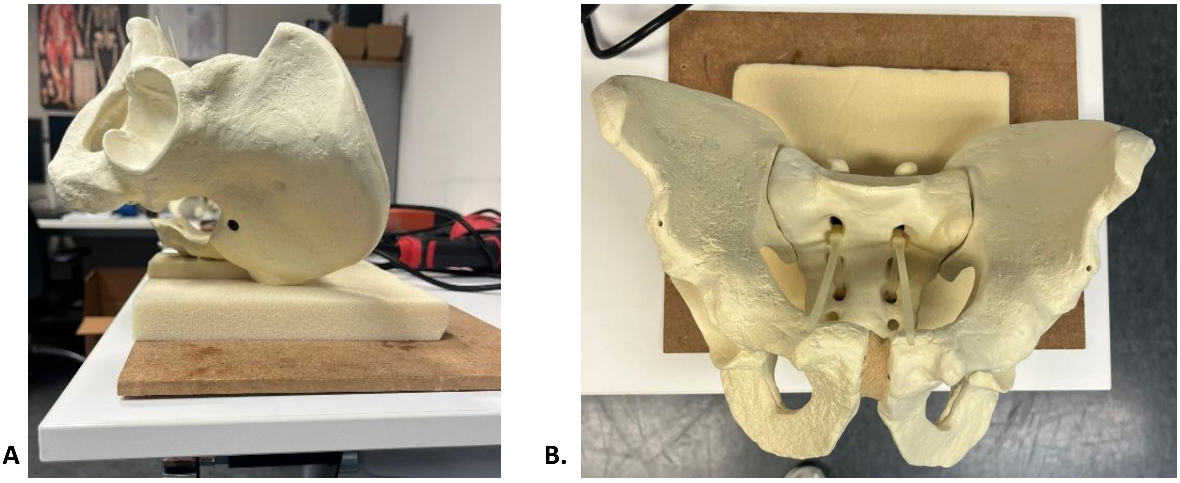

Figure 23: A. Sideview of the set-up of the saw bone. B. Frontal view of the set-up of the saw bone.

8.1.4. Execution of the test

An orthopaedic surgeon with more than ten years of experience preformed the Y-osteotomy and fixation using the tools

The test originally included the following steps:

1) The saw bone pelvis was fixated on the table and tested for stability.
2) The drilling guides for the plate were positioned and secured with k-wires before drilling holes.
3) The saw guides for cut one were positioned left and right, secured by k-wires. With the oscillating saw the first cuts were made.
4) Leaving one of the first saw guides fixed on the right, the second guide was placed on the left to make the second cut. After re-fixation of the left one and removal of the right one, the second cut on the right was made.
5) The wedges of bone were removed, and the rotation guides were placed. Then the fixation of the saw cuts was removed, so that the caudal pelvis could rotated around the cranial pelvis.
6) Using the pre-drilled holes, the fixation plates were positioned and screwed into position.
7) The guiding parts for the lag screws were positioned and fixated. After this, the lag screws were inserted in the desired directions.
8) Lastly, the bone wedges are pressed into the opened wedge spaces.

The k-wires used and placed during the complete execution were first measured and marked with the intended length. This length could be found on the side of the k-wire guides.

8.1.5. Test evaluation

The evaluation included:

- **Observations and semi-structured interviews:** The surgeon's feedback was gathered through direct observation and semi-structured interviews.
- **USE Questionnaire:** A USE questionnaire, using a 7-point Likert scale, was used to assess the overall usability of the fixation system, guiding tools, and procedure. This questionnaire focused on the ease of use, efficiency, and satisfaction. It was chosen because of its high rating and common use in usability testing. Furthermore, it has a simple structure that can be applied for systems containing multiple components. [64] [65] The questionnaire can be found in Appendix D.

- **3D scan analysis**: post-procedure, a 3D scan using a Revopoint Miraco 3d scanner was conducted. The scan was analysed in Materialise 3-Matic to check the accuracy of alignment, bone contact, and achieved correction angle.

Planned bone contact and PI value

The planned bone contact and PI value are measured in the saw bone in 3Matic before the test. This allows to compare the bone contact pre- and post-procedure. The bone contact is measured after rotation, comparing the surface of the osteotomy surface with the bone contact surface giving the following formula:

$$\text{Bone contact } (\%) = \frac{bone\ contact\ surface\ of\ ilium\ parts\ (mm^2)}{bone\ surface\ at\ osteotomy\ surface\ (mm^2)} * 100\%$$

The planned bone contact is 61%.

The approximated PI value before the osteotomy is 61° measured on the left side using a geometric triangle. After planning the osteotomy with a 15° angle, the approximated PI value was 51°.

8.2. Results

The 3D scans of the saw bone before and after the Y-osteotomy and fixation are visualized in Figure 24, where the PI angle is also displayed. The achieved angles were 16.63° on the right hemipelvis and 19.50° on the left hemipelvis, resulting in deviations of 1.63° and 4.5° from the original plan of 15°. The achieved bone contact was approximately 62%, compared to the planned 61%. The measured post-procedure PI value on the left side was approximately 41°.

Procedural adjustments

During the execution of the procedure, several adjustments were made. Not all k-wires were used as initially planned. Due to the limited length of the saw blade, the first cuts were completed by hand. The second cut on the right was guided using the guiding tool but, again, completed by hand, while the left second saw cut was done entirely freehanded.

Additional k-wires were used to stabilize the drilling guide for the plate. As the procedure sequence was adjusted mid-operation, k-wires were also used to secure the caudal and cranial part before sawing the second cut. The rotation guides were not used. The tool intended to protect the sciatic nerve was not utilized; typically, a Hohman retractor would be employed for this purpose, so this aspect of the procedure remains untested. Lastly, not all screws were placed in the PS-plates.

Fixation system performance

The lag screw was correctly placed in the right side but penetrated the acetabulum on the left. The design of the fixation system provides enough stability and fits the bone properly. The PS plate allows for precise control and the location was good. The PS plate maintained sufficient space around the acetabulum which was deemed safe in this context. The screws were placed according to the pre-drilled holes. Lastly, the bone wedges were not cut and further evaluated.

Tool and guiding system accuracy

The pre-drilling guide did not fit well, resulting in a loose fit to the bone reducing accuracy. Additionally, the saw guides for cut one were too bulky, limiting a complete saw cut. Further, the angle of the second saw guide was too medial, complicating the sawing process.

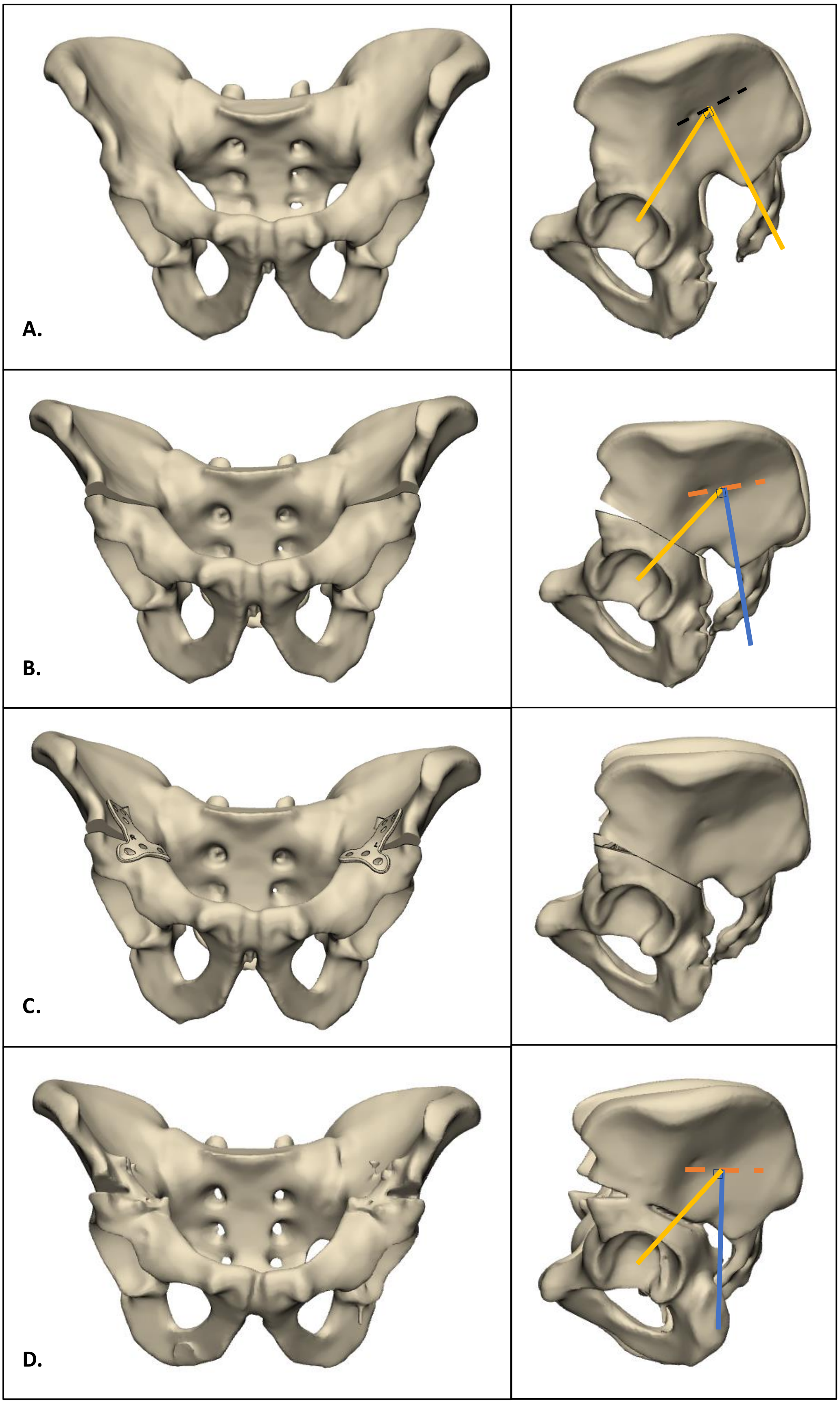

Figure 24: A. The initial saw bone with the PI angle. B. Saw bone model showing the planned Y-osteotomy, with the PI angle rotated according to the planned surgical correction. C. Saw bone model with the planned Y-osteotomy and PS plate attached for fixation (see section 6.2 for details). D. Post-procedure saw bone model displaying the rotated PI angle after the Y-osteotomy and fixation.

Anatomical feasibility

The first cut location was chosen appropriately, minimizing damage to the rectus femoris. The ASIS was preserved, protecting this attachment point.

The USE questionnaire

The overall procedure scored 4.67, the fixation system 3.88, and the guiding tools 2.5. One question in the first component was inversely structured to reduce bias, and its score was adjusted accordingly. Three questions were omitted: two due to a lack of a specific instruction list following a not fitting question, and one question could only be hypothesized.

8.3. Discussion

Correction angles and bone contact

The deviation of the correction angles can be explained by the inaccurate sawing, particularly the second cut. The short blades required freehand completion of the saw cuts significantly affecting the precision. As the second cut on the left side was completely freehanded this resulted in a larger deviation. For further applications, the use of longer sawblades can avoid this. Additionally, the saw guides were too bulky, limiting their effectiveness. Adjusting the angle of the second saw guide to a more perpendicular view would improve reach and accuracy.

The post-operative bone contact was slightly larger than planned (62% versus 61%). However, both are larger than the planned 25% thereby meeting requirement 2 of the requirement list of the new osteotomy concept (Section 3.1.1). As a result of the inaccurate sawing, more malalignment was observed in the left hemipelvis which could impact stability and clinical feasibility. Further investigation is needed to determine if this has negative effect on the outcome.

PI value comparison

The post-procedure PI reduction on the left hemipelvis was approximately 19°. This matches the 19.5° osteotomy angle post-procedure on the left side. This reduction was more than the planned 10°, likely due to the inaccuracies of the second cut. Ochtman's study, which involved 10 cadavers, found a mean PI reduction of 10.4° for a 15°, see Section 1.2.2. This aligns more closely with the planned reduction. However, given that our results are based on a single saw bone, they are not directly comparable to the larger sample size used by Ochtman. Further testing with a larger sample size is required to validate these findings.

The fixation system

The fixation system received positive feedback overall. It allows for precise control, and the surgeon would like to keep the PS plate in. However, variability in practice is inevitable. To accommodate for this, the surgeon suggested to avoid pre-drilling all screw holes for the plate. However, pre-drilling seems essential for LP plates due to the predefined screw angles for optimal anatomical placement. An option could be to create an initial hole for correct positioning and drill the remaining holes after the procedure.

On the left side, the lag screw penetrated the acetabulum due to the angle deviation disrupting the planned pathway. On the right side, the lag screw was correctly placed, indicating that the pathway can handle minor angle deviations. While the lag screw's use was satisfactory, the surgeon proposed an alternative placement below the plate in the caudal pelvis. This alternative, however, results in the screw pointing towards the SI joint. As not all screws were inserted in the PS plate, the solution worked in the current setup but may not be effective if all screws are placed. The alternative placement should be tested with all the screws inserted, either virtually (3Matic) or through a saw bone test.

The guiding tools

The guiding tools scored low on their feasibility. The saw guides, while fitting the bone properly and providing specific and accurate positioning, were found too bulky, which limited their clinical practicality. The drilling tool was rated the lowest. It was not sufficient location-specific and lacked stability on the bone in three planes. This guide needs redesigning to improve accuracy and anatomical fixation. The second drilling tool for the lag screw performed better but still requires a redesign. The rotation guide was not used during the evaluation and therefore could not be assessed. It was not used because manual rotation by hand was more practical. However, in a clinical setting where the pelvis is surrounded by muscles and soft tissues, a guide might be needed. Therefor it needs a redesign and should be reviewed for its intended function and added value. Finally, all guiding tools had an excess of k-wires, which complicated the procedure. Future designs should aim to minimize the use of k-wires.

Clinical feasibility

The surgeon hypothesized that muscle damage during the procedure would be minimal and was satisfied with the chosen locations. However, the bulkiness of the sawing guides could potentially damage the tissue and might need a larger incision. Although the protection of the sciatic nerve was considered throughout the process, it was not specifically tested. Therefore, no definitive statement can be made regarding the safety of the sciatic nerve. The surgeon suggested that using the Hohman tool could offer protection for the sciatic nerve. However, future practical testing is needed before any conclusions can be drawn.

Further limitations

The test was conducted with only one surgeon, reflecting just one perspective. Since surgical techniques and views vary, including more surgeons in future analyses could yield different results. The PI value was approximated and derived from an image-based line. More precise visual tools are needed to accurately assess the osteotomy outcomes.

General discussion

This study aimed to develop and evaluate a new osteotomy concept with a corresponding fixation system to improve the osteotomy in the pelvis to correct sagittal balance. The results of this study show positive outcomes towards the new osteotomy concept, the Y-osteotomy, and the belonging fixation system consisting of a patient specific plate and a thick lag screw. The Y-osteotomy demonstrated a significantly amount of posterior bone contact (62%) that could enhance stability and achieved the desired decrease of PI to achieve the desired sagittal balance correction. The fixation system showed that the PS plate can handle the approximated forces on the osteotomy side, and that the lag screw can provide adequate compression. Initial clinical feasibility, based on the saw bone test, suggest that the procedure and fixation system are viable, although further validation in real-world scenarios is needed. However, despite the positive outcomes, there remain some uncertainties particularly regarding the stability.

The stability of osteotomy and fixation system is a key concern of this study. Hypothesized is that posterior bone contact significantly increases the stability. This is based on existing research indicating that most of the forces are transmitted posteriorly. While the fixation system was tested on and designed for the approximated forces applied on the osteotomy side, the overall stability was not tested. As the PS plate on itself showed to be able to hold the forces, this could say that the bone contact, and fixation system, can hold the forces and provide enough stability. However, more testing is needed to fully validate the hypothesis.

Another aspect concerning the stability, is the hypothesis that the piece of bone to transfer (the bone wedge) can be used in the open wedge. However, the bone can undergo necrosis, be rejected by the body, or fails to fit even after reshaping. As autograft bone is used, the changes are lower for this to happen. [39] Additionally, the cortical bone is the strongest element of the bone but only covers the outer layer. If trimmed, cancellous bone will remain which may not provide sufficient resistance to compressive forces. This could lead to increased stress on the PS plate, a slower healing process, and mostly, a higher risk of instability or improper healing. While the plate has been tested on these forces and is expected to hold the forces even with a suboptimal bone wedge, it may still be beneficial to explore alternative solutions for managing the open wedge, such as the use of bone graft substitutes.

The forces applied on the PS plate were simplified for the purpose of this study, as discussed in Section 5.5. They provide a foundational understanding of the biomechanical demands placed on the fixation system accurate enough for this phase in the development process.

The positioning of the osteotomy cuts and the fixation system appears to be well chosen based on literature, theoretical models, experts' opinion and the saw bone test. Nevertheless, these decisions have only been tested on saw bone models, which do not include soft tissue and muscles. Further testing, particularly in the presence of these anatomical structures, is necessary to assess the risk of damage of surrounding tissues and to verify to overall feasibility of the procedure. One important element is the sciatic nerve, which was hypothesized to remain unaffected. However, this must be confirmed in practice. Additionally, the current procedure remains somewhat complex particularly due to the guiding tools, which require improvements. A posterior approach might be worth considering for the sawing cuts and for the placement of the lag screw.

Most patients with a loss of lumbar lordosis are elderly, a population that commonly suffers from osteoporosis. [66] Osteoporotic bone increases the risk of screw loosening. While the current system used angle stable screws to mitigate this risk, specialized tools such as anchoring screws, might be required. [67]

Since every patient has different anatomical dimensions and proportions, the current findings are based on a limited number of models and a single saw bone test. While the results provide valuable insights, they cannot guarantee that the osteotomy concept and fixation system will be effective for all patients. Further studies should involve a broader range of anatomical variations to verify the generalizability of the approach. This could lead to a potential finetuning of the design.

Although the Y-osteotomy aims to restore sagittal balance, it remains challenging to establish its effectiveness. The Pelvic Incidence (PI) serves as a crucial parameter and is showed to be reduced by the osteotomy. However, only the pelvis was observed in this study while the spine plays a crucial role in the overall posture. One important factor in the sagittal alignment is the sagittal vertical axis (SVA), which should be included in further simulations to assess the effect of the osteotomy. [7]

To better understand the osteotomy's effect on overall balance, future research should explore the interaction between the pelvis and the spine. Additionally, it is important to investigate how patient's posture, that compensated the imbalances, may affect the correction. The muscles may change as a result of the correction. Their role should also be considered and investigated in future studies.

General conclusion

Assessing the requirements

In this study the key requirements for the new osteotomy concept and the fixation system were established in Chapter 3. Both tables are placed below, summarizing if a requirement is met, not met, or not assessed/not answered (N/A).

The Y-osteotomy

#	Demands	Achieved yes/no?
Technical feasibility		
1.	The correction must be at least 15 degrees. [7]	Yes
2.	The bone contact must be at least 25% of the area. [8]	Yes
Anatomical feasibility		
3.	The sciatic nerve must not be compressed.	N/A
4.	A surgical approach must be feasible.	Yes
5.	The acetabulum must be preserved with a minimal margin of 15 mm from the cuts.	Yes
Wishes		
6.	Position the second saw cut on the inner pelvic ring.	Yes
7.	Minimize muscle damage.	Yes
8.	The transferred bone should fit the open wedge with minimal protrusion.	N/A
9.	Ensure precise anatomical alignment post-osteotomy, minimizing malalignment between the pelvic segments.	No

The fixation system

The table below shows a shortened version of the requirement list for the fixation system.

#	**Requirements description**	**Achieved Yes/no?**
1. Mechanical constraints and performance		
1.1.	The fixation system must not interfere with the point of rotation.	Yes
1.2.	The closed wedge should be fixed by compression.	Yes
2. Mechanical stability and performance		
2.1.	The fixation system must ensure fixation of the anterior and posterior side of the hemipelves.	Yes
2.2.	The fixation system must withstand the global forces and loads at the osteotomy site in a static position.	Yes
3. Anatomical and physiological requirements		
3.1.	Placement of the components must not interfere with the SI joint.	Yes
3.2.	Insertion points of the fixation system must not interfere with the osteotomy site.	Yes
3.3.	The acetabulum must be protected.	Yes
3.3.1.	No components must penetrate the acetabulum.	Yes
3.3.2.	Maintain a minimum distance of 5 mm from the acetabulum edge.	Yes
3.4.	The fixation system must assure an opening of 15 degrees in the open wedge.	Yes
3.5.	The sciatic nerve must be protected during and after fixation.	N/A

3.6.	Avoid gaps to reduce malunion/nonunion risks.	N/A
4. Clinical feasibility and safety		
4.1.	The fixation system must have accessible screw holes.	N/A
4.2.	The fixation system must fit post-procedure alignment with high accuracy.	Yes + N/A
4.3.	Materials must be CE-approved.	Yes
5. Design and user specifications		
5.1.	Must be patient specific.	Yes
5.1.1.	The design must allow application across different patients.	Yes
5.2.	Components that must be pre-formed to match the anatomy, should be formed within three adjustments.	Yes
5.3.	Components must ensure intuitive use and placement.	Yes/No
5.4.	All the elements must have no sharp edges.	Yes
6. Wishes		
6.1.	Minimize the sacrifice of ligaments and muscles.	Yes
6.2.	Components should be as small as possible.	Yes
6.3.	Limit soft tissue damage as much as possible.	Yes
6.4.	Elements should be visible on X-ray during surgery.	Yes
6.5.	The fixation system's location and orientation must be visible on CT scans.	Yes
6.6.	Ideally, the fixation system should be suitable for osteoporotic bones.	N/A

Overall conclusion

This study successfully introduced and evaluated a new and promising osteotomy concept, the Y-osteotomy. It offers a promising alternative to the existing BEPO concept. The BEPO technique had a high risk of unpredictable posterior fractures resulting in instability. The Y-osteotomy minimizes these risks by providing more stability due to the large posterior bone contact. The correction angle of the Y-osteotomy proves to be at least the same or even better.

The fixation system developed for the Y-osteotomy consists of patient-specific (PS) plate and a lag screw. The PS plate was evaluated for its ability to withstand the estimated forces acting on the osteotomy site. The results were positive, indicating initial stability. The posterior bone contact and the lag screw further enhance stability by reducing the load on the plate. However, overall stability has not yet been tested, and additional biomechanical testing is required to validate the complete structural stability.

The saw bone test used to evaluate the Y-osteotomy concept and corresponding fixation system, showed a promising feasibility for both. Further validation in clinical scenario including soft tissues and muscles interaction is necessary. The procedure is currently unhandy and should be improved by improving the guiding tools.

All with all, the Y-osteotomy provides a viable and potentially more stable solution for correcting sagittal balance than the BEPO concept. With the corresponding fixation system, the osteotomy can be fixated. Further clinical and biomechanical testing is needed.

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Appendices

Appendix A: Transformations and rotation of the Joint Reaction Forces of Bergmann

In this appendix the Joint reaction forces calculated by Bergmann will be transferred to the pelvic coordinate system. As the forces of Bergmann are presented in the femur coordinate system, but the analysis will be performed in the pelvic coordinate system (PCS) this is necessary. The chosen PCS has in the frontal view: z positive up, the x positive to the right and y positive backward. In the sagittal view: z positive up, x positive to the front, and y positive to the right.

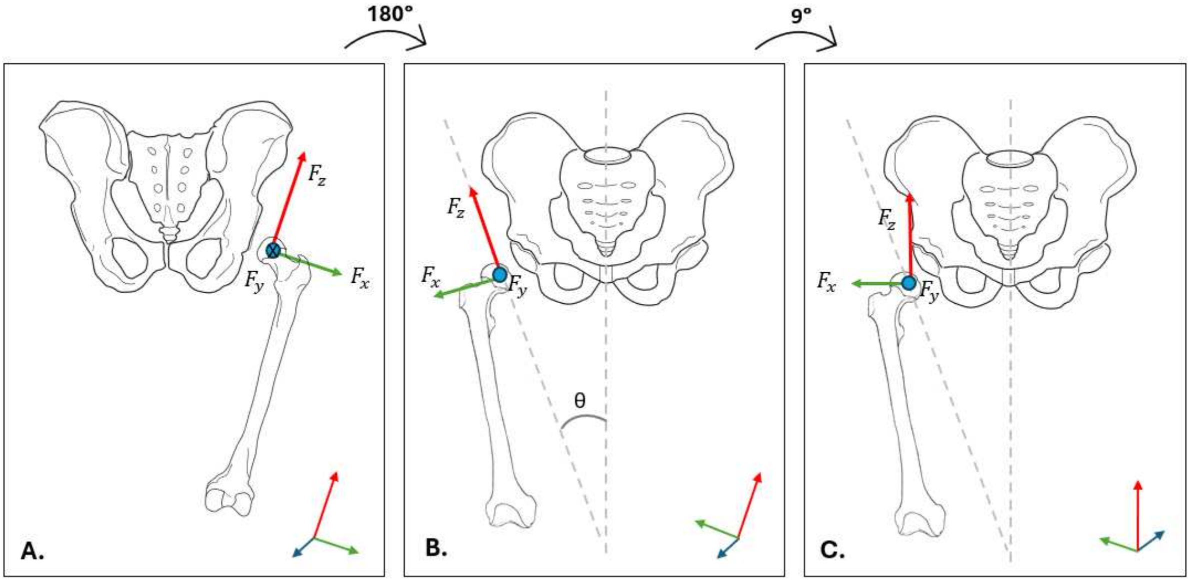

Figure 25: The transformation of JRFs from the femur coordinate system to the pelvic coordinate system. A. the initial orientation of the JRFs. B. The 180 ° rotation. C. Rotation of 9 ° to the vertical axis.

Coordinate system and transformation/rotation of the forces

The transformation of the femur coordinate system to the pelvic coordinate system requires two steps, illustrated in Figure 13:

1) **180° rotation around the z-axis**. – This step aligns the femur coordinate system with the pelvis by flipping the orientation from front-to-back. This rotation changes the lateral and posterior axes, while the vertical axis remains unchanged.
2) **9° rotation around the y-axis** – after the first rotation, the femur axis is not aligned with the pelvic axis. An 9° angle is found between the femur and pelvic (vertical) axes, which accounts for the anatomical difference between the systems, θ = 9°. This rotation aims to bring the two in alignment.

Lastly, as the third step, Newton's third law (Action = -Reaction) is applied because the JRFs provided by Bergmann are measured on the femur.

Transformation for the two-legged stance JRF Bergmann forces:

Forces from the figure 4 of Bergmann determined by HIGH100 the lines of the stance activity (red line, stance = one leg stance) give approximately the following forces for a two-legged stance:

$$\begin{vmatrix} F_x \\ F_y \\ F_z \end{vmatrix} = \begin{vmatrix} 347 \\ -50 \\ 1000 \end{vmatrix} N.$$

1) Around the z-axis gives the matrix:

$$R_z(\theta) = \begin{vmatrix} cos\theta & -sin\theta & 0 \\ sin\theta & cos\theta & 0 \\ 0 & 0 & 1 \end{vmatrix}$$

With $\theta = 180\ degrees.$

Gives:

$$\begin{bmatrix} x' \\ y' \\ z' \end{bmatrix} = \begin{bmatrix} x \\ y \\ z \end{bmatrix} \begin{bmatrix} \cos(180) & -\sin(180) & 0 \\ \sin(180) & \cos(180) & 0 \\ 0 & 0 & 1 \end{bmatrix} = \begin{bmatrix} 347 \\ -50 \\ 1000 \end{bmatrix} \begin{bmatrix} -1 & 0 & 0 \\ 0 & -1 & 0 \\ 0 & 0 & 1 \end{bmatrix} = \begin{bmatrix} -347 \\ 50 \\ -1000 \end{bmatrix} \text{Newton}$$

2) Around the y-axis:

$$R_y(\alpha) = \begin{vmatrix} \cos(\alpha) & 0 & \sin(\alpha) \\ 0 & 1 & 0 \\ -\sin(\alpha) & 0 & \cos(\alpha) \end{vmatrix}$$

With $\alpha = 9\ degrees.$

$$\begin{bmatrix} x'' \\ y'' \\ z'' \end{bmatrix} = \begin{bmatrix} x' \\ y' \\ z' \end{bmatrix} \begin{bmatrix} \cos(\alpha) & 0 & \sin(\alpha) \\ 0 & 1 & 0 \\ -\sin(\alpha) & 0 & \cos(\alpha) \end{bmatrix}$$

With $\cos(9°) \approx 0.988$ and $\sin(9°) \approx 0.156$

$$\begin{bmatrix} x'' \\ y'' \\ z'' \end{bmatrix} = \begin{bmatrix} -347 \\ 50 \\ -1000 \end{bmatrix} \begin{bmatrix} 0.988 & 0 & 0.156 \\ 0 & 1 & 0 \\ -0.156 & 0 & 0.988 \end{bmatrix}$$

$$\begin{bmatrix} x'' \\ y'' \\ z'' \end{bmatrix} = \begin{bmatrix} -397 \\ 50 \\ -832 \end{bmatrix} Newton$$

3) Joint reaction force (JRF) from femur to the pelvis on the right side:

$$\begin{bmatrix} x''' \\ y''' \\ z''' \end{bmatrix} = \begin{bmatrix} -397 \\ 50 \\ -832 \end{bmatrix} = \begin{bmatrix} 397 \\ -50 \\ 832 \end{bmatrix} Newton$$

Appendix B: Calculations of the FBD equations

In this appendix the calculations performed on the equations of the FBD's from Chapter 5 are described. This includes, the chosen distances, FBD's, angles, and results.

Frontal osteotomy configuration – using two-legged stance:

We assume that the pubic symphysis allows rotation but has a horizontal and vertical force. The vertical force cancels out (up and down) so we assume we only have a normal force.

The two-legged stance forces are used, since on one leg the forces will be unevenly distributed on the osteotomy sites. Using the two-legged stance we can assume a symmetry on both sides, and an equal distribution on both sides.

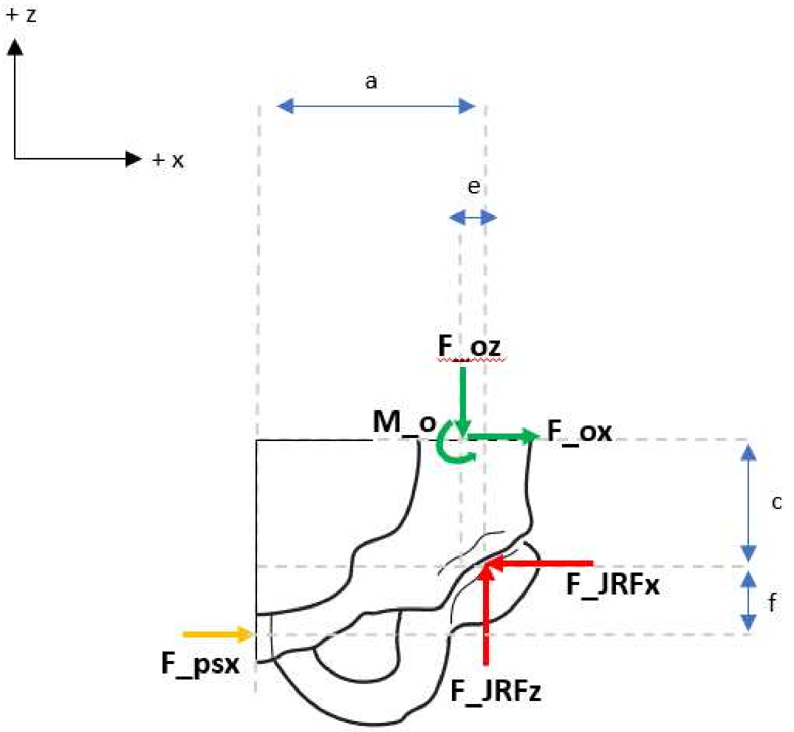

Figure 26: The osteotomy configuration in the frontal plane. In green the osteotomy forces, in red the joint reaction forces, and in yellow the force of the pubic symphysis. The distances needed to calculate the moment are illustrated with the blue arrows. The moment is chosen around the osteotomy point.

Dimensions:

Letters (distance):	**Value:**	**Explanation/assumptions.**
a =	83 mm	Distance centre pelvis and body to the centre of the joint where the joint reaction force is placed. Assume, 2/3 of the half of the length from left ASIS to right ASIS (anterior upper spinal breadth). So, 0.5*248 = 124 mm. 2/3*124 = 83 mm.
c =	55 mm	Distance between middle of the pelvis (centre of mass) and attachment point of the JRF. Assume half size of d, so 109/2=55mm
e =	5 mm	0.5*Anterior upper spinal breadth – 0.5*Transverse diameter of pelvic brim = 0.5*148-0.5*129=9 mm. Assume point O to be at the half of this length: 9/2=4.5=5 mm.
f =	14 mm	About 1/4 of c.

Calculation frontal osteotomy configuration:

Forces Bergmann two leg stance:

$$\begin{bmatrix} x''' \\ y''' \\ z''' \end{bmatrix} = \begin{bmatrix} 397 \\ -50 \\ 832 \end{bmatrix} Newton$$

$$\begin{aligned} &\sum F_x = 0 && \rightarrow F_{ox} - F_{JRFx} + F_{psx} = 0 \\ &\sum F_z = 0 && \rightarrow F_{JRFz} - F_{oz} = 0 \\ &\sum M_{JRF} = 0 && \rightarrow M_o - F_{ox} * c + F_{oz} * e + F_{psx} * f = 0 \end{aligned}$$

We have four unknowns; thus, the equation is not solvable. Therefor we take two extreme cases for the osteotomy configuration in the frontal view, as described in Section 5.4.2.. The fixation system is hereby assumed to be modelled as an implant, through which the forces will work.

1) **Case 1 – stiff implant:** The pubic symphysis force in the x direction (defined by F_{psx}) is assumed to be zero. The moment at the implant (defined by M_o) must offer balance indicating that the implant must be very stiff.
2) **Case 2 – flexible implant:** The implant is assumed to be very flexible and thus $M_o = 0$. F_{psx} must offer the balance.

The truth will lay in between.

The calculation of the two extreme cases:

Case 1: $F_{psx} = 0$.

$\sum F_x = 0 \rightarrow F_{ox} - F_{JRFx} + F_{psx} = 0$, Gives: $F_{ox} = F_{JRFx} + 0$

With $F_{JRFx} = 397$. Gives: $F_{ox} = 397\ Newton.$

$\sum F_z = 0 \rightarrow F_{JRFz} - F_{oz} = 0$. We know the $F_{JRFz} = 832\ Newton$. So, $F_{oz} = 832\ Newton$

Filling this in gives:

$$\sum M_{JRF} = 0 \rightarrow M_o - 397 * c + 832 * e + 0 * f = 0$$
$$M_o - 397 * 0.055 + 832 * 0.005 = 0$$
$$M_o = 397 * 0.055 - 832 * 0.005 \approx 18\ N * m$$

Case 2: $M_o = 0$.

$\sum F_z = 0 \rightarrow F_{JRFz} - F_{oz} = 0$. We know the $F_{JRFz} = 832\ Newton$. So, $F_{oz} = 832\ Newton$

$$M_o - F_{ox} * c + F_{oz} * e + F_{psx} * f = 0$$
$$0 - F_{ox} * c + F_{oz} * e + F_{psx} * f = 0$$
$$F_{ox} = \frac{F_{oz} * e + F_{psx} * f}{c}$$

From the horizontal sum:

$$F_{ox} = F_{JRFx} - F_{psx}$$

We get:

$$F_{JRFx} - F_{psx} = \frac{F_{oz} * e + F_{psx} * f}{c}$$
$$F_{JRFx} - \frac{F_{oz} * e}{c} = F_{psx} + \frac{F_{psx} * f}{c}$$
$$F_{JRFx} - \frac{F_{oz} * e}{c} = F_{psx} + F_{psx} * \frac{f}{c}$$
$$397 - \frac{832 * 0.005}{0.055} = F_{psx} * (1 + \frac{0.014}{0.055})$$
$$321 = F_{psx} * (1.25)$$
$$F_{psx} \approx 257\ Newton$$

Obtaining F_{ox}:

$$F_{ox} = F_{JRFx} - F_{psx} = 397 - 257 = 140 \text{ Newton}$$

Results Frontal view:

Scenario one: $\begin{bmatrix} F_x \\ F_z \\ F_{px} \\ M_O \end{bmatrix} = \begin{bmatrix} 397\ N \\ 832\ N \\ 0\ N \\ 18\ N * m \end{bmatrix}$ vs. Scenario two: $\begin{bmatrix} F_{ox} \\ F_z \\ F_{px} \\ M_O \end{bmatrix} = \begin{bmatrix} 140\ N \\ 832\ N \\ 257\ N \\ 0\ N * m \end{bmatrix}$

Sagittal osteotomy configuration - two-legged stance:

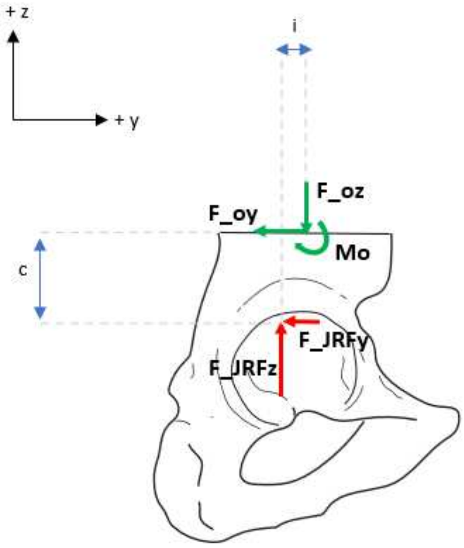

Figure 27: The osteotomy configuration of the sagittal view. In green the osteotomy forces, in red the joint reaction forces. I and j are the distance needed to calculate the moment, which is chosen around the osteotomy point.

Dimensions:

Letters (distance):	Value:	Explanation/assumptions.
c =	55 mm	Distance between middle of the pelvis (centre of mass) and attachment point of the JRF. Assume half size of d, so 109/2=55mm
i =	11 mm.	Dimension 4 of Dzupa et al. [44] – male and female: (6.34+5.91)/2= 6.125 cm. = 61 mm. Assume that point O will be at 1/2of this length and JRF at 1/3. 61.125*0.5=30.56 and 61.125*1/3=20.375. I = 30.56-20.375=10.185

Equations:

$$\sum F_y = 0 \rightarrow \sum F_y = -F_{oy} + F_{JRFy} = 0$$

$$\sum F_z = 0 \rightarrow \sum F_z = -F_{oz} + F_{JRFz} = 0$$

$$\sum M_{JRF} = 0 \rightarrow \sum M = -F_{oz} * i + F_{oy} * c - M_o = 0$$

Two-leg stance:

$$\begin{bmatrix} x''' \\ y''' \\ z''' \end{bmatrix} = \begin{bmatrix} 397 \\ -50 \\ 832 \end{bmatrix} Newton$$

1) $F_{oy} = F_{JRFy}$ so: $F_{oy} = 50\ N$.

2) $F_{oz} = F_{JRFz}$ so: $F_{oz} = 832\ N$.
3) $M_o = -F_{oz} * i + F_{oy} * c$, so, using 1 and 2: $M_o = -832 * 0.011 + 50 * 0.055 = -6.402 \approx -6.4\ N * m$

Results Sagittal view:

$$\begin{bmatrix} F_{oy} \\ F_{oz} \\ M_o \end{bmatrix} = \begin{bmatrix} 50\ N \\ 832\ N \\ -6.4\ N * m \end{bmatrix}$$

Validation of the calculated forces:

To validate the forces calculated from the simplified free body diagrams of the pelvis, a comparison with values found in literature was performed. Various studies report different force magnitudes applied to the pelvis, reflecting variations in assumptions and methodologies. However, the forces estimated in this analysis fall within a comparable range to those reported in literature. This suggests that the calculated forces provide a reasonable approximation of the loading conditions.

Appendix C: Dimensions of the Fixation Plate and Guiding tools

This appendix provides some detailed specifications of the fixation plate, and the guiding tools developed in the study. The data is organized under two headings: dimensions of the fixation plate and dimensions of the guiding tools. These measurements serve as a reference for potential adjustments or future development of the surgical procedure.

Dimensions of the Fixation Plate

Firstly, the STL file of the pelvis, post- Y-osteotomy, was imported. A plane was established over the open wedge (see Figure 28), allowing for a clear view of the dimensions and position of the upper and lower sections.

The fixation plate is based on the diameter of the screws used, which measure 5.0 mm. This diameter serves as the foundation for the plate structure. As illustrated in Figure 28, the outer circles were constructure with a minimum 6 mm distance form the centre of each screw hole to the edge of the plate. Additionally, a consistent distance of 10 mm was maintained between the centres of adjacent screw holes, as shown in Figure 29.

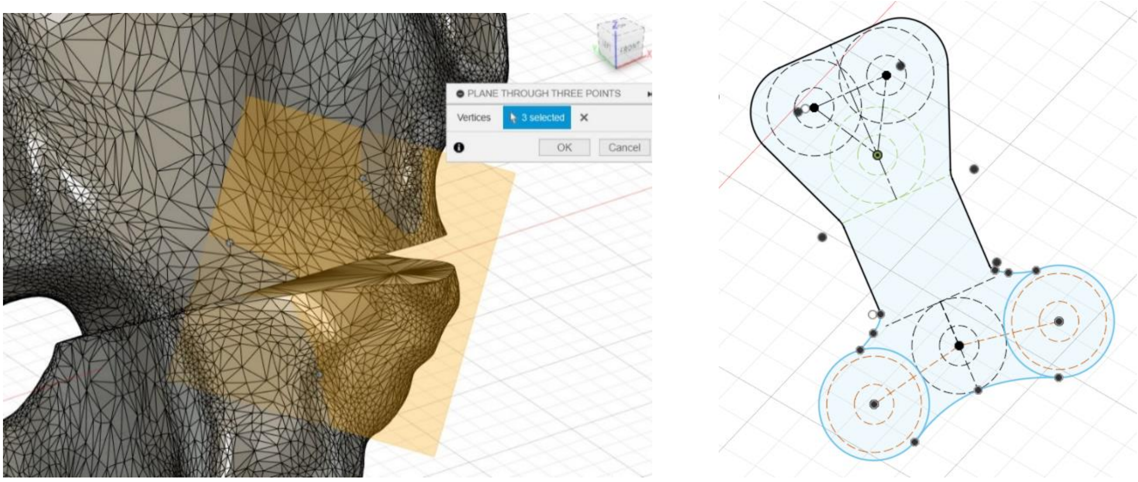

Figure 28: Left: the plane created over the open wedge in the pelvis. Right: the design of the final plate, with a broader bridge of 15 mm.

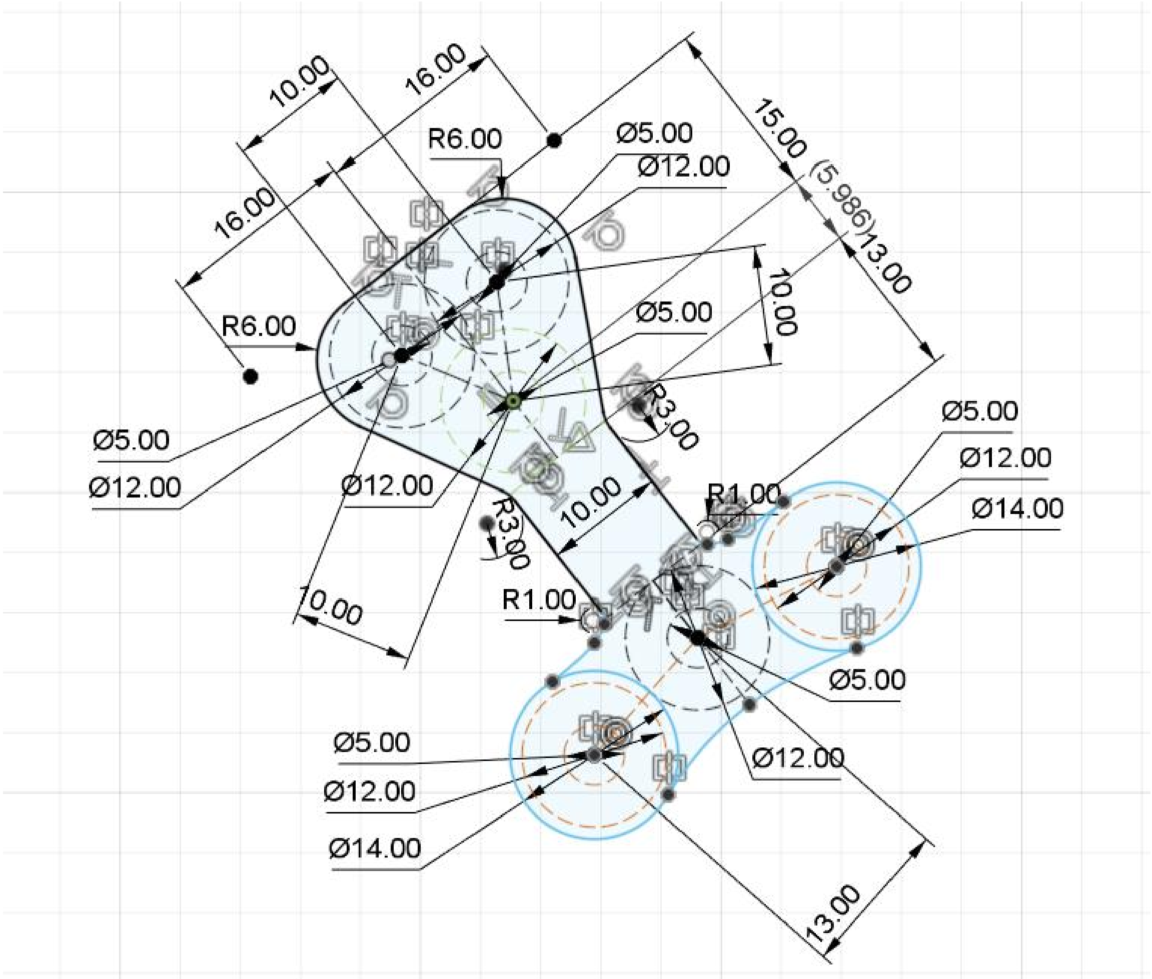

Figure 29: Dimensions of the initial plate design, with a 10 mm bridge width. This width is adapted in the final version.

Dimensions of the guiding tools

The dimensions of the k-wire guides for all the tools are as follows:

- Inner circle diameter: 1.8 + 0.25 = 2.05 mm
- Outer circle diameter: 4.05 mm, with a minimum distance of 2 mm between inner circle and the edge.

A margin of 0.25 is added to the inner circle to ensure a proper fit of the k-wire, which has a diameter of 1.8 mm. The minimum length of the k-wire guides is 15 mm.

The dimensions of saw guides 1 and 2 are given below. Other tools have approximated dimensions and are not illustrated.

Saw guide 1

The dimensions of saw guide 1 are illustrated in the figure below, Figure 30. It is important to note that the anatomical part of the guide is approximated, as its exact dimensions are not defined in detail.

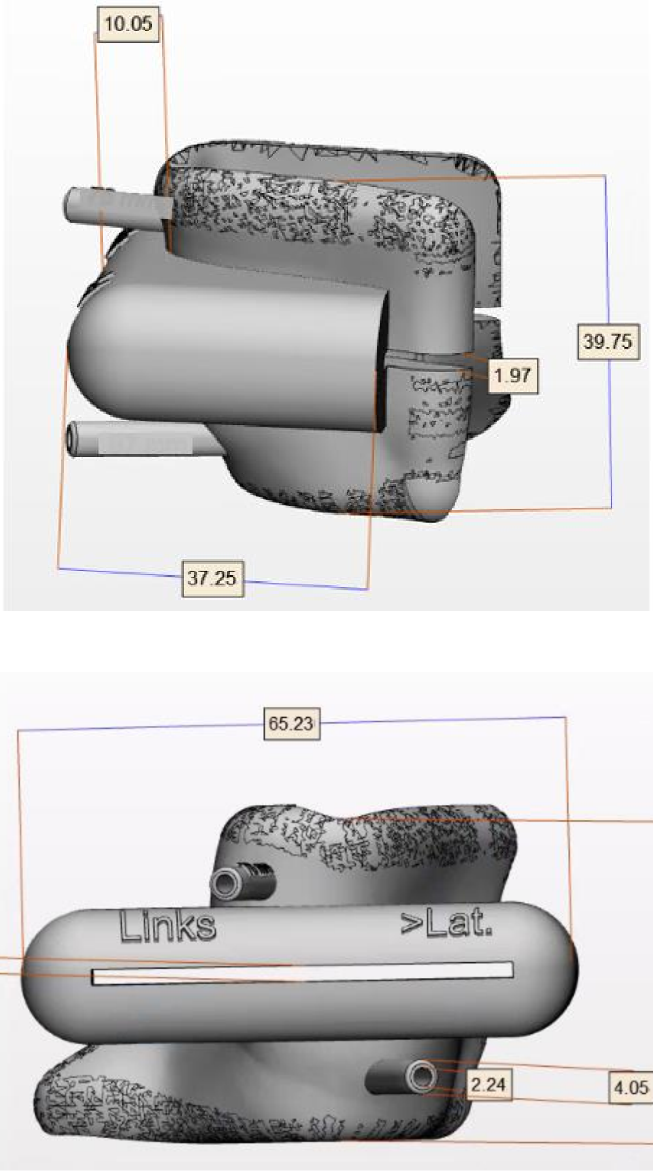

Figure 30: Saw guide 1. Above: the side view. Below: the frontal view.

Saw guide 2

Similarly, the dimensions of saw guide 2 are illustrated in the figure below, Figure 31. Like saw guide 1, the anatomical section is approximated due to the lack of refined measurements.

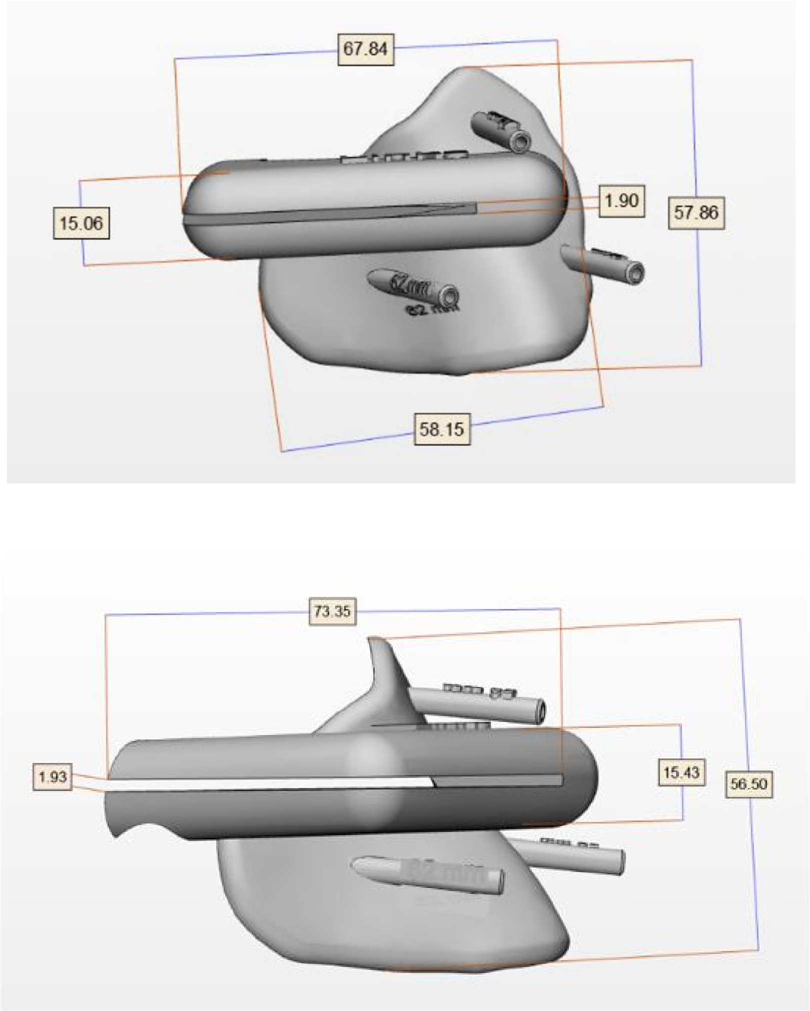

Figure 31: Dimensions of saw guide 2.

Appendix D: The USE questionnaire

In this appendix, the USE questionnaire used for the saw bone test in Chapter 8 is attached. This questionnaire is created to measure the three most important dimensions of usability for users and to measure those dimensions across the domains. The three domains are: usefulness, satisfaction, and ease of use. This test can be applied to multiple components that needs to be evaluated, with all three dimensions assessed for each component. A seven-point Likert scale is used for the ratings.

The questionnaire was completed by the participant and the executor of the saw bone test, an orthopedic surgeon with more than 10 years of experience.

Evaluatie formulier - Saw bone test

Dit formulier is bedoeld om een indicatie en inzage te krijgen in uw ervaring omtrent de saw bone procedure waarbij de y-osteotomie met bijbehorende tools getest zal worden. Gevraagd zal worden om een aantal vragen te beantwoorden voor drie elementen; de algehele procedure, het fixatiesysteem, en de boor-en zaagmallen. De vragen van het fixatiesysteem en de boor-en zaagmallen zijn opgebouwd volgens de USE questionnaire. Een methode voor het testen van de usability aan de hand van 3 aspecten, usefulness, satisfaction, en de ease of use.

Voor het beantwoorden van de vragen wordt een 7-punten Likert schaal gebruikt. Geef aan of je het met de stelling/vraag eens ben of oneens. Hierbij is 1 = Helemaal mee oneens, 4 = neutraal, en 7 = helemaal mee eens.

Algehele procedure:

		Helemaal oneens			Neutraal			Helemaal eens
		1	**2**	**3**	**4**	**5**	**6**	**7**
1.	**Ik vond de algehele procedure onnodig ingewikkeld.**	☐	☐	☐	☐	☐	☒	☐
2.	**De y-osteotomie lijkt een haalbare nieuwe methode als vervanging voor de BEPO.**	☐	☐	☐	☐	☒	☐	☐
3.	**Het acetabulum is voldoende beschermd bij zowel het fixatie systeem als bij de chirurgische hulpmiddelen.**	☐	☐	☐	☐	☒	☐	☐
4.	**De nervus ischiadicum wordt niet in gevaar gebracht en is voldoende beschermd tijdens de gehele procedure.**	☐	☐	☒	☐	☐	☐	☐
5.	**De anterieure benadering lijkt klinisch haalbaar.**	☐	☐	☐	☐	☒	☐	☐
6.	**De rotatie van het caudale deel om het craniale deel lijkt klinisch haalbaar.**	☐	☐	☐	☐	☒	☐	☐
7.	**Het botcontact na rotatie is voldoende voor een stabiele fixatie.**	☐	☐	☐	☐	☐	☒	☐
8.	**Het oppervlakte van het bot dat op het ilium nodig is lijkt klinisch vrijgemaakt te kunnen worden.**	☐	☐	☐	☐	☒	☐	☐
9.	**Onnodige opoffering van de aanhechtingen van belangrijk grote spieren wordt voorkomen. Zoals: m.gluteus maximus, m.gluteus medius, m. Tensor fascia latea, m.sartorius, m. iliopsoas, en de m. Rectus formoris**	☐	☐	☐	☐	☐	☒	☐

Comments/toelichting mits van toepassing/verbeterpunten:

Te veel k-draden. (opmerking bij vraag 1)

Fixatie systeem:

Usefulness:	**1**	**2**	**3**	**4**	**5**	**6**	**7**
1. Het fixatie systeem zorgt voor voldoende primaire fixatie van de osteotomie.	☐	☐	☐	☐	☐	☒	☐
2. Het fixatie systeem zorgt voor een nauwkeurige uitlijning en fixatie van de botdelen.	☐	☐	☐	☒	☐	☐	☐
3. De wig lijkt reëel voor gebruik in klinische praktijk.	☐	☒	☐	☐	☐	☐	☐
Satisfaction:	**1**	**2**	**3**	**4**	**5**	**6**	**7**
4. Het fixatiesysteem werkt zoals ik zou willen dat het zou werken.	☐	☐	☒	☐	☐	☐	☐
5. Ik heb er vertrouwen in het fixatie systeem veilig genoeg is.	☐	☒	☐	☐	☐	☐	☐
6. Ik heb er vertrouwen in dat de lag-schroef voldoende compressie biedt aan het gesloten deel van de osteotomie.	☐	☐	☐	☐	☒	☐	☐
Ease of use:	**1**	**2**	**3**	**4**	**5**	**6**	**7**
7. Het fixatiesysteem is makkelijk aan te brengen.	☐	☐	☒	☐	☐	☐	☐
8. De instructies voor het gebruiken en bevestigen van het fixatie systeem zijn duidelijk.	☐	☐	☐	☐	☐	☐	☐
9. De wig is makkelijk aan te passen naar de gewenste vorm.	☐	☐	☐	☐	☐	☒	☐

Comments/toelichting mits van toepassing/verbeterpunten:

Chirurgische hulpmiddelen (zaag- en boormallen):

Usefulness:	**1**	**2**	**3**	**4**	**5**	**6**	**7**
1. De zaag- en boormallen zijn voldoende om de osteotomie effectief uit te voeren.	☐	☒	☐	☐	☐	☐	☐
2. De zaag- en boormallen versterken de precisie van het uitvoeren van de procedure.	☐	☐	☒	☐	☐	☐	☐
3. De chirurgische hulpmiddelen zorgen ervoor dat de procedure gecontroleerd uit gevoerd kan worden.	☐	☐	☐	☐	☐	☐	☐
Satisfaction:	**1**	**2**	**3**	**4**	**5**	**6**	**7**
4. Ik ben tevreden met het design van de chirurgische hulpmiddelen.	☐	☐	☒	☐	☐	☐	☐
5. Ik ben tevreden over de positie van de k-draden.	☐	☐	☒	☐	☐	☐	☐
6. De chirurgische hulpmiddelen voldoen aan mijn verwachtingen.	☐	☒	☐	☐	☐	☐	☐
7. De chirurgische hulpmiddelen werken zoals ik zou willen dat ze zouden werken.	☐	☒	☐	☐	☐	☐	☐
Ease of use:	**1**	**2**	**3**	**4**	**5**	**6**	**7**
8. De zaag- en boormallen zijn makkelijk in gebruik.	☐	☐	☒	☐	☐	☐	☐
9. Het gebruik van de chirurgische hulpmiddelen is intuïtief.	☐	☒	☐	☐	☐	☐	☐
10. De aanwijzingen voor het gebruik van de chirurgische hulpmiddelen zijn duidelijk en goed te volgen.	☐	☐	☐	☐	☐	☐	☐

Comments/toelichting mits van toepassing/verbeterpunten:

Bij 1: te veel oppervlak en fixatie.
3: Mogelijk. Maar nu niet te zeggen.
10: ?, niet gezien?

Post-test interview vragen:

1. Kunt u eventuele moeilijkheden beschrijven die u tijdens de procedure hebt ondervonden
2. Waren er kenmerken van het fixatiesysteem of de fixatiehulpmiddelen die u bijzonder nuttig of problematisch vond?
3. Heeft u suggesties voor verbetering van het fixatiesysteem of de hulpmiddelen?

Comments/toelichting mits van toepassing/verbeterpunten: