Bioabsorbable Screws for Pelvic Osteotomies in Children

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Gothenburg, Sweden, 2022

Cover illustration by Emma Lundberg

Illustrations by Pontus Andersson,
Pontus Art Production

Layout by Guðni Olafsson, GO grafik

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ISBN: 978-91-8009-548-8 (TRYCK)
ISBN: 978-91-8009-549-5 (PDF)

Printed by Stema Specialtryck AB,
Borås, Sweden 2022

Trycksak
3041 0234

That’s that,
through tough thorough thought, though

ABSTRACT

Multiple conditions, with developmental dysplasia of the hip being a prime example, affect the congruity of the pediatric hip joint. A Salter osteotomy (SO) or a triple pelvic osteotomy (TPO) can be used to address suboptimal biomechanical conditions in the hip joint by improving containment and load distribution. Traditionally these osteotomies use metal implants to stabilize the osteotomy of the ilium, necessitating a second surgery for implant removal. If Kirschner-wires are used there are also risks related to wire migration and lack of stability.

The general aim of this thesis was to explore the novel use of poly lactic-co-glycolic acid (PLGA) screws for osteotomy fixation in SO and TPO. The feasibility of this concept was examined regarding the stability of fixation as well as the biocompatibility of the implants. Bioabsorbable screws negate the need for implant removal which would be a major benefit for children.

Study I reported on a novel surgical method for SO using PLGA screws instead of metal implants. A case series of 21 patients was reported on and the stability of the osteotomy fixation was evaluated using the post-operative radiographs. Migration percentage, acetabular index and center-edge angle were used to decide if an osteotomy collapsed or remained stable. In all patients but one the osteotomy remained stable and healed with maintained perioperative correction. There were no local reactions to the bioabsorption of the screws.

Study II presented a retrospective analysis of the bioabsorption of 4.5mm PLGA screws as interpreted on Magnetic Resonance Imaging (MRI). Twelve patients who had undergone a SO or TPO with PLGA screws as the method of fixation were included. Eighteen MRIs were performed 0.5-4.5 years postoperatively and were analyzed according to eight parameters. After 2-4.5 years all screw canals were replaced with >90% bone with one exception where most, but not 90%, was replaced with bone. The local reactions seen during the bioabsorption were minor.

Study III described a modified surgical method for TPO utilizing PLGA screws for the ilium osteotomy. A case series of 11 patients was reported on and the postoperative stability of the osteotomy was evaluated using migration percentage, acetabular index, center-edge angle as well as Sharp's angle. The osteotomy angle was, as an addendum, suggested as a parameter to evaluate the integrity of an osteotomy. All patients maintained the initial correction and there were no signs of implant failure nor any local reactions to the implants.

In Study IV the finite element method was used to analyze how different screw configurations affect stability in a TPO. Relative flexibility for loads in all translational degrees of freedom was calculated for five different screw configurations in a standardized hemi-pelvis. In two of these configurations the entry points used are only viable options if bioabsorbable implants are used. The screw configurations with a more perpendicular angle to the osteotomy and with a greater spread in the osteotomy plane between the screws resulted in increased stability. The use of bioabsorbable implants enables entry points that can provide improved biomechanical stability in a TPO.

In summary, the presented studies support that 4.5 mm PLGA screws provide sufficient stability in SO and TPO in children with no major local reactions to the implants. After bioabsorption the screw canals were mostly replaced by bone and the use of bioabsorbable implants enables fixation configurations that seems to improve stability of the osteotomy. The use of bioabsorbable screws for pelvic osteotomies can eliminate suffering associated with a second surgery and save resources.

SAMMANFATTNING PÅ SVENSKA

Barn kan antingen födas med, eller senare i livet utveckla, sjukdomstillstånd som påverkar höftledens normala biomekanik. I många fall är då lårbenshuvudet dåligt täckt av ledpannan. Två operationer som kan användas för att åstadkomma en bättre täckning av lårbenshuvudet är Salterosteotomi (SO) och trippelosteotomi (TPO). Vanligen har man tidigare använt metallstift eller metallskruvar för att fixera dessa osteotomier. Metallimplantat hos barn behöver dock extraheras vid en senare operation och metallstift har visat en tendens att migrera från sitt ursprungliga läge.

I denna avhandling undersöks hur bioabsorberbara skruvar av poly lactic-co-glycolic acid (PLGA) kan användas för att stabilisera SO och TPO för att undvika flera av de problem som är associerade med metallimplantat.

I studie I och III presenterades kirurgiska metoder för SO och TPO med PLGA-skruvar. Två fallserier på 21 respektive 11 barn följdes med röntgen postoperativt för att utvärdera stabiliteten i osteotomin. I studie II användes postoperativa magnetkameraundersökningar för att utvärdera hur PLGA-skruvar bryts ned och vilken vävnad som bildas i skruvkanalerna. Studie IV utgjordes av en virtuell matematisk analys av hur olika skruvplaceringar påverkar stabiliteten i en TPO. Beräkningarna genomfördes med en metod som kallas Finita elementmetoden.

Sammanfattningsvis stödjer resultaten i den här avhandlingen användning av 4.5 mm PLGA-skruvar för SO och TPO. Skruvarna verkade ge tillräcklig stabilitet i osteotomin och efter 2-4.5 år är skruvhålen till största delen fyllda av ben. Skruvarna uppvisar god biokompabilitet under nedbrytningsprocessen. Att inte behöva överväga senare extraktion möjliggör för kirurgen att placera skruvarna utifrån biomekaniskt optimala vinklar. Användning av bioabsorberbara skruvar vid bäckenosteotomier på barn kan minska lidande förknippat med en andra operation och spara resurser för sjukvården.

LIST OF PAPERS

This thesis is based on the following publications.

I. Hedelin H, Larnert P, Hebelka H, Brisby H, Lagerstrand K, Laine T

Innominate Salter osteotomy using resorbable screws: a retrospective case series and presentation of a new concept for fixation.

J Child Orthop. 2019 Jun 1;13(3):310-317

II. Hedelin H, Hebelka H, Brisby H, Laine T

MRI evaluation of resorbable poly lactic-co-glycolic acid (PLGA) screws used in pelvic osteotomies in children-a retrospective case series.

J Orthop Surg Res. 2020 Aug 14;15(1):329

III. Hedelin H, Larnert P, Antonsson P, Lagerstrand K, Brisby H, Hebelka H, Laine T

Stability in Pelvic Triple Osteotomies in Children Using Resorbable PLGA Screws for Fixation.

J Pediatr Orthop. 2021 Aug 191;41(9):e787-e792

IV. Hedelin H, Bryneskog E, Larnert P, Iraeus J, Laine T, Lagerstrand K

Post-operative stability following a triple pelvic osteotomy is affected by implant placement- a finite element analysis.

(In manuscript)

ADDITIONAL PAPERS PUBLISHED IN THE SAME FIELD

Hedelin H, Swinkels CS, Laine T, Mack K, Lagerstrand K. J.

Using a 3D Printed Model as a Preoperative Tool for Pelvic Triple Osteotomy in Children: Proof of Concept and Evaluation of Geometric Accuracy.

Am Acad Orthop Surg Glob Res Rev. 2019 Mar 19;3(3)

CONTENT

ABBREVIATIONS

3D	Three dimensional
ATD	Articulo-trochanteric distance
AI	Acetabular index
CE	Center edge (angle)
CT	Computed Tomography
DDH	Developmental dysplasia of the hip
FAI	Femoroacetabular impingement
FE	Finite element
ICC	Intra-class correlation coefficients
K-wire	Kirschner wire
LCPD	Legg-Calvé-Perthes disease
MP	Migration percentage
MRI	Magnetic resonance imaging
OA	Osteotomy angle
PAO	Periacetabular osteotomy
PFO	Proximal femoral osteotomy
PGA	Poly glycolic acid
PLA	Poly lactic acid
PLGA	Poly lactic-co-glycolic acid
PLLA	Poly-(L)-lactic acid
SA	Sharp's angle
TPO	Triple pelvic osteotomy

1. INTRODUCTION

THE PEDIATRIC HIP

The hip joint undergoes a remarkable maturation and adaptation during the first years of life. Initially the acetabulum is shallow and steep with a poorly seated femoral head but during the growth of an infant the acetabulum and femoral head jointly develop into a congruent joint. The anteversion of the femoral neck gradually decreases from around 30° at birth to approximately 15° in an adult and the femoral neck inclination grows from a relative valgus to the approximately 130° in the average adult [(1)]. The acetabulum and the femoral head interact during the growth of a child and dysplasia or injury in one of the two will normally affect the other as is evident in both Developmental Dysplasia of the Hip (DDH) and Legg-Calvé-Perthes Disease (LCPD).

DEVELOPMENTAL DYSPLASIA OF THE HIP (DDH)

DDH represents a spectrum of pathology ranging from neonatal instability, acetabular dysplasia, hip subluxation, and complete dislocation of the hip. Untreated DDH is an important cause of childhood disability and of osteoarthritis in adults [(2)]. The severity of the condition can be exemplified by the fact that, according to one report, 29% of patients that receive a hip replacement before the age of 60 years of age have DDH as the underlying diagnosis [(3)].

Meticulous screening of infants and early diagnosis enable treatment with abduction braces like the Pavlik harness, Frejka splint and von Rosen splint and greatly decrease the risk for persistent dysplasia needing surgical treatment [(4-6)]. Despite some version of screening programs in most affluent countries, some hips are either falsely interpreted as normal during the initial screening or develop dysplasia despite appropriate treatment. Lack of compliance or understanding by parents during abduction brace treatment in infancy is another possible reason for residual dysplasia.

DDH can be classified according to a variety of systems ranging from ultrasound-based systems in infants to radiographic classifications in adults [(7, 8)]. Singular radiological parameters like the Center-edge (CE) angle, acetabular index (AI) and migrations percentage (MP) can also be utilized along with symmetry based signs like ”Shenton's line” (figure 11-12) [(9)]. In younger children the most used radiograph-based classification system today is that of the International Hip Dysplasia Institute (IHDI), an evolution of the Tönnis classification method (figure 1) [(10)].

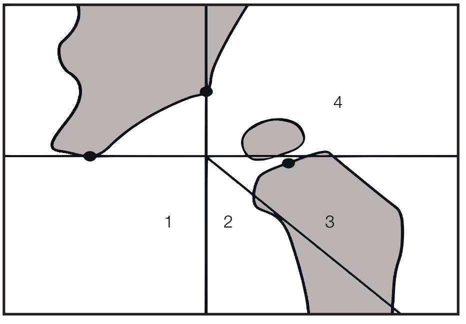

Figure 1. The IHDI classification of DDH. The midpoint of the superior margin of the metaphysis (black dot) will be situated in one of the four fields visualized in the figure. The horizontal line is drawn from the margin of the tri-radiate cartilage (as opposed to the Tönnis classification). Published with permission from IHDI.

In children with late diagnosed hip dislocation initial treatment is usually an attempt at closed reduction under anesthesia (figure 2-4). If this intervention fails, open reduction followed by a hip spica is the next step [11]. Applying skin traction for two weeks prior to reduction may increase the likelihood of success and decrease the risk for avascular necrosis, for both closed and open reduction [12]. There are no established age limits for any given treatment but in one study children diagnosed after ten months of age had a 12-fold increase in needing open reduction, compared to children diagnosed before the age of six weeks [13].

In children presenting at an even later stage with DDH (>1.5-2.0 years of age) further surgical treatment is warranted to achieve a stable hip joint with sufficient containment. The choice of treatment depends on the degree of dysplasia or dislocation. A pelvic osteotomy, like a Salter osteotomy (SO) or Pemberton, is usually necessary and a concomitant shortening femoral varus osteotomy may be resorted to (see below). Some authors prefer a one-stage treatment with open reduction and pelvic osteotomy in one session while others opt for a two-stage solution, performing open reduction at a younger age and waiting with a possible pelvic osteotomy until after the age of three [14]. Persistent or neglected DDH has substantial morbidity, such as early onset of osteoarthritis, and early treatment is paramount for a satisfactory outcome [12].

LEGG-CALVÉ-PERTHES DISEASE (LCPD)

LCPD is an enigmatic condition, with largely unknown etiology, characterized by an idiopathic avascular necrosis of the femoral head in children between the ages of 2-10 years [15, 16]. The epiphysis of the femoral head undergoes gradual collapse followed by re-ossification and eventually healing. The prognosis of LCPD is highly linked to the age of onset, with younger children having a markedly better prognosis [17]. The second vital factor is the extent of femoral head involvement [18]. During the healing process of the femoral head, the ”creeping remodelling” and the plasticity of the tissue can lead to a deformity. When residual deformity develops after LCPD it is characterized by a mushroom-like incongruent shape of the femoral head and a short femoral neck (figure 5). These deformities may cause restricted mobility, femoroacetabular impingement (FAI), gait disturbance, and pain [17].

The degree of epiphyseal involvement can be classified by the Catterall or Salter-Thomson methods, but the Herring lateral pillar classification is the most widely used in contemporary clinical practice with superior inter-observer reliability and prognostic ability [19-22]. The long-term outcome after skeletal maturity is most commonly classified according to the Stulberg

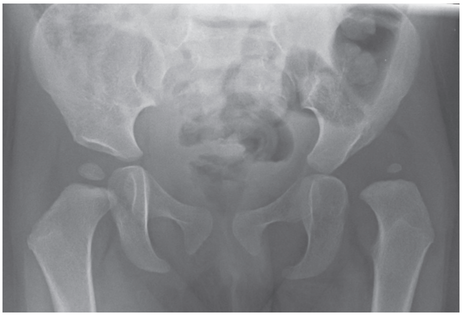

Figure 2. A child with a left hip dislocation discovered at one year of age. The acetabular index is steep on the left side and the ossific nucleus is smaller than on the right side.

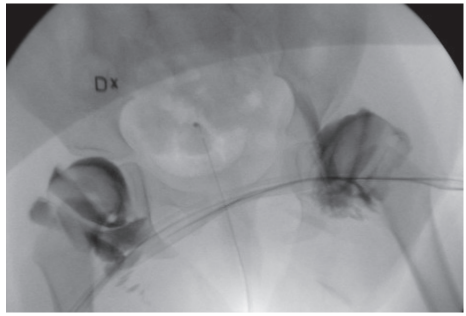

Figure 3. The same child as figure 2 after closed reduction and an arthrogram. The repositioning was deemed stable enough and treatment was continued with a hip spica.

grading system. Stulberg uses five grades describing the congruity and shape of the femoral head in relation to the acetabulum (23) but the intraobserver reliability has been questioned (24). The deformity index has recently been proposed as a new, continuous, parameter (25).

The treatment of LCPD has evolved from the non-surgical treatment ambitions of the mid 20th century in the form of abduction braces (26-28). In milder cases and younger children conservative non-operative treatment is still the path of choice (29). Children above the age of six years at onset and especially those with a lateral pillar type B, B/C or C tend to have poor outcomes after non-surgical treatment (17, 28).

When surgery is necessary the basic principle, whether resorting to a proximal femoral osteotomy (PFO) or a pelvic osteotomy, is that of containment (30-32). By improving the acetabular coverage of the femoral head during or before the re-ossification phase the ambition is to allow the acetabulum to function as a template for the femoral head. Containment surgery should therefore be performed in the fragmentation phase, as soon as the diagnosis is established (27). A PFO may also have a modest load-relieving effect on the hip joint, but on the other hand result in leg shortening and decreased articulo-trochanteric distance, ATD (33). Physiotherapy aiming to maintain mobility and muscle strength has commonly been advised in Scandinavia, but the scientific evidence is scarce (34, 35). The recommendations regarding restricted weight bearing is conflicting with no convincing scientific support for any specific strategy (35).

If a hip joint with LCPD has healed with a prominent residual deformity the patient is likely to suffer from early osteoarthritis, FAI and pain (17). Trochanteric overgrowth, leading to a decreased ATD, may also result in a Trendelenburg gait and abductor weakness (36). Joint preserving surgical treatment options for these patients usually require a femoral neck lengthening and a distalalization of the greater trochanter (37). An earlier varus osteotomy can also leave the hip with a poor ATD, unfavorable load distribution and leg length discrepancy. Once the hip has healed a valgus osteotomy may, in these cases, improve the biomechanical configuration of the hip joint. In selected cases an open dislocation and revision of the femoral head is used to treat residual dysplasia from LCPD (38, 39). As a last resort, hip replacement may be necessary even at a fairly young age (40). The role of hip arthroscopy in the treatment of residual deformity after LCPD is being explored and will likely be indicated for selected patients with focal impingement or deformity in the future (41-43).

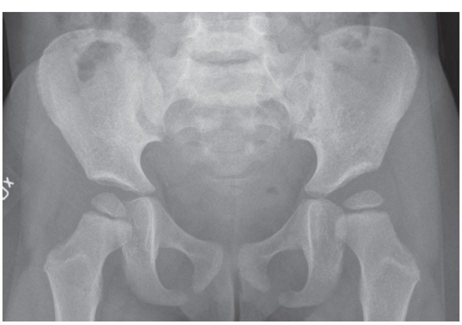

Figure 4. The same child as figure 2 and 3. Two years after closed reduction the left hip joint still exhibits signs of dysplasia with a steep acetabular index. A Salter osteotomy was performed a few years later.

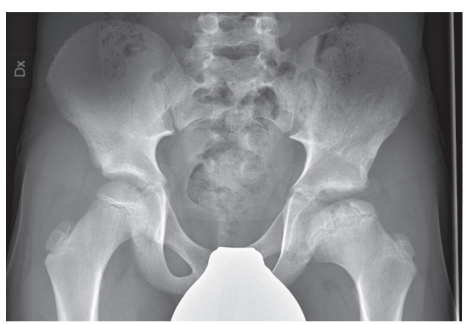

Figure 5. A nine-year-old boy with LCPD, who underwent a Salter osteotomy at the age of four (figure 6). The left hip has a characteristic shape as seen after a healed LCPD.

DOWN SYNDROME AND NEUROMUSCULAR DISORDERS

Multiple syndromes are associated with hip dysplasia and stability or containment challenges. Down syndrome, being one of the more common syndromes, is often characterized by joint laxity and a retroverted acetabulum (44). Children with Down syndrome are also prone to DDH but no causality has been established between the laxity and shape of acetabulum and the hip instability (44). One potential cause might instead be the muscular imbalance around the hip joint, but this is so far a hypothesis. If DDH secondary to Down syndrome needs to be addressed surgically, the anteversion of the acetabulum should be evaluated on an individual basis since even though many patients do have a decreased anteversion, some do not (45).

SURGICAL TREATMENT

GENERAL ASPECTS

The different femoral head containment disorders outlined in the previous section make potential surgical treatments as diverse as the indications. The conditions listed above do, however, have one thing in common: The shape or orientation of the acetabulum creates sub-optimal biomechanical conditions for the hip joint. Pelvic osteotomies address this by reorienting or reshaping the acetabulum. Since the acetabulum and the femoral head function as each other's template during growth improving hip joint containment in childhood and, possibly, adolescence enables the joint to develop into a more favourable biomechanical position. Pelvic osteotomies in adults do not carry this benefit but may still decrease the risk for osteoarthritis and improve function by improving the load distribution in the joint (46).

When a pelvic osteotomy should be performed, and the most appropriate surgical technique is the source of continued debate and scientific exploration. Generally pelvic osteotomies can be divided into re-directing, re-shaping and salvage procedures. Redirecting osteotomies, like SO, triple osteotomy (TPO), periacetbular osteotomy (PAO), maintain the volume of the acetabulum but improve coverage by rotating the acetabular fragment. Re-shaping osteotomies, like Dega and Pemberton, hinge the acetabular roof on a bone bridge superior to the tri-radiate cartilage. The result is improved containment but has traditionally been deemed to decrease acetabular size (47). Recent papers have however, questioned the proposition that a Dega osteotomy decreases acetabular size (48). In salvage osteotomies the ambition is no longer to re-create an anatomical acetabulum but to establish any kind of femoral head coverage (47).

SALTER OSTEOTOMY

The SO has remained a mainstay surgical method to improve the acetabular coverage for multiple diagnoses, including DDH and LCPD, since its introduction by Salter in the 1960s (49). The SO involves an osteotomy of the iliac bone above the acetabulum at the level of the sciatic notch. The acetabular fragment can then be reoriented to increase lateral and anterior coverage and the correction is maintained by a bone graft from the iliac wing (figure 6). The desired intraoperative correction is approximately 25-30° of anterio-lateral rotation corresponding to around 10-15° decrease in the acetabular index (AI) (50).

Figure 6. A boy with Legg-Calvé-Perthes disease (LCPD) and pain debut at 4 years of age who underwent a Salter osteotomy the same year to improve containment. As can be seen, the containment of the femoral head has been improved. The iliac osteotomy is stabilized with bioabsorbable screws.

Since the SO relies on using a malleable symphysis as a hinge the degree of correction that can be achieved decreases with age. Initially Salter suggested his method could be used up to the age of 10 but a follow-up on his initial series, confirmed by later studies, revealed worse results for children above the age of 6 (51).

Today other surgical methods, like TPO, are normally resorted to above the age of 6-8 years (30). The SO surgical technique aims at an anterior and lateral displacement of the distal segment and as such is less suited for conditions where improved dorsal coverage is desired, like in most patients with Down syndrome (45). In these cases, a TPO can be performed even in younger age groups.

Salter presented six prerequisites for successful surgery with a SO (51). They are, in short: opposed femoral head and socket, releasing all contracted structures, concentric reduction, good range of motion, joint congruity and correct age. After a fifteen-year follow-up of his initial series Salter concluded that a SO should not be performed below the age of 18 months or above the age of six (51).

TRIPLE PELVIC OSTEOTOMIES

Though early versions of TPOs were introduced in the late 1960s the concept was modified and popularized by Steel (52, 53). A TPO creates a completely free-floating acetabular segment allowing correction in all dimensions and the method can therefore be used in all age groups and for a variety of acetabular deficiencies (figure 7). Since the acetabular fragment is rotated in three osteotomies the correction (and subsequent graft size) that is needed in the iliac osteotomy tend to be smaller than in an isolated SO (30). The clinical outcomes are, however, not as good in adults compared to children and different PAOs are methods more commonly elected in this age group (54, 55).

Most TPOs employ an innominate osteotomy ad modum Salter but differ in the osteotomies of the two rami. The Steel osteotomy is technically the easiest, since the surgical approach is straightforward and the osteotomies are in relatively safe locations regarding neurovascular structures (52). Correction of an acetabular dysplasia does, however, produce displaced osteotomies in the pubis and ischium that are prone to pseudoarthrosis. The Tönnis technique is a more challenging method with osteotomies placed as close to the acetabulum as possible (56). Tönnis' motive for this level of osteotomy was that it does not leave the sacrospinous ligament attached to the acetabular fragment, which theoretically could benefit stability (57). The Tönnis level of osteotomy also operates close to neurovascular bundles (58). The Carlioz method is a compromise, with a safer, and surgically more accessible distance from the acetabulum but without leaving the pubic and ischial osteotomies too prone to displacement or non-union (figure 7) (59). Numerous studies have explored further modifications to both the Salter and the TPO with regard to surgical technique (60-67). A TPO can be performed through a three or two incision approach but even a one-incision technique has been proposed (68, 69).

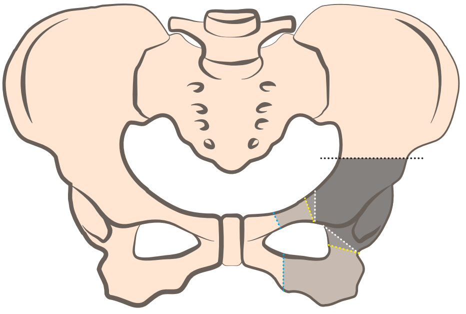

Figure 7. Three different triple osteotomies. The Salter osteotomy (black line), above the acetabulum, is identical. The surgically challenging Tönnis' osteotomy (white lines) operates closest to acetabulum while the Steel (blue lines) has more medial osteotomies. The Carlioz method (yellow lines) can be considered a compromise and leaves the sacrospinous ligament attached to the acetabular fragment as opposed to the Tönnis' osteotomy.

Improved coverage of the femoral head is desirable for both SO and TPO but it appears that the degree of increased coverage, as measured by radiological parameters, does not necessarily have a direct correlation to clinical outcome (55, 70). It has been hypothesized that this fact is due to other parameters, such as decreasing shear forces and improved distribution of the loading forces (70).

Especially for TPO there is a known risk for overcoverage of the lateral and frontal aspects of the femoral head. This can result in a pincer-like FAI as well as posterior undercoverage (55, 70). It is still uncertain though to what extent overcoverage after a TPO results in a poor clinical outcome (71).

Both a SO and TPO can be combined with a varus PFO to achieve even more complete coverage of the femoral head. When a pelvic osteotomy should be combined with a PFO is the source of some debate. For LCPD some argue that femoral osteotomies are preferable to pelvic osteotomies as the initial method to improve containment, since femoral rotation can also be addressed and the relative shortening can help to decompress the joint (72). Others argue that it is an unattractive path to perform surgery resulting in femoral shortening and varus in a condition that itself has this effect (73). According to some studies there does not appear to be any major differences in the functional outcome between the two methods (74).

OTHER PELVIC OSTEOTOMIES

In neuromuscular conditions like CP the hip dysplasia is often characterized by both a steep and a shallow acetabulum and re-shaping osteotomies like Dega (figure 8, left) are usually the surgical method of choice (often combined with a PFO) (75). Globally it is also common to use Dega as the method of choice for DDH (76).

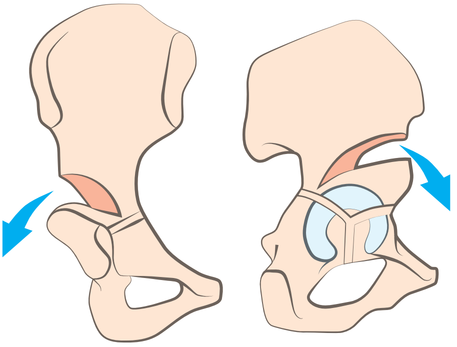

Figure 8. A Dega (left) and Pemberton (right) osteotomy, both incomplete re-shaping osteotomies. Both techniques use a bone-graft, but no internal fixation, to maintain the correction. The Dega osteotomy improves the lateral and anterior cover but can be adapted to give more posterior coverage. The Pemberton is a more extensive osteotomy, normally employed to increase lateral and anterior coverage.

The Pemberton osteotomy has been used for a wide range of indications. Several studies compare SO and Pemberton and they are, to a certain extent, used for the same indication (figure 8, right) (77, 78).

This is despite the fact that, in theory, Pemberton is a re-shaping osteotomy while SO is a redirectional. The Pemberton osteotomy has the advantage of not requiring internal fixation but altering the shape of the acetabulum may predispose the hip joint to FAI (79).

The PAO is a surgical method to enable complete redirectional freedom of the acetabulum without disrupting the pelvic ring (80). Since the osteotomies encircle the acetabulum, the technique is not advisable in children with an open triradiate cartilage. The surgical learning curve is steep, and complications are not uncommon (81, 82). In adults with residual DDH, PAO has proven to be a tool to delay the onset of osteoarthritis and decrease pain (83).

Salvage osteotomies like Chiari or shelf osteotomies are nowadays, like the name implies, normally a choice of last resort. The Chiari osteotomy entails an iliac cut, similar to a Salter but slightly inclined, followed by a medialization of the acetabular fragment to improve head coverage (by non-cartilage bone). Shelf osteotomies involves different methods of bony augmentation of the acetabular lateral roof. In both these methods there is no longer an ambition to re-create a normal anatomy but rather to strive for any kind of improved containment [84, 85].

METHODS OF PELVIC OSTEOTOMY FIXATION

Modifications of the Salter osteotomy have been proposed that could negate the need for fixation of the iliac osteotomy [63] but many surgeons still use K-wires, as advised in the original method [49]. Smooth K-wires are, however, prone to migrate and multiple reports of migration-related complications have been reported [86-89]. Threaded K-wires may reduce the risk of migration but still require removal and local implant related complications are not uncommon [90, 91].

In TPOs multiple methods of fixation have been used for the iliac osteotomy including K-wires, Steinmann pins, and screws and plates [92-94]. Many surgeons opt for K-wires for fixation [8] while some, like with a Salter, advocate threaded wires to decrease the risk of migration [9]. The most common method of fixation today is, however, probably metal screws [62, 95]. Some surgeons advocate internal fixation of the pubic osteotomy in addition to the innominate osteotomy arguing that this enables earlier weight bearing [96].

Recently, bioabsorbable screws have been presented as an alternative, negating the need for implant removal in both SO and TPO [97, 98]. Since the 1990s PLLA screws have shown favorable results in rotational acetabular osteotomies in regard to stability but some local reactions to the implant degradation have been reported [99-102]. In SO thin bioabsorbable pins have been proposed as a substitute for K-wires but have not gained widespread popularity in clinical practice [103, 104]. Bioabsorbable implants as the means of fixation do enable the the surgeon to place the screws (or pins) in configurations that do not need to take later removal into account. The main advantage, however, is that a second surgery for implant removal is no longer required, a major benefit especially for children.

POSTOPERATIVE IMMOBILIZATION

In the classic papers on pelvic osteotomies immediate postoperative immobilization was mandated. Salter advocated a 6-week hip spica, followed by a month of orthosis in older children. Both Steel, Tönnis, and Carlioz also mandated a minimum of six week immobilization after a TPO [52, 56, 59].

Many of the surgical modifications that have been proposed to increase the stability of the osteotomies aim to shorten or completely avoid post-operative immobilization [62, 105]. Interestingly Adamczyk et al [106], in a biomechanical study of TPO, concluded that the osteotomy was less stable when loaded with the femur in a flexed and abducted position in a hip spica. This implies that the classic spica cast position, that is used to maintain a favorable position of a dysplastic or dislocated hip, may not be optimal for the stability of the osteotomy.

BIOABSORBABLE IMPLANTS

The use of bioabsorbable internal fixation has seen a rapid evolution over the last decades and the clinical applications are vast in the field of orthopaedics [107-110]. The gradual improvement of polymers regarding biocompatibility, rate of resorption and stability has improved clinical outcome. The early use of poly glycolic acid (PGA) based implants was associated with implant failure due to rapid resorption as well as local reactions [107, 111]. The lactic acid based poly-(L)-lactic acid (PLLA) polymer, on the other hand, provide sufficient stability for multiple indications [111]. Bioabsorption occurs at a slow rate and larger implants are not fully degraded in the body even after >5 years [112-115]. PLLA implants are however known to cause local inflammatory reactions during bioabsorption [100, 101].

Different compositions of the co-polymer poly lactic-co-glycolic acid (PLGA) have been manufactured to create a polymer with sufficient stability combined with biocompatibility and a tissue friendly resorption pattern [111, 116]. The 85L/15G PLGA composition has been proven to have favorable traits in multiple studies for orthopedic implants [117-120].

The bioabsorption of both PLLA and PLGA occurs mainly through hydrolysis of the ”backbone” of the polymer. This results in PLA hydrolyzing into lactic acid, which is a normal by-product in muscles, while PGA is degraded by hydrolysis and esterases to glycolic acid which, in turn can be directly secreted or used in metabolic pathways [111].

The cytotoxicity and biocompatibility of the products of both PLA and PGA degradation have been explored in vivo and in vitro [121, 122]. In general, the cytotoxicity has been deemed tolerable but the degradation process, especially of PLA may cause local inflammatory response [122]. This is predominantly due to the build-up of acidic by-products which is why the location of an implant matters. In certain anatomic locations the body may be unable to flush away the degradants creating an acidic environment which will catalyze further degradation and consequently reduce pH even more [117]. It can also be noted that it appears that the two optical isomers of lactic acid, D and L, with the latter being the naturally occurring isomer, have different cytotoxicity [122].

The exact time for bioabsorption varies greatly between in vitro tests, animal models and clinical trials [111, 116, 123-125]. For PLGA screws the time for bioabsorption has in in-vivo test been reported to be between one and five years depending on setting[125]. PLLA screws have markedly slower bioabsorption and can, to some extent, remain after more than ten years [115]. It is also worth noting that the soft tissue padding and vascular supply to the surrounding tissue likely affect the speed and nature of the bioabsorption. According to the few reports available on the subject, bioabsorption in the pediatric population appears to be quicker and the cavity of the implant seems to be replaced by solid bone to a greater extent than in adults [120, 126].

In recent years bioabsorbable magnesium alloy implants have also been introduced in the pediatric population for a number of indications with promising results [127].

FINITE ELEMENT (FE) ANALYSIS

The FE method is a mathematical approach to describe a mechanical system, like the biomechanics of an anatomical model, by approximately solving a large number of partial differential equations. By creating many finite elements in a model, and ascribing mechanical properties to each of them, the kinetics and kinematics of the system can be simulated. Boundary conditions and contact algorithms are defined to prescribe the physical interactions between each part (figure 9). A prerequisite for reliable FE calculations is that the mechanical properties of the anatomical (and artificial) structures are known. For a human pelvis traits like stiffness of cortical and cancellous bone has been approximated in earlier studies [128].

FE analysis has been used in the field of orthopedics for a variety of applications. Examples include how the acetabulum should be optimally positioned after a virtual PAO [129], how contact pressure in the hip joint is affected by DDH [130] and how biomechanical stability is affected by fixation after proximal femoral osteotomies [131].

FE analysis enables the study of component stiffness, static/dynamic response, failure, crack propagation, etc. One of the main advantages is that FE enables paired testing using the exact same object, something that is near impossible on cadaver studies and difficult when using plastic models.

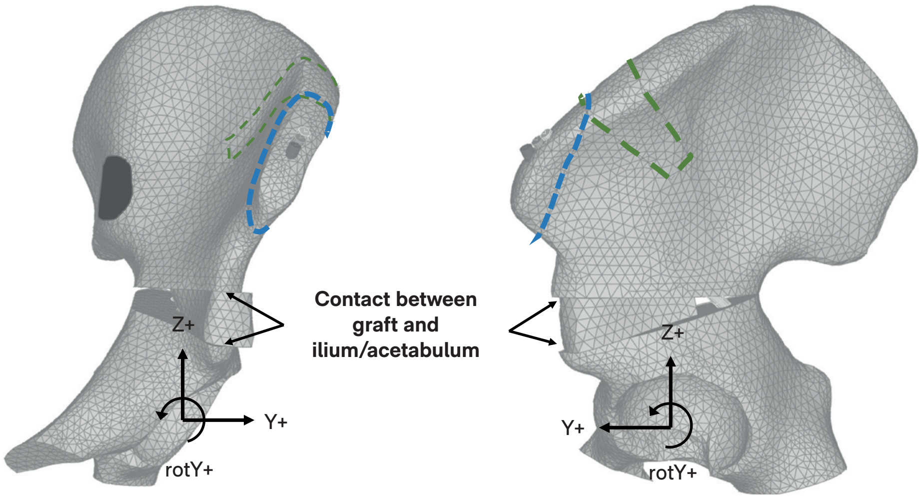

Figure 9. A FE analysis of a standardized hemi-pelvis as used in study IV for one of the five screw configurations. The finite elements are visible along with the graft and graft sites (the dorsal graft site was used for harvesting).

2. AIM

OVERALL AIMS

The overall aim of the studies included in this thesis was to explore and evaluate the feasibility of using bioabsorbable screws in pelvic osteotomies in children.

STUDY I

Study I aimed to examine the feasibility of a novel modified method for SO using bioabsorbable PLGA screws for osteotomy fixation.

STUDY II

Study II aimed to evaluate the resorption pattern of 85L/15G PLGA screws used in pelvic osteotomies and to map local reactions during this process.

STUDY III

In study III a modified surgical method for TPO using bioabsorbable PLGA screws for fixation was evaluated in a case series, with focus on the postoperative stability of the osteotomy.

STUDY IV

Study IV used FE to mathematically examine how screw placement configurations, in a standardized model of a triple osteotomy, affect stability.

3. PATIENTS AND METHODS

PATIENTS

Patient characteristics are presented in table 1 for study I-III. Study IV does not include any patient specific data or information. Study II involved patients that were also included in study I (n=5) and III (n=6). None of the radiographic or MRI based data used in study II was used in the other studies and vice versa.

Table 1. Patient characteristics of study I-III. *Denotes one child, who had two surgeries six years apart.

	Study I	Study II	Study III
Total (n)	21	12	12
Boys (n)	13	10	8
Girls (n)	8	2*	4
Median age in years(range)	6.6 (7.5)	8(6.7)	7.8 (9.7)
LCPD	13	9	6
DDH	8	3	2
Down syndrome	0	0	4
Concomitant PFO	7	N/A	4
SO	21	6	0
TPO	0	6	12

SURGICAL METHODS

Study I focuses on SOs while study III and IV investigate different aspects of a TPO. Study II covers a MRI based follow-up after both SO and TPO but the surgical method is of less relevance for this study.

The SOs were performed as described by Salter with the exception of the method of fixation and graft harvest site [49]. The alternative harvest site, further dorsally on the iliac wing, enabled more entry points and the potential benefits of this was further explored in study IV. In some cases, the apophysis of the iliac crest could not be easily closed after correction and a second graft was harvested from the classic harvest site along the anterior superior iliac spine. This second graft was also inserted into the osteotomy for added stability and to enable tension free closure of the apophysis. An oscillating saw was used for the iliac osteotomy, except for the last centimeter where an osteotome was employed.

The TPO presented in this thesis utilizes the technique as described by Carlioz (59) with a three incision approach. The iliac osteotomy was performed as for a Salter. The pubic and ischial osteotomies were performed with an osteotome.

METHOD OF OSTEOTOMY FIXATION

In both the SO and TPO two or three 4.5 mm 85L/15G PLGA screws (Activa Screw, Bioretec, Tampere, Finland) were used for fixation of the iliac osteotomy (figure 10). The number of screws and the exact entry points for the screws were made at the discretion of the surgeon. At least one, and preferably two, of the screws were placed through the graft and maximal spread in the plane of the osteotomy was strived for. To achieve this, most of the screws were placed from the cleft of the harvest site of the graft. In the TPO no fixation was used for the pubic or ischial osteotomies. After the initial correction and the placement of the graft two or three 1.6 mm K-wires temporarily stabilized the osteotomy. Under fluoroscopy the position of the K-wires and the length of the screw was evaluated. After drilling and tapping the cannulated screws were inserted and the K-wires removed. The head of the PLGA screw, was cauterized along the bone surface.

Figure 10. A 4.5mm 85L/15G PLGA cannulated screw (Activa Screw, Bioretec, Tampere, Finland).

POSTOPERATIVE IMMOBILIZATION

In the case series of study I and III postoperative immobilization was decided on a case-to-case basis. In most cases non-weight bearing in a wheelchair for six weeks was adhered to, followed by a radiograph to verify callus formation. If healing was deemed satisfactory gradually increased weight bearing was allowed. Children who were expected to be non-compliant due to age or neuropsychiatric conditions were immobilized in a hip spica, or a Petrie cast for six weeks.

In both study I and study III most patients, 62% and 58% respectively, did not receive postoperative cast immobilization.

RADIOLOGICAL ASSESSMENT

In study I the acetabular index (AI), migration percentage (MP) and center-edge angle were evaluated. In study III the same parameters were measured along with SA. In all cases the bony edge was used as the lateral landmark as opposed to the edge of the sourcil that has been proposed as an alternative (figure 11-12) (132, 133). In study I MP is referred to as "Reimers' Index" but this terminology was changed to MP in the later papers, more correctly reflecting the original reference (134). In study III the osteotomy angle (OA) was suggested as a complementary measurement to evaluate the stability of the osteotomy.

GENERAL STATISTICS

SPSS Statistics (IBM Corp, released 2017. IBM SPSS Statistics for Mac, Version 25.0. Armonk, New York: IBM Corp v25.0.0.0) was used for study I and II while v26.0.0.0 of the same software was used for study II.

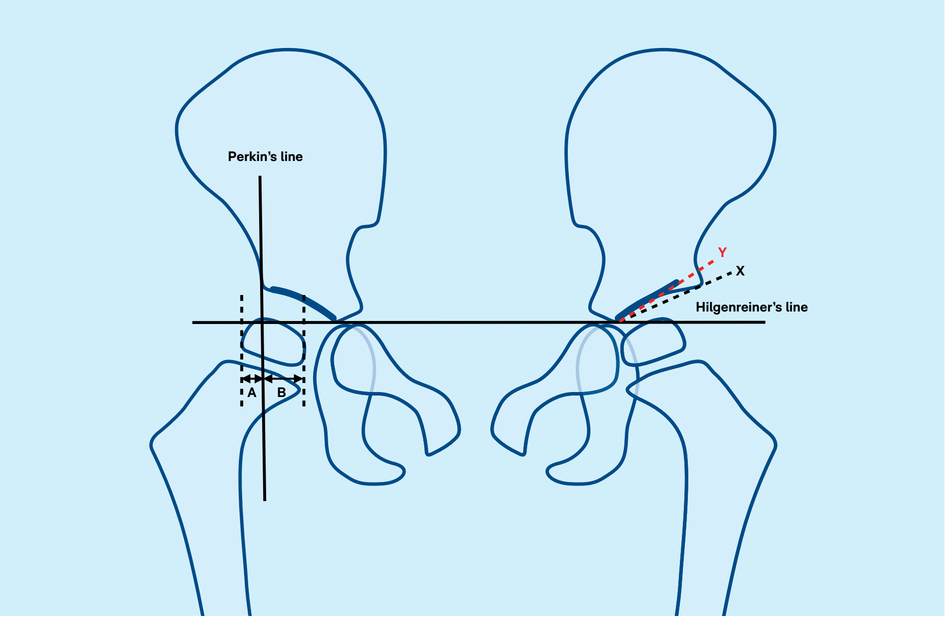

Figure 11. A pediatric pelvis illustrating Hilgenreiner's and Perkin's line. The migration percentage is defined as A/(A+B). The acetabular index is the angle between the dotted X line and Hilgenreiner's line. The red Y line represents the alternative acetabular index using the edge of the condensed "sourcil" as the lateral reference

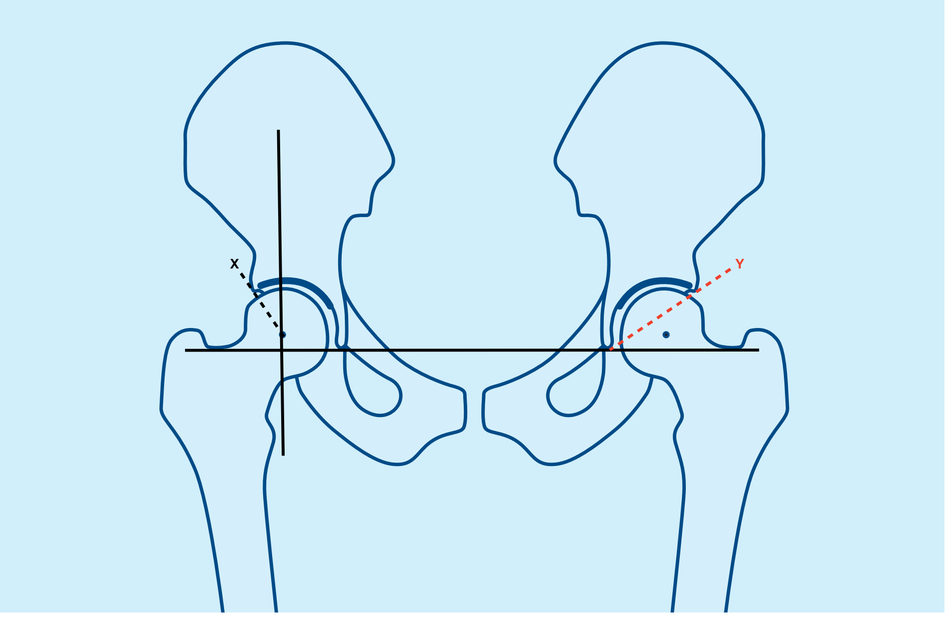

Figure 12. An adult pelvis illustrating the centre edge angle (dotted black line "X") and Sharp's angle (dotted red line "Y").

STUDY I

The surgical method was presented and the use of the bioabsorbable 4.5mm PLGA screws is described. Special attention was paid to the insertion sites available. In the study group all postoperative radiographs within 180 days were evaluated with the preoperative radiograph as a baseline image. The 180 days limit was decided based on the expected time for sufficient healing to evaluate short-term radiographic outcome. The initial interpretation and measurements, by a senior orthopedic surgeon, were followed by a second evaluation of six patients to evaluate inter-observer reliability. At a separate occasion all images were also visually interpreted to evaluate callus formation and healing. Hospital charts were reviewed for length of hospital stay, time for surgery and postoperative complications.

STATISTICAL METHODS STUDY I

In study I the ICC was calculated for numerical data using one-way, absolute agreement average measures. An ICC above 0.8 was considered excellent [135].

STUDY II

Study II evaluated MRIs performed postoperatively after either a SO or a TPO. The MRIs were interpreted independently by two senior radiologists (using AGFA Enterprise Imaging Xero Viewer AGFA Health care, version 8.1.3, Mortsel, Belgium). One of the radiologists made a second interpretation one month later to enable inter- and intraobserver reliability.

Table 2. Time intervals for postoperative MRI, study III.

Patient ID	1	2	3	4	5	6	7	8	9	10	11	12
Postop MR 1 (Years)	1.7	1.5	1.5	2.6	2.3	2.2	1.7	1.6	1.4	0.5	3.2	1.5
Postop MR 2 (Years)	3.6	3.6			3.6		4.2	4.5				2.8

The time intervals between postoperative MRIs were decided based on clinical relevance for the patient and not primarily for the purpose of this study (table 2). As such the intervals are not entirely consistent and two different MRI devices were used (3T and 1.5T). Since there are no standardized methods to interpret implant bioabsorption on MRIs we utilized parameters based on expected potential local reactions as predicted by earlier studies [115, 126].

Two parameters evaluated the integrity of the PLGA screws and the tissue in the screw canal while the other parameters looked for local reactions to the bioabsorption.

The parameters examined were:

- Tissue in the screw canals >90%? (Fluid/ Mix/ Solid bone)
- Full visualization of the screw integrity? (Yes/no)
- Other MRI signal in the bone, adjacent to the screw canals? (Yes/no)
- Intraosseous cysts adjacent to the screw canals (Yes/no)
- Metal particle artefacts in relation to the screw canals (Yes/no)
- Edema adjacent to the screw insertion site (Yes/no)
- Ectopic bone formation (Yes/no)

As can be seen the tissue in the screw canal was interpreted using three categories while all other variables had binary categories. The outcome refers to all screws/screw canals in a patient.

STATISTICAL METHODS STUDY II

Cohen's kappa was used to calculate both inter- and intraobserver reliability for the categorical variables (136). The cut-off values chosen were 0.41–0.60 for moderate agreement, 0.61–0.80 for substantial agreement, and 0.81–0.99 for near perfect agreement. These intervals are in line with generally accepted terminology (137) but, just as with ICC, multiple factors influence the reliability of any calculation for Cohen's kappa.

STUDY III

A case series was presented to evaluate the stability of the osteotomies using 4.5mm PLGA screws for the iliac osteotomy (figure 13). A surgical method of using bioabsorbable implants was also suggested. The preoperative radiograph (or arthrogram in some cases) served as the baseline. Postoperative radiographs were evaluated within the first days after surgery, after 6-8 weeks and at expected healing of the iliac osteotomy (minimum of 20 weeks). The radiographic parameters presented above were measured along with the degree of bony healing of the iliac osteotomy; 1. No signs of callus, 2. Callus formation, 3. Healed osteotomy as defined by a continuous lateral cortex. The healing or pseudoarthrosis of the rami osteotomies were interpreted as a binary variable. All radiographs were evaluated by two independent observers and six of the patients were re-evaluated after two weeks, with the observers blinded to earlier results. Hospital charts were reviewed for length of hospital stay, time for surgery and postoperative complications.

STATISTICAL METHODS STUDY III

In this paper both categorical and numerical measurements were used and evaluated for reliability. For the categorical values Cohen's Kappa was utilized and, as in study II, values above 0.80 was considered strong agreement and thus satisfactory. For the continuous numerical values two-way absolute agreement average measures were used to calculate ICC. An ICC above 0.8 was considered excellent.

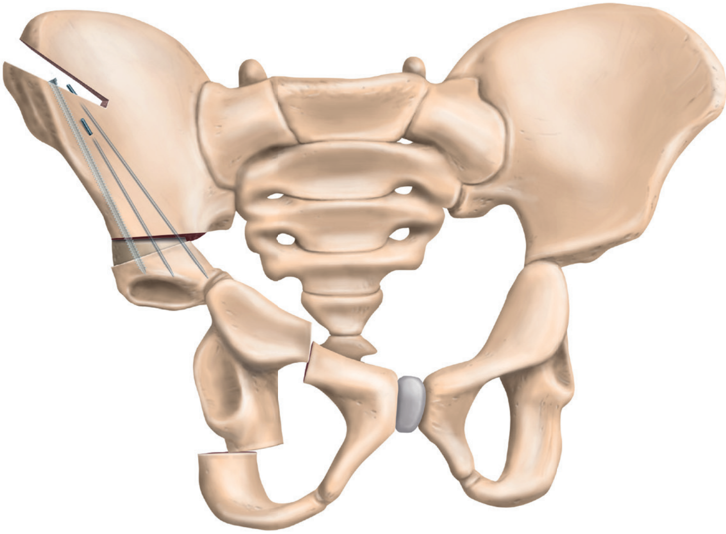

Figure 13. A triple osteotomy, as performed in study III. The two K-wires are replaced by PLGA screws.

STUDY IV

The virtual osteotomy and the choice of implant configurations was made jointly by the authors. The aim was to create a virtual model of a TPO according to Carlioz, to study the post-operative stability using different implant placement configurations.

An FE model was created from an average hemi-pelvis geometry (138) using Abaqus 2020. HF3 (Dassault systemes, Vélizy-Villacoublay, France). The pelvis model was oriented in a standing anatomical position as has been established and standardized for similar methods (139) to illustrate and define the applied loading directions. A virtual osteotomy was performed by splitting the model superior to the acetabulum and across the ischial and pubic bones. A standardized graft was harvested from the iliac wing and placed in the osteotomy after re-aligning the acetabular fragment using a standardized correction.

The ilium was constrained in all degrees of freedom at the SI joint while the loading was applied to the lunate surface of the acetabulum via the femoral head center. The load was defined as a unit displacement (1 mm) or a unit rotation (1 degree) since only relative stability was of interest. In total, five different implant configurations where analyzed (figure 14).

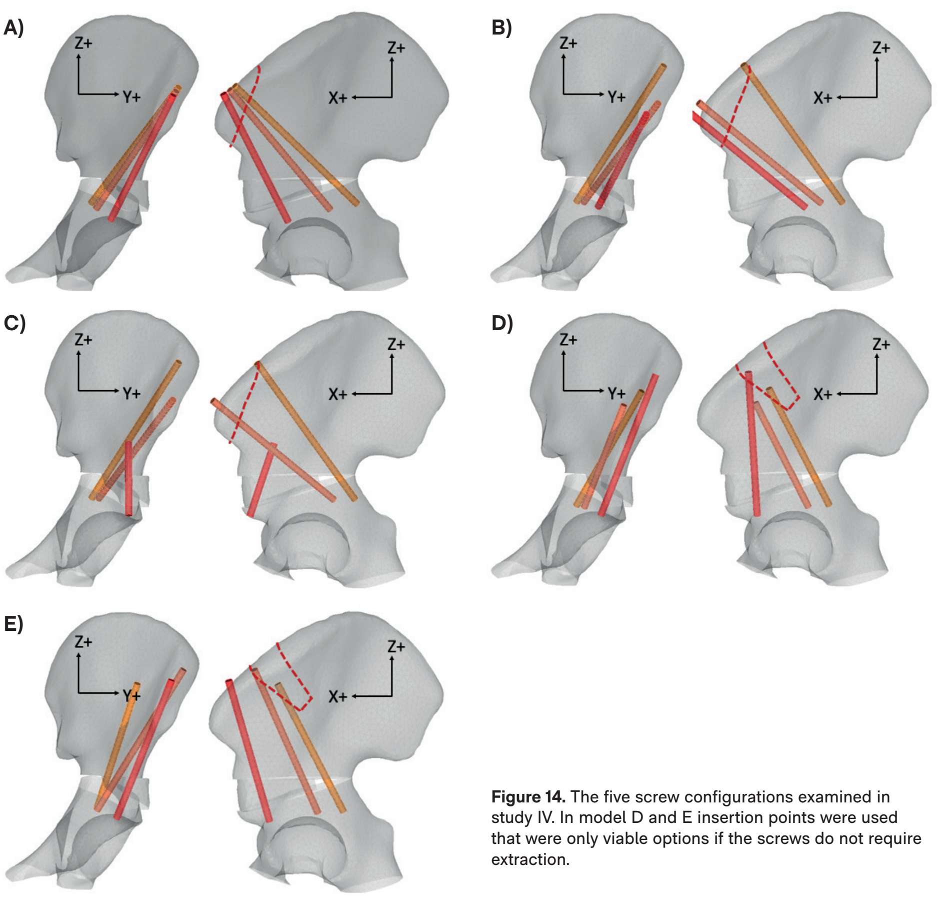

Figure 14. The five screw configurations examined in study IV. In model D and E insertion points were used that were only viable options if the screws do not require extraction.

FE ANALYSIS STUDY IV

The FE modelling and calculations were performed by co-authors JI and EB from Chalmers University of Technology. The virtual osteotomy was evaluated in terms of flexibility (displacement for a given load), where low flexibility corresponds to greater stability. For each implant configuration the computed flexibility metric was normalized by the average value for the respective load case to show relative measures in a comparable scale.

4. ETHICAL CONSIDERATIONS

STUDY I
Approved by the Swedish Ethical Review Committee (Dnr 836-15).

STUDY II
Approved by the Swedish Ethical Review Committee (Dnr 836-15/2019-05868).

STUDY III
Approved by the Swedish Ethical Review Committee (Dnr 836-15/2020-02872).

STUDY IV
Approved by the Swedish Ethical Review Committee (Dnr 836-15/2020-02872).

GENERAL CONSIDERATIONS

The use of implants for a novel indication is always associated with valid concerns regarding implant safety and biocompatibility. The use of 85L/15G PLGA 4.5mm screws for SO and TPO has not been published previously but implants made of the same polymer have been used for numerous indications in both children (120) and adults (117) . A different, but related, polymer, PLLA, has also been studied in other pelvic osteotomies in adults (99, 102). PLLA screws, with a stiffness comparable to the PLGA screws, have been shown to create sufficient stability in a Tönnis type TPO (106).

5. SUMMARY OF RESULTS

STUDY I

All patients had a stable osteotomy without signs of implant failure except one patient, who fell on his hip the first postoperative day (patient 3). The mean correction achieved in AI, from the preoperative to the last postoperative radiograph, was -14.2° and -9.5° for the DDH and LCPD group respectively. CE-angle had a mean correction of 14.2° in the DDH group and 10.5° in the LCPD group. For MP the mean change was -15.6 and -7.8% in the two groups. The intraobserver reliability was excellent (ICC >0.95) for all three parameters.

STUDY II

All screw canals were replaced with >90% bone within 4.5 years in all cases but one, which exhibited a mixed signal of bone and fluid. No signs of significant soft tissue reactions like sinus formation, fluid deposits or ectopic bone formation could be noted. A few minor bone cysts were observed and metal artifacts from drilling were common.

Using Cohen's Kappa Inter- and intraobserver reliability was near perfect for the integrity of the screw, bone cysts and ectopic bone formation (>0.8). The tissue in the screw canal and edema adjacent to the screw insertion sit also had excellent intraobserver reliability (>0.8) and inter-observer reliability was slightly poorer but still with substantial agreement. (0.74, 0.64). The "other MRI signals in the bone adjacent to the screw canals" parameter, and metal artifacts both showed poor agreement.

STUDY III

All patients had series of postoperative radiographs that signified stable correction. As expected, there were minor inconsistencies and fluctuations in measurements, but no case had a consistent loss of correction over multiple parameters. The mean (SD) correction (from preoperative to last postoperative) was -16.7° (5.2) for SA, -20.9° (6.0) for AI and 24.7° (17.0) for CE. All iliac osteotomies had healed at the last control.

The intraobserver reliability was >0.9 for all numerical values. The inter-observer reliability (ICC) was >0.9 for both SA and MP while the OA and CE angle had an ICC 0.77 and 0.74 respectively. The AI exhibited less interobserver reliability with an ICC of 0.61. For the healing evaluation Cohen's Kappa was >0.8 for both intra- and interobserver reliability.

STUDY IV

In the clinically most relevant directions X-, Y- and Z+ the C, D and E configurations of screws provided the least flexibility (i.e most stability). Configuration C, with a retrograde screw placed from the acetabular fragment, had overall better stability than A and B, that only utilized entry points close to the anterior superior iliac spine. Configuration E, that took full advantage of all possible entry points, had overall the most consistent stability (table 3).

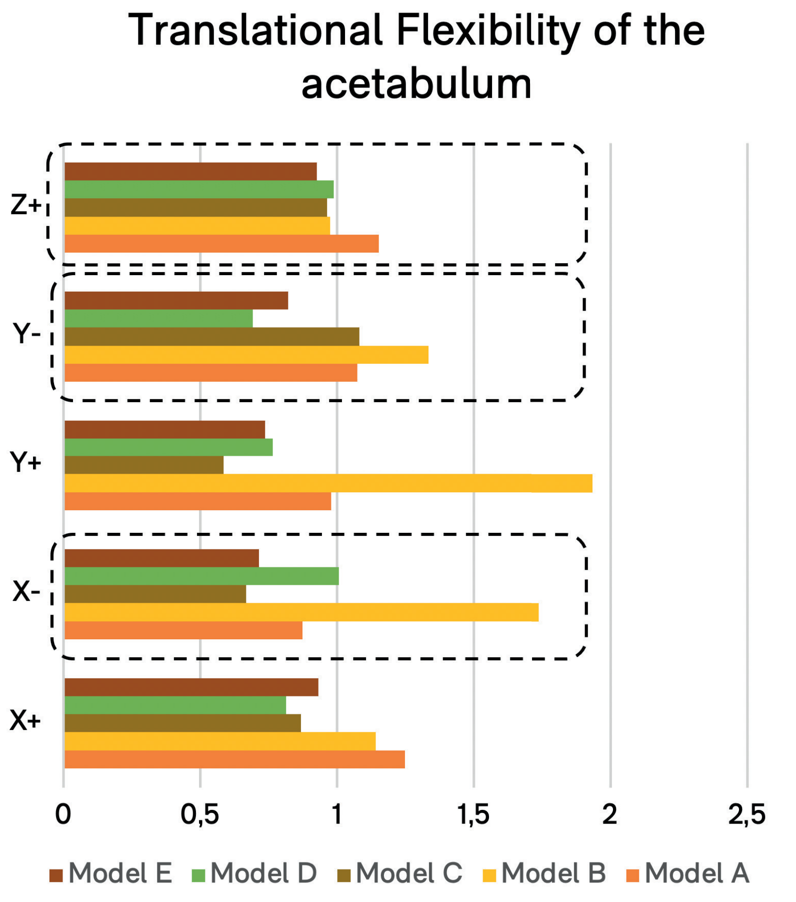

Table 3. The flexibility for translational loads, normalized to the average flexibility, for each direction. Lower bars thus represent greater stability for the respective direction.

6. DISCUSSION

Two of the studies in this thesis present and evaluate the surgical technique using bioabsorbable implants for a SO and TPO respectively. The surgical method for the PLGA screws used in study I and III is not technically demanding for an experienced orthopedic surgeon. The same basic procedure is used for any cannulated screw with some aspects unique for this implant; a) The screw itself is not radiolucent and the position of the K-wire before drilling must be used to verify the implant position with fluoroscopy (figure 15-16) b) The screw must not be overly tightened to avoid breakage and c) The screw head should be cauterized flush to the bone surface. The added time for using bioabsorbable screws, as compared to metal implants, is estimated to be 10-15 minutes. Bioabsorbable screws are more expensive than metal implants but, as presented in study I, the total costs are decreased since a second surgery is no longer necessary. The choice of using the more posterior graft harvest site has been proposed by some surgeons before [53]. With the use of bioabsorbable screws this harvest site has new benefits in enabling more entry points for the surgeon to choose from (figure 16).

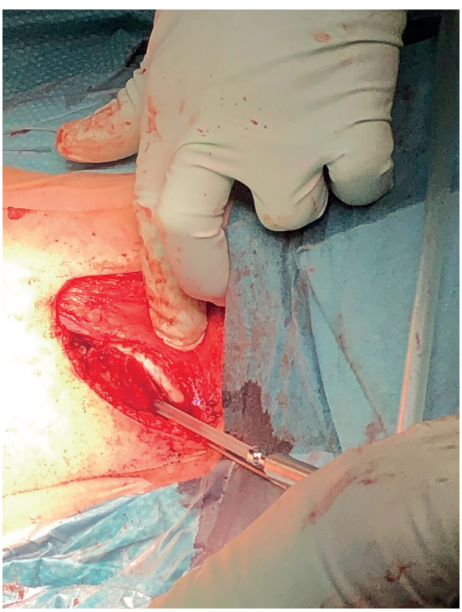

Figure 15. A perioperative photograph of a Salter osteotomy. Two guidewires have been temporarily placed and a cannulated 4.5mm PLGA screw is being inserted over one of the wires after drilling and tapping.

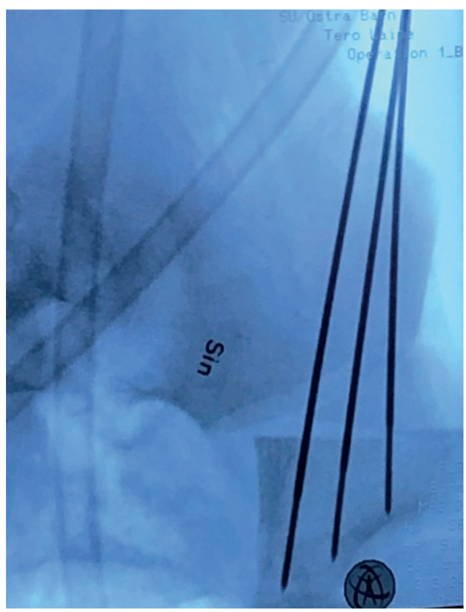

Figure 16. Perioperative flouroscopy of a Salter osteotomy using three guidewires to identify the correct positions before insertion of the PLGA screws. Two of the guidewires are inserted from the graft site and one from the anterio-medial aspect of the ilium.

The two case series, following children after a SO and TPO respectively did not show any signs of instability of the osteotomies, with the exception of the child who fell from the bed. Clinical complications, like wound infections, were rare and well-known K-wire related complications, like migration, were not an issue. The most obvious advantage of the implants was, of course, that a second surgery for implant removal could be avoided.

A few studies present favorable outcomes after using thin resorbable (PLLA) pins to stabilize SOs (103, 104, 140). As opposed to screws, pins have no pull-out strength and may still be prone to migration. Regardless of which bioabsorbable material is used screws likely present a more viable choice of implant than pins for pelvic osteotomies.

Since the introduction of resorbable implants two factors have been the main focal points for discussion, and critique; The absorption pattern and the strength of the implant. In study II we re-visit the absorption pattern from the specific perspective of 85L/15G 4.5mm PLGA screws in a pediatric pelvis. Our results do confirm that the screws, over the course of a few years are resorbed and replaced by bone, or at least mostly bone. The local reactions seen in PLLA implants in adults (141) were not seen in this case series. The minor reactions, like small bone cysts, noted on MRI are expected for any bioabsorption process and could potentially also be seen in relation to metal implants though this is difficult to evaluate using MRI.

Regarding radiographic interpretation, the poor ICC of AI reflects the difficulty in correctly finding the anatomical landmarks associated with the tri-radiate cartilage after a major pelvic osteotomy in patients > 6 years of age. Postoperative radiographs in young children in pain and possibly cast immobilization are also technically challenging to obtain. The SA and MP on the other hand, proved reliable and could probably provide more consistent measurements, especially if multiple observers are involved. On the note of statistical interpretation of ICC it can be noted that in contemporary papers references are frequently made to motivate certain cut-off values for words like ”good”, ”fair” or ”excellent”. These words are, to a degree, arbitrary and in-depth papers on reproducibility point out that any given value for ICC is affected by multiple factors and a certain value will not necessarily represent the same reproducibility in different settings (142). Hence the chosen cut-off values used in this thesis are based on commonly used definitions but are not universally accepted.

As expected, and shown in study IV, screw placement configuration in a TPO has biomechanical consequences for stability. On the other hand so do the shape of the osteotomies, and the material used in the implants obviously impact the strength of the fixation. It is interesting to note that, even in a TPO, the implants do not take the full load to stabilize the osteotomy but rather stabilize the graft to allow the bone-to-bone pillar to carry the load (106). It is, of course, still desirable to optimize the screw configuration per-operatively but adhering to well-known principles like making sure the cortex of the graft is in line with the cortical edge of the ilium may be even more important. Future studies will hopefully clarify which factors have the most effect on stability.

Most biomechanical studies on pelvic osteotomies have been performed on cadavers or plastic models (106, 143). These trials have provided useful information but require multiple, resource demanding, simulations and are by necessity limited in what they can measure. FE analysis allows for virtual simulation of any configuration and can also include variables taking soft tissue, like ligaments, into consideration. Based on MRI models FE has, in this manner, been used to evaluate the articular contact pressure in infant hips during Pavlik harness treatment (144). It is also possible to perform FE simulations on a patient specific CT-based 3D model enabling the surgeon to make decisions on an individual basis. This has been demonstrated on customized prosthesis reconstruction (145) but the principle can also be applied on dysplastic pediatric hips.

7. LIMITATIONS

Study I, II and III are all retrospective studies and the study group size was also an obvious limitation. The retrospective nature resulted in the radiological data not being completely uniform in regard to timing and methodology. The preoperative radiograph was, for example, occasionally an arthrogram or a CT scout.

In study I and III the radiological parameters used to evaluate the stability of the osteotomy suffer from inconsistent application in contemporary science and ICCs have been reported as modest or even poor [146, 147].

Study II used MRI protocols not designed for evaluation of implant degradation and this limits detailed interpretation. It should also be noted that the results regarding implants being replaced with bone may only be valid in the pelvis of children and not in other anatomical locations or in adults.

Study IV was a virtual simulation and results should be validated through future clinical trials. Furthermore, the simulation was based on the load required for a 1mm displacement in any given direction. This method has both strengths and weaknesses. The implants used in the model were given mechanical traits to simulate 4.5mm PLGA screws and the results only apply to the variables used in the simulation. The relative stiffness is expected to be consistent between implant configurations even for other implant materials, but this is an assumption. The properties of the adult hip joint used for the simulation may, in theory, differ from that of a pediatric dysplastic hip.

8. CONCLUSIONS

OVERALL CONCLUSIONS

The use of 4.5mm 85L/15G PLGA screws appeared to stabilize the iliac osteotomy in both SO and TPO to a satisfactory degree until bony healing had occurred. The bioabsorption process of PLGA implants, in the pelvis of children, had few local side effects.

STUDY I

A SO can successfully be stabilized using 4.5mm 85L/15G PLGA screws. In this case series the osteotomy remained stable until healing with one exception and there were no local reactions to the implants. The use of bioabsorbable implants barely increase surgical time and there is no need for a second surgery for implant removal.

STUDY II

Within 4.5 years after a pelvic osteotomy 4.5mm 85L/15G PLGA screws were bioabsorbed and >90% replaced by bone in a pediatric pelvis. There were no significant local reactions to the degradation process as seen on MRI.

STUDY III

Stabilizing the iliac osteotomy of a TPO with 2-3 PLGA screws provided sufficient stability for the osteotomy. The PLGA screws were well tolerated with no sign of local reactions to the screw resorption process.

STUDY IV

According to the presented FE analysis of a virtual TPO, model implant configuration affected the stability of the osteotomy; A greater spread of implants in the osteotomy plane along with a more perpendicular angle to the osteotomy improved stability. Using entry points without taking later implant removal into consideration enabled superior implant configurations.

CLINICAL IMPACT

The results in this thesis support the continued use of 4.5mm PLGA screws for osteotomy fixation in SO and TPO. The option to avoid a second surgery for implants removal decreases suffering for children and the load on the health care system. PLGA screws, and potentially other future bioabsorbable implants, may enable the surgeon to optimize implant configuration for stability rather than for later extraction.

9. FUTURE PERSPECTIVES

The surgical procedures examined in this thesis are used to treat severe cases of DDH and LCPD. Future research will likely deepen our understanding of the pathogenesis of these conditions and likely open up new non-surgical or preventive treatment strategies. The role for bisphosphonates in LCPD is still to be established and future pharmacological treatment may be able to target other aspects of bone resorption and formation (148). Whether non-weight bearing is beneficial in LCPD has been a source of discourse for decades and more solid scientific evidence would provide needed therapeutic guidance.

As for surgical treatment there are today many gaps in knowledge regarding both indications, methods and timing. The plethora of surgical techniques available for pelvic osteotomies is likely due to the fact that few centers have the required number of patients to undertake long-term comparative prospective studies. Another factor is the "in my hands" bias of surgeons where whatever procedure they are most accustomed to appears more attractive and successful. If possible, prospective multi-center studies comparing different surgical regimens could likely clarify indications for both surgical technique, method of fixation and postoperative immobilization.

Regarding method of fixation and choice of implant the future is bound to be dynamic. The research and development of new biodegradable materials continue at a high and accelerating rate. The use of biodegradable screws and pins is likely to expand, especially in the field of pediatric orthopedics where removal of implants is otherwise the norm. Magnesium based bioabsorbable implants have in addition to the implants discussed in this thesis so far showed promising results (127).

Finite Element analysis is a method that allows researchers to virtually simulate loads and stress in an anatomical model. More aspects of orthopedics will most probably be explored with this tool in the future. Regarding pediatric hip conditions, further studies on how the 3D dynamic anatomy and loads on the hip joint are affected by different pelvic osteotomies could assist in the decision of which surgical method to resort to in a given patient. As these methods become more accessible FE analysis can be performed on patient-specific 3D CT- or MRI models.

Historically plain radiographs have been the main diagnostic and preoperative tool. In the future virtual modeling, along with 3D printed models, will make preoperative planning much more three-dimensionally detailed than what a two-dimensional image ever could. 3D printed models also allow for mock-surgery on the model and testing out of custom-made implants and drill guides.

Most of our diagnostic criteria for DDH or LCPD are based on radiographic parameters like the CE-angle, AI, MP, SA and Tönnis' angle. While these parameters are still valid and helpful tools, they have mediocre ICC and inconsistent application in contemporary literature. In the future diagnosis and grading classifications of femoral head containment disorders like DDH and LCPD will need to use 3D coverage classifications from CT, MRI or other imaging modalities. Regarding the evaluation of movement in osteotomies and prosthesis in the hip region radiostereometric analysis (RSA) using tantalum beads has been the gold standard [149]. Although RSA has been used in children [150] the insertion of tantalum beads along with specialized equipment needed for RSA radiographs makes for a fairly complicated process. In recent years the use of CT-based motion analysis (CTMA), without any tantalum beads, has proven to be as accurate as RSA [151]. The studies presented in this thesis evaluated if the osteotomies showed signs of collapse/implant failure as seen on radiographs. Techniques like CTMA could, in the future, be used to analyze micro-movements as well.

The most important variable for any treatment is, of course, not radiographic outcome but rather the short and long-term effects for the patient. Sufficiently large multi-center studies may be able to include both validated clinical outcome measures and patient reported outcome measures in the future.

10. ACKNOWLEDGEMENT

I would like to thank the University of Gothenburg and the Institute of Clinical Sciences for supporting my thesis and the orthopedic department at Sahlgrenska University hospital for enabling my research ambitions.

This dissertation would not have been possible without my main supervisor, Tero Laine, who provided inspiration as well as advice on many matters. His skill in the field of pelvic orthopedic surgery and understanding of three-dimensional anatomy has taught me many things.

Hanna Hebelka and Professor Helena Brisby, my co-supervisors, were invaluable. Thank you for providing both support and advice throughout these years. I could not have done this without you.

Kerstin Lagerstrand, not formally responsible but always there, thank you for great feedback and mental sparring. Your genuinely curious mind is inspiring.

I would like to extent my gratitude to my colleagues and co-authors Per Larnert and Pavel Antonsson who make every day work even more interesting.

Mikael Sansone, an old friend, and a colleague, deserves acknowledgement as a mental haven for discussing anything research related.

Professor Jon Karlsson, thank you for helping me out with my first steps in medical research many years ago. You were, and are, always friendly, helpful, and resourceful.

Charlotte Stor Swinkels- thank you for our smooth cooperation during our joint ventures and regarding many minor matters since.

Yvonne Simrén provided valuable and competent assistance with MRI interpretation in study II.

Jens Rydell, my mentor for research in the field of biology, deserves acknowledgement. His scientific and curious mind inspired me and many others in a critical and inquisitive way of thinking. Sadly, he passed away in 2021.

Cina Holmer, thank you for always helping PhD students like me with innumerable inquiries.

I would like to thank Göteborgs Läkarsällskap for financial support throughout the research process (GLS-960069 and GLS-934779) including grants from Vera and Hans Albrechtssons foundation.

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