NIKKE PARTIO

Trends in Foot and Ankle Surgery

Hardware Removal and the Use of Bioabsorbable Implants
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Hardware Removal and the Use of Bioabsorbable Implants

ACADEMIC DISSERTATION
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TIIVISTELMÄ

Tämän väitöskirjan tavoitteena oli selvittää vaivaisenluun leikkausmäärit ja mahdolliset muutokset edellisten vuosien aikana, tutkia metallisten implanttien poistomääriä nilkkamurtumaleikkauksen jälkeen sekä arvioida biomekaanisten testauksien avulla biomateriaaleja, jotka soveltuisivat jalkateräkirurgiaan.

Tutkimuksen yhtenä tärkeimmistä löydyksistä oli, että vaivaisenluuleikkausin ilmaantuvuus vähensi merkittävästi 1997-2014 välisenä aikana. Samaan aikaan isovarpan tyvinivelen ja ensimmäisen jalkapöytänivelen luudutusleikkaukset kasvattivat suosioaan ja ensimmäisen jalkapöytäluun osteotomia leikkaus pysyi suosituimpana toimenpiteenä.

Toiseksi todettiin, että metalli-implanttien poistomääri oli jopa 27% nilkkamurtumaleikkausen jälkeen. Huomionarvoista oli myös havaita ensimmäisen kerran, että poistomäärit olivat merkittäviä myös 3-vuoden jälkeen leikkausen. Metalli-implanttien poistoleikkaukset aiheuttivat merkittävää kustannusta yhteiskunnalle.

Kliinisessä seurantatutkimuksessa todettiin, että biohajoavalla piennivelimplanttilla saavutettiin hyviä pitkäaikaisia tuloksia niveliikkoisessa vaivaisenluu tai jäykäisovarvas leikkauksissa. Tosin seurantatutkimuksen potilasmäärä oli vähäinen, mutta tutkimuksessa selkeästi nähtiin suurella osalla potilaista merkittävää hyötyä kahdella eri potilasmittarilla.

Lisäksi väitöskirjassa todettiin kahdessa kokeellisessa työssä, että biohajoava ruuvi voi mahdollisesti toimia yhtä hyvin isovarpan tyvinivelen ja ensimmäisen jalkapöytänivelen luudutusleikkauksissa. Tutkimuksilla haluttiin varmistaa, että on turvallista aloittaa klininen tutkimuskokonaisuus, jolla osaa voidaan todella todentaa.

Tässä väitöskirjassa on kuvattu erilaisia kirurgisia menetelmiä isovarpaan tyvinivel- ja ensimmäisen jalkapöytänivelen luudutusleikkauksissa. Ensimmäisessä osatyössä todettiinkin juuri näiden leikkaustekniikoiksen kasvattaneen viimeaikana suosiota. Väitöskirjassa selvitettiin, että nykyisin käytettyihin implanttimateriaaleihin liittyvyyttä sekä niiden poisto-operaatioiden määrä on merkittävä myös taloudellisesti yhteiskunnalle. Vaikka nämä biohajoavat implanttimateriaalit ovat vielä kehityksen alaisia ja tarvitsevat vielä lisätutkimusta, on mahdollista, että ne voisivat korvata osittain nykyiset implanttimateriaalit.
ABSTRACT

In Finland, first ray surgical indications and techniques have varied over time. Because foot surgery is still a relatively new and narrow subspecialty within orthopedic surgery, there is very little systematic follow up or knowledge in foot surgery. The aim of this dissertation was to establish the number of first ray surgeries performed in recent years and to find out whether there have been any changes in surgical procedures during this time. A further aim is to ascertain the removal rate for metallic implants after ankle fracture surgery.

Bioabsorbable materials first came into use in the 1980s and became a keen focus of research thereafter. One part of this dissertation deals with bioabsorbable materials in foot and ankle surgery. In this part of the study, the long-term results of a bioabsorbable interpositional implant were investigated and bioabsorbable screws were compared with titanium alloy screws in two biomechanical specimens.

Two of the main findings of the study were that the incidence of HV surgery reduced significantly between 1997 and 2014 and that the rate of implant removal was as high as 27% after ankle fracture surgery. A clinical follow-up study found that the bioabsorbable interpositional implant achieved good long-term results in MTP-1 surgery. Furthermore, in this dissertation, it is demonstrated that a bioabsorbable screw may work equally well in TMT-1 and MTP-1 arthrodesis, although a clinical study is still required to verify this finding.

This dissertation describes a surgical technique in TMT-1 and MTP-1 surgeries that could lead to the future replacement of titanium alloy and steel implants. In the first part of the study, it was found that these surgical techniques have recently gained popularity. The finding of this dissertation demonstrate that the implant materials currently in use have drawbacks, such as stress-shielding and associated soft tissue irritation in addition to the significant economic cost to society of the large number of hardware removal operations. These bioabsorbable implant materials are, of course, still under development and still require more development and further research before they are ready to completely replace existing implant materials.
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AHT</td>
<td>Abductor hallucis tendon</td>
</tr>
<tr>
<td>AO</td>
<td>Arbeitsgemeinschaft für Osteosynthesefragen</td>
</tr>
<tr>
<td>AOFAS</td>
<td>The American Orthopaedic Foot &amp; Ankle Society</td>
</tr>
<tr>
<td>CLS</td>
<td>Cannulated lag screw</td>
</tr>
<tr>
<td>DRG</td>
<td>Diagnosis-related group</td>
</tr>
<tr>
<td>EHB</td>
<td>Extensor hallucis brevis</td>
</tr>
<tr>
<td>EHL</td>
<td>Extensor hallux longus</td>
</tr>
<tr>
<td>FHB</td>
<td>Flexor hallux brevis</td>
</tr>
<tr>
<td>FHL</td>
<td>Flexor hallux longus</td>
</tr>
<tr>
<td>NHDR</td>
<td>Finnish National Hospital Discharge Register</td>
</tr>
<tr>
<td>HV</td>
<td>Hallux valgus</td>
</tr>
<tr>
<td>HR</td>
<td>Hallux rigidus</td>
</tr>
<tr>
<td>IFCS</td>
<td>Interfragmentary compression screw</td>
</tr>
<tr>
<td>IMA</td>
<td>Intermetatarsal angle</td>
</tr>
<tr>
<td>IP</td>
<td>Interphalangeal</td>
</tr>
<tr>
<td>MT</td>
<td>Metatarsal</td>
</tr>
<tr>
<td>MA</td>
<td>Metatarsus adductus</td>
</tr>
<tr>
<td>MTP</td>
<td>Metatarsophalangeal</td>
</tr>
<tr>
<td>NOMESCO</td>
<td>Nordic Medico-Statistical Committee</td>
</tr>
<tr>
<td>NCSP</td>
<td>NOMESCO Classification of Surgical Procedures</td>
</tr>
<tr>
<td>NCSP-F</td>
<td>NCSP - A Finnish translation</td>
</tr>
<tr>
<td>ORIF</td>
<td>Open reduction and internal fixation</td>
</tr>
<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
</tr>
<tr>
<td>PROM</td>
<td>Patient-reported outcome measurement</td>
</tr>
<tr>
<td>PDS</td>
<td>Polydioxanone</td>
</tr>
<tr>
<td>PGA</td>
<td>Polylgcolide</td>
</tr>
<tr>
<td>PLA</td>
<td>Polylactide</td>
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<tr>
<td>PLLA</td>
<td>Poly-L-lactic acid</td>
</tr>
<tr>
<td>PLDLA</td>
<td>Poly-L-D-lactic acid</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>ROM</td>
<td>Range of movement</td>
</tr>
<tr>
<td>TMT</td>
<td>Tarsometatarsal</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual analogue scale</td>
</tr>
</tbody>
</table>
This dissertation is based on the following original publications, which are referred to in the text by the Roman numerals I-IV:

I

II

III

IV

V
Partio N, Mattila VM, Mäenpää H. Comparison of “cup and cone” and straight cut techniques using bioabsorbable and titanium screws in first metatarsophalangeal joint arthrodesis: an in vitro study. Submitted
1 INTRODUCTION

First ray disorders of the foot are still poorly understood, and the treatment of these disorders is controversial. The most common disorder of the first ray is hallux valgus (HV). In western countries, it is estimated that the occurrence of HV in the general population varies between 23% and 36% (Benvenuti et al., 1995; Nix et al., 2010). Although a genetic predisposition has been identified, the etiology and pathogenesis of HV still remain unclear, and the disorder is thought to be multifactorial (Coughlin & Jones, 2007; Perera et al., 2011). Hallux rigidus (HR) and hallux varus are also first ray disorders, although there are differences in the etiology and pathogenesis between HR and hallux varus and HV. Surgical interventions are, however, quite similar for all first ray disorders. Although more than 100 different surgical techniques for the operative treatment of first ray disorders have been described, there is still no consensus on the optimal technique or timing of the operation (Easley & Trnka, 2007; Robinson & Limbers, 2005).

All surgery is related to the risk for complications, and HV surgery is no exception. Several described complications after first ray surgery exist, and it seems that the complications associated with surgical procedures are mainly related to the implant material, such as screws and plates, or iatrogenic complications. Due to problems with titanium alloy and steel hardware, hardware removal procedures are common. Moreover, stress-shielding is still a relatively unknown problem after titanium alloy or steel fixations, especially when the fixation is done between trabecular bone fragments. Bioabsorbable fixation materials have been suggested to be a solution for hardware problems.

This dissertation covers different aspects of foot surgery with the aim of identifying the problems associated with different implant materials and determining surgery trends in foot and ankle disorders.
2 REVIEW OF THE LITERATURE

2.1 First metatarsophalangeal joint disorders

2.1.1 Hallux Valgus

According to Kellikian, the term *hallux valgus* (HV) was first introduced by Carl Hueter in 1871 to define a static subluxation of the first metatarsophalangeal (MTP-1) joint characterized by lateral deviation of the great toe and medial deviation of the first metatarsal (Kellikian, 1965). It has been estimated that one third of the population in western countries suffer from a HV deformity (Coughlin, 1996; Nix et al., 2010). Although a genetic predisposition has been identified, the pathoanatomy and pathophysiology of HV still remain unclear and are thought to be multifactorial (Coughlin & Jones, 2007; Perera et al., 2011).

2.1.1.1 Pathoanatomy and Pathophysiology

The valgus deviation of the phalanx derives the varus position of the first metatarsal and, as a result, becomes destabilized and begins to subluxate medially. Once the metatarsal head displaces medially from the sesamoids, the sesamoid complex is left laterally translated relative to the metatarsal head. Finally, the sesamoids crista on the plantar surface, which normally acts to stabilize the sesamoids, is gradually flattened due to pressure from the tibial sesamoid. With this loss of stabilization, the fibular sesamoids displace laterally into the first intermetatarsal space. This lateral displacement can lead to transfer metatarsalgia due to a shift in weight bearing and the medial MTP joint capsule becoming stretched. Thereafter, the lateral capsule becomes contracted and the adductor hallucis, which is unopposed by the abductor hallucis, pulls the great toe further into valgus. In addition, the flexor hallucis brevis, flexor hallucis longus, and extensor hallucis longus increase the valgus deformity (Figure 1).
The most stable MTP-1 articulation has a flatter articular surface. Conversely, the most unstable MTP-1 articulation has a “cup to cone” surface. Likewise, a congruent MTP-1 joint is more stable than an incongruent or subluxated joint. The pathophysiology of a HV deformity varies, depending on the nature of the deformity. With an early phase HV deformity, the MTP-1 joint remains congruent, and the deformity
consists of a prominent medial bunion that can cause pressure against the shoe and result in a painful bursa or cutaneous nerve over the prominence. With incongruent or subluxated HV deformity, there is usually a progressive deformity.

While this deformity is occurring, the sesamoid sling, which is anchored laterally by insertion of the adductor hallucis muscle and the transverse metatarsal ligament, remains in place as the metatarsal head moves medially, and thereby creates pressure on the medial joint capsule. The weakest portion of the medial capsule lies just above the abductor hallucis tendon, and with chronic pressure this portion of the capsule gives way. As a result, the abductor hallucis muscle gradually slides beneath the medially deviating metatarsal head. As this process slowly progresses, atrophy of the crista occurs beneath the first metatarsal head, which normally helps stabilize the sesamoids. Thus, the intrinsic muscles no longer contribute to the stabilization of the MTP-1 joint but actually help enhance the deformity. Furthermore, the abductor hallucis rotates beneath the metatarsal head and, because it is connected to the proximal phalanx, it spins the proximal phalanx around on its long axis and gives rise to varying degrees of pronation. Ultimately, as the MTP-1 joint becomes less stable, the hallux carries less weight, body weight is transferred laterally in the forefoot, and callus may develop beneath the second, third, or both metatarsal heads.

With severe HV deformities, the extensor halluc longus (EHL) tendon is displaced laterally as the medial hood ligament and capsule become stretched. As a result, when the EHL contracts, it not only extends the toe but also tends to adduct it, and thus further aggravates the deformity. The abductor hallucis tendon loses its remaining abduction power. The flexor hallucis longus (FHL), which retains its relationship to the sesamoids, moves laterally and also becomes a dynamic deforming force.

### 2.1.1.2 Movement

In the MTP-1 joint, motion is greatest in the sagittal plane, where the range of motion (ROM) is estimated to be from approximately 45 degrees of plantar flexion to almost 90 degrees of dorsiflexion (Buell et al., 1988). The normal dorsiflexion of the MTP-1 joint during gait is at least 65 degrees (Dananberg, 1986). Nawoczenski et al. suggested that the standard for the “normal” range of dorsiflexion of the great toe joint should be set at approximately 45 degrees (Nawoczenski et al., 1999). However, this dorsiflexion range has only been verified for walking gait, not running. Coughlin et al. found that the mean total passive MTP-1 joint ROM was 79 degrees (60 degrees dorsiflexion, 19 degrees plantarflexion) (Coughlin & Jones, 2007). Furthermore, it
has been theorized that some small degree of motion, particularly abduction-adduction in the transverse plane, may occur at the MTP-1 joint during weight bearing and non-weight bearing.

2.1.1.3 Etiology

There is lack of knowledge about the complex etiology of HV. Although many causes of HV in adults have been suggested, there is a scarcity of critical supporting evidence (Table 1) (Coughlin & Jones, 2007). A genetic predisposition has, however, been identified by several authors (Coughlin, 1995; Coughlin & Shurnas, 2003; Perera et al., 2011).

In their study, Coughlin et al. reported 84% (86 of 103) of patients had a positive family history, and a history of a concurrent bunion in the mother was noted in 73% (63 of 86) of patients (Coughlin & Jones, 2007). The same study reported a high incidences of both female involvement and maternal transmission and concluded that there is a genetic predisposition for hallux valgus deformities in the female population (Coughlin & Jones, 2007).

The pes planus is usually associated with the development of HV, but there are still controversial theories about it (Choi et al., 2017). Although numerous studies have observed that HV and pes planus appear to be closely related, other studies have reported that pes planus is no more common in those with HV than in the normal population. Grebing and Coughlin reported no correlation between either the magnitude of the HV deformity and pes planus or pes planus and first ray mobility. Nowadays, the theoretical mechanism between HV and pes planus is quite clear; foot pronation increases loading on the plantar medial of the hallux during heel rise. The pes planus disorder also produces a functional lengthening of the first metatarsal, which can limit MTP-1 joint movement so the peroneus longus is less able to stabilize the first ray. If this insufficiency is prolonged, hypermobility of the first ray can result. In the planovalgus, forefoot eversion and abduction reduce the load on the MTP-1 joint, although weight-bearing through the medial arch increases. This change is due to the relative mobility of the MTP-1 joint compared with the MTP-2 joint and the loss of pull of the peroneus longus. As the hindfoot everts, the foot becomes abducted to the line of progression, increasing the abduction force in dorsiflexion on heel rise. There is early and excessive firing of the abductor and adductor hallucis in the pronated foot. Their line of pull alters as the sesamoids rotate, resulting in an overall valgus moment.
Morton and Lapidus were the first researchers to suggest that first ray hypermobility is associated with foot disorders, such as HV (Lapidus, 1956; Morton, 1928). Recent attempts to quantify first ray mobility have measured motion in terms of either degrees or millimeters of dorsal displacement has been challenging, especially because the first tarsometatarsal (TMT-1) joint has a height to width ratio (Doty et al., 2014; Shibuya et al., 2017). Although hypermobility of the (TMT-1) joint has been implicated in the development of HV deformity, it has not been proven that first ray “hypermobility” is itself a pathologic entity (Shibuya et al., 2017). In 2011, Van Beek and Greisberg suggested that measures of first ray mobility should be defined and applied to large populations to create guidelines for hypermobility. However, there is still a lack of consensus about the guidelines (Van Beek & Greisberg, 2011).

In 1981, Mann and Coughlin reported that a contracted Achilles tendon may be associated with the development of HV, a finding supported by many other studies. However, in recent studies of HV deformities, Achilles tightness is rarely noted (Coughlin & Jones, 2007; DiGiovanni et al., 2002; Mann & Coughlin, 1981; Veri et al., 2001). Grebing and Coughlin reported a series of patients with HV in which 21% had 5 degrees or less of dorsiflexion and 67% had 10 degrees or less of ankle dorsiflexion (Grebing & Coughlin, 2004). Coughlin and Jones reported somewhat similar results, with 12% of patients having 5 degrees or less of ankle dorsiflexion and 67% having 10 degrees or less of ankle dorsiflexion (Coughlin & Jones, 2007). Some studies recommend a gastrocnemius lengthening with HV surgery for patients with a limitation of 5 degrees or more of ankle dorsiflexion. According to these recent studies, however, it is difficult to recommend Achilles tendon lengthening in an asymptomatic patient (Coughlin & Jones, 2007; DiGiovanni et al., 2002; Veri et al., 2001).

Metatarsus adductus (MA) is a congenital transverse plane deformity in which there is adduction of all of the metatarsals, supination of the subtalar joint, and plantarflexion of the first ray (Harley et al., 1995). The incidence of MA in the general population is approximately 0.1%, but it is more common with a positive family history (Wynne-Davies, 1964). MA has been thought to be a risk factor for the development of HV, and previous studies have documented this association (Aiyer et al., 2014; Reimann & Werner, 1975). The incidence of MA in patients with HV has been reported to be 21.6% to 29.5% (Aiyer et al., 2014; Coughlin, 1995). In the presence of MA, HV deformity is characterized by an abnormally low first and second intermetatarsal angle due to medial deviation of both the first and second metatarsals.
The association of a curved metatarsal articular surface with HV is controversial (Mancuso et al., 2003). Many studies have suggested that a curved surface is less stable and could therefore lead to HV deformity (Coughlin, 1996; Coughlin & Shurnas, 2003; Coughlin & Jones, 2007). However, one study did not observe any difference in the shape of the MTP joint when patients with HV or HR were compared (Schweitzer et al., 1999). There is indirect biomechanical evidence that proves a planar shaped articulation is more stable and tends to resist subluxation (Harris et al., 2017).

High heel shoes have been implicated in previous studies to be a factor in the development of HV, but the prevalence of HV in women who wear shoes with a narrow toe-box or a high heel is certainly not 100% (Coughlin, 1997; Kato & Watanabe, 1981). The role of high heel shoes and the mechanism of the development and progression of HV in adults is unknown. However, wearing high-heeled shoes can cause excessive overload of the forefoot and flexion of the toes in the interphalangeal (IP) joints, which stretches the ligaments stabilizing the transverse arch as well as lowering the arch. This overload could lead to a flatter transversely and a more laterally flexed hallux compared to the feet of those wearing low-heeled or flat-soled shoes. There is still quite strong evidence that wearing high heel shoes plays a role in the development and progression of HV deformities.

HV occurs exclusively in shod societies; however, it does occasionally occur in unshod individuals (Maclennan, 1966). A study in the late 1950s by Sim-Fook and Hodgson reported that 33% of 118 shod individuals had some degree of HV compared with an incidence of 2% in 107 unshod individuals (Sim-Fook & Hodgson, 1958).

There is limited evidence that some occupations can cause HV. Only studies from the 1930s have concluded that occupation could be the cause of HV (Greer, 1938). This conclusion is no longer relevant because the work environment has changed a great deal since those days. Coughlin et al. reported that only 17% of patients associated their deformity with their job, but this might also be a subjective observation (Coughlin & Jones, 2007). There is only a weak association between ballet dancing and occupation-related HV (Einottir et al., 1995).
Table 1. Hallux valgus etiology / Risk factors

<table>
<thead>
<tr>
<th>Extrinsic factors</th>
<th>Intrinsic factors</th>
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<tbody>
<tr>
<td>Shoes with high heels</td>
<td>Heredity</td>
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<tr>
<td>Shoes with narrow toe box</td>
<td>Pes Planovalgus</td>
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<tr>
<td>Occupational factors</td>
<td>Hypermobility of metatarsocuneiform joint</td>
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<tr>
<td></td>
<td>Medial slanted metatarsocuneiform joint</td>
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<tr>
<td></td>
<td>Hyperpronated 1st ray</td>
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<tr>
<td></td>
<td>Ligamentous laxity</td>
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<td></td>
<td>Tight Achilles tendon</td>
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<td></td>
<td>Metatarsus primus varus</td>
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<tr>
<td></td>
<td>Neuromuscular disorders</td>
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<tr>
<td></td>
<td>Rheumatoid arthritis</td>
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<td></td>
<td>female preponderance</td>
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<tr>
<td></td>
<td>Age: 4th-6th decade</td>
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<tr>
<td></td>
<td>Miscellaneous factors</td>
</tr>
</tbody>
</table>

2.1.1.4 Treatment

The aims of treatment in first ray disorders should be to reduce pain, to conserve normal gait pattern and weight-bearing mechanism, to realign the sesamoids, to correct deformity in the sagittal and transverse plane, and to preserve the ROM of the MTP-1 joint, if possible.

The first treatments of HV should include shoe modifications and insoles and orthosis, along with appropriate physiotherapy (Coughlin, 1996; Coughlin & Shurnas, 2003). However, if there is persistent pain or inability to wear shoes, surgery is indicated, especially when there are obvious osseous elements (Coughlin, 1996).

There have only been a few studies on the conservative treatment of HV, and thus the effectiveness of these interventions remains unclear (Easley & Trnka, 2007; Gur et al., 2017; Karabicak et al., 2015). Du Plessis and colleagues have, however, reported a reduction in pain and discomfort using night splints or manipulative therapy (du Plessis et al., 2011). A recent randomized controlled trial (RCT) by Plaas et al. showed that using a dynamic splint can reduce pain, delay subjective deterioration of the toe position, and is well accepted by patients in the short term (Plaass et al.,
although no significant difference with the control group was found. To date, only one RCT study from the late 1990s has demonstrated that the operative management of HV with chevron osteotomy (n=71) has led to superior functional outcome and patient satisfaction compared with orthotic management (n=69) at a minimum follow-up of 12 months (Torkki et al., 2001). In that study, orthoses also provided short-term (under 6 months) symptomatic relief of HV. However, after 1-year follow-up, there was no differences compared to the starting point (Torkki et al., 2001). Thus, surgical intervention was superior with the American Orthopaedic Foot & Ankle Society (AOFAS) score, pain relief in visual analogy scale (VAS), and Quality of life (15-D). Since then, however, there has been no evidence that conservative treatment is effective in the treatment of symptomatic HV, and therefore conservative treatment is still questionable. When conservative treatment does not yield good outcomes, there is a need for surgical treatment. Although more than 100 different surgical techniques for the operative treatment of HV have been described, there is still no consensus on the optimal technique or timing of the operation (Pinney et al., 2006; Robinson & Limbers, 2005). The different surgical methods are described in a later chapter.

2.1.2 Hallux varus

Hallux varus is a rare forefoot condition and the majority of the cases are iatrogenic – a complication of HV surgery (Akhtar et al., 2016; Chiodo et al., 2004; Hawkins, 1971). This forefoot deformity is characterized by medial deviation of the first ray at the MTP-1 joint and may present with varying degrees of severity, causes, and symptoms (Hawkins, 1971). However, should the symptoms become significant and affect daily activities, then surgery should be considered. The incidence of idiopathic, congenital, traumatic, and otherwise acquired hallux varus is unknown. After corrective surgery for HV deformity, however, the incidence of iatrogenic postoperative hallux varus varies from 2% to 14% (Cho et al., 2018).

2.1.2.1 Pathoanatomy and pathophysiology

Hallux varus is characterized by medial deviation of the great toe relative to the first metatarsal bone. The disorder is multifactorial. It could be caused by loss of bone stability due to the resection of the medial eminence and lateral sesamoid that impairs
function in the lateral head of the flexor hallucis brevis (FHB) and/or muscle imbalance at the base of the phalanx due to lateral soft-tissue release and excessive medial tightening (Leemrijse & Devos, 2020). To this is added malalignment of the extrinsic tendons FHL and EHL, which promote the deformity with respect to the rotational axis of the MTP-1 joint. The intermetatarsal angle (IMA) may also be altered by metatarsal osteotomy, which is frequently performed to correct hallux valgus. Defective or excessive phalangeal correction also contributes to hypercorrection (Leemrijse & Devos, 2020).

2.1.2.2 Etiology

Congenital hallux varus is a very rare condition, and it is typically caused by connective tissue disorders or is associated with Down syndrome and neuromuscular disorders (Munir & Morgan, 2020). Flexible hallux varus can be seen in newborns, but it corrects in early childhood when walking begins. Congenital hallux varus is divided into primary and secondary pathologic deformity. Primary hallux varus is related to an overactive abductor hallucis, and secondary hallux varus is related to great toe polydactyly, delta phalanx longitudinal epiphyseal bracket syndrome, and metatarsus adductus (Munir & Morgan, 2020). Other causes of hallux varus, such as inflammatory arthropathy, which includes psoriatic and rheumatoid arthritis, and traumatic hallux varus, have been described (Munir & Morgan, 2020).

More frequently, the causes of this condition are iatrogenic after HV surgery due to overcorrection, the global release of lateral structures of the MTP-1 joint, over-resection of medial eminence, over-tightening of medial capsule, zero-degree or negative IMA, or inappropriate postoperative bandaging (Edelman, 1991; Hawkins, 1971; Skalley & Myerson, 1994). Over time, the hallux varus deformity can become fixed, and thereafter it is difficult for the patient to obtain comfortable footwear. Some patients complain of the deformity and have difficulty in wearing shoes, instability, decreased ROM, and weakness with push-off. Pain also indicates an underlying arthritic process. Patients may present with chronic pain, difficulty walking and standing for long periods, foot weakness, ingrown toenails, limited MTP joint ROM, swelling of the foot, and occasionally redness/ulceration of the great toe.
2.1.2.3 Treatment

The aims of hallux varus surgery should be to restore and maintain normal gait pattern and weight-bearing mechanism, to realign sesamoids, to correct deformity in the sagittal and transverse plane, and to preserve the ROM of the MTP-1 joint, if possible.

Treatment of the hallux varus is primary non-operative, and it includes shoe modifications and insoles as well as appropriate physiotherapy (Akhtar et al., 2016). For early iatrogenic postoperative varus deformities after HV surgery, taping or splinting the toes can be effective. However, if there is persistent pain or inability to wear shoes, surgery is indicated, especially if there are obvious osseous elements (Akhtar et al., 2016).

Operative treatment depends on whether the varus deformity is flexible or rigid. There are several surgical procedures for the treatment of hallux varus deformity, such as abductor hallucis tendon (AHT) release and re-attachment with tendon extensor hallucis brevis (EHB) and EHL transfers or IP-arthrodesis, different arthroplasty techniques, and MTP-1 joint arthrodesis. Salvage procedures may be necessary, and corrective iatrogenic hallux varus procedures are 60% to 80% effective (Braito et al., 2019; Shibuya et al., 2017).

Hallux varus deformity is well tolerated after HV surgery and most patients remain asymptomatic, although some studies have found conservative treatment to be beneficial in only 22% of patients (Mann et al., 1992; Skalley & Myerson, 1994; Trnka et al., 1997). Despite such findings, no consensus exists on the best approach to managing this rare but important complication.

It is important to measure outcomes after surgical or conservative interventions to ensure the effectiveness of the treatment method. The best way to measure these outcomes is a combination of objective and patient-reported outcome measurements (PROMs). The objective measurements, such as gait-analysis with portable gait orthosis or in laboratory conditions, provide objective data with which to measure interventions. On the other hand, PROMs provide data on how effectiveness the intervention was. A great deal of work has been done to validate PROMs, such as AOFAS and VAS, in the Finnish language.
2.1.3 Hallux rigidus

Hallux rigidus (HR) is a degenerative osteoarthritic progression characterized by progressive loss of ROM of the MTP-1 joint and notable dorsal or periarticular osteophyte formation associated with restriction of dorsiflexion (Figure 2) (Shurnas, 2009). According to Patel, Davies-Colley was the first to describe the condition in 1887. Later, Cotterill coined the term HR to characterize the painful limitation of motion of the MTP-1 joint (Patel, J. & Swords, 2020). HR is a very common forefoot disorder of the MTP-1 joint. It has been estimated that HR affects about 2.5% of people over the age of 50, and women are twice as likely as men to suffer from the disorder (Coughlin & Shurnas, 2003; Gould et al., 1980; Mann, 1995).

2.1.3.1 Pathoanatomy and Pathophysiology

Those factors suggested to be associated with HR are a flat or chevron-shaped joint, metatarsal osteochondritis dissecans, metatarsal length, trauma, MA, metatarsus primus elevatus, first ray hypermobility, positive family history, and female gender (Lucas & Hunt, 2015).

Elevation of the first ray noted radiographically is thought to be a sign of worsening MTP-1 joint function. Nonoperative care is aimed at improving the comfort of the toe and foot with roomy shoes, selective joint injections, taping, and the selective use of orthotics. HR is characterized by joint space narrowing, osteophytic lipping of the metatarsal head and proximal phalanx, and sesamoid hypertrophy, which is easily seen in X-rays (Hanft et al., 1993).
2.1.3.2  Etiology

As described earlier, there are multiple mechanisms and risk factors associated with HR, but the cause of HR remains unclear. Moreover, most of these explanations of the mechanisms and risk factors associated with HR are theoretical and unsupported. Arthrosis can be idiopathic or caused by traumatic or iatrogenic injuries that cause damage directly to the articular cartilage of the MTP joint (Coughlin & Shurnas, 2003). Bilateral involvement is more common and is associated with family history and female gender in up to two-thirds of cases (Coughlin & Shurnas, 2003). Achilles contracture, shoe wear, and an elevated metatarsal head do not appear to contribute to the development of MTP-1 joint arthritis (Coughlin & Shurnas, 2003).

2.1.3.3  Treatment

Non-surgical intervention can be started with shoe modifications and orthotics designed to limit irritation of the dorsal osteophyte. In addition, anti-inflammatory medications can reduce motion, impingement, and mechanical stress on the joint (Smith et al., 2000). Shurnas and coworkers reported better long-term pain relief with insoles than with nonsteroidal anti-inflammatory drugs alone. Therefore, the use of a stiff insole (Morton’s extension) to reduce excursion of the MTP joint may be useful (Shurnas, 2009). Solan and colleagues observed 6 months of clinical improvement with intra-articular steroid injection and gentle MTP joint manipulation for
mild to moderate grades of HR. However, limited benefit was seen in more advanced grades (Solan et al., 2001). The results of these studies indicate that nonoperative management can be successful for many patients. In a retrospective review of 772 patients, Grady et al. also reported a 55% success rate with non-operative treatment that included orthotics, corticosteroid injections, and shoe modifications (Grady et al., 2002).

Choosing the most appropriate operation for a patient is not always straightforward. During the decision-making process, many factors, such as age, activity level, the severity of disease based on clinical and radiographic evaluation, and the comorbidities of the patient, are considered. Numerous surgical procedures have been presented for the management of HR and other first ray disorders. These procedures can be divided into two broad categories: joint salvage and joint destructive procedures, both of which are described in later chapters.

2.2 Surgical techniques involving the MTP-1 joint

2.2.1 History and development of the techniques

Since the late nineteenth century when the surgical technique for the MTP-1 joint was first described, many surgical treatments for the correction of first ray problems have been proposed. Indeed, more than 130 different surgical techniques for the operative treatment of MTP-1 joint disorder have been described, although there is still no consensus on the optimal technique or timing of the operation (Easley & Trnka, 2007; Robinson & Limbers, 2005). All surgical methods aim to restore the normal anatomy and biomechanics of the forefoot to as close to normal as possible. The most common procedures which have been described include modified McBride procedure, distal metatarsal osteotomies, metatarsal shaft osteotomies, the Akin osteotomy, proximal metatarsal osteotomies, various soft tissue procedures, cheilectomy, MTP-1 and TMT-1 joint fusion, and more recently minimally invasive procedures and different arthroplasty surgery techniques. Resection arthroplasty has played a historical role in MTP-1 surgery. Nowadays, however, it is well known that resection arthroplasty carries a high risk for postoperative metatarsalgia due to the instability and poor function of the MTP-1 joint (Coutts et al., 2012).
2.2.2 MTP-1 arthrodesis

This procedure is mainly indicated for advanced HV with osteoarthritis or HR and hallux varus deformities. The goal of the procedure is to transform a painful and often stiff joint into a fused, non-painful, and stable joint. For an effective arthrodesis procedure, it is recommended that positioning of the hallux relative to the floor is 10 degree to 15 degree valgus and 15 degree to 20 degree dorsal flexion for males, and 20 degree to 25 degree for females. Even though the best position for MTP-1 arthrodesis remains a matter of debate, the correct positioning of the fusion can give a successful clinical outcome (DeSandis et al., 2016). The literature shows that MTP-1 arthrodesis gives very good functional results.

![MTP-1 arthrodesis with bioabsorbable screws](image)

Two crossing interfragmental screws, usually titanium alloy or steel, and a locking plate or a plate with a interfragmentary compression screw (IFCS) are the most common fixation methods for MTP-1 joint arthrodesis (Figure 3) (Yu & Gorby, 2004). One study showed in a cadaver model that a dorsal plate and cannulated lag screw (CLS) had greater failure load than 2 CLSs. Another study showed fully threaded compression screws had higher mean stiffness and similar load-to-failure and plantar gapping compared with a locking plate (Campbell et al., 2017; Fuld et al., 2019). Even though dorsal plates with a CLS have superior failure loads, the titanium alloy or steel hardware can be prominent and can become painful (Figure 4).
Although good results are achieved after MTP-1 arthrodesis, the reported revision rates range from 0% to 24% (Gaudin et al., 2018; Roukis et al., 2012; Wanivenhaus et al., 2017). The primary reason for secondary surgery is hardware removal due to local discomfort (Gaudin et al., 2018). With a revision rate of 4.5% to 17%, hardware removal rates vary, depending on the surgical methods used and implant placement (two crossing screws, plate and crossing screw and plate) (Gaudin et al., 2018; Wanivenhaus et al., 2017, Wadia & Sundar, 2012). The discomfort caused by the fixation material is very difficult to determine, and it could be multifactorial (Gaudin et al., 2018; Hyer et al., 2008; Roukis, 2011).

Nonunion after MTP-1 joint arthrodesis is reported in approximately 5% to 10% of cases (DeSandis et al., 2016; Roukis, 2011; Gaudin et al., 2018). Of these, about 30% of patients with nonunion are symptomatic and the revision rates range from 0% to 20% (Agoropoulos et al., 2001; Hope et al., 2010; Wassink & van den Oever, 2009). It is, however, still unclear whether only hardware removal or re-arthrodesis is preferable after non-union. Two studies have suggested that it is reasonable to perform only hardware removal for symptomatic nonunion, although re-arthrodesis after nonunion has resulted in a 91% union rate (Gaudin et al., 2018; Hope et al., 2010).

Malunion can negatively affect the outcome, although very few revision cases have been published on this topic (Desmarchelier et al., 2012; van Doeselaar et al.,
At present, the recommend position is 15° to 20° of dorsiflexion relative to the floor, 10° to 20° of valgus, and neutral rotation, but the malunion is difficult to determine because there is a lack of consensus on the optimal position of the MTP-1 joint after arthrodesis, considering different foot types. Revisions are rarely described, and the revision rate ranges between 2% and 8% (Goucher & Coughlin, 2006; Hope et al., 2010). Long-term complications, such as osteoarthritis at the first IP joint, metatarsalgia and/or claw toe, are not often reported because there have only been a few long-term studies (Agoropoulos et al., 2001; Chraim et al., 2016; Goucher & Coughlin, 2006; Gregory et al., 1990).

### 2.2.3 TMT-1 arthrodesis

TMT-1 joint arthrodesis (the Lapidus procedure) has been a common procedure since it was first introduced by Lapidus in 1934 (Lapidus, 1956). Since then, several modifications have been made to the original Lapidus procedure. TMT-1 joint arthrodesis is most often used to repair severe HV deformities or TMT-I instability in flatfoot deformity (Easley & Trnka, 2007; Shibuya et al., 2017). The procedure is technically demanding and has been associated with a prolonged period of recovery and increased morbidity when compared with metatarsal osteotomies (Toolan, 2007).

The typical approach to osteosynthesis in the fusion of TMT-1 is two or three crossing interfragmentary compression screws, usually titanium alloy or steel, and/or a combination of a locking plate or a plate with an IFCS (Figure 5). Today, locking plate fixation methods are the most popular. It is interesting to note, however, that biomechanical studies have not clearly shown any mechanical advantage to be associated with a dorsomedial plate alone or a combination of a dorsomedial plate with an IFCS when compared to a 2-screw arthrodesis in static tests (Baxter et al., 2015; Cottom & Rigby, 2013; Gruber et al., 2008; Klos et al., 2010).
Peterson and colleagues reported a hardware removal rate of 15% in patients who underwent TMT-1 arthrodesis (Peterson et al., 2016). In their study, 18 patients (72%) had a locking plate and CLS removed and 7 patients (28%) had crossing CLS removed (Peterson et al., 2016). Another study reported hardware removal rates of 12% (an intraplate compression screw fixation), 11% (crossing solid core screw fixation), and 0% (a single interfragmentary screw with a simple locking plate) (Barp et al., 2017). After TMT-1 joint arthrodesis, the rate of patient satisfaction varies between 75% and 90%, with fusion rates of approximately 90% (Donnenwerth et al., 2011; Mallette et al., 2014).

The procedure is also used to treat patients with metatarsus primus varus and either post-traumatic or end-stage arthritis. TMT-1 joint arthrodesis provides good correction and stability to the first ray (Bednarz & Manoli, 2000). Klemola and colleagues have suggested an operation technique for TMT-1 joint arthrodesis that accentuates the rotational correction of the first ray (Klemola et al., 2014). The rotational stabilization of the TMT-1 joint and the improved function of the windlass mechanism and peroneus longus could enhance the weight-bearing properties of the foot and have a satisfactory long-term outcome (Klemola et al., 2017).
2.2.4 MTP joint preserving techniques

Keller performed the first resection interpositional arthroplasty in two clinical studies in 1904 and 1912 (Keller, 1904; Keller, 1912). Brandes performed the first resection in the proximal phalanx and inserted a part of the medial joint capsule into the joint to serve as a pillow (Brandes, 1929). Since then, the Keller–Brandes resection arthroplasty has been a popular procedure for the correction of symptomatic HV or HR. However, today it is well known that resection arthroplasty carries a high risk for postoperative metatarsalgia due to the instability and poor function of the MTP-1 joint (Coughlin & Mann, 1987; Vienne et al., 2006).

Interpositional arthroplasty was first developed to retain foot function and eliminate pain (Berlet et al., 2008; Hyer et al., 2012). The procedure involves the use of a spacer made of autograft, allograft, or synthetic biologic material (Berlet et al., 2008; Coughlin & Shurnas, 2003; DelaCruz et al., 2011; Hyer et al., 2012; Roukis, 2010; Watson et al., 2019). The purpose of the technique is to maintain MTP-1 mobility while at the same time stabilizing the varus-valgus movement of the joint and retaining the length of the toe. The interpositional technique is a surgical option for patients with moderate to severe HR or arthritic HV that would prefer to preserve the ROM of the MTP joint. To date, however, there is no clear evidence nor studies that have compared the different techniques, and therefore no gold standard exists for interpositional arthroplasty. A recent systematic review and meta-analysis has shown that interpositional arthroplasty is an effective treatment option with acceptable clinical outcomes in patients with moderate to severe HR who prefer to maintain the range of motion and who accept the risk for future complications (Patel & Swords, 2020).

2.2.5 Osteotomies

The distal first metatarsal (MT) procedure is considered to be relatively easy with fast recovery and few early postoperative complications (Figure 6) (Coughlin & Smith, 2008). On the other hand, diaphyseal and proximal MT-1 osteotomies have been thought to be more effective in correcting the deformity compared with distal MT-1 osteotomies (Chuckpaiwong, 2012; Deenik et al., 2008; Tsikopoulos et al., 2018). Indeed, the findings of a recent RCT by Lee et al. and a recent meta-analysis showed no difference in outcomes between distal and proximal MT-1 osteotomies (Lee et al., 2015; Tsikopoulos et al., 2018). An RCT study by Torkki and colleagues in 2001 showed that a Chevron osteotomy was an effective treatment method for
painful HV (Torkki et al., 2001). Another study by the same group showed that HV surgery was also cost-effective (Torkki et al., 2003).

Figure 6. MT-1 osteotomy with bioabsorbable pin (Chevron)

2.3 Development of materials in foot and ankle surgery

2.3.1 Early years of steel and titanium alloy in foot and ankle surgery from a historical perspective

Plates for the internal fixation of fractures have been used for approximately 150 years. According to Roberts, the field of orthopedic surgery underwent revolutionary change in the 19th century when French surgeons Cucel and Rigaud performed the first internal fixation in 1850 (Roberts et al., 2013). Since then, efforts have been made to develop new techniques and materials for the field of orthopedic surgery. Belgian surgeon Robert Danis was the first to recognize the need for compression between fracture fragments, and thus he developed a plate (coapteur) that suppressed interfragmentary motion and increased the stability of the fixation and screw design. This allowed for both early mobilization of the patient and primary bone healing that characteristically lacked external callus formation. This innovative development led to the birth of Arbeitsgemeinschaft für Osteosynthesefragen (AO) German for "Association for the Study of Internal Fixation". The influential AO group and the Mayo clinic in the United States of America have developed CLS,
tension band wires, and plates. Today, the most commonly used materials in foot and ankle surgery are screws and plates made of titanium alloy or steel.

2.3.2 Hardware removal procedures

In total, implant removal contributes to almost 30% of all planned orthopedic operations (Busam et al., 2006). Previous studies have reported that the rate of hardware (titanium alloy or steel) removal has ranged from 12% to 80% (Bostman & Pihlajamaki, 1996; Richards et al., 1992; Sanderson et al., 1992). This high variation might be due to cultural and treatment policy differences and may also be attributed to the different lengths of observation periods or analytic methods between studies (Hanson et al., 2008; Jamil et al., 2008). The reason for this perception and behavior mismatch remains unclear, particularly considering the associated high complication rate of 20% with an infection rate of up to 14%, a nerve injury rate of 2%, and a refracture rate of 0.5% (Richards et al., 1992).

Hardware removal causes a significant cost to patients, hospitals, and societies through the consumption of health care resources and absence from work (Fenelon et al., 2018). The total economic cost of removal is difficult to estimate due to the multifactorial nature and financing of the health care systems in different countries (Tan et al., 2014).

2.4 Bioabsorbable implants

2.4.1 History and development of bioabsorbable implants

During the last decades, steel and titanium alloy osteosynthesis devices have made modern operative fracture care possible. However, these steel or titanium alloy implants are still associated with major disadvantages. Complications after surgery can be attributed to patient characteristics, fracture factors, and iatrogenic factors (Leyes et al., 2003). In addition, rigid fixation may cause stress-shielding of the bone, especially cortical bone. Furthermore, implants can cause irritation of the tissues, resulting in plate removal (Fenelon et al., 2018; Haase & Rouhi, 2013).

The first bioabsorbable implants for the fixation of bone tissue were developed by Tormala et al. in 1987 (Tormala et al., 1987). Bioabsorbable devices were initially
developed as an alternative to the internal fixation of fractures, osteotomies, arthrodesis, ligament, and meniscal injuries, as these devices maintain fixation during healing, decompose gradually, and stresses are transferred gradually to the healing tissue.

The ideal strength of a bioabsorbable material for orthopedic use is thought to be equal to that of cortical bone tissue (Morgan et al., 2018). However, trabecular and cortical bone density varies among populations (Siris et al., 2001; Morgan et al., 2018). Therefore, it would be more beneficial to develop implants that are stronger than bone density. There is, however, no evidence as to what the optimal strength of fixation should be in different fractures, arthrodesis, or osteotomies. The main advantage of bioabsorbable implants is that they degrade during the healing process, allowing the load to gradually transfer to the healing tissue. However, the polymers currently available still do not have mechanical characteristics equal to those of steel or titanium alloy implants.

The bioabsorbable materials most commonly used in the fixation of procedures in trauma or orthopedics are bioabsorbable synthetic polyglycolide (PGA), polylactide (PLA), and polydioxanone (PDS). The first gut sutures made from a biomaterial are thought to have first been developed by Galen as early as the second century (Mackenzie, 1973). Recent improvements in polymer science have led to the development of new orthopedic implants made of bioabsorbable materials (Rokkanen et al., 2000). The major advantage of these implants is that they allow initial stability adequate for healing and then gradual resorption after biologic fixation has been established. In addition, these materials limit stress shielding of bone, gradually apply load as they degrade, obviate hardware removal procedures, and facilitate postoperative radiologic imaging.

Although bioabsorbable fracture fixation devices appear to have obvious advantages over steel or titanium alloy implants, concerns about the initial fixation strength of these materials have limited their widespread acceptance. First generation bioabsorbable materials in particular have had problems with adverse tissue reactions, and variable biosorption times have been reported (Juutilainen et al., 2002; Rokkanen et al, 2000). Pihlajamaki et al. showed in animal tests that there were no adverse tissue reactions after complete degradation of PGA and PDS, with degradation times clearly shorter than those of poly-L-lactic acid (PLLA) (Pihlajamaki et al., 2006). These materials must have the initial fixation strength necessary to maintain the reduction of bone fragments during the healing process and must control degradation thereafter. In a review by Rokkanen et al. of more than 2 500 fracture-fixation cases in which bioabsorbable implants were used, the incidence of bacterial wound
infection was 3.6%; nonspecific foreign body reaction 2.3%; and failure of fixation 3.7% (Rokkanen et al., 2000).
### Table 2. History of lactic-based bioabsorbable screws by different manufactures

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<tbody>
<tr>
<td>Dexon Suture</td>
<td>1971</td>
<td>Polyglycolic acid (PGA)</td>
<td>1 - 2</td>
<td>4 - 6</td>
<td>140 MPa</td>
<td>68 MPa</td>
<td>138 MPa</td>
<td>Based on the PGA suture</td>
</tr>
<tr>
<td>BioFix</td>
<td>1989</td>
<td>Self-reinforced Polyglycolic acid (SR-PGA)</td>
<td>5 - 9</td>
<td>&gt;200</td>
<td>190 MPa</td>
<td>146 MPa</td>
<td>137 MPa</td>
<td>Strongest absorbable suture</td>
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<td>BioScrew</td>
<td>2002</td>
<td>Self-reinforced Polyglycolic acid (SR-PLA)</td>
<td>80 - 120</td>
<td>20 - 40</td>
<td>50 - 70</td>
<td>100</td>
<td>&gt;100</td>
<td>First FDA approved absorbable interference screw</td>
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<tr>
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<td>2001</td>
<td>Injection molded Poly-L-lactic acid (PLLA)</td>
<td>60 - 70</td>
<td>&gt;200</td>
<td>100</td>
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<td>100</td>
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<tr>
<td>SmartPin™ PDX</td>
<td>2006</td>
<td>Self-reinforced Poly-85Lactic/15 glycolic acid (SR-PLA 85/15)</td>
<td>10 - 12</td>
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<tr>
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<td>2020</td>
<td>Self-reinforced Poly-85Lactic/15 glycolic acid</td>
<td>10 - 12</td>
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</table>
2.4.2 Testing of bioabsorbable implants

The adequacy of bioabsorbable screws needs to be demonstrated prior to their approval by researchers in vitro testing before clinical studies. The in vitro testing in bioabsorbable screws typically consists of the testing of mechanical and biomechanical properties. The mechanical properties of a bone fixation screw alone are determined by pull-out, tensile, compression, bending, shear, and torsional tests. The purpose of a biomechanical test is to simulate a specimen, such as bone fragments fixed with screws. Accordingly, the results of biomechanical testing reflect actual fixation properties. Biomechanical testing of bioabsorbable bone fixation screws can be carried out by using either static or cyclic loading. In a static test, the specimen is usually loaded at a constant speed or load until failure of the specimen occurs. Conversely, a cyclic load testing specimen is placed under several sequential displacement controlled loading cycles.

2.4.3 Bioabsorbable interpositional implant

A bioabsorbable poly-L-D-lactic acid (PLDLA) Regjoint™ Scaffdex© Tampere, Finland interpositional implant has been developed at Tampere University of Technology (Kellomaki & Tormala, 2004). The porous implant is designed to provide temporary support for the joint and is later replaced by the patient’s own soft tissue ingrowth. This allows the gradual optimized replacement of the implant with fibrous tissue and provides a flexible and durable pseudojoint (Kellomaki & Tormala, 2004). The support provided by the implant is preserved for more than two months, and it takes between two and three years before the implant is fully replaced by the patient’s own scar tissue (Ella et al., 2011).

2.4.4 Bioabsorbable screws and pins

Bioabsorbable screws have been used in different indications since the 1980s. Early prospective studies of ankle surgery operations reported excellent or good subjective results in more than 90% of patients with a fracture (Partio et al., 1992; Rokkanen et al., 1985). Since then, the aim has been to develop more bioabsorbable implants. Today, PLLA is the most commonly used material in bioabsorbable screws due to its excellent biocompatibility, strength, and poor inflammatory reactivity.
The fixation strength of bioabsorbable implants, such as screws, remains a source of argument, and a recent study reported that steel screws are stronger in the fixation of tibial tubercle transfer in cadavers than bioabsorbable screws (Nurmi et al., 2017). The study did suggest, however, that the fixation strength of bioabsorbable screws seemed clinically sufficient. Moreover, there is now clear evidence of how to measure fixations and what is clinically sufficient fixation. A recent meta-analysis with 11 cadaveric biomechanical studies reported that bioabsorbable syndesmosis screws demonstrate similar mechanical strength properties as metal screws (Lee et al., 2020). There is, however, a lack of knowledge about the biomechanical strength of bioabsorbable screws in different surgical procedures, and it is unclear which measurement is the most important in clinical use (maximum strength, fatigue strength, or properties of the screw). In the studies carried out as part of this dissertation, we used the ActivaScrew™ (Bioretec Oy, Tampere Finland), the benefit of which lies in the patented Auto-Compression™ technology. In human body conditions, the diameter of the screw increases and the length decreases by 1% to 2%, locking itself in place and maintaining the required compression needed for appropriate bone healing.
3 AIMS OF THE STUDY

This thesis covers various aspects of foot surgery with the aim of identifying the problems associated with various implant materials and determining surgery trends in the treatment of foot and ankle disorders. The aim of this study was to investigate the incidence of HV surgery and hardware removal procedures after ankle surgery and to make initial biomechanical tests of the ActivaScrew™ (Bioretect Oy, Tampere Finland) in MTP-1 and TMT-1 arthrodesis.

The specific aims of the study were the following:

1. To describe the incidence of HV surgery in Finland between 1997 and 2014.

2. To describe the nationwide incidence and rate of hardware removal procedures after ankle fracture surgery.

3. To assess the long-term results of the PLDLA interposition implant in MTP-1 joint-preserving procedures.

4. To compare the biomechanics of bioabsorbable cannulated screws and titanium alloy screws for TMT-1 arthrodesis.

5. To compare the biomechanics of two MTP-1 arthrodesis (“cup and cone” vs straight cut) using two bioabsorbable crossing screws.
4 MATERIALS AND METHODS

4.1 Incidence of hallux valgus primary surgical treatment

Studies I and II were based on data from the Finnish National Hospital Discharge Register (NHDR). The NHDR was founded in 1967, and the data are collected and maintained by the National Institute for Health and Welfare, Helsinki, Finland. With internal validity checks, the reliability of the data is excellent (Sund et al., 2007). Moreover, with regard to cruciate ligament injury, Mattila et al. also found both the coverage (92%) and accuracy (89%) of the register data to be excellent (Mattila et al., 2008).

The data collected by the NHDR is mandatory for all Finnish hospitals, including private, public, and other institutions. Over many years, the NHDR database has been intensively used in medical and epidemiological research. Indeed, the NHDR database is ideal for epidemiological studies, as it contains data on age, sex, domicile of the subject, length of hospital stay, primary and secondary diagnosis, and operations performed during the hospital stay.

In 1996, the Nordic Medico-Statistical Committee (NOMESCO) published the first printed edition of the NOMESCO Classification of Surgical Procedures (NCSP). The Finnish version of the NCSP (NCSP-F) was introduced in 1997, and the Finnish procedural coding changed accordingly. Thus, the patient data for this present study were obtained from the Finnish NHDR between the years 1997 and 2014.

The aim of this first epidemiologic study was to compute the incidence ratios and trends of HV surgery. We included all adult patients (≥ 18 years) who underwent primary HV operation. Patients were included into the study if they had been operated with a diagnosis of HV (ICD-10 code M20.1). The procedural codes (according to the Finnish version of the NOMESCO classification) for HV included NHK30 (MT-1 osteotomy including proximal, diaphyseal, and distal ones), NHK99 (other operation on bone of ankle or foot - bunionectomy and cheilectomy), NHG80 (MTP-1 joint arthrodesis), NHG70 (MTP-1 joint arthroplasty – including resection, interpositional, and replacement), and NHG26 (TMT-1 joint arthrodesis). Both outpatient and inpatient operations were included in the study.
4.2 Reduced incidence and economic cost of hardware removal after ankle fracture surgery

The second epidemiological study was also based on NHDR data. We included all adult patients (≥ 18 years) who underwent ankle fracture surgery open reduction and internal fixation (ORIF) between January 1, 1997 and December 31, 2016. Patients were included if they had been operated with a diagnosis of ankle fracture (ICD-10 code).

According to the NCSP-F, the procedural codes for ankle fracture include NHJ10 (internal fixation of fracture of ankle using plate, wire, rod, cerclage, or pin) and NHU20 (hardware removal). The primary outcome was the incidence of the operative treatment of ankle fractures and hardware removal. Since the FNHDR does not include laterality of the operation, only the patient’s first ankle fracture ORIF operation performed during the study period was included in the analysis.

A secondary outcome was the cost of hardware removal as determined by diagnosis-related group–based (DRG-based) hospital payment system pricing. DRG-based hospital payment systems are used in Finland and most Organization for Economic Co-operation and Development (OECD) countries. The basic idea of DRG-based hospital payment systems is that all patients treated by a hospital are classified into a limited number of DRGs that are supposed to be clinically meaningful and relatively homogenous in their patterns of resource consumption.

We decide to choose ankle fractures because the diagnosis code (ICD-10) is more obvious than foot surgery codes, and bilateral foot surgery is more common than bilateral ankle fractures in the NHDR. We are, however, planning a retrospective research study of hardware removal procedures in elective foot surgery.

4.3 Interpositional arthroplasty of the MTP-1 joint with bioresorbable PLDLA implant in the treatment of hallux rigidus and arthritic hallux valgus: a 9-year case series follow-up

In study III, we assessed the long-term results of PLDLA implant in interpositional arthroplasty (Figure 7). Eighteen patients underwent interpositional arthroplasty using the PLDLA implant at Tampere University Hospital between February 1997 and October 2002. Of these 18 patients, 15 (83%) were compliant with clinical examination and radiologic assessment in long-term (average 9.4 years) follow-up. In addition, a further 6 patients underwent bilateral operation, and thus the study comprised
21 joints. Twelve of the patients were female and 3 were male. The mean age of the patients was 48.3 (range, 28-67) years at the time of the operation. Six patients underwent surgery due to arthritic HV and 9 patients due to HR.

Figure 7. The RegJoint implant

The physical function of patients was evaluated using the American Orthopaedic Foot and Ankle Society (AOFAS) score. The AOFAS scores were obtained with a systematic interview and study that was done during a follow-up visit. Preoperative AOFAS scores were calculated from data collected from the medical histories of patients. Pain was evaluated using the VAS from 0 to 10, where a higher number indicates higher pain and vice versa. The pain VAS was obtained before surgery and at the time of the follow-up visit. Furthermore, the palpation of the joint was clinically estimated, and any tenderness and swelling were recorded. The patients were evaluated at an outpatient clinic, and the symptoms and findings were classified into four groups: no symptoms, slight symptoms, moderate symptoms, and substantial symptoms.
Plain radiographs were obtained from each patient, and the images were analyzed (anteroposterior, oblique, and lateral views) by a radiologist. The radiologist estimated the joint as descriptive, as no radiological classification exists for operations involving the bioabsorbable PLDLA interpositional implant.

4.4 Bioabsorbable vs. titanium alloy screws for TMT-1 joint arthrodesis

This first biomechanical study (Study IV) compared TMT-1 joint arthrodesis (the Lapidus procedure) in two groups, each with 15 anatomical models (Sawbone® anatomical foot models, Sawbones Europe AB, Malmo, Sweden), by using two crossing interfragmentary CLS. The bioabsorbable screws were manufactured by Bioretec (ActivaScrew™, Bioretec Oy, Tampere Finland) from poly(L-lactide-co-glycolide) (85L/15G) raw material purchased from Boehringer Ingelheim GmbH (resomer LG857, Ingelheim am Rhein, Germany). The screws were gamma sterilized using 26 kGy at Gamma-Service Produktbestrahlung GmbH (Radeberg, Germany). In this study, we used the CLS 3.5x35 mm and 3.5x40 mm and the Stryker Asnis™ Stryker (titanium alloy) CLS 4.0x36 mm and 4.0x40 mm.

Each model was modified by cutting the TMT-1 joint using a saw to make a straight cut between the medial cuneiform and the MT-1 bone. The bioabsorbable and titanium alloy screws were placed one at a time by the same researcher in exactly the same location in each model, according to careful measurements. The Lapidus fusion was temporarily fixed with Kirschner wires (K-wires). The guide wire was then overdrilled with a 2.7 mm cannulated drill for the bioabsorbable screws and with a 3.5 mm cannulated drill for the titanium alloy screws. The bioabsorbable screw channels were tapped without fully closing the osteotomy site. The cannulated cortical CLS was inserted from dorsal-to-plantar over the osteotomy with Kirschner wires. The longer screw (the 3.5x40 mm bioabsorbable screw and the 4.0x40 mm titanium alloy screw) was inserted into the MT-1 to the medial cuneiform, and the shorter screw (the 3.5x35 mm bioabsorbable screw and the 4.0x36 mm titanium alloy screw) was inserted into the medial cuneiform to the MT-1. The Kirschner wires were then removed (Figure 8 and 9).

All 30 models were then analyzed using a material testing device (MTS Insight 30, Eden Prairie, USA). The biomechanical testing protocol consisted of the single-cycle load-to-failure test. In the single-cycle load-to-failure test, each model was oriented 15° to the platform to simulate its position to the ground during mid-stance.
(Figure 10). Then, the models were subjected to plantar-to-dorsal loading at a compression rate of 5 mm/s. The response of each model to the loading was automatically recorded as a load-displacement curve, and the stiffness (determined as the slope of the linear region of the load-displacement curve corresponding to the steepest straight-line tangent to the loading curve), yield load (described as the load at the point where the slope of the load-displacement curve first clearly decreased), and maximum failure load were determined. All the tests were video-recorded, and the failure mechanism was analyzed afterwards.

**Figure 8.** Sagittal view (TMT-1 arthrodesis)

![Sagittal view (TMT-1 arthrodesis)](image)

**Figure 9.** Dorsal view (TMT-1 arthrodesis)

![Dorsal view (TMT-1 arthrodesis)](image)
4.5 Bioabsorbable vs. titanium alloy screw in MTP-1 arthrodesis; a cup and cone preparation or straight saw

In this second biomechanical experimental study (Study V), we first compared bioabsorbable screw fixation in two different arthrodesis methods: “cup and cone” versus straight saw. In a second experiment, we compared bioabsorbable screws and titanium alloy screws in “cup and cone” models. Load, stiffness, and displacement as well as failure mode were determined. All three setup groups included 5 anatomical models (Sawbone® anatomical foot models, Sawbones Europe AB, Malmo, Sweden) and titanium alloy (Asnis™ Stryker Cannulated Screw) and bioabsorbable (ActivaScrew™ CLS, Bioretec Oy, Tampere, Finland) crossing interfragmentary CLS. The bioabsorbable screws were manufactured from poly(L-lactide-co-glycolide) (85L/15G). It was decided to use Sawbones® bone models in this study for three reasons: 1. In cadaver studies, bone mineralization has a large variation and fixation is grounded on the strength of the implant, but also on the strength of bone itself (Coskun et al., 2006; Landsman & Chang, 1998; Muehleman et al., 1999) 2. It is difficult to find similar anatomical models for MTP-1 arthrodesis in animal studies, and 3. In this model, the imaginary bone properties are similar for both fixation groups, and ethically it is also appropriate to choose the bone model experiment study setup where possible, rather than animal testing.

In the first experiment, we compared “cup and cone” and straight saw arthrodesis models. We used bioabsorbable CLS with diameters of 3.5x35 mm and 3.5x30 mm. Five Sawbones® bone models were cut in the MTP-1 joint with a straight cut between the first proximal phalangeal and the MT-1 bone. The MTP-1 joint fusion was
temporarily fixed with K-wires. The guide wire was then over-drilled with a cannulated drill (2.7 mm) and the channels were tapped without fully closing the osteotomy site. The CLS was inserted from dorsal-to-plantar over the osteotomy with K-wires. The longer screws (3.5x35 mm) were inserted into the MT-1 to the proximal phalanx. The shorter screws (3.5x30 mm) were inserted into the proximal phalanx to the MT-1. The K-wires were then removed (Figure 11 and 12).

Figure 11. Sagittal view (MTP-1 titanium alloy)
In the second experiment, we compared bioabsorbable screws and titanium alloy screws in “cup and cone” models. We used bioabsorbable CLS with diameters of 35 mm and 30 mm and titanium alloy CLS of 34 mm and 30 mm. The diameters of these screws were chosen because we assumed that there were no significant differences when comparing these two screws, and no remarkable differences between the real diameters of the screws were found (bioabsorbable screw: head 5 mm, body 3 mm, thread 3.5 mm) (titanium alloy screw: head 3.73 mm, body 2.07 mm, thread 3.10 mm) (Figure 13). Ten models were modified into “cup and cone” form. The bioabsorbable and titanium alloy screws were placed one at a time in exactly the same location in each model using a tape measure. The MTP-1 joint fusion was temporarily fixed with K-wires. The guide wire was then over-drilled with a 2.7 mm cannulated drill for the bioabsorbable screws and with a 2.1 mm cannulated drill for the titanium alloy screws. The channels were then tapped without fully closing the osteotomy site. The CLS was inserted from dorsal-to-planar over the osteotomy with K-wires, closing the osteotomy fully. The longer screws (35 mm bioabsorbable screw and the 34 mm titanium alloy screw) were inserted into the MT-1 to the proximal phalanx. The shorter screws (30 mm) were inserted into the proximal phalanx to the MT-1, after which the K-wires were removed.
All 15 models were analyzed with a material testing machine (MTS Insight 30, Eden Prairie, USA). The feet were interfaced with the device and shaped exactly congruent to the anatomic Sawbones® foot models by using a laser cutting machine. Each model was oriented 15 degrees to the platform to simulate its position to the ground during mid-stance. Then, the models were subjected to the single-cycle load-to-failure test (Figure 14). The compression rate was 5 mm/s. The load was discontinued after the extension between the proximal phalanx and MT-1 bone was extended 20 mm or the screws were pulled loose (Figure 15). The groups were then compared on yield load, stiffness, displacement, and maximum failure. Yield load describes the load at which the material changed from the elastic zone to the non-elastic zone in the load displacement curve. The displacement at the point of yield load was recorded. The yield load and stiffness were derived for each model from load-versus-displacement curves. All the tests were video-recorded, and the failure mechanism was analyzed afterwards.
4.6 Statistical analysis

To compute the incidence ratios of the epidemiology studies (I and II), the annual mid-population data for each calendar year of the study period were obtained from the Finnish National Hospital Discharge Register. The resulting rates (per 100 000
person-years) were based on the entire adult population of Finland rather than co-
hort or sample-based estimates, and thus 95% intervals or other statistical estimation
methods were not used.

Clinical study (III) data and sociodemographic data are presented as means with
ranges or as counts with percentages. Means of the paired continuous variables were
compared with Wilcoxon test. Confidence interval was determined at 95%, and there-
fore P values of <0.05 were considered to be statistically significant.

The Biomechanical test (IV and V) results of the quantities were reported as mean
and standard deviation (SD). In statistical calculations of the biomechanical single-cycle
load-to-failure test (IV and V) the differences between groups (yield load, yield load
extension, stiffness, and max failure) in each test was determined by using a paired
Student t-test. A P value less than 0.005 was considered statically significant.

Analyses were performed using IBM© SPSS software 24, R© (version 3.5.3)
(Foundation for Statistical Computing, Vienna, Austria) and Microsoft Excel© (Ver-
sion 16.15).

4.7 Ethical considerations

Studies I and II were approved by the Finnish National Institute of Health and Wel-
fare (THL): THL/89/5.05.00/2012. The study was funded by the Finnish Govern-
ment’s Research and Development Foundation. Funding sources were not involved
in the study design, data collection, analysis, interpretation, or completion. Study III
was approved by the Medical Director of Pirkanmaa Hospital District.
5 RESULTS

5.1 Incidence of hallux valgus primary surgery

A total of 47,597 HV operations were performed in Finland between 1997 and 2014. The number of surgeries/operations in men was 6267 (13.2%) and 41,330 (86.8%) in women. The total incidence of primary HV operations was 66.7 per 100,000 person-years in 1997 (2,951 operations) and 41.4 per 100,000 person-years in 2014 (2,012 operations). In men, the incidence was 10.1 per 100,000 person-years in 1997 and 6.2 per 100,000 person-years in 2014 (Figure 16). In women, the corresponding figures were 64.9 per 100,000 person-years in 1997 and 38.3 per 100,000 person-years in 2014 (Figure 16).

Figure 16. Primary HV operations in Finland from 1997 to 2014 in men and women
In patients aged 50 to 59 years, the incidence of primary HV operations decreased from 190.5 per 100,000 person-years in 1997 to 88.8 per 100,000 person-years in 2014, whereas in persons aged 40 to 49 years the incidence of primary HV operations decreased from 92.8 per 100,000 person-years in 1997 to 50.5 per 100,000 person-years in 2014. There was no marked change in patients aged 70 or older, the incidence being 11.4 per 100,000 person-years in 1997 and 10.3 per 100,000 person-years in 2014. In patients aged 60 to 69 years, the incidence of primary HV operations decreased from 123 per 100,000 person-years in 1997 to 84.4 per 100,000 person-years in 2014.

During the 18-year study period, MT-1 osteotomy was the most common primary operative procedure performed (n=26,667; 62.1%) followed by MTP-1 resection arthroplasty (n=8,910; 20.8%), MTP-1 arthrodesis (n=4,527; 10.4%), TMT-1 arthrodesis (n=1,574; 3.7%), and other operations on the bone of the ankle or foot, including bunionectomy and cheilectomy (n=1,259, 2.9%).

Figure 17. Proportion of primary operation technique
The incidence of resection arthroplasty operations of the MTP-1 joint decreased from 30.9 per 100 000 person-years in 1997 (n=1 369, 47%) to 1.8 per 100 000 person-years in 2014 (n=86, 4%), whereas the incidence of MTP-1 joint arthrodesis increased from 1.3 per 100 000 person-years in 1997 (n=56, 2%) to 14.9 per 100 000 person-years in 2014 (n=725, 36%) (Figure 17). Overall, the incidence of MT-1 osteotomy decreased from 32.1 per 100 000 person-years in 1997 (n=1421, 48%) to 20.7 per 100 000 person-years (n=1 005, 50%) in 2014, but the proportion of MT-1 osteotomies of all surgical procedures remained the same between 1997 and 2014. Between 1997 and 2005, the proportion of MT-1 osteotomies increased from 48% to 73% but decreased again to 50% in 2014. The incidence of TMT-1 joint arthrodesis increased from 0.2 per 100 000 person-years in 1997 (n=7, 0.2%) to 3.1 per 100 000 person-years in 2014 (n=149, 8%) (Figure 18).
Figure 18. Incidence of primary HV surgery technique in Finland from 1997 to 2014

5.2 Reduced incidence and economic cost of hardware removal after ankle fracture surgery

The second epidemiology study was also based on NHDR data. The data showed a total of 68,865 adult patients had a surgically treated ankle fracture with ORIF in Finland during the 20-year study period between 1997 and 2016. The total number of operations in men was 33,751 (49% CI 48-49) and 35,114 (51% CI 51-51) in women. The mean age at the time of the first surgery in 1997 was 52 years in women and 44 years in men. In 2016, the corresponding ages were 57 years in women and
47 years in men. The total incidence of ankle fracture surgery was 81 (CI 78-83) per 100 000 person-years in 1997 (3 218 operations) and 74 (CI 71-76) per 100 000 person-years in 2016 (3 276 operations). In men, the incidence was 87 (CI 83-91) per 100 000 person-years in 1997 and 72 (CI 68-75) per 100 000 person-years in 2016. In women, the corresponding figures were 80 (CI 76-84) per 100 000 person-years in 1997 and 82 (CI 79-86) per 100 000 person-years in 2016.

During the 20-year study period, a total of 18 648 hardware removal procedures were performed (27%) after primary ankle fracture surgery. The total number of hardware removals performed was 8 942 (48%) in men and 9 706 (52%) in women. The mean age at the time of the first hardware removal in 1997 was 53 years in women and 45 years in men. In 2016, the corresponding ages were 56 years in women and 57 years in men. The incidence of hardware removal procedures after ankle fracture surgery decreased from 31 (CI 29-32) per 100 000 person-years in the highest year 2001 (n=1 247) to 13 (CI 12-14) per 100 000 person-years in 2016 (n=593) (Figure 19). In 1997, the incidence of hardware removal was 10 per 100 000 person-years; however, since follow-up also started in 1997, the incidence was expected to be low. In men, the incidence was 32 (CI 29-34) per 100 000 person-years in 2001 and 12 (CI 11-13) per 100 000 person-years in 2016. In women, the corresponding figures were 30 (CI 27-32) per 100 000 person-years in 2001 and 15 (CI 13-16) per 100 000 person-years in 2016.
The mean time between ankle fracture surgery and hardware removal procedure was 425 days. In the 0 to 3 months period, there were n=8 005 (43%) hardware removal procedures, followed by n=1 434 (8%) procedures in the 3 to 6 months period, n=2 851 (15%) in the 7 to 12 months period, n=3 828 (21%) in the 13 to 24 months period, n=1 014 (5%) in the 25 to 36 months period, and n=1 516 (8%) in the over 36 months period. Hardware removals were conducted within 3 months for 538 (52%) of the 1 029 patients who underwent hardware removal in the highest year 2007 (Table 2). Thereafter, the removal rate remained steady until 2012 when the removal rate decreased markedly from 49% in 2012 to 26% in 2016.
According to Finnish DRG-based hospital payment pricing system, the direct costs of one ankle fracture surgery were €2 880.66 per patient in 2016. This amounted to
an annual direct cost of ankle fracture surgery of approximately €9 500 000 in 2016. The DRG-based costs for one hardware removal are €797.04. Thus, the costs of removal procedures in 2016 were approximately €472 600, whereas the corresponding removal costs in 2001 were almost €994 000.

5.3 Interpositional arthroplasty of the MTP-1 joint with bioabsorbable PLDLA implant in the treatment of hallux rigidus and arthritic hallux valgus: a 9-year case series follow-up

During this long-term follow-up study, the mean AOFAS score and pain VAS improved after the operation in all patients (Table 3). The improvements were most notable in the Pain and Function subscales. All examined patients reported that the joint felt better than before the operation. The decrease of pain (VAS) after the operation was statistically significant (10.0 vs. 77.5, p<0.001).

Table 4. Direct comparison between the pre- and postoperative AOFAS-score and its subscales together with pain VAS

<table>
<thead>
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<th></th>
<th>Preoperative score</th>
<th>Postoperative score</th>
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<td>AOFAS total score, mean (range)</td>
<td>40 (27 to 65)</td>
<td>80.5 (70 to 95)</td>
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<tr>
<td>Pain</td>
<td>10.5 (0 to 20)</td>
<td>37.6 (30 to 40)</td>
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<tr>
<td>Alignment</td>
<td>8.2 (0 to 15)</td>
<td>11.6 (0 to 15)</td>
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<tr>
<td>Function</td>
<td>16.8 (17 to 37)</td>
<td>31.6 (31 to 34)</td>
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<tr>
<td>pain VAS, median (range)</td>
<td>77.5 (40 to 100)</td>
<td>10.0 (0 to 60)</td>
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The radiological findings were contradictory during this follow-up, since the radiographs contained multiple pathological features, yet most of the patients were painless (Figure 20; Table 4). Osteophytes and articular space narrowing were detected in all joints. Two joints included intra-articular loose bodies, and none of the patients had congruence. There are no specific guidelines for X-rays regarding bioabsorbable materials.
<table>
<thead>
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<th>Radiological findings</th>
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<td>Osteophytes</td>
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<tr>
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</tr>
<tr>
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<td>21</td>
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<tr>
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<td>20</td>
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<tr>
<td>Subchondral sclerosis</td>
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<tr>
<td>Rugged of joint surface</td>
<td>18</td>
</tr>
<tr>
<td>Subchondral cyst</td>
<td>16</td>
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<tr>
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<td>Joint congruence</td>
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</table>
The patients were evaluated at an outpatient clinic. In total, 18 joints were asymptomatic, and 3 joints had slight symptoms. None of the joints were considered to have severe symptoms. Swelling was moderate in 2 joints and substantial in 1 joint. Postoperative complications occurred in 3 (14.3%) joints of 2 HR patients. For these 2 HR patients, surgery only temporarily eased the pain, and therefore they underwent reoperation with arthrodesis.
5.4 Bioabsorbable vs. titanium alloy screws for TMT-1 joint arthrodesis

In the first biomechanical study, we determined in the single-cycle load-to-failure test to simulate TMT-1 arthrodesis (Figures 21 and 22). The mean yield load was 61.4 N ± 5.7 N (range, 50.1 N – 70.3 N) in the bioabsorbable screw group and 81.2 N ± 12 N (range, 61.7 N – 113.4 N) in the titanium alloy screw group (P < .001). The respective values for the stiffness of the fixation were 8.1 N/mm ± 0.8 N/mm (range, 6.7 N/mm – 9.1 N/mm) and 9.7 N/mm ± 1.8 N/mm (range, 6.9 N/mm – 12.6 N/mm) for the bioabsorbable and titanium alloy groups (P = .004). The mean maximum failure loads in the bioabsorbable group were 85.1 N ± 8.5 N (range, 67.1 N – 97.2 N) and 120.6 N ± 13.2 N (range, 96.7 N – 136.7 N) in the titanium alloy group (P < .001).

Figure 21. Single-cycle load-to-failure test bioabsorbable screws in TMT-1 arthrodesis
The bioabsorbable fixation showed deformation of 9.0 mm ± 1.4 mm (range, 7.7 mm – 11.8 mm) compared with titanium alloy fixation of 9.9 mm ± 2.2 mm (range, 7.4 mm – 16.1 mm) (P=0.271). The failure modes of the bioabsorbable screws and the titanium alloy screws are presented in Table 5. An analysis of the failure models showed a difference in breakage models between the bioabsorbable and the titanium alloy groups. The titanium alloy screws failed (6/15) as the result of bending. In other cases, failure occurred as the result of breakage of the cuneiform medial caused by a small split (9/15). In the bioabsorbable group, breakage occurred more often (11/15) due to bending. One bioabsorbable model failed by the pull out of the MT at the site of screw (1/15), and two bioabsorbable models broke the cuneiform medial (2/15), as was the case with most of the titanium alloy screw failures (Table 5).
Table 6. Fixation failure modes of titanium alloy and bioabsorbable screws after TMT-1 arthrodesis setup

<table>
<thead>
<tr>
<th>Fixation</th>
<th>Breakage</th>
<th>Bending</th>
<th>Pull</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium screw fixation</td>
<td>9</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Bioabsorbable screw fixation</td>
<td>3</td>
<td>11</td>
<td>1</td>
</tr>
</tbody>
</table>

5.5 Bioabsorbable vs. titanium alloy screw in MTP-1 arthrodesis; a cup and cone preparation or straight saw

In this second biomechanical study, we found that there were differences between the bioabsorbable “cup and cone” and bioabsorbable straight cut techniques in yield load, stiffness, and max failure (Table 6). There were also differences between the bioabsorbable and titanium alloy groups in yield load, stiffness, and max failure (Table 6; Figure 23). All the load-displacement curves act like a stress-strain curve profile, as described in the first biomechanical study. The curve profile was similar in all three groups.
<table>
<thead>
<tr>
<th></th>
<th>Bioabsorbable screw fixation (Q1: Mean: Q3) cup and cone</th>
<th>Bioabsorbable screw fixation (Q1: Mean: Q3) straight saw</th>
<th>Titanium screw Fixation (Q1: Mean: Q3) cup and cone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yield load (N)</td>
<td>52.57: 58.18: 62.75</td>
<td>78.49: 81.02: 85.16</td>
<td>90.62: 91.82: 99.43</td>
</tr>
<tr>
<td>p</td>
<td>p=.009</td>
<td>p=.009</td>
<td>p=.009</td>
</tr>
<tr>
<td>p</td>
<td>p= .917</td>
<td>p=.117</td>
<td>p=.917</td>
</tr>
<tr>
<td>p</td>
<td>p=.009</td>
<td>p=.009</td>
<td>p=.009</td>
</tr>
<tr>
<td>Max failure (N)</td>
<td>61.34: 78.01: 86.33</td>
<td>116.87: 125.91: 131.48</td>
<td>127.75: 132.94: 138.30</td>
</tr>
<tr>
<td>p</td>
<td>p=.009</td>
<td>p=.009</td>
<td>p=.009</td>
</tr>
</tbody>
</table>
Figure 23. Yield load boxplot graphs of bioabsorbable and titanium alloy screws fixations after MTP-1 arthrodesis setup.
Table 8. Summary of materials

<table>
<thead>
<tr>
<th></th>
<th>PATIENTS</th>
<th>MEN</th>
<th>WOMEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY I</td>
<td>47 597</td>
<td>6 267</td>
<td>41 330</td>
</tr>
<tr>
<td>STUDY II</td>
<td>68 865</td>
<td>33 751</td>
<td>35 114</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>PATIENTS</th>
<th>MEN</th>
<th>WOMEN</th>
<th>AGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY III</td>
<td>15</td>
<td>3</td>
<td>12</td>
<td>48.3 (range 28-67)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>SPECIMENS</th>
<th>TITANIUM ALLOY</th>
<th>BIOABSORBABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY IV</td>
<td>30</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>SPECIMENS</td>
<td>TITANIUM ALLOY</td>
<td>&quot;Cup and cone&quot;</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>&quot;Cup and cone&quot;</td>
<td>5</td>
</tr>
<tr>
<td>STUDY V</td>
<td>15</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>
6 DISCUSSION

6.1 Trends of HV operations

This dissertation has covered different aspects of foot surgery with the aim of identifying the problems associated with different implant materials and determining surgery trends in foot and ankle disorders. The first study described the significant decreasing trend of HV operations in Finland between 1997 and 2014. The unique data used in this study included the whole population of Finland, a total of 47,597 primary HV operations over a period of 18 years. The gender distribution seen in our study (13% men, 87% women) is consistent with the findings of previous studies (Nix et al., 2010; Saro et al., 2008). According to Coughlin et al., HV deformities in males are an early onset and more severe deformity than that which occurs in women (Coughlin & Jones, 2007). A finding of our study was that the decrease in the rate of HV operations mostly concerned women, whereas the rate of operations in men remained steady. Moreover, based on the results of our study, it seems the number of primary HV operations have decreased during the last two decades, especially in persons aged 40 to 59 years and women. We believe that this decreasing trend, especially among middle-aged women, could be because HV deformities are more common in women. Moreover, the fact that knowledge of the complications and the long-term outcomes of HV surgery may affect this group and that smaller numbers of small surgeries, such as bunectomies and cheilectomies, are being performed could explain this decreasing trend (Roukis, 2010; Sidon et al., 2019).

In 2001 and 2003, Torkki and co-workers reported that operative treatment (distal osteotomy) of HV was cost-effective and beneficial compared with orthoses or no treatment (Torkki et al., 2001; Torkki et al., 2003). Consequently, after 2001, the incidence of HV primary operations increased slightly, and one explanation for this increase could be the evidence of cost-effectiveness provided by Torkki and co-workers (Torkki et al., 2001). Since then, however, there have only been a few studies on the subject, which could imply that there are some indications for the conservative treatment of HV disorders (Abdalbary, 2018; Gur et al., 2017; Karabicak et al., 2015). Nonoperative treatments aim to decrease the HV angle by stretching the contracted soft tissue around the joints using night splints, improving muscle strength.
through foot exercises, or resolving abnormal function with orthoses. Abdalbary presented an exercise program combined with the use of a toe orthosis that improved AOFAS score from 46.1 ± 1.4 to 76.2 ± 1.5 at 1-year follow-up (Abdalbary, 2018).

There are numerous different osteotomies in the MT-1 bone. There is, however, no evidence that one particular osteotomy type is superior to another (Chuckpaiwong, 2012; Ma et al., 2019; Wester et al., 2016). Surprisingly, the incidence of MT-1 osteotomy in our study nearly halved between 2005 and 2014, even though it was still the most common treatment method for HV deformity in 2014. This is an interesting finding since, in general, it had been thought that middle-aged individuals are nowadays more physically active than previously and would therefore insist on more active treatment and be more demanding to improve their ability to function through correction of their foot deformities. On the other hand, a better understanding of foot biomechanics and the risk for complications after surgery could also explain the decreasing trend. This increased knowledge resulted in a remarkable reduction in resection arthroplasty of the MTP-1 joint (Keller’s) procedure in the late 1990s. In 2014, resection arthroplasty accounted for only 4% of the surgical procedures for HV in Finland, and nowadays this procedure is not recommended. Resection arthroplasty may be effective in pain relief, but it carries a high risk for postoperative metatarsalgia due to the instability and poor function of the MTP-1 joint, which often needs second surgery (Coughlin & Mann, 1987; Vienne et al., 2006). This phenomenon can be explained by the complexity of the anatomy of the MTP-1 joint. Furthermore, it has been concluded that nowadays this joint is not suitable for arthroplasty replacement or resections (Pinney et al., 2006).

While the incidence of resection arthroplasty and osteotomies of the MT-1 have decreased, fusion operations of the MTP-1 and TMT-1 joints have gained in popularity, especially after 2005. For severe HV, an MTP-1 or TMT-1 joint arthrodesis is an excellent procedure for the correction of deformity and leads to a permanent and satisfactory result (DeSandis et al., 2016; Moerenhout et al., 2019). This increased popularity could be explained by the lack of knowledge of the biomechanics of the first ray or the impossibility of correcting soft tissue balance. Arthrodesis could be an easy way to control first ray disorders, as arthrodesis locks down the dynamic forces on the first ray, which does not happen in osteotomies or different arthroplasty techniques. There are, however, also significant complications after MTP-1 and TMT-1 arthrodesis. Roukis et al. showed that the overall incidence of radiographically confirmed nonunion after MTP-1 arthrodesis, regardless of the osteo-
The incidence of hardware removal was lowest for crossed compression screws (4.8%) and essentially equal for dorsal plate and screws with or without oblique compression screws (8.1%) and orthogonal compression staples (10.9%). The highest incidence of hardware removal was for a single intramedullary axial compression screw (13.3%) (Roukis, 2011). It seems that the complications associated with arthrodesis procedures are mainly related to implant materials, such as screws and plates, or iatrogenic complications.

6.2 Hardware removals by metallic implants

The purpose of the second epidemiology study was to investigate problems caused by metallic hardware. We decided to choose ankle fractures because the diagnosis code (ICD-10) is more accurate and obvious than other foot surgery codes, and bilateral foot surgery is more common than bilateral ankle fractures in the NHDR. We are planning, however, a retrospective research study on hardware removal surgery in elective foot surgery in future. Our nationwide study included a large number of ankle fracture surgeries (n=68 865) as well as hardware removal procedures 27% (n=18 648) during a 20-year study period. Previous studies have reported that the rate of hardware removal has ranged from 12% to 80% (Bostman & Pihlajamaki, 1996; Richards et al., 1992; Sanderson et al., 1992). This high variation might be due to cultural and treatment policy differences and may also be attributed to the different lengths of observation periods or analytic methods used between studies. The lowest hardware removal rates (12.5%) were reported by Fenelon et al. in 2018 (Fenelon et al., 2018). However, the authors of the study suggest that their results were an underestimation because of the retrospective nature of their study that could have led to a larger loss to follow-up. Additionally, Fenelon et al. showed that the majority of removals were due to symptomatic hardware (Fenelon et al., 2018). In another retrospective study by Naumann et al., it was reported that about 17% of patients underwent hardware removal over a 3-year period (Naumann et al., 2016).

A notable number, 8% (n=1 516), of hardware removal procedures were performed after 3 years. Taking this into account, we believe that previous studies have underestimated the hardware removal rate due to a shorter or total loss to follow-up. Moreover, we assume that most of the removals performed after more than three years were due to symptomatic hardware.
Approximately 10% of all ankle fractures have concomitant syndesmotic injury. In 15% to 23% of operatively treated ankle fractures, a syndesmotic disruption necessitates surgical repair with a syndesmotic screw (Egol et al., 2010; Jensen et al., 1998). Although surgical repair with a metallic screw is the gold standard technique, the need to remove the screw remains controversial. In their literature review in 2011 (including 7 studies between 2000 and 2010), Schepers reported that there is no need to routinely remove the syndesmotic screws (Schepers, 2011). In another systematic review, Dingemans et al. also suggested that the current literature does not support the routine removal of syndesmotic screws (Dingemans et al., 2016). Furthermore, the complication rate for routine syndesmotic screw removal is about 20% (Schepers, 2011). In their study, Fenelon et al. showed that 6.1% of all patients underwent planned hardware removal and that the majority were for the removal of a syndesmosis screw with a median time of 3 months (Fenelon et al., 2018). Our register study could not separate all hardware removals (n=18,648) from only syndesmotic screw removal (0-3 months; n=8,005), but we assume that most removals within 3 months were syndesmotic screws. This assumption is supported by the fact that these procedures decreased markedly between 2011 and 2016, most likely due to changed evidence suggesting that syndesmotic screws do not need to be removed (Dingemans et al., 2016; Schepers, 2011).

Hardware removal causes significant costs to patients, hospitals, and societies through the consumption of health care resources and absence from work. The total economic cost of removal is difficult to calculate due to the multifactorial nature and financing of the Finnish health care system. However, Fenelon et al. reported the cost of hardware removal to be €1,113 per patient in Ireland (Fenelon et al., 2018). A study by Lalli et al. from the United States found the average cost of syndesmosis screw removal was $3,579, ranging from $287 to $9,981 (Lalli et al., 2015). In this figure, they included anesthesia, operating room fees, recovery room fees as well as pharmacy, laboratory, and supplies costs. In this present study, the DRG-based hospital payment system was used to reflect the cost of hardware removal (€794.04), but this sum does not include the costs of drug prescriptions, missed work, or loss of income.

According to our results, the annual cost of hardware removal decreased due to a decrease in removal rates (n=1,247 in 2001 and n=593 in 2016). In other words, in 2001 the nationwide cost of hardware removals was approximately €994,000, but in 2016 it was €472,600.

Bioabsorbable fixation materials have been suggested as a solution to the hardware removal problem. Indeed, good outcomes with bioabsorbable screws in ankle
fractures without secondary surgery have been reported (Partio et al., 1992). In a meta-analysis including four studies comparing bioabsorbable and metallic screws, Wang et al. showed that all metallic screws were routinely removed 6 to 8 weeks after primary operation, whereas only two symptomatic patients (2.6%) in the absorbable screw group needed re-surgery (Wang et al., 2013). In their meta-analysis, van der Eng et al. found no significant differences in the incidence of complications between patients treated with a PLA/PLLA screw and patients treated with a metallic screw in using the syndesmosis screw (van der Eng et al., 2015). In the past, rapidly degrading PGA screws were associated with delayed inflammatory reactions, foreign body reaction, formation of a sinus, tract or fistula, and osteolysis. However, there is no evidence that the PLA/PLLA combination has such problems (Bostman et al., 2005; Wang et al., 2013). The key advantage of using biomaterials is that hardware removal becomes unnecessary.

6.3 Interpositional arthroplasty

Interpositional arthroplasty techniques aim to resolve the problems associated with resection arthroplasty and arthrodesis (Patel et al., 2019). To our best knowledge, our study is the first clinical evaluation of the long-term results (average 9.4 years) of MTP interpositional arthroplasty using a bioabsorbable PLDLA interpositional implant. Results show that the operations reduced pain and that patients were satisfied with the improved movement of the MTP-1 joint in long-term follow-up.

The PLDLA implant was initially developed to retain joint movement and to avoid postoperative deformities caused by the formation of loose connective tissue inside the joint (Waris et al., 2008). We cannot compare our technique with the Brandes-Keller procedure, but it seems that there might not be similar problems with postoperative metatarsalgia or deformities with the PLDLA implant. Complications associated with the interpositional arthroplasty technique may include shortening of the first ray, lesser metatarsalgia, and weakness with hallux plantarflexion (Coughlin & Shurnas, 2003; Lau & Daniels, 2001; Perler et al., 2013; Polzer et al., 2014).

Bertlet et al. reported good short-term results with a regenerative tissue matrix without wound healing problems, infections, inflammatory reactions, instabilities, malalignments, or loss of push-off strength at 12.7-month average follow-up (Berlet et al., 2008). They also reported that the average postoperative AOFAS scores of the same cohort were 65.8 (range, 58 – 68) with notable pain relief and preserved foot function at 5-year follow-up (Hyer et al., 2012). All patients reported their surgery
had been successful at a mean 5-year follow-up (Hyer et al., 2012). In our cohort, the average postoperative AOFAS scores were 80.5 (range, 70 – 95) compared with preoperative scores of 40 (range, 27 – 65).

As described earlier, the MTP-1 joint arthrodesis is nowadays a common procedure and its popularity has grown during the last years. Today, the procedure is even considered to be the gold standard. However, the procedure has several drawbacks, such as loss of foot function, failure of fixation, nonunion, and transfer metatarsalgia (Yu & Gorby, 2004). A recent prospective multicenter RCT did not report any differences between the interposition of a synthetic hydrogel cartilage matrix and the gold standard primary arthrodesis (Baumhauer et al., 2016). The interpositional technique offers a motion-sparing alternative for the treatment of severe HV and end-stage HR of the MTP-1 joint, but it does not exclude a later arthrodesis (Grimes & Coughlin, 2006).

The PLDLA implant is osteolytic, which explains the findings in the follow-up radiographs with all patients. There is a controversial view that these osteolytic changes in bioabsorbable materials could lead to infection or non-union (Honkanen et al., 2009; Pelto-Vasenius et al., 1997). Nevertheless, these radiological changes are thought to be part of the process of hydrolysis (Pelto-Vasenius et al., 1997). In this study, the radiological findings did not correlate with the clinical outcomes.

To date, there have been no high-quality level I studies describing the outcomes of interpositional arthroplasty that can be compared with other HV or HR techniques. In our study, the sample size of 15 patients (21 MTP joints) was quite small. However, other studies have had comparable sample sizes (Berlet et al., 2008; Patel et al., 2019). Moreover, an additional strength of this study is the much longer follow-up compared with other studies.

6.4 Biomechanical testing

An alternative choice for interpositional arthroplasty is MTP-1 arthrodesis. Therefore, we decided to do two biomechanical tests for TMT-1 and MTP-1 arthrodesis in order to find out whether the bioabsorbable screw can be used to make reliable fixations. These bioabsorbable screws could solve the problems that are associated with titanium alloy or steel implants after the arthrodesis procedure. In the first biomechanical study, we compared the initial strength between titanium alloy and bioabsorbable screws in TMT-1 arthrodesis. The results of the study showed that titanium alloy screw fixation is stronger than bioabsorbable screw fixation in TMT-1
arthrodesis. However, although titanium alloy screws provided higher fixation strength, the bioabsorbable screws might also have exceeded the estimated maximum force required to retain stability until union occurs in the TMT-1 bone, which has to be proven in a clinical series (Dayton et al., 2018). We therefore consider that both screws could provide clinically sufficient strength for TMT-1 arthrodesis fixation.

In the second biomechanical study, we compared two different surgery techniques in MTP-1 arthrodesis with bioabsorbable screws. The results of the study showed that the straight cut technique is biomechanically stronger than “cup and cone” when using two bioabsorbable crossing screws. One cadaver biomechanical study also reported that planar MTP surfaces are stronger than “cup and cone” using the cancellous screw fixation device (Sykes & Hughes, 1986). Harris et al. showed in synthetic bone models that planar joint preparation allowed less deformation than “cup and cone” using dorsal plating combined with IFCS (Harris et al., 2017). In a biomechanical study, Curtis et al. reported the superiority of cup-cone reaming and fixation with IFCS and plate when compared with planar excision combined with either crossed Kirschner wires, dorsal plate, or single IFCS (Curtis et al., 1993). It is unclear, however, which preparation is the best possible for MTP-1 arthrodesis while still retaining the first ray length. The “cup and cone” preparations allow for a high degree of adjustability compared to planar surface, making final alignment of the hallux easier (Goucher & Coughlin, 2006). As a result, it should be easier to achieve the recommended dorsiflexion fusion angle of between 15 degrees and 20 degrees from the metatarsal axis and the recommended valgus fusion angle of 15 degrees to 20 degrees (Aas et al., 2008).

We found that titanium alloy screw fixation is more rigid in both TMT-1 and MTP-1 arthrodesis than bioabsorbable fixation. However, from the clinical point of view, it is not known whether rigid fixation could lead to more reliable union. There is the possibility that more rigid fixation could lead to more reliable union, but there is no clear evidence to support this. The main complications in TMT-1 and MTP-1 arthrodesis are non-union, malposition, hardware removal, IP joint and arthritis, metatarsalgia, and first ray shortening (Buddecke et al., 2020; Coughlin & Shurnas, 2003; Hope et al., 2010; Mallette et al., 2014; Peterson et al., 2016). Rashid et al. reported that the complication rate was 26% after MTP-1 arthrodesis with a plate and CLS. Moreover, in patients treated with a CLS or plate alone, the complication rate was 20% (Rashid et al., 2015). A systematic review of patients that underwent MTP-1 arthrodesis showed a similar complication rate of 23.1% (Stevens et al.,
2017). Faber et al. reported long-term results after TMT-1 arthrodesis with a complication rate of 8.7% (Faber et al., 2013).

6.5 Limitations and strengths of the dissertation

Our epidemiological studies have some limitations. Most importantly, studies were register-based and bilateral operations to the same patient cannot be differentiated from the registry data. Additionally, the reason for hardware removal remained unclear because the reason for removal is poorly recorded using ICD-coding. Also, patient-related risk factors, such as smoking, diabetes, or alcohol consumption, are not reliably recorded to the NHDR. A further limitation of our study was the retrospective design and the debatable preoperative evaluation with PROM measures. Conversely, a strength of the studies was the accuracy and coverage of the NHDR database, which is collected from all Finnish hospitals.

NHDRs that have national coverage are rare and seem to be a Scandinavian phenomenon. The validity of the NHDR has been reported in numerous studies. This is important, as the National Institute of Health and Welfare and also individual hospital districts routinely use the register data to assess the need for various treatments (Huttunen et al., 2014; Keskimäki & Aro, 1991; Mattila et al., 2008; Sund et al., 2007). Furthermore, a part of the billing of Finnish public hospitals is based on NHDR data. The data in the NHDR have also been used in research, which places a high demand on the validity of the data.

Our biomechanical studies also have some limitations. Although biomechanical testing with Sawbones® products is widely used, and thus an acceptable method of testing different fixations, biomechanical results using this material are not directly comparable to a clinical setting, as synthetic bones may not accurately reflect the properties of real bone (Landsman & Chang, 1998). Further, the degradation process of bioabsorbable screws and changes in mechanical properties during the degradation process cannot be tested with Sawbones® models. On the other hand, the advantages of synthetic bones are the homogeneity of specimens and the good reproducibility of fixation. Studies were conducted by applying a single continuously increasing load, and therefore do not address the question of the effect of repetitive loading on the constructs.

Our test results indicate that the MTP-1 joint arthrodesis and TMT-1 joint arthrodesis with bioabsorbable screws could be an alternative fixation material. When compared with titanium alloy implants, bioabsorbable fixation implants have several
clinical advantages. The most important of these is that the use of bioabsorbable implants eliminates the need for secondary surgery due to implant removal. Peterson and colleagues showed that the incidence of symptomatic hardware removal after TMT-1 arthrodesis is approximately 15% and commonly occurs 9 months after surgery (Peterson et al., 2016). Furthermore, in contrast to titanium alloy implants in clinical use, bioabsorbable implants do not interfere with imaging or cause stress shielding, growth restriction, or an accumulation of titanium alloy in tissues (Rokkanen et al., 2000).

Several studies have reported good results in using bioabsorbable materials in foot and ankle surgery (Rokkanen et al., 2000). Kim and colleagues reported that the use of bioabsorbable screws in scarf osteotomy yielded good radiographic outcomes and good patient satisfaction in a cohort of 115 patients with only a small number of complications (Kim et al., 2016). The complications included skin irritation (1 patient), foreign body reaction (1 patient), dorsal cutaneous nerve symptoms (3 patients), and iatrogenic metatarsal fracture (4 patients) (Kim et al., 2016). Bioabsorbable fixation with a bioabsorbable pin has been used in Chevron osteotomy with good outcomes. Moreover, one study showed that fixation with a bioabsorbable pin was as reliable as fixation with a metal screw and allowed major angular corrections in 5-year follow-up (Morandi et al., 2013). Bioabsorbable screw fixations were comparable to other fixation devices for proximal interphalangeal joint fusion fixation with regard to success rate, revisions, and patient acceptance (Wendelstein et al., 2017). Bioabsorbable screws have also been used in foot and ankle trauma. Ahmad and Jones reported that bioabsorbable screws are comparable and not significantly different from steel screws in the treatment of unstable Lisfranc injuries (Ahmad & Jones, 2016). The use of bioabsorbable screws has also been reported in calcaneal fractures, and they were shown to provide sufficient stabilization and calcaneal fracture healing/union with the added advantage of not needing to remove the implant (Zhang et al., 2011; Zhang et al., 2012). It seems that there have been good results in a variety of indications for the use of bioabsorbable implants, although several studies have reported that titanium alloy or steel screws are mechanically stronger than bioabsorbable screws (Ciccone et al., 2001; Daghino et al., 2019; Rokkanen et al., 2000).

The main disadvantage of bioabsorbable implants is the difficulty in controlling the degradation process. The rate of biodegradation depends on several factors, such as the chemical composition of the material, its molecular weight, the presence of impurities, its crystallinity, the sterilization process, the shape and size of the implant, and the surface quality of the implant (Tormala, 1992; Tormala et al., 1998). During
the degradation process, the bioabsorbable screw gradually loses its strength, but it remains functional for at least 8 weeks (Tormala et al., 1998). Because there are differences in degradation process between bioabsorbable materials (Table 2), there is a need for clinical trials to validate our conclusions.

As described earlier, there are still disadvantages with the orthopaedic implant materials we use today. Therefore, attempts are being made to develop new implant materials and surgery methods to improve surgical outcomes. We still do not know what the optimal strength of fixation is in different indications, and there is no evidence of how different implant materials influence the inside of the bone. Moreover, we also lack knowledge of whether all patients should have the same treatment or implant despite differences in their age or functional ability. Future studies should therefore focus on developing new implant materials with a wide range of biomechanical strength and more beneficial and cost-effective surgery methods.
7 CONCLUSION

This dissertation has shown that the overall incidence of HV surgery decreased markedly between 1997 and 2014 in Finland. MT-1 osteotomy is still the most common technique used in the surgical treatment of HV. However, there is an increasing trend to use MTP-1 and TMT-1 arthrodesis in the primary surgical treatment of HV.

The findings of this 20-year nationwide study show that 27% of patients underwent a hardware removal procedure after ankle fracture surgery. The number of routine syndesmosis screw removals has, however, decreased, resulting in lower economic costs. A remarkable number of hardware removal procedures are being performed after the 3-year postoperative period.

We reported good long-term results using a bioabsorbable interpositional PLDLA implant. The results of our study indicate that interpositional arthroplasty using a PLDLA implant is a safe technique that should be evaluated in future in a randomized controlled study setting with low rate reoperations (2 patients).

Bioabsorbable cannulated screws are a potential alternative to titanium alloy or steel screws for TMT-1 and MTP-1 arthrodesis, but the results should be confirmed in clinical RCT studies. The cannulated screws make fixation easier by using Kirschner wires, and with bioabsorbable screws the need for a second surgery to remove the screws can be avoided. This study shows that the straight cut technique is biomechanically stronger than “cup and cone” with two bioabsorbable crossing screws.


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Törnä, P., Vainionpaa, S., Kilpikari, J., & Rokkanen, P. (1987). The effects of fibre reinforcement and gold plating on the flexural and tensile strength of


Incidence of hallux valgus primary surgical treatment. Finnish nationwide data from 1997 to 2014

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ABSTRACT

Background: Many surgical procedures have been described for hallux valgus. Evidence provided by the current literature on the different procedures is, however, poor. The purpose of this study was to assess the incidence of HV surgery in Finland between 1997 and 2014 and to find out whether changes in operation techniques of HV have occurred during the study period.

Methods: The study included all adult patients (≥18 years) who underwent primary HV operation. Patients were included into study if they had been operated with a diagnosis of HV (ICD-10 code M20.1). The data were collected by the Finnish National Hospital Discharge Register (NHDR).

Results: The total incidence of primary HV operations was 66.7 per 100,000 person-years in 1997 and 41.4 per 100,000 person-years in 2014. The incidence of arthroplasty operations of the MTP-1 joint decreased while at the same time the incidence of the MTP-1 joint arthrodesis and TMT-1 arthrodesis increased. The gender difference (13% men, 87% women) is consistent with previous studies.

Conclusion: This study shows a significant decreasing trend of HV operations in Finland between 1997 and 2014. During the study period, the incidence of MTP I joint arthroplasty decreased, and since 2005 the incidence of MT-1-osteotomies has almost halved. At the same time, the incidence of MTP-1 joint arthrodesis increased by over 1000% and TMT-1 joint arthrodesis by nearly 2000%.

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arthrodese are mainly recommended [11]. Resection arthroplasty has played a historical role in HV surgery. Nowadays, however, it is well known that resection arthroplasty carries a high risk of postoperative metatarsalgia due to the instability and poor function of the first MTP joint [12,13]. First toe phalangeal osteotomies are mainly used as additional procedures.

The distal MT-1 procedure is considered to be relatively easy with fast recovery and few early postoperative complications [14,15]. On the other hand, diaphyseal and proximal MT-1 osteotomies have been thought to be more effective in correcting the deformity compared with distal MT-1 osteotomies [16–18]. The findings of a recent RCT by Lee et al., however, showed no difference in outcome between distal and proximal MT-1 osteotomies [19]. An RCT study by Torkki et al. in 2001 showed that a Chevron osteotomy was an effective treatment for painful HV [9]. Another study by the same group showed that HV surgery was also cost-effective [20].

Arthrodesis of the first MTP joint is an established procedure in the treatment of severe HV [21,22]. The procedure has been shown to reliably reduce the pain caused by HV, improve foot function, and allow a return to previous physical activity [22]. TMT I arthrodesis provides very powerful correction of HV, intermetatarsal I–II angle, and also the rotational deformity of the first metatarsal, which is rarely discussed and not addressed in most HV correcting procedures [23–26].

In their epidemiological study, Saro et al. found a higher prevalence of foot problems in women and showed that HV surgery was by far the most common foot procedure in Sweden [27]. The study included 4,409 surgical procedures for footfoot deformities between January 1997 and December 2000 in Sweden and gave a valid estimate of the amount of foot and HV surgery performed in six different regions of Sweden, but did not provide national incidence of the primary HV surgery [27].

The main purpose of this study was to assess the incidence of HV surgery between 1997 and 2014 in Finland. A second purpose was also to identify whether any changes in surgical techniques for the treatment of HV occurred during the study period. To our knowledge, this is the first nationwide epidemiological study that provides comprehensive data on primary HV surgery and surgical techniques.

2. Materials and methods

Founded in 1967, the Finnish National Hospital Discharge Register (NHDR) provides data on age, sex, domicile of the subject, duration of hospital stays, primary and secondary diagnosis, and operations performed during the hospital stay. The data collected by the NHDR is mandatory for all hospitals, including private, public, and other institutions. The validity of the NHDR is excellent regarding both the coverage and accuracy of the database [28–31].

In 1996, the Nordic Medico-Statistical Committee (NOMESCO) published the first printed edition of the NOMESCO Classification of Surgical Procedures (NCSF) [32]. A Finnish translation (NCSF-F) was introduced in 1997, and the Finnish procedural coding changed accordingly. The patient data for this study were therefore obtained from the Finnish NHDR between 1997 and 2014.

For the purpose of this study, we included all adult patients (≥18 years) who underwent HV operation. Patients were included into study if they had been operated with a diagnosis of HV (ICD-10 code M20.0). The procedural codes (according to the Finnish version of the NOMESCO classification) for the HV included NHK30 (MT-1 osteotomy including proximal, diaphyseal and distal ones), NHK99 (other operation on bone of ankle or foot—bunionectomy and cheilectomy) and NHG80 (MTP-1 joint arthrodesis), NHG70 (MTP-1 joint arthroplasty – resection, interposition), and NHG26 (TMT-1 joint arthrodesis). Both outpatient and inpatient operations were included in the study. Since the NHDR does not include laterality of the operation, only the patient’s first HV operation (primary) during the study period was included in the analysis.

3. Statistical analysis

To compute the incidence ratios of the HV surgery, the annual mid-population data for each calendar year of the study period was obtained from the Official Statistics of Finland [33]. The resulting rates of operatively treated HV (per 100,000 person-years) were based on the entire adult population of Finland rather than cohort or sample-based estimates. Therefore, in full accordance with our previous national studies, 95% intervals or other statistical estimation methods were not used [34]. Data were analyzed with SPSS Statistics 24 (IBM).

4. Results

Between 1997 and 2014, a total of 47,597 primary HV operations were identified in Finland. The number of primary operations was 62,676 (15.2%) in men and 41,330 (84.8%) in women. The total incidence of primary HV operations was 66.7 per 100,000 person-years in 1997 (2951 operations) and 41.4 per 100,000 person-years in 2014 (2951 operations). In men, the incidence was 10.1 per 100,000 person-years in 1997 and 6.2 per 100,000 person-years in 2014. In women, the corresponding figures were 64.9 per 100,000 person-years in 1997 and 38.3 per 100,000 person-years in 2014 (Fig. 1).

In patients aged 50–59 years, the incidence of primary HV operations decreased from 190.5 per 100,000 person-years in 1997 to 88.8 per 100,000 person-years in 2014 while in persons aged 40–49 years the incidence of primary HV operations decreased from 92.8 per 100,000 person-years in 1997 to 50.5 per 100,000 person-years in 2014. There was no marked change in patients aged 70 or older, the incidence being 11.4 per 100,000 person-years in 1997 and 10.3 per 100,000 person-years in 2014. In patients aged 60–69 years, the incidence of primary HV operations decreased from 123 per 100,000 person-years in 1997 to 84.4 per 100,000 person-years in 2014 (Fig. 2).

During the 18-year study period, MT-1 osteotomy was the most common primary operative procedure performed (n = 26,667; 62.1%) followed by MTP-1 arthroplasty (n = 8910; 20.8%), MTP-1 arthrodesis (n = 4527; 10.4%), TMT-1 arthrodesis (n = 1574; 3.7%), and other operation on bone of ankle or foot, including bunionectomy and cheilectomy (n = 1259, 2.9%).

The incidence of arthroplasty operations of the MTP-1 joint decreased from 30.9 per 100,000 person-years in 1997
(n = 1369, 47%) to 1.8 per 100,000 person-years in 2014 (n = 86, 4%) while the incidence of MTP-1 joint arthrodesis increased from 1.3 per 100,000 person-years in 1997 (n = 56, 2%) to 14.9 per 100,000 person-years in 2014 (n = 725, 36%). Overall, the incidence of MT-1 osteotomy decreased from 32.1 per 100,000 person-years in 1997 (n = 1421, 48%) to 20.7 per 100,000 person-years (n = 1005, 50%) in 2014, but the proportion of MT-1 Osteotomies of all surgical procedures maintained between 1997 and 2014. Between 1997 and 2005 the proportion of MT-1 osteotomies increased from 48% to 73%, but decreased again to 50% in 2014. The incidence of TMT-1 joint arthrodesis increased from 0.2 per 100,000 person-years in 1997 (n = 7, 0.2%) to 3.1 per 100,000 person-years in 2014 (n = 149, 8%) (Fig. 3).

5. Discussion

This study is the first to describe the significant decreasing trend of HV operations in Finland between 1997 and 2014. To the best of our knowledge, there have been no previous studies that have covered nationwide trends in primary HV surgery. The unique data used in this study included the whole population of Finland, a total of 47,597 primary HV operations over a period of 18 years. This large number of patients provides a comprehensive sample of HV surgery. The gender distribution seen in our study (13% men, 87% women) is consistent with previous studies [27,35]. Accordingly to our results, it seems that during the last two decades the numbers of primary HV operations are decreasing, especially in persons aged 40–59 years. During the study period, the incidence of MTP-1 joint arthroplasty decreased from being the second most popular procedure to the least used. Furthermore, the incidence of MT-1 osteotomies has almost halved since 2005. At the same time, the incidence of MTP-1 joint arthrodesis increased by over 1000% and TMT-1 joint arthrodesis by nearly 2000%. In 2014, the most common operative procedure to treat HV was MT-1 osteotomy (n = 1005, 50%), followed by MTP-1 joint arthrodesis (n = 725, 36%), and TMT-1 joint arthrodesis (n = 149, 8%).

The majority of HV patients were women. In women, the incidence was 64.9 per 100,000 person-years in 1997 and 38.3 per 100,000 person-years in 2014. The incidence of primary operation in men was 10.1 per 100,000 in 1997 and 6.2 per 100,000 person-years in 2014. At the end of the study period, the mean age of the operatively treated HV patient was 58 years, and 86% of the patients were female. The female-male ratio of HV operation has also been confirmed in other studies [3,5]. The etiology of HV differs between men and women [35]. It has been previously suggested that HV is more often associated in women with lower BMI and high heels worn between the ages of 20 and 64. In men, HV is associated with higher BMI and pes planus [35].

In 2001 and 2003, Torkki et al. showed that the operative treatment of HV was cost-effective [9,20]. Interestingly, after 2001, the incidence of HV primary operations increased slightly and one explanation for this increase could be the evidence of cost-effectiveness provided by Torkki et al. However, a decrease in the incidence of HV operations began in 2005, especially in persons aged 40–59 years. This is an interesting finding because, in general, it had been thought those middle-aged individuals are more physically active than previously and would thus insist on more active treatment. On the other hand, a better understanding of foot biomechanics and the factors behind the pathogenesis of HV have provided better conservative means of treating mild deformities and ways for patients to better cope with the deformity. To date, however, there are no studies to support this claim. Moreover, there have been no studies that explain the overall decreasing trend in HV operations. Economical or insurance policy changes can hardly explain the decreasing trend seen in this study because the public health care system in Finland is free.

![Incidence in-age-group](image)

**Fig. 2.** Incidence of HV operation by age-group.

![Proportion of primary operation technique](image)

**Fig. 3.** Proportion of primary operation technique.
A limitation of our study is that the reoperations or bilateral operations to the same patient cannot be differentiated from the registry data. Therefore, only the first HV operation of each patient was included in the analysis, and thus resulted in a slight underestimation of the true incidence of HV operations. The most important strength of the current study is the accuracy and coverage of the obligatory Finnish NHDR which provided the data for the study. Furthermore, this is the first nationwide study that has assessed the incidence of HV surgery.

To date, there have been no studies that show that one technique is better than any other for HV surgery. This study has shown that the overall incidence of HV operation has decreased remarkably during the last two decades. It is not known, however, whether this decrease is due to an increased incidence of the deformity itself, an increased awareness of the short- and long-term complications after HV operations, or the improved means of conservative treatment. This study has also shown that during the last two decades the popularity of resection arthroplasty of the first MTP joint in the treatment of HV has decreased. During the first decade of the study period there was an increase in the proportion of MT-1 osteotomies but after 2008 the proportion of MT-1 osteotomies decreased again. Towards the end of the study period the proportion of MT-1 and TMT-1 arthrodeses increased in Finland, leading to a reduction in the proportion of MT-1 osteotomies. Overall, the proportion of MT-1 osteotomies maintained steady in this study period (from 48% in 1997 to 50% in 2014).

6. Conclusions

The overall incidence of HV surgery has decreased markedly in Finland between 1997 and 2014. This study shows that MT-1 osteotomy is the most common technique in the surgical treatment of HV, but there is an increasing trend to use MTP-1 and TMT-1 arthrodesis in the primary surgical treatment of HV.

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Reduced incidence and economic cost of hardware removal after ankle fracture surgery: a 20-year nationwide registry study

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Reduced incidence and economic cost of hardware removal after ankle fracture surgery: a 20-year nationwide registry study

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Background and purpose — Open reduction and internal fixation (ORIF) is a treatment method for unstable ankle fractures. During recent years, scientific evidence has shed light on surgical indications as well as on hardware removal. We assessed the incidence and trends of hardware removal procedures following ORIF of ankle fractures.

Patients and methods — The study covered all patients 18 years of age and older who had an ankle fracture treated with ORIF in Finland between the years 1997 and 2016. Patient data were obtained from the Finnish National Hospital Discharge Register.

Results — 68,865 patients had an ankle fracture treated with ORIF in Finland during the 20-year study period between 1997 and 2016. A hardware removal procedure was performed on 27% of patients (n = 18,648). The incidence of hardware removal procedures after ankle fracture decreased from 31 (95% CI 29–32) per 100,000 person-years in the highest year 2001 (n = 1,247) to 13 (CI 12–14) per 100,000 person-years in 2016 (n = 593). Moreover, the proportion and number of removal operations performed within the first 3 months also decreased. The costs of removal procedures decreased from approximately €994,000 in 2001 to €472,600 in 2016.

Interpretation — Removal of hardware after ankle surgery (ORIF) is a common operation with substantial costs. However, the incidence and cost of removals decreased during the study period, with a particular decrease in hardware removal operations within 3 months.
Patients and methods

Study design and data sources
The Finnish National Hospital Discharge Register (FNHDR) was founded in 1967. It provides data on age, sex, domicile of the subject, duration of hospital stays, primary and secondary diagnosis, and surgical procedures performed during the hospital stay. The data collected by the FNHDR are mandatory for all hospitals, including private, public, and other institutions. The validity of the FNHDR has been proven to be excellent regarding both the coverage and accuracy of the database.

In 1996, the Nordic Medico-Statistical Committee (NOMESCO) published the first printed edition of the NOMESCO Classification of Surgical Procedures (NCSP) followed by the Finnish translation (NCSP-F) in 1997.

Study population
We included all adult patients (≥18 years) with a diagnosis of ankle fracture (ICD-10 code) and who underwent ankle fracture surgery (ORIF) between January 1, 1997 and December 31, 2016.

The procedural codes (according to the Finnish version of the NOMESCO classification) for the ankle fracture included NHJ10 (internal fixation of fracture of ankle using plate, wire, rod, cerclage, or pin) and NHU20 (hardware removal). The primary outcome was the incidence of operative treatment of ankle fractures and hardware removal. Since the FNHDR does not include laterality of the operation, only the patient’s 1st ankle fracture ORIF operation performed during the study period was included in the analysis.

A secondary outcome was the cost of hardware removal as determined by diagnosis-related group-based (DRG-based) hospital payment system pricing. In Finland as well as in most Organization for Economic Co-operation and Development (OECD) countries, DRG-based hospital payment systems are being used. The basic idea of DRG-based hospital payment systems is that all patients treated by a hospital are classified into a limited number of DRGs that are supposed to be clinically meaningful and relatively homogeneous in their patterns of resource consumption.

Statistics
The trends for operatively treated ankle fracture and hardware removal (per 100,000 person-years) were based on the entire adult population of Finland rather than cohort or sample-based estimates. Mid-year population size was estimated by taking the geometric mean of year-end population sizes of consecutive years. Incidence density rate and operations total rate are presented with the 95% confidence interval (CI). Data were analyzed with R 3.5.3 (R Foundation for Statistical Computing, Vienna, Austria).

Ethics, registration, funding, and potential conflicts of interest
The study was approved by Finland: National Institute of Health and Welfare (THL): THL/89/5.05.00/2012. The study was funded by Finland’s government research and development foundation. Funding sources were not involved in study design, collection, analysis, interpretation, or completion. The authors declare no conflicts of interest regarding this study.

Results
68,865 adult patients (51% women) had an ankle fracture surgically treated with ORIF in Finland during the 20-year study period between 1997 and 2016. The mean age at the time of the 1st surgery in 1997 was 52 years in women and 44 years in men. In 2016, the corresponding ages were 57 years in women and 47 years in men. The total incidence of ankle fracture surgery was 81 (CI 78–83) per 100,000 person-years in 1997 (3,218 operations) and 74 (CI 71–76) per 100,000 person-years in 2016 (3,276 operations) (Figure 1). In men, the incidence was 87 (CI 83–91) per 100,000 person-years in 1997 and 72 (CI 68–75) per 100,000 person-years in 2016. In women, the corresponding figures were 80 (CI 76–84) per 100,000 person-years in 1997 and 82 (CI 79–86) per 100,000 person-years in 2016.

During the 20-year study period, a total of 18,648 (27%) hardware removal procedures (52% women) were performed after primary ankle fracture surgery. The mean age at the time of the first hardware removal in 1997 was 53 years in women and 45 years in men. In 2016, the corresponding ages were 56 years in women and 57 years in men. The incidence of hardware removal procedures after ankle fracture surgery decreased from 31 (CI 29–32) per 100,000 person-years in the highest year, 2001 (n = 1,247), to 13 (CI 12–14) per 100,000 person-years in 2016 (n = 593) (Figure). In men, the incidence was 32 (CI 29–34) per 100,000 person-years in 2001 and 12 (CI 11–13) per 100,000 person-years in 2016. In women, the corresponding figures were 30 (CI 27–32) per 100,000 person-years in 2001 and 15 (CI 13–16) per 100,000 person-years in 2016.

The mean time between ankle fracture surgery and hardware removal procedure was 14 months. 43% of the hardware removals occurred during 0–3 months after surgery, 8% during 3–6 months, 15% during 7–12 months, 21% during 13–24 months, 5% during 25–36 months, and 8% at over 36 months (Table). Hardware removals were conducted within 3 months for 538 (52%) of the 1,029 patients who underwent hardware removal in the highest year, 2007 (Table). Thereafter, the removal rate remained steady until 2012 when the removal rate decreased markedly from 49% to 26% in 2016.

According to Finnish DRG-based hospital payment pricing, the direct costs for one ankle fracture surgery were €2,881 per patient in 2016. This amounted to an annual direct cost of...
ankle fracture surgery of approximately €9,500,000 in 2016. The DRG-based costs for one hardware removal are €797. Thus, the costs of removal procedures in 2016 were approximately €472,600, whereas the corresponding removal costs in 2001 were almost €994,000.

Discussion

This study is the 1st nationwide study that shows a large number of ankle fracture surgeries (n = 68,865) as well as hardware removal procedures (27%; n = 18,648) during a 20-year study period. This study confirms the previous findings that the incidence of ankle fracture surgery is higher in young men and in older women (Kannus et al. 2016, Juto et al. 2018). The decreasing incidence of ankle fracture surgery might have been caused by the increasing knowledge of nonoperatively treated Weber-B type fractures, which can be either stable or unstable (Kortekangas et al. 2019). Stable ankle fractures can be treated non-surgically and account for about one half of all ankle fractures (Pakarinen et al. 2011, Van Schie-Van der Weert et al. 2012).

Previous studies have reported 12–80% of hardware removal (Richards et al. 1992; Sanderson et al. 1992, Bostman and Pihlajamaki 1996). This variation might be due to cultural and treatment policy differences and may also be attributed to the different lengths of observation periods or analytic methods between studies. The recent lowest hardware removal rates (13%) were reported by Fenelon et al. (2019). However, the authors suggest that their results were an underestimation because of the retrospective nature of their study that could have led to a larger loss to follow-up. Additionally, they showed that the majority of removals were due to symptomatic hardware. In another retrospective study reported that about 17% of patients underwent hardware removal over a 3-year period (Naumann et al. 2016).

Our study showed that 27% of patients underwent hardware removal. A notable number, 8% (n = 1,516), of hardware removal procedures were performed after 3 years. Therefore, we believe that previous studies have underestimated the hardware removal rate due to shorter follow-up. Moreover, we assume that most of the removals performed after more than 3 years were due to symptomatic hardware. Williams et al. (2018) reported improvement in function following ankle implant removal, but their sample size was small (43 patients) and there was no control group. Patient symptomatic relief after hardware removal is still controversial.

Approximately 10% of all ankle fractures have concomitant syndesmotic injury. In 15–23% of operatively treated ankle fractures, a syndesmotic disruption necessitates surgical repair with a syndesmotic screw (Jensen et al. 1998, Egol et al. 2010). However, the need to remove this screw remains controversial. In his literature review in 2011 (including 7 studies between 2000 and 2010), Schepers (2011) reported that there is no need to routinely remove the syndesmotic screws. In a recent systematic review, Dingemans et al. (2016) also suggest that the current literature does not support the routine removal of syndesmotic screws. Furthermore, the complication rate for routine syndesmotic screw removal is about 20% (Schepers et al. 2011). Fenelon et al. (2019) showed in their study that 6% of all patients underwent planned hardware removal and that the majority of procedures were for the removal of a syndesmotic screw after a median time of 3 months. Our register study could not separate all hardware removals from only syndesmotic screw removal, but we assume that most removals

<table>
<thead>
<tr>
<th>Year</th>
<th>Hardware removals 0–3 months</th>
<th>Total</th>
<th>Ratio (%)</th>
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<tbody>
<tr>
<td>1997</td>
<td>239</td>
<td>350</td>
<td>68</td>
</tr>
<tr>
<td>1998</td>
<td>343</td>
<td>941</td>
<td>37</td>
</tr>
<tr>
<td>1999</td>
<td>372</td>
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</tr>
<tr>
<td>2000</td>
<td>269</td>
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<tr>
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<td>528</td>
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</tr>
<tr>
<td>2016</td>
<td>152</td>
<td>593</td>
<td>26</td>
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</tbody>
</table>

Table 1. Frequencies and ratios of under 3 months hardware removals by year
within 3 months were of syndesmotic screws. This assumption is supported by the fact that these procedures decreased markedly between 2011 and 2016, most likely due to the changed evidence suggesting syndesmotic screws need not be removed (Figure) (Schepers 2011).

Hardware removal causes significant costs to patients, hospitals, and societies through the consumption of healthcare resources and absence from work. The total economic cost of removal is difficult to evaluate due to the multifactorial nature and financing of the Finnish healthcare system. However, Fenelon et al. (2019) reported the cost of hardware removal to be €1,113 per patient in Ireland. A study by Lalli et al. (2015) from the United States found the average cost of syndesmosis screw removal to be $3,579 ($287 to $9,981). In this figure, they included anesthesia, operating room and recovery room fees, as well as pharmacy, laboratory, and supplies costs. In our study, the DRG-based hospital payment system was used to reflect the cost of hardware removal (€794), but this sum does not include the costs of drug prescriptions, missed work, or loss of income.

According to our results, the annual cost of hardware removal decreased due to a decrease in removal rates (n = 1,247 in 2001 and n = 593 in 2016). In other words, in 2001 the cost of hardware removals was approximately €994,000 but in 2016 it was €472,600.

Bioabsorbable fixation materials have been suggested as a solution to the hardware removal problem. Good outcomes with bioabsorbable screws in ankle fractures without secondary surgery have been reported (Partio et al. 1992). In a meta-analysis including 4 studies comparing bioabsorbable and metallic screws, Wang et al. (2013) showed that all metallic screws were routinely removed 6–8 weeks after primary operation while only 2 symptomatic patients (3%) in the absorbable screw group needed re-surgery. In their meta-analysis, van der Eng et al. (2015) found no significant differences in the incidence of complications between patients treated with a polylactide acid (PLA)/polylactide acid (PLLA) screw and patients treated with a metallic syndesmotic screw. In the past, rapidly degrading polyglycolide acid (PGA) screws were associated with delayed inflammatory reactions, foreign body reaction, formation of a sinus, tract, or fistula, and osteolysis. However, there is no evidence that the PLA/PLLA combination has such problems (Bostman et al. 2005, Wang et al. 2013). The key advantage of using biomaterials is that hardware removal becomes unnecessary.

Our study has some limitations. Importantly, the study is register-based and bilateral operations on the same patient cannot be differentiated from the registry data. Additionally, the reason for removal remained unclear because the reason for removal is poorly recorded using ICD coding. Also, patient-related risk factors, such as smoking or alcohol consumption, are not recorded in the NHDR. A strength of the study is the accuracy and coverage of the NHDR database, which is collected from all Finnish hospitals. Indeed, the national coverage of the NHDR provided a large population of surgically treated ankle fractures for a 20-year period.

In summary, this 20-year nationwide study showed that 27% of patients underwent a hardware removal procedure after ankle fracture surgery. The number of routine syndesmosis screw removals seemed to decrease, resulting in lower economic costs. A substantial number of hardware removal procedures are being performed after the 3-year period.


INTERPOSITIONAL ARTHROPLASTY OF THE FIRST METATARSOPHALANGEAL JOINT WITH BIORESORBABLE PLDLA IMPLANT IN THE TREATMENT OF HALLUX RIGIDUS AND ARTHRITIC HALLUX VALGUS: A 9-YEAR CASE SERIES FOLLOW-UP

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ABSTRACT

Background and Aims: The interpositional arthroplasty was developed to retain foot function and to relieve pain due to the arthritis of the first metatarsophalangeal joint. The bioabsorbable poly-L-D-lactic acid RegJoint® interpositional implant provides temporary support to the joint, and the implant is subsequently replaced by the patient’s own tissue. In this study, we retrospectively examined the results of the poly-L-D-lactic acid interpositional arthroplasty in a 9-year follow-up study among patients with hallux valgus with end-stage arthrosis or hallux rigidus.

Material and Methods: Eighteen patients and 21 joints underwent interpositional arthroplasty using the poly-L-D-lactic acid implant between February 1997 and October 2002 at Tampere University Hospital. Of these, 15 (83.3%) (21 joints) patients were compliant with clinical examination and radiographic examination in long-term (average 9.4 years) follow-up. The mean age of the patients was 48.3 (from 28 to 67) years at the time of the operation. Six patients underwent the operation due to arthritic hallux valgus and nine patients due to hallux rigidus.

Results: The mean Ankle Society Hallux Metatarsophalangeal–Interphalangeal Scale and visual analogue scale (VAS) for pain scores improved after the operation in all patients. The decrease of pain (visual analogue scale) after the operation was statistically significant (77.5 vs 10.0; p < 0.001). Postoperative complications were observed in 3 (14.3%) joints of two hallux rigidus patients. For these patients, surgery had only temporarily relieved the pain, and they underwent reoperation with arthrodesis.

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BACKGROUND AND AIMS

Hallux valgus (HV) is a common chronic foot complaint, and hallux rigidus (HR) is the most common degenerative arthropathy of the foot (1, 2). The term HV describes the situation wherein the first metatarsophalangeal (MTP-1) joint is in malposition. The malposition forms when the first metatarsal rotates to valgus and turns to abduction, and this malposition can lead to MTP-1 degeneration. HR of the MTP-1 joint is a common arthritis condition that affects the big toe leading to a restricted and painful motion at the MTP-1 joint (1). Since the etiology is not the same, it is challenging to select the appropriate surgical method to correct arthritic HV and HR and to avoid the shortening of the first ray (1, 3).

A variety of surgical techniques for the treatment of arthritic HV and HR are described in the literature (2, 4). Keller performed the first resection interpositional arthroplasty, and Brandes performed the first resection in the proximal phalanx and inserted a part of the medial joint capsule into the joint to serve as a pillow (5). However, it is well known nowadays that resection arthroplasty carries a high risk of postoperative metatarsalgia due to the instability and poor function of the MTP-1 joint. Therefore, there is a need to research new techniques that will retain the mobility of the MTP-1 joint after HV or HR surgery (6).

Interpositional arthroplasty was first developed to retain foot function and to eliminate pain (7, 8). The purpose of the technique is to maintain MTP-1 mobility while at the same time stabilizing the varus–valgus movement of the joint and retaining the length of the toe. Several modifications have been used for interpositional arthroplasty, including the MTP-1 joint capsule, the extensor hallucis brevis (EHB), the flexor hallucis longus, the plantaris, and the gracilis tendons, and the bioresorbable implant. To date, however, there is no clear evidence or studies to compare different techniques, so there are no golden standard for interpositional arthroplasty (9).

A bioabsorbable poly-L-D-lactic acid (PLDLA) RegJoint® interposition implant has been developed at Tampere University of Technology (10). The porous implant provides temporary support for the joint, and it is designed to be replaced later by the patient’s soft tissue ingrowth to allow a gradual optimized replacement of the implant with fibrous tissue, providing a flexible, but durable, pseudojoint (10). The support provided by the implant is preserved for more than 2 months, and it takes between 2 to 3 years before the implant is fully replaced by own tissue (11). In this retrospective study, we examined the results of the PLDLA interpositional arthroplasty in a 9-year follow-up study among patients with HV with end-stage arthritis of the MTP-1 or HR.

MATERIAL AND METHODS

Eighteen patients underwent interpositional arthroplasty using the PLDLA implant (16, 18, or 20 mm) between February 1997 and October 2002 at Tampere University Hospital by five experienced foot and ankle surgeons. Of these 18 patients, 15 (83.3%) were compliant with clinical examination and radiologic assessment in long-term (average 9.4 years) follow-up. Six patients underwent bilateral operation; hence, the study comprised 21 joints. Twelve of the patients were female, and three were male. The mean age of the patients was 48.3 (from 28 to 67) years at the time of the operation. Six patients underwent surgery due to arthritic HV and nine patients due to HR.

Patients were controlled at a follow-up visit 9 years after the operation. Physical function was evaluated using the American Orthopedic Foot and Ankle Society Hallux Metatarsophalangeal-Interphalangeal scale (AOFAS). Preoperative AOFAS scores were collected from patients’ medical histories. Pain was evaluated using the visual analogue scale (VAS) from 0 to 10, where a higher number indicates higher pain and vice versa. The pain VAS was obtained before surgery and at the time of the follow-up visit. Furthermore, the palpation of the joint was clinically estimated, and any tenderness and swelling were recorded. The symptoms and findings were classified into four groups: no symptoms, slight symptoms, moderate symptoms, and substantial symptoms.

Plain radiographs were obtained from every patient, and the images were analyzed (anteroposterior, oblique, and lateral views) by a radiologist. The radiologist estimated the state of the joint, as no radiological classification exists for operations involving the bioabsorbable PLDLA interpositional implant.

Clinical and sociodemographic data are presented as means with ranges or as counts with percentages. Means of the paired continuous variables were compared with Wilcoxon test. Confidence interval was determined at 95%, and therefore p values of < 0.05 were considered to be statistically significant. Statistical analysis was performed using IBM® SPSS Statistics, version 22 software.

HV TECHNIQUE

Six patients with seven joints were operated due to end-stage arthritic HV. The operations were performed through a dorsal or dorsomedial longitudinal

Conclusion: In conclusion, interpositional arthroplasty using a poly-L-D-lactic acid implant yielded good results. This study indicates that the poly-L-D-lactic acid interpositional implant may be a good alternative for arthrodesis for treatment of end-stage degeneration of the first metatarsophalangeal joint.
incision. The capsule was then released and opened. The osteophytes were removed if needed. The bone resection was performed to base of proximal phalanx in four cases and to first metatarsal head in two cases, and in one case, the both sides were resected. The PLDLA implant was fixed in three joints with absorbable sutures through holes in the bone. In four joints, implants were inserted in the joint space without fixation. Bunonecction was done in three and adductor tenotomy in four cases. Additional procedure of the second toe was performed in two cases.

HR TECHNIQUE

Nine patients and 13 joints were operated due to HR. The approach and the opening of the capsule were the same as used in the HV technique. To create an adequate space for interposition implant, bone resections were made for all patients. Resection of the base of proximal phalanx was performed in 10 cases; first metatarsal head in five cases, and in one case, the both sides were resected. Bunionectomy was done in seven joints.

The mean postoperative immobilization time was (range) 23.7 (from 2 to 42) days. Postoperative regimen varied considerably; most patients used orthosis or postoperative shoe for 2–6 (average 3) weeks.

RESULTS

The mean AOFAS score and pain VAS improved after the operation in all patients (Table 1). The improvements were most notable in the Pain and Function subscales. All examined patients reported that the joint felt better than before the operation. The decrease of pain (VAS) after the operation was statistically significant (10.0 vs 77.5, p < 0.001).

The radiological findings are shown in Table 2. The radiographical findings were contradictory, since the radiographs contained multiple pathological features, yet most of the patients were painless. Osteophytes and articular space narrowing were detected in all joints. Two joints included intra-articular loose bodies and none of the patients had congruence.

The patients were evaluated at an outpatient clinic, and the symptoms and findings were classified into four classes: (1) no symptoms, (2) slight symptoms, (3) moderate symptoms, and (4) substantial symptoms. In total, 18 joints were considered to be Class 1 and 3 joints to be Class 2. None of the joints were considered to be Class 3 or 4. Swelling was not observed in 18 joints, swelling was moderate in 2 joints, and swelling was substantial in 1 joint.

Postoperative complications occurred in 3 (14.3%) joints of two HR patients. For these two patients, surgery had only temporarily relieved the pain, and they underwent reoperation with arthrodesis of the MTP-1 joint.

DISCUSSION

To the best of our knowledge, this study is the first clinical evaluation of long-term results (average 9.4 years) of MTP arthroplasty using a PLDLA interpositional implant. Results show that the operations reduced pain and that patients were satisfied with the improved range of motion (ROM) of the MTP-1 joint in long-term follow-up.

Tiihonen et al. (12) reported 1-year results after PLDLA implant for lesser MTP joint interpositional arthroplasty for rheumatoid foot deformities. They reported no significant differences when conventional metatarsal head resection (MHR) and PLDLA implant were compared (12). Moreover, a recent study by Horita et al. (13) also reported good results after MHR and joint-preserving technique. However, it is currently known that distal metatarsal resection can cause metatarsalgia and lead to postoperative deformities. Still, studies have shown no significant differences between these two techniques (14, 15). Furthermore, multiple previous studies have concluded that the interpositional technique may lead to postoperative metatarsalgia (16–19). The PLDLA implant was initially developed to retain joint movement and to avoid postoperative deformities caused by the formation of loose connective tissue inside the joint (20). Tiihonen et al. (12) did not report any deformities or metatarsalgia in 1-year follow-up. Our 9-year case series did not show similar problems as those seen in the Brandes–Keller procedure in long-term follow-up (6). In this study, the bone resections
were performed in both sides of phalangeal and metatarsal bones or only metatarsal, depending on the arthritis of the bones. According to our results, we cannot compare our technique with the Brandes–Keller procedure, yet it seems that there might not be similar problems with postoperative metatarsalgia or deformities with PLDLA implant.

Multiple graft techniques, including autogenous fascia lata, gracilis autograft, tendon allograft, amniotic membrane graft, collagenous tissue matrix, meniscal allograft, and synthetic hydrogel cartilage matrix, have all been described for MTP-1 interpositional arthroplasty with favorable outcomes (7, 21–23). Complications associated with the interpositional arthroplasty technique may include shortening of the first ray, lesser metatarsalgia, and weakness with hallux plantarflexion (24). In 2003, Coughlin and Shurnas (21) published a retrospective review, and they found that interpositional arthroplasty with gracilis tendon bundle in the MTP-1 joint increased the pressure under the second metatarsal head after 4 years average follow-up. The results of this study showed that there were no signs of problems affecting the lesser metatarsals. Lau and Daniels (25) retrospectively compared cheilectomy with a capsular interpositional arthroplasty technique involving the use of an EHB tendon graft. They reported complications that included asymptomatic callus (27.3%), postoperative weakness of the great toe (72.7%), and metatarsalgia (27.3%) (25).

Berlet et al. (7) reported good short-term results with a regenerative tissue matrix without wound healing problems, infections, inflammatory reactions, instabilities, malalignments, or loss of push-off strength at 12.7 months average follow-up. They also reported that the average postoperative AOFAS scores of the same cohort were 65.8 (range: 58–68) with notable pain relief and preserved foot function at 5 years follow-up (26). The preoperative AOFAS were 38 (range: 34–43). All patients reported that their surgery had been successful at a mean 5-year follow-up (26).

The MTP-1 joint arthrodesis is a common procedure for the treatment of arthritic HV and end-stage HR of the MTP-1 joint, and nowadays it is even considered to be the golden standard procedure. However, the procedure has several drawbacks, such as loss of ROM in the MTP-1, failure of fixation, nonunion, malunion, and transfer metatarsalgia (27). A recent prospective randomized multicenter trial did not report any differences between the interposition arthroplasty of a synthetic hydrogel cartilage matrix and the primary arthrodesis of the MTP-1 joint (28). The interpositional technique offers a ROM sparing alternative for the treatment of arthritic HV and end-stage HR of the MTP-1 joint. Interpositional arthroplasty also reserves the option for later arthrodesis (29).

The PLDLA implant has shown to induce osteolysis, which explains the findings in the follow-up radiographs (30). Nevertheless, these radiological changes are thought to be part of the process of hydrolysis (31). Honkanen et al. (30) showed in their study that osteolytic changes in PLDLA implant were minor. There is a controversial view that these osteolytic changes in bioabsorbable materials could lead to infection or nonunion (31, 32). The absorbable interposition implants, acting as joint spacers will be simultaneously replaced by ingrowing fibrous tissue. This process of absorbable implants could explain these radiological manifestations like grainy of joint surface and subchondral cysts (Figs 1 to 3). Mattila et al. recently reported high rate of adverse tissue reactions related to the degradation process of the PLDLA interposition implant for trapeziometacarpal osteoarthritis arthroplasty. Although, end of their 3 years follow-up when degradation process settle down, there were no signs of ongoing adverse tissue reactions (33). In our clinical study, we did not find any adverse tissue reactions which emerge out in clinical aspect.

To date, there are no high-quality level-I studies comparing the outcomes of interpositional arthroplasty with other techniques to treat arthritic HV and
Interpositional arthroplasty of the first metatarsophalangeal joint with bioresorbable PLDLA implant in the treatment of hallux rigidus and arthritic hallux valgus

HR. In this study, the sample size of 15 patients (21 metatarsophalangeal joints) was quite small. However, other studies have had comparable sample sizes (7, 12, 34). Another limitation of this study is the retrospective design and the lack of preoperative evaluation with patient-reported outcome measures. The strength of this study, however, is a long follow-up time compared to other studies. The interpositional technique may be performed on young and active patient with advanced HR or HV with arthritis, to preserve the ROM of the MTP-1 joint. Interpositional arthroplasty using a bioabsorbable PLDLA implant should be studied in future in a prospective, randomized controlled study setting.

In conclusion, the results of this study on interpositional arthroplasty using a bioabsorbable PLDLA implant were generally good. Only two patients went to secondary surgery. This study indicates that the PLDLA interpositional implant is a good alternative for MTP-1 joint arthrodesis. The findings of this study show decreased pain and increased patient satisfaction after 9 years follow-up. The results of our study indicate that the interpositional arthroplasty using PLDLA implant is a safe technique to be evaluated in the future with randomized controlled study setting.

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Fig. 2. 6 months after operation.

Fig. 3. 2 years after operation.

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Bioabsorbable vs. titanium screws for first tarsometatarsal joint arthrodesis: An in-vitro study

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A R T I C L E   I N F O

Keywords: TMT-1 arthrodesis, Biomechanical testing, Bioabsorbable, Hallux Valgus

A B S T R A C T

Background: The TMT-1 joint arthrodesis is a common repair for severe hallux valgus. Two crossing interfragmental screws, usually titanium or steel, and a locking plate or a plate with a compression screw are the most common fixation methods for first TMT joint arthrodesis. The qualities of an ideal fixation material include adequate strength and rigidity, biocompatibility, lack of interference with bone healing, lack of visibility and palpability, and a low risk of surgical removal. We sought to determine whether bioabsorbable cannulated screws would perform as well as titanium screws in anatomical models.

Methods: Identical anatomical TMT-1 arthrodesis was created with a saw by making a straight cut in 30 anatomical models (Sawbone®). The bioabsorbable and titanium screws were placed one at a time in exactly the same location in each model according to careful measurements. All 30 models were analyzed with a material testing machine (MTS Insight30, Eden Prairie, USA). Each model was oriented 15° to the platform to simulate its position to the ground during mid-stance.

Results: In the single-cycle load-to-failure test, the mean yield load was 61.4 N ± 5.7 N (range, 50.1 N –70.3 N) in the bioabsorbable screw group and 81.2 N ± 12 N (range, 61.7 N –113.4 N) in the titanium screw group (P < .001). The respective values for the stiffness of the fixation were 8.1 N/mm ± 0.8 N/mm (range, 6.7 N/mm to 9.1 N/mm) and 9.7 N/mm ± 1.8 N/mm (range, 6.9 N/mm to 12.6 N/mm) for the bioabsorbable and titanium groups (P < .004). The mean maximum failure loads in the bioabsorbable group were 85.1 N ± 8.5 N (range, 67.1 N –97.2 N) and in the titanium group 120.6 N ± 13.2 N (range, 96.7 N –136.7 N), respectively (P < .001). Analysis of the failure models shows bioabsorbable fixation failures caused by bending occur more often than in the titanium group.

Conclusion: In biomechanical testing, titanium screws were stronger than bioabsorbable screws in the TMT-1 arthrodesis model tested, although bioabsorbable cannulated screws may be an alternative to titanium screws in the fixation Lapidus procedure.

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approximately 90\% \(^{9-11}\). Peterson and colleagues have reported that the rate of hardware removal after TMT-1 arthrodesis was 15\% of all patients. Of these, 18 patients (72\%) had a locking plate and lag screw removed, and 7 patients (28\%) had crossing lag screws removed.\(^{12}\) Another study has reported hardware removal rates of 12\% (an intraplate compression screw fixation), 11\% (crossing solid core screw fixation), and 0\% (a single interfragmentary screw with a simple locking plate).\(^{13}\)

Bioabsorbable implants have been used as bone fixation materials since 1985.\(^{14}\) Most bioabsorbable implants are composed of the monomers or copolymers of polylactic acid (including a levorotary and dextrorotary configuration), polyglycolic acid, and polydioxanon.\(^{15,16}\) Most biomaterials degrade primarily by hydrolysis in vivo, and their respective monomers are excreted as carbon dioxide and water.\(^{17,18}\) The rate of biodegradation depends on several factors, such as the chemical composition of the material, molecular weight, impurities, crystallinity, sterilization, shape and sizes of the implant, and surface quality.\(^{19}\) The ideal composition of bioabsorbable implants is, however, still a matter of debate.\(^{20}\) The main advantage of using bioabsorbable implants is the reduced need for secondary surgery.

The fixation strength of bioabsorbable implants, such as screws, remains a source of argument, and a recent study showed that metallic screws are stronger in the fixation of tibial tubercle transfer in cadavers than bioabsorbable screws. The study did suggest, however, that the fixation strength of bioabsorbable screws seemed clinically sufficient.\(^{21}\)

The qualities of an ideal bioabsorbable fixation material include adequate strength and rigidity, biocompatibility, lack of interference with bone healing, lack of visibility and palpability, and a low risk of surgical removal. Bioabsorbable implants are well-known alternatives for the titanium implants used in the internal fixation of certain fractures and osteotomies, such as TMT-1 joint arthrodesis, radial head fractures, ankle fractures, Chevron osteotomy, and proximal tibiae osteotomy and fracture.\(^{22-26}\) In this study, we sought to determine whether bioabsorbable cannulated screws could perform as well as titanium cannulated screws in an in vitro study of the foot with a simulated hallux valgus deformity corrected with TMT-1 joint arthrodesis using two crossing interfragmentary lag screws for fixation. To the best of our knowledge, there have been no previous studies that have evaluated bioabsorbable materials in TMT-1 joint arthrodesis or compared them with titanium.

2. Methods

This study compared TMT-1 joint arthrodesis divided into two groups each comprising 15 anatomical models (Sawbone® anatomical foot models, Sawbones Europe AB, Malmo, Sweden) using two crossing interfragmentary lag screws. These 15 anatomical models were chosen to reduce the variability introduced by the use of cadaveric specimens. The bioabsorbable screws were manufactured from poly(\(-\)lactide-co-glycolide) (85L/15G) raw material (resomer LG857, Ingelheim am Rhein, Germany). In this study, we used the ActivaScrew™ Cannulated LAG 3.5 mm×35 mm and 3.5 mm×40 mm screws and the Stryker Asnis™ Cannulated Screw 4.0 mm×36 mm and 4.0 mm×40 mm. Although the manufacturers claim there are differences in the diameters of the screws, the real dimensions of the screws are very similar (Fig. 1). The dimensions of the bioabsorbable screw were head 5 mm, body 3 mm, and thread 3.5 mm, and the dimensions of the titanium screw were head 5 mm, body 2.5 mm, and thread 4 mm.

Each anatomical foot model was modified by cutting the TMT-1 joint using a saw and making a straight cut between the medial cuneiform and the first metatarsal bone. The bioabsorbable and titanium screws were then placed one at a time in exactly the same location in each model by the same researcher. Measurements were taken using a drawing device to determine the entry and output points for Kirschner wires (K-wires) (Figs. 2 and 3). The Lapidus fusion was then temporarily fixed with the K-wires. The guide wire was then overdrilled with a 2.7 mm cannulated drill for the bioabsorbable screws and a 3.5 mm cannulated drill for the titanium screws. The channels were tapped without fully closing the osteotomy site. The cannulated cortical lag screw was inserted from dorsal-to-plantar over the osteotomy using K-wires. The longer bioabsorbable (3.5 mm×40 mm) and titanium (4.0 mm×40 mm) screws were inserted into the first metatarsal to the medial cuneiform, and the shorter bioabsorbable (3.5 mm×35 mm) and titanium (4.0 mm×36 mm) screws into the medial cuneiform to the first metatarsal. The K-wires were then removed.

All 30 models were analyzed using a material testing device (MTS Insight 30, Eden Prairie, USA). The biomechanical testing protocol consisted of the single-cycle load-to-failure test. In the single-cycle load-to-failure test, each model was oriented 15° to the platform to simulate its position to the ground during mid-stance (Fig. 4). Then, the models were subjected to repetitive plantar-to-dorsal loading at a compression rate of 5 mm/s. The response of each model to the loading was automatically recorded as a load-displacement curve, and the stiffness (determined as the slope of the linear region of the load-displacement curve corresponding to the straight-line tangent to the loading curve), yield load (described as the load at the point where the slope of the load-displacement curve first clearly decreased), and maximum failure load were determined.\(^{21}\) All the tests were video-recorded, and the failure mechanism was analyzed afterwards.

2.1. Statistical methods

Data are shown as mean ± SD unless otherwise stated. The mean...
3. Results

In the single-cycle load-to-failure test, the mean yield load was 61.4 N ± 5.7 N (range, 50.1 N–70.3 N) in the bioabsorbable screw group and 81.2 N ± 12 N (range, 61.7 N–113.4 N) in the titanium screw group (P < .001). The respective values for the stiffness of the fixation were 8.1 N/mm ± 0.8 N/mm (range, 6.7 N/mm to 9.1 N/mm) and 9.7 N/mm ± 1.8 N/mm (range, 6.9 N/mm to 12.6 N/mm) for the bioabsorbable and titanium groups (P = .004). The mean maximum failure loads in the bioabsorbable group were 85.1 N ± 8.5 N (range, 67.1 N–97.2 N) and in the titanium group 120.6 N ± 13.2 N (range, 96.7 N–136.7 N), respectively (P < .001) (Table 1).

The bioabsorbable fixation showed deformation of 9.0 mm ± 1.4 mm (range, 7.7 mm–11.8 mm) compared with titanium fixation of 9.9 mm ± 2.2 mm (range, 7.4 mm–16.1 mm) (p = .271). The failure modes of the bioabsorbable screws and the titanium screws are presented in Table 1. An analysis of the failure models showed a difference in breakage models between the bioabsorbable and the titanium groups. The titanium screws failed (6/15) as the result of bending. In other cases, failure occurred as the result of the breakage of the cuneiform medial caused by a small split (9/15). In the bioabsorbable group, breakage occurred more often due to (11/15) bending. One bioabsorbable model failed by the pull out of the metatarsal at the site of screw (1/15), and two bioabsorbable models broke the cuneiform medial (2/15), as was the case with most of the titanium screw failures (Table 2).

4. Discussion

To the best of our knowledge, this is the first study to compare bioabsorbable and titanium screw fixation in TMT-1 arthrodesis. The results of the study show that titanium screws are stronger than bioabsorbable screws in TMT-1 arthrodesis. However, although titanium screw provided higher fixation strength, the bioabsorbable screws also exceeded the estimated maximum force required to retain stability until ossification occurs in first metatarsal bone.27,28 We consider that both screws could provide clinically sufficient strength for TMT-1 arthrodesis fixation.

Bioabsorbable fixation implants have several clinical advantages when compared with titanium implants. The most important of these is that the use of bioabsorbable implants eliminates the need for secondary surgery due to implant removal. Peterson and colleagues showed that incidence of symptomatic hardware removal after TMT-1 arthrodesis is approximately 15% and commonly occurs 9 months after surgery.29 Furthermore, in contrast to titanium implants, bioabsorbable implants do not interfere with imaging or cause stress shielding, growth restriction, or an accumulation of titanium in tissues.30

Bioabsorbable screws are more elastic and flexible than titanium screws, and the splits near the insertion points noted in the titanium screws occurred less often with the bioabsorbable screws (Fig. 5). This difference can be explained by the different composition of the screws and the interaction with the Sawbones® material. This Sawbones® study setup cannot correlate strictly with the

Table 1

<table>
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<tr>
<th>Measurement</th>
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<th>Bioabsorbable screw fixation</th>
<th>p-value</th>
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<tr>
<td>Yield load (N)</td>
<td>81.2 SD ± 12.0</td>
<td>61.4 SD ± 5.7</td>
<td>P &lt; .001</td>
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<tr>
<td>Max Failure (N)</td>
<td>120.6 SD ± 13.2</td>
<td>85.1 SD ± 8.5</td>
<td>P &lt; .001</td>
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<tr>
<td>Yield load extension (mm)</td>
<td>9.9 SD ± 2.2</td>
<td>9.0 SD ± 1.4</td>
<td>P &lt; .271</td>
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<tr>
<td>Stiffness (N/mm)</td>
<td>9.2 SD ± 3.1</td>
<td>7.5 SD ± 2.3</td>
<td>P &lt; .091</td>
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Table 2

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<th>Fixation</th>
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<tr>
<td>Titanium screw fixation</td>
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<td>0</td>
</tr>
<tr>
<td>Bioabsorbable screw fixation</td>
<td>3</td>
<td>11</td>
<td>1</td>
</tr>
</tbody>
</table>
clinical aspect, but the different stress holding between the tita-
nium and bioabsorbable screw groups indicates that bioabsorbable
material could be a better choice with regard to the stress holding
aspect. This bioabsorbable screw characteristic could lead to
reduced stress shielding, while incrementally transferring load to
healing bone.

Several studies have reported good results in using bio-
absorbable materials in foot and ankle surgery. Kim and colleagues
reported that the use of bioabsorbable screws in scarf osteotomy
yielded good radiographic outcomes and good patient satisfaction
with only a small number of complications.33 Bioabsorbable fixa-
tion with a bioabsorbable pin has been used in Chevron osteotomy
with good outcomes, and one study showed that fixation with a
bioabsorbable pin was as reliable as fixation with a metal screw and
allowed major angular corrections in 5-year follow up.32 The bio-
absorbable screw fixation were comparable to other fixation de-
vices for PIP fixation focusing on success rate, revisions, and
patient acceptance.32,33 Bioabsorbable screws have also been used in
foot and ankle trauma. Ahmad and Jones showed that bio-
absorbable screws are comparable and not signi-
ficantly different from steel screws for treating unstable Lisfranc injuries.34 The use
of bioabsorbable screws have also been reported in calcaneal
fractures, and they provided sufficient stabilization and calcaneal
fracture healing/union with the added advantage of no implant
removal needed.35 It seems that there are good results in a variety of
indications for the use of bioabsorbable implants, although
several studies have shown that titanium or steel screws are
stronger than bioabsorbable screws.20,21

The main disadvantage of bioabsorbable implants is the dif-
culty in controlling the degradation process. The rate of biodegra-
dation depends on several factors, such as the chemical
composition of the material, its molecular weight, the presence of
impurities, its crystallinity, the sterilization process, the shape
and size of the implant, and its surface quality.10,19,21 During the
degradation process, the bioabsorbable screw gradually loses its
strength but remains functional for at least 8 weeks.9,10 As bone is
considered to be adequately healed after 6–8 weeks,9,10 this quality
offers temporary mechanical support for the bone until it gradually
gains its original load-carrying capacity.

We selected the ActivaScrew™ cannulated lag screw and the
Stryker AnSs™ cannulated screw for testing because the profiles of
the screws are similar (Fig. 1). Still, the screws differed in that the
titanium screws had a wider thread than that of the bioabsorbable
screws. This wider diameter provides stronger fixation and it could
help explain the differences between the two groups. One bio-
absorbable screw fixation failure caused by pull-out could be
explained by the thinner thread diameter of the bioabsorbable
screw. This finding indicates that screw geometry could be of
remarkable significance for the biomechanical properties of bio-
absorbable screws.

Our study has some limitations. Although biomechanical testing
with Sawbones® products is widely used, and thus an acceptable
method of testing different fixations,36–38 biomechanical results
using this material are not directly clinically comparable, since
synthetic bones may not accurately reflect the properties of real
bone. Further, the degradation process of bioabsorbable screws and
changes in mechanical properties during the degradation process
cannot be tested with Sawbones® models. On the other hand, the
advantages of synthetic bones are the homogeneity of specimens
and the good reproducibility of fixation.

Bioabsorbable cannulated screws are a potential alternative to
titanium or metallic screws for TMT-1 arthrodesis. The cannulated
screws make fixation easier by using Kirschner wires, and bio-
absorbable screws avoid the possibility of a second surgery to
remove the screws. Further testing of these screws in larger and
densely powered clinical studies is feasible.

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Fig. 5. Breakage caused by small split with titanium screw fixation.
Comparison of “cup and cone” and straight cut techniques using bioabsorbable and titanium screws in first metatarsophalangeal joint arthrodesis: an in vitro study

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