Linda Korhonen

PEDIATRIC FOREARM FRACTURES WITH SPECIAL REFERENCE TO OPERATIVELY TREATED SHAFT FRACTURES AND ULNAR STYLOID PROCESS NONUNION
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PEDIATRIC FOREARM FRACTURES WITH SPECIAL REFERENCE TO OPERATIVELY TREATED SHAFT FRACTURES AND ULNAR STYLOID PROCESS NONUNION

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Abstract
During childhood, the forearm is the most typical area to succumb to fractures. Of these fractures, shaft fractures and ulnar styloid process (USP) fractures are overwhelmingly associated with impaired union. Elastic stable intramedullary nailing (ESIN) is the preferred surgical treatment method for shaft fractures; yet, the method has its limitations. ESIN is not always performed according to recommendations, resulting in inferior outcomes. Furthermore, there are limitations in traditional methods to measure the function during follow-up, clinically. The rate and risk factors of USP nonunion are mostly unknown.

This study aimed to compare the new surgical method, biodegradable intramedullary nailing (BIN), with ESIN. Another aim was to critically analyze the tension metal frame construct of two pre-bended, opposing nails in ESIN. The congruence between the new computer-assisted measuring method and handheld goniometer/dynamometer was aimed to be researched, as well as the rate and long-term morbidity of USP nonunion.

Biodegradable nails were produced of poly(L-lactide-co-glycolide) (PLGA) for the purposes of the study. A randomized trial was performed using either BIN or ESIN, and outcomes were evaluated at the two-year mark. The technical deviations of ESIN, as compared with the current recommendations, were studied in a retrospective cohort. E-link was analyzed through comparative study. The rate of USP nonunion in the patients with a previous distal forearm fracture was analyzed with a mean of 11 years of follow-up.

The two-year clinical outcomes of forearm shaft fractures were good regardless of the BIN or ESIN treatment option. Two unexpected refractures occurred in adolescents treated with BIN. The recommended tension metal frame in ESIN was not achieved in 79% of the cases. Thicker nails and open reduction were associated with impaired bone healing. The computer-assisted measuring method was feasible in practice but not congruent with the traditional measuring methods. The nonunion rate of USP fractures was high (16%), but long-term morbidity was low. Half of the nonunion cases had not been diagnosed for USP fractures at the time of injury.

Keywords: biodegradable intramedullary nailing, children and adolescents, computer-assisted measuring, distal forearm, dynamometer, elastic stable intramedullary nailing, forearm, forearm shaft, goniometer, pediatric, range of movements, short- and long-term follow-up, surgical treatment, ulnar styloid process
Korhonen, Linda, Lasten kyynärvarren operatiivisesti hoidetut varsiosan murtumat sekä kyynärluun puikkolisäkkeen luutumattomuus.

Oulun yliopiston tutkijakoulu; Oulun yliopisto, Lääketieteellinen tiedekunta, Medical Research Center Oulu; Oulun yliopistollinen sairaala

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Tiivistelmä

Lapsilla luun murtumat ovat kaikkein yleisimpää kyynärvarren alueella. Kyynärvarren murtumista putkilun keskiosan kahden luun murtumat sekä kyynärluun distaalisen puikkolisäkkeen murtumat ovat alttiita komplikatioille.

Tutkimuksen tavoitteena oli selvittää kyynärvarren keskiosan murtumien hoitoa uudella ydinnaulaustekniikalla käyttäen sulavia ydinnauloja (biodegradable intramedullary nailing, BIN). Lisäksi tavoitteena oli tutkia joustavan ydinnaulauksen (elastic stable intramedullary nailing, ESIN) teknistä onnistumista. Tavoitteena oli tutkia ylärajamurtuman klinisten myöhäistuloksien mittauksissa tietokoneavustettuna menetelmällä sekä selvittää kyynärluun puikkolisäkkeen (ulnar styloid process, USP) luutumattomuutta.

Sulavien ydinnaulojen kahden vuoden tuloksia verrattiin titaanisilla joustavilla ydinnauloilla hoidettuihin potilaisiin satunnaisessa, etenevässä hoitokokeessa. ESIN:n muodostaman jännitteen, metallisen kaksoiskaaren saavuttamista analysoitiin taanehtivastin tietokoneavustossa. Tietokoneavustettuna mittausmenetelmä tutkittiin vertailevassa työssä ja USP:n luutumattomuudesta seurauvia pitkäaikaistuloksia arvioitiin pitkäaikaisessa (keskimäärin 11 v.) seurantatutkimuksessa.

Sulavilla ydinnauloilla hoidettujen potilaiden 2-vuoden liikeala ja puristusvoimat olivat yhtä hyvät kuin titaanisilla naulolla hoidetuilla. Titaaniset esitatututut ydinnaulat olivat useimmissa (79 %) potilaila aseteltu vastoin suositusta niin, että ydinnaulat eivät muodostaneet jännitteen kaksioiskaarkehikkoa. Tietokoneavustettuna mittauksen etuna oli vaivattomuus, mutta mittaus tulokset eivät olleet yhtenevätkin perinteisen kulma- ja puristusvoimamittauksen kanssa. Puikkolisäkkeen luutumattomuus oli yleistä (16 %) rannemurtuman jälkeen, mutta oireita oli harvalla. Puolet puikkolisäkkeen murtumista oli jäänyt alun perin havaitsematta.

Asiasanat: biodegradoituvat materiaalit, biohajoaminen, implantit, joustavat titaaniset ydinnaulat, kyynärvarsimurtuma, lapset (ikäryhmät), leikkaushoito, liikelaajuus, luumurtumat, lyhyt- ja pitkäaikaiset tulokset, nuoret, puristusvoima, ranteet, sulavat implantit
For my beloved ones
Acknowledgments

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“For as the heavens are higher than the earth, so are my ways higher than your ways and my thoughts than your thoughts. Isaiah 55:9”

April 2020, Oulu

Linda Korhonen
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AO</td>
<td>the Arbeitsgemeinschaft für Osteosynthesefragen</td>
</tr>
<tr>
<td>BIN</td>
<td>Biodegradable Intramedullary Nail</td>
</tr>
<tr>
<td>CT</td>
<td>Computer tomography</td>
</tr>
<tr>
<td>DASH</td>
<td>The disabilities of arm, shoulder, and hand</td>
</tr>
<tr>
<td>DRUJ</td>
<td>Distal radio-ulnar joint</td>
</tr>
<tr>
<td>E-LINK</td>
<td>Computer-assisted measuring method</td>
</tr>
<tr>
<td>ESIN</td>
<td>Elastic Intramedullary nail</td>
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<tr>
<td>IOM</td>
<td>Interosseous membrane</td>
</tr>
<tr>
<td>K-wire</td>
<td>Kirschner wire</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
</tr>
<tr>
<td>PGA</td>
<td>Poly(glycolic acid)</td>
</tr>
<tr>
<td>PLGA</td>
<td>Poly(lactide-co-glycolide)</td>
</tr>
<tr>
<td>PLLA</td>
<td>Poly(L-lactide-co-D,L-lactide</td>
</tr>
<tr>
<td>(β-TCP)</td>
<td>Tricalcium-phosphate marker</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>ROM</td>
<td>Range of motion</td>
</tr>
<tr>
<td>SH</td>
<td>Salter-Harris fracture</td>
</tr>
<tr>
<td>TFCC</td>
<td>Triangular fibrocartilage complex</td>
</tr>
<tr>
<td>USP</td>
<td>Ulnar styloid process</td>
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List of original publications

This thesis is based on the following publications, which are referred to throughout the text by their Roman numerals:


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1 Introduction

One in three children suffers from a fracture before the age of 16 years. Two-thirds of the fractures are seen in upper extremities, and nearly half in the forearm (Kapila, Sharma, Chugh, & Goyal, 2016), with the distal radius being the most common fracture site (Korner, Gonser, Bahr, & Hemmann, 2019). Forearm (radius and ulna) shaft fractures represent about 5 to 10% of all fractures in children (Schmittenbecher, 2005) and their incidence has increased since 2002 (Korner et al., 2019).

Bone union is rapid, and the remodeling potential in children is high; thus, the majority of fractures can be treated non-operatively (Herman & Marshall, 2006; Lefevre, Journeau, Angelliaume, Bouty, & Dobremez, 2014; Mayranpaa, Makitie, & Kallio, 2010; Noonan & Price, 1998; Wilkins, 2005). However, the forearm fractures, in particular, fractures of the ulna shaft and ulnar styloid process (USP), are associated with disturbed bone healing, like malunion, re-displacement and nonunion (Mulders, Fuhri Snethlage, de Muinck Keizer, Robert-Jan O, Goslings, & Schep, 2018). Due to their instability, both-bone forearm shaft fractures often require surgical treatment (Cosma & Vasilescu, 2014; Lascombes, Haumont, & Journeau, 2006; Wall et al., 2012). Operative treatment of forearm fractures has increased markedly during the last 10 to 20 years (Helenius, Lamberg, Kaariainen, Impinen, & Pakarinen, 2009; Sinikumpu, Lautamo, Pokka, & Serlo, 2012).

Elastic stable intramedullary nailing (ESIN) is the gold-standard procedure (Kapila et al., 2016; Lascombes et al., 2006) in cases of complicated, unstable, or irreducible forearm shaft fractures in children (Johnson, Carmichael, Morris, & Gilner, 2009; Lascombes et al., 2006; Pace, 2016). Theoretically, ESIN works as an internal splint aligning the bone fragments (Kruppa, Bunge, Schildhauer, & Dudda, 2017). The technique is fundamentally dependent on the tension of the metal frame achieved by pre-bending two nails (Hunter, 2005; Lascombes et al., 2013), one place in each bone. This technique is usually minimally invasive, and periosteal stripping is minimized. The elasticity of the nails allows micro-motion between the fragments, which may promote undelayed callus formation (Shaha et al., 2017). Forearm fractures in children heal in close to all cases by secondary ossification, instead of primary ossification. Callus formation is an important stage in secondary bone healing.

However, the high elasticity of ESIN compared to more stable implants, such as plates, is not exclusively an advantage for bone healing, as nails that are too thin may not provide enough support for the fracture parts (Hope, Williamson, Coates,
It has been discussed whether intramedullary implants, which are too thick are too rigid as well, and may not only hinder bone bridging but also prevent normal lateral curving of the radius (Hunter, 2005; Sun, Penna, Haralabatos, & Carrion, 2001). Moreover, there are just a few reports about the impact on bone healing of conventional versus inferior metal implant frame designs including nail pre-bending, opposite concavities of the nails with opposite configuration, the location of the maximal radius curve at the fracture site, and satisfactory interosseal tension (Hunter, 2005).

Despite all of the advantages of ESIN in treating forearm shaft fractures, there are many limitations. Metallic implants predispose the patient to bacterial infections and may cause local pain and soft-tissue irritation (Mittal, Hafez, & Templeton, 2004). Moreover, they may interfere with later radiological imaging. For these reasons, the ESIN implants are traditionally removed six months postoperatively, which is according to the original technical procedure (Korhonen et al., 2014). As a consequence, a new mini-invasive surgical procedure to treat unstable forearm shaft fractures with a technique called Biodegradable Intramedullary Nailing (BIN) has been developed (Korhonen et al., 2014; Sinikumpu, Keranen, Haltia, Serlo, & Merikanto, 2013). These biodegradable nails were designed to maintain mechanical strength and be absorbed in the tissue during bone healing. The implant material was chosen to be poly(lactide-co-glycolide) (PLGA) with a tricalcium phosphate (β-TCP) marker at the tip of the nail. The implants were taken to be highly elastic, and they therefore completely follow the natural form of the bone. However, they cannot hold the curved form of the bones, particularly in the more curved radius, similar to the pre-bent titanium nails. Therefore, a tension frame could not be constructed and the angular strength of the BIN is lower than the respective strength of ESIN (Hunter, 2005; Lascombes et al., 2006). The operative procedure of BIN is nevertheless mostly similar to that of ESIN procedure.

When the outcomes of upper extremity fractures are to be evaluated, full range of motion (ROM) of the elbow and forearm and adequate grip strength are the key treatment goals (Beumer & Lindau, 2014; Franklin, Robinson, Noonan, & Flynn, 2012; Mittal et al., 2004). These are also clinically relevant indexes to measure impairment. One should be able to determine the functional outcome within the outpatient visit, as the radiographic healing is not the only significant determinant of recovery (Franklin et al., 2012).

In current clinical practice, functional measurements are made by a physician with a free-hand transparent goniometer and hydraulic dynamometer (Jamar,
Lafayette Ltd.) due to their ease of use and sufficient availability in outpatient clinics (Gerhardt & Rondinelli, 2001). As a limitation, the results of these traditional, manual measurements must be recorded in the clinical charts. New devices have been developed to make the measurement process of the upper extremity functions as accurate, fast, and safe as possible (Hirschhorn, Lockhart, & Breckenridge, 2015; Levanon, 2013; Meals, Saunders, Desale, & Means, 2017; Remigio, Tsai, Layos, & Chavez, 2017; Trehan et al., 2017). Furthermore, it is more important, nowadays, that experts, other than medical doctors and surgeons, such as occupational therapists, be incorporated in the follow-up outpatient visits. However, the congruence and potential interchangeability of the traditional and computer-based measuring methods has not yet been studied.

Although the distal radius fractures usually heal well, they may be associated with accompanying injuries such as ligament injuries or USP fractures. The fracture of the USP may tear the triangular fibrocartilaginous complex (TFCC). The USP fracture frequently fails to unite regardless of the treatment method. However, the risk factors of USP nonunion are unclear. The possible long-term morbidity of pediatric USP nonunion has not been widely investigated.

In this study, the aim was to analyze the BIN method in treating unstable childhood radius and ulna shaft fractures, compared with titanium ESIN and thus, test the hypothesis that there is no difference in rotation ROM between the patients treated by BIN versus ESIN at the two-year mark. It was also aimed to critically analyze bone healing in forearm shaft fractures treated with ESIN, and evaluate technical characteristics of the procedure in the light of current recommendations of surgical technique. In particular, the metal tension frame, developed by two intramedullary nails, one in every bone, was analyzed in detail. Keeping the high clinical importance of the ROM and grip strength in child patients with previous upper limb fractures in mind, the congruence of two different measuring methods was also investigated in this study: a computer-assisted method versus free-hand goniometer and hydraulic dynamometer methods. Furthermore, it was aimed to determine the rate of USP nonunion and to evaluate the clinical and radiographic recovery of USP nonunion in children with previous distal radius fractures in long-term follow-ups. Previously, most studies concerning the clinical importance of childhood USP nonunion were based on short-term outcomes, and the understanding of long-term outcomes is thus insufficient.
2 Literature Review

2.1 Anatomy of the forearm

The forearm is comprised of two long bones: the radius and the ulna. The wrist is at the distal end and the elbow joint is at the proximal end of the forearm. Also, the forearm itself is a non-synovial joint, where the radius pivots around the straight ulna.

Mechanically, the forearm is not just a passive shaft, but rather a complex structure with dynamic and static properties. The dynamic stabilizers and muscles contribute to keeping the radius and ulna together. The oblique muscles from ulna to radius also attach the radius to the wrist (LaStayo & Lee, 2006).

The static structures of the forearm are formed of the bones and two articulating joints between them: proximal and distal radioulnar joints (DRUJ). Also, the ligaments, joint capsules, the triangular fibrocartilage complex (TFCC), and the interosseous membrane (IOM) are essential structures involved in forearm stability (Soubeyrand et al., 2017; Wijffels et al., 2014).

The pediatric skeleton can sometimes be mistaken as a smaller version of the adult skeleton, but that is far from the truth: the unique properties in anatomy and histology of the pediatric skeleton allow fast growth and bone remodeling that are not seen in mature skeletons. The most remarkable difference between immature and mature skeleton is open physes, which are seen in all immature long bones and the radius and ulna (Atanelov & Bentley, 2019).

The physes (growth plates), which are cartilaginous structures, are located in both the distal and proximal ends of the radius and ulna. The growth in length happens through endochondral ossification until skeletal maturity. This type of growth differs from intramembranous ossification, which occurs, e.g., during fracture healing by the aid of periosteum. The thickening of the long bones occurs mostly via intramembranous ossification (Atanelov & Bentley, 2019).

Radius and ulna

The radius and ulna are long bones with three borders and three surfaces. As the radius grows, its maximal radial curve increases (Firl & Wunsch, 2004). However, the site of the curve remains constant as compared with the total length of the radius. The clinical significance of the radius curve is in its pivoting movement over the
straight ulna. Describing the anatomy, starting from the proximal end, the anatomic landmarks of the radius are the head of the radius (caput), the neck (collum) and the radial tuberosity that is an attachment for the biceps muscles.

The head of the radius is a disk-shaped part of the bone which originates from a proximal secondary ossification center, i.e. epiphysis. It is thicker medially, where it takes part in the proximal radioulnar joint. The radial neck is a narrow area between the radial head and the radial tuberosity. The biceps brachii muscle is attached to the radial tuberosity and it lies 180° in the opposing direction compared with the distal radius styloid process. Distally essential structures are the ulnar notch of the radius and the styloid process.

The ulna is much less curved than the radius. Both proximal and distal ends are in slight varus (Cravino, Oni, Sala, & Chu, 2014). The lateral curve is located at 75% of ulnar length measured from proximal to the distal end (Hreha, Congiusta, Ahmed, & Vosbikian, 2020). Important anatomical landmarks are the olecranon which serves as an attachment for the tricep brachial muscle, the coronoid process in the anterior aspect of the elbow, the trochlear notch that is essential in forming the humeroulnar joint, radial notch, and the tuberosity of ulna.

The proximal and distal epiphyses of the forearm bones are asymmetric. At the elbow, the ulnar epiphysis is larger than the radial one, while the opposite is true at the wrist. Also, the distal radius continues more distal than the ulna, while the proximal ulna ends more proximal than the radius. This particular anatomy is crucial for the complex function of the forearm.

During rotational movement, the radius pivots over the ulna, enabling pronation and supination movements. This rotational movement, together with the motions of the elbow and wrist, allows the hand to achieve its targets in countless positions. Without the curved radius, the bones would hit with each other when rotating, which is seen in postinjury cases with disturbed bone anatomy (Soubeyrand et al., 2017). Moreover, another mechanically important function of the forearm is its role as the axis for load transmission.

**Interosseus membrane, IOM**

The radius and ulna are connected by a particular connective tissue that forms a large membrane along the bones from the proximal to the distal area. This membrane, the interosseous membrane, or IOM plays an essential part in stabilizing the forearm shaft and in load transmission when the upper extremity is used. The load is transmitted in the forearm in two directions: between the radius
and the ulna, when the axial, longitudinal load is delivered, and also between the wrist and elbow when the external force is directed from the hand to the upper part of the extremity and the body. The IOM is comprised of several different fiber groups, of which the central part is the thickest one and the most important (Soubeyrand et al., 2017). That central part of the IOM slightly lengthens while the forearm is in a neutral or pronated position (Farr, Werner, McGrattan, Zwerling, & Harley, 2015). It is in an oblique position and optimally resists the external load that is transmitted from radius to ulna, e.g., the movement of pushing an object with one’s hand.

*Muscles*

There are 18 muscles located in the forearm area. The muscles of the forearm enable the movement of the elbow, forearm, wrist, and fingers. In particular, the forearm is vital for the function of the hand, given that most muscles responsible for the movement of the fingers are located in the forearm. Anatomically, forearm muscles are located in two muscle groups, i.e., compartments: the anterior (flexor) compartment and the posterior (extensor) compartment. The anterior compartment is further classified as superficial, intermediate, and deep regions.

Based on their function, the forearm muscles can be classified into intrinsic and extrinsic muscles. The intrinsic muscles produce the pronation and supination movements of the forearm (e.g., m. supinator and m. pronator teres and m. pronator quadratus), while the extrinsic muscles bend and straighten the wrist and fingers.

The brachioradialis muscle is proximally attached to the elbow (humeral bone) from where it continues distally by its long tendon and attaches to the radius styloid process. The brachioradialis flexes the elbow, together with a humeral biceps muscle. The biceps also works in supinating the fully rotated forearm.

### 2.2 Development of long bones

All long bones, like the radius and ulna, develop in early fetal age from the cartilaginous model. From that scaffold, the bone tissue is synthetized through two processes called endochondral and intramembranous ossification. The ossification begins in the middle part of the long bone from calcified cartilaginous structures called primary ossification centers. In endochondral ossification, the hyaline cartilage is replaced with the new bone tissue. Later, the endochondral ossification mechanism occurs during the physeal growth.
The radius and ulna become apparent in the embryo at week four and they ossify at week eight. At the early fetal age, the other principal structure of growing bone is developed dividing the bone into three histologically different structures (Figure 1). Epiphysis and metaphysis are seen at each end, while the diaphysis (shaft) is located between them. The epiphysis has special epiphyseal growth plates, where the longitudinal and transversal bone growth occurs. Similarly to embryological bone development, the growth plates use the endochondral ossification mechanism for bone tissue formation (secondary ossification center).

The distal secondary ossification center appears at the age of one in the radius and the age of six in the ulna. The metaphysis is the part close to the physis, where endochondral ossification leads to bone tissue formation by various complex mechanisms. During the process, the bone grows in length. The diaphysis is the shaft of the long bone and it is primarily composed of endochondral bone. It differentiates to bone marrow, forming a medullary cavity, and cortical bone during growth. This ossification process continues until skeletal maturity when growth plates closure occurs (Fossey, Vahle, & Leininger, 2018).

Intramembranous ossification, in contrast, happens by the aid of surrounding periosteum. The cartilaginous growth plate is not involved at all in this type of ossification. In intramembranous ossification, the new bone is synthesized by mesenchymal: undifferentiated tissue around the previous bone. Intramembranous ossification occurs in pediatric bones when the bone grows in diameter (oppositional growth), and the bone becomes stronger against external bending force. This periosteal ossification mechanism also happens during bone fracture healing. Periosteum in children is particularly metabolically active, which clarifies the rapid callus formation that is usual in growing bones.

Local factors mostly control bone development in response to mechanical stimuli that act on the bone, as well as hormones and nutrition (Mayranpaa et al., 2010). Many gestational factors, such as maternal smoking, affect bone quality and also later bone fracture risk (Parviainen, Auvinen, Pokka, Serlo, & Sinikumpu, 2017). Height and other individual anthropometric variables like the final bone mass are determined mostly by the genes (Harris, Nguyen, Howard, Kelly, & Eisman, 1998).
Bone histology

The bone tissue is histologically differentiated to make it lightweight, hard tissue. Cortical bone is the thick and hard surface of the bone that is seen in all long bones. Cortical bone provides strength to the bone, while the intramedullary tissue has no mechanical strength. The cortical bone tissue contributes approximately 80% to the weight of the bone tissue (Fuchs, Thompson, & Warden, 2019).

Beyond the cortical bone, the bone tissue is lighter, softer, and entirely different. The bone is called cancellous bone or spongy bone, and while it does not contribute to the mechanical properties of the long bones, it has its special functions. Cancellous bone is highly vascular and contains red bone marrow with potential stem cells. Hematopoiesis, the production of blood cells, occurs in the bone marrow.

Periosteum

The periosteum is a dense connective tissue layer that covers the whole bone surface except those parts which are covered with articular cartilage. Instead, the membrane that surrounds the joint areas is called the chondrostoeum. The periosteum is an active part of the skeleton and responsible for bone growth in thickness via endochondral ossification. Therefore, it is highly vascular, having lots
of nerves and lymph vessels. Due to the need for good blood supply, the periosteum is significant in bone healing.

In children, the periosteum is strong and thick but only loosely attached to the bone. In contrast, the periosteum is light, thin, and fixed to the mature bone surface. Therefore, in childhood injury, the periosteum may tear from the fracture side but remain intact in the opposite (compression) side of the fracture. This mechanism explains why children face different types of fractures than adults. In some cases, the intact periosteum increases the risk for worsened reduction if it is intact asymmetrically. The periosteum is crucial in fracture healing, while it contributes to endochondral callus formation (Atanelov & Bentley, 2019).

### 2.3 Functions

*Rotational movements*

Forearm rotation enables hand movements such as facing the palm upwards (supination) or downwards (pronation). The *normal* pronation-supination range is close to 150–170° (Teoh, Chee, Shortt, Wilkinson, & Porter, 2009). The rotation of the radius occurs around a single mechanical axis that starts from the radial head and continues until the ulna styloid process (USP) (Figure 2). During rotation, the hand follows the movement of the radius.

The proximal radioulnar joints (PRUJ) and DRUJ and the humeroradial joint are the three joints involved in forearm rotation. The PRUJ and the DRUJ are cylindrical joints, while the humeroradial joint is a ball-and-socket joint. So, the forearm itself is a joint that begins and ends at joints (Soubeyrand et al., 2017).

The PRUJ is located between the radial head and the radial notch of the ulna. The radius is held in place by the annular ligament, which is a strong transversally organized connective tissue structure. The radius head rotates within the ligament during the forearm rotation.

The humeroradial joint is placed between the head of the radius and the humerus. This joint is partially responsible for the load transmission from the forearm to the humerus.
In the DRUJ, the ulnar head is articulated with the ulnar notch of the radius. An anatomic bone congruity, the triangular fibrocartilage complex (TFCC), and the pronator quadratus are the primary stabilizers of the DRUJ (Kazemian et al., 2011). Clinically, this is important because the wrist needs to remain stable in any position, even if the hand is bearing a load.

In addition to the PRUJ and DRUJ, the radial and ulnar shafts form a joint-like structure with the IOM, which connects them. This structure, which is called a medial radioulnar joint (MRUJ), is a certain kind of syndesmosis, also seen in the ankle. All these structures may be involved in forearm instability or stiffness (Soubeyrand et al., 2017).

Several muscles enable rotational movements of the forearm. Supination movements are produced by the brachial biceps and the supinator muscle, inserted in the proximal radius. Also, the brachioradialis muscle is involved in supination
when the hand is fully pronated. Pronation, in contrast, is produced by m. pronator teres and m. pronator quadratus (Soubeyrand et al., 2017).

**Flexion-extension movement**

The forearm is an axis that enables flexion and extension movements of the elbow joint. Extension means that the upper extremity is straightened while in flexion the lower arm elevated toward the upper arm. Extension is produced by the brachial triceps muscle in the backside of the upper arm and the anconeus muscle of the forearm. Flexion is produced by the brachialis and brachial biceps muscles in the humerus, and brachioradialis muscle in the forearm. During this flexion-extension movement, the radius tends to slide proximally due to several muscles pulling it directly and indirectly, while the elbow joint remains stable and able to bear high tension or traction forces.

**Load transmission**

Understanding the anatomy of the forearm bones and muscle insertions is essential for understanding the complex load transmission process in the forearm. While both ends of the radius and ulna are asymmetric in configuration, the force is transmitted unequally between both bones. In other words, the compression force from hand to shoulder is directed by a particular mechanism. Distally, the majority of longitudinal force passes through the dominating bone in the wrist: the radius. In a normal, neutral position, 80% of the axial load is transmitted through the radiocarpal joint while 20% is transmitted through the TFCC directly to the ulna (Palmer & Werner, 1984).

As this force is transmitted proximally via the forearm axis, some of the load is transferred from the radius to the ulna with aid from the central part of the IOM that lies in the middle area of the forearm. Therefore, proximally in the elbow, the ulna is larger and the passing force that transmits to upper arm increases. At the elbow, approximately 60% of the axial load is born by the radiocapitellar joint and 40% by the humeroulnar joint (Birkbeck, Failla, Hoshaw, Fyhrie, & Schaffler, 1997) (Figure 3).
2.4 Pediatric fractures

The forearm fractures in children are generally classified based on the fracture site: distal forearm fractures, close to the wrist, middle shaft fractures in the diaphyseal area, or proximal fractures. Depending on soft tissue involvement, the fractures are also classified as open or closed fractures. Transverse, oblique, spiral, butterfly, and comminute fracture types are also seen in adults, but children have unique fracture types, which are torus, i.e. buckle, greenstick, and bowing fractures (Figure 4).

Fig. 3. The figure represents the load transmission from the radius to ulna through the interosseous membrane.
Fig. 4. Diaphyseal fracture patterns are coded based on the fracture type. The division continues further to single or multifragmentary fractures. The classification is based on the Arbeitsgemeinschaft für Osteosynthesefragen (AO) Pediatric long-bone fracture classification (Meinberg et al., 2018).

During growth, the cortical bone in children has a lower mineral content than that of adults’ (Mabrey & Fitch, 1989), meaning that growing bone is more flexible and able to bend: pediatric long bones are compliant when compared to adult bones (Chasm & Swencki, 2010). Due to their mostly calcified cartilage composition, the bones tend to bend and bow under stress (Atanelov & Bentley, 2019). Furthermore, the pediatric periosteum, as mentioned above, is strong and thick, allowing it to remain intact on the concave (compression) side of a fracture.

2.4.1 Fractures of immature skeleton

Torus fracture

Torus fractures, also known as buckle fractures, are bone expanding fractures and are caused by an external compression force. They are a mix of plastic deformations and complete fractures. However, the cortical structure does not break, and the
cortex continuity is saved. This fracture type occurs in the transition area from the metaphyseal bone to the diaphyseal bone, mostly in the distal metaphysis and not at the more passive diaphyseal area (Light, Ogden, & Ogden, 1984). The fracture is entirely stable. Therefore, some authors do not name it as a fracture at all. They do not recommend any immobilization for these fractures (Jiang, Cao, Ma, Lin, & Yu, 2016). A short (less than three-weeks) immobilization for a forearm buckle fracture may be performed for pain management but any more prolonged immobilization is meaningless and may increase the risk for joint stiffness. A removable splint is a good option, which is also easy to remove by the parents (Baig & Egan, 2017).

Bowing fracture

Pediatric bones absorb more energy before breaking when compared to mature bones. For that reason, bowing fractures, also called plastic deformations, occur in children. It happens due to multiple microfractures through the long bone, most commonly in the ulna. The fracture is often under-diagnosed because it may not be evident in radiographs. The patient may have only slight symptoms; however, in case of significant angular deformity, the risk for decreased functional results is high (Slongo, 2005). Thus, closed reduction is sometimes indicated with the same indications as other fractures. The bowing fracture is stable. Immobilization is in general useless while no worsening of the alignment will happen.

Greenstick fracture

Pediatric bones are more flexible than bones in the mature skeleton; greenstick fractures are an example of the high competence to absorb external deforming forces. Greenstick fractures are special fractures that typically have a fissure in one cortex as a result of traction and a buckle as a result of compression in the opposite cortex (Atanelov & Bentley, 2019; Randsborg et al., 2013; Schmittenbecher, 2005). The greenstick fracture requires more energy for its production than complete fractures in adults (Atanelov & Bentley, 2019). The injury mechanism resulting in a distal forearm greenstick fracture is mostly a supination injury leading to an apex-volar angulation and supination deformity. A direct injury against the volar side of the forearm usually causes pronation apex-volar fractures, e.g., falling on their forearm. Greenstick fractures always require frequent follow-up, despite their
relative stability, given the higher risk mal-alignment (Randsborg et al., 2013; Schmittenbecher, 2005).

2.4.2 Complete fractures

Complete fractures are mostly seen in more matured skeleton and in adults. In the forearm, the complete fractures are usually both bone fractures (Pace, 2016) but they are rarely comminuted or severely displaced in children. The fractures have a detailed classification system that includes all slight differences between each fracture type, or Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification (Meinberg, Agel, Roberts, Karam, & Kellam, 2018). A complete one-bone fracture in a forearm is usually a consequence of a direct hit against the forearm.

Transverse fracture

The fracture line is straight across the bone. The fracture results from a tremendous external force. The force is perpendicular to the axis. The periosteum often tears in the tension side and forms an intact periosteal hinge on the compression side, which needs to be recognized during the treatment and follow-up of these fractures. Thus, these are different from greenstick fractures, given that for greenstick fractures, the cortex on the compression side remains intact (Schmittenbecher, 2005).

Spiral fracture

A torsional force causes a spiral fracture. A longitudinal band of the periosteum is usually left intact. A spiral fracture is best reduced by rotation of the distal fragment back to its original position. Upon reduction, however, the fracture may be unstable.

Oblique fracture

An oblique fracture is produced by the compression force (axial loading) of the forearm. The periosteum is widely torn. An oblique fracture is best reduced by straight pulling, but the fracture is considered to be unstable. Surgical intervention is often required to maintain the reduction.
"Butterfly" fracture

The fracture is a result of compression (axial loading) and perpendicular (angulation) forces. The loose fragment, called the butterfly fragment, is seen on the side where the bone was hit. This fracture is predominantly seen as unstable, and significant periosteal damage is usually present. Three-point pressure in the cast may be used; however, the risk of re-displacement is high.

Comminuted fracture

These fractures happen after high energy injury. They are more uncommon in children than in adults. Comminuted fractures usually require surgical fixation.

Open fracture

Open fractures are mainly caused by significant trauma leading to significant dislocation and soft tissue involvement. The skin is torn which predisposes the patient to bacterial infections. In open fracture management, prophylactic antibiotics are indicated with the operation (Greenbaum, Zions, & Ebramzadeh, 2001) However, there is increasing evidence that open fractures do not always require operative fixation, and lesser Gustilo-Anderson type-1 injuries may justify nonoperative treatment if reduction is acceptable.

2.4.3 Treatment goals

In the early 20th century, the fracture treatment was focused mainly on restoring the bony union, while some, currently known as essential considerations of fracture care, were left out. In the early years of fracture care, the primary treatment method of care was plaster immobilization. The immobilization was often prolonged, as no adequate follow-up could be performed. The treatment did not support but rather hindered the proper restoration of the forearm function during the healing process. Arthrofibrosis and severe deformities were usual in the past (Jeannet, 2019; Joeris et al., 2019).

When the fracture patient is a child, the situation challenges the parents and the whole healthcare team. Pain is the most usual symptom that brings these patients and their families to the hospital. Management of acute pain, particularly in children, is essential because inadequate pain management has long-lasting effects
on a child. It has been reported that as many as 8 to 14% of children develop posttraumatic stress disorder (PTSD) after an accidental injury (Alisic, E. et al., 2014; van Meijel et al., 2015). Not only from the injury itself but from the medical procedure as well: this is frightening for a child. The likelihood of PTSD is higher in case of higher initial pain during the injury. Also, higher pain is associated with a higher experience of pain in the future and to avoidance of future medical procedures (Alisic, Eva, Jongmans, van Wesel, & Kleber, 2011).

Due to the presence of a tough periosteum, the functional remodeling capacity, and open physis in the pediatric population, the majority of the fractures, in general, can be treated non-operatively (Noonan & Price, 1998). However, the diaphyseal forearm fractures remodel poorly and are prone to changing alignment; thus, operative treatment is often indicated (Alrashedan et al., 2018; Schmittenbecher, 2005). A functional outcome following a midshaft both-bone pediatric forearm fracture is one of the primary considerations in choosing between operative treatment and conservative management. The current principles of fracture treatment, in general, are as follows (Helfet et al., 2003; Slongo, 2005):

- The patient’s age, weight, fracture type, and site define the treatment method.
- The fracture is reduced and fixed to restore anatomical position and alignment
- Gentle reduction techniques are preferred for the preservation of the blood supply to soft tissues and bone
- The restoration of function is supported by early and safe mobilization, and rehabilitation if needed

The examination of an acute injury includes inspection of a visible deformity and accompanied injuries. The patient’s circulation (radial and ulnar pulses and capillary filling in the periphery), and peripheral neurological status must be measured, and they must be checked for soft-tissue lesions as well (Helfet et al., 2003; Jeannet, 2019).

A prompt reduction and frequent follow-up in children is essential, given that the healing process is also faster in children than in adults. In a forearm, acute fractures usually start to stabilize in two to three weeks, at which point reduction becomes more difficult. The closed reduction is performed by traction and manipulation, while the elbow is usually held at 90° of flexion or is fully extended. The periosteum may be intact, which needs to be noted. It may be necessary to exaggerate the dislocation to loosen the periosteum and to allow gentle reduction. However, there is no agreement on whether to break the periosteum or not. Fluoroscopy is used to ensure the reduction. In fractures with apex-volar angulation,
the hand is usually supinated and, with apex-dorsal angulation, pronated (Noonan & Price, 1998). A reversing reduction movement is needed to return to the original position while performing the reduction maneuver. A long-arm plaster cast or splint with three-point fixation is used for immobilization. In the unstable midshaft fractures an above-the-elbow cast is required for satisfactory stability. The splint has a lower risk for finger swelling and discomfort but may increase the risk for loss of reduction (Pace, 2016). In case of unsuccessful closed reduction or instability, the fracture is treated surgically.

Radiographs

Radiological examination is used routinely for fracture diagnosis. In the forearm, the examination includes standard anterior-posterior (AP) and lateral views. Both the elbow and wrist joints need to be captured in the plain films (Figure 5). The radiographs reveal the fracture displacement and angulation relatively clearly. However, rotational deformity may be more difficult to evaluate (Noonan & Price, 1998; Pace, 2016). A few bony landmarks may help in the deduction of rotational deformity. In the AP view, the radial tuberosity should point to the ulna and be 180° from radial styloid. In the lateral view, the ulnar styloid is posterior, and the coracoid process is anterior.

The radiographic evaluation is also used to follow the bone healing process. During the follow-up, the alignment, displacement, and new bone formation are evaluated via radiographs. Radiographic evaluation for bone healing and disturbed union is discussed below.

There are some situations when more comprehensive imaging modalities are needed in forearm fractures, especially injuries involving soft-tissue, joints, and cartilaginous epiphyses, which are all invisible in radiographs, requiring the use of magnetic resonance imaging (MRI). MRI gives valuable information also in cases of late morbidities, such as the suspected damage of the TFCC. In exceptional cases, a computer tomography (CT) is useful, e.g., when evaluating a late deformity with three-dimensional (3D) imaging is needed. These images can be compared with the corresponding images of the uninjured side. The posttraumatic deformity can be corrected surgically, when needed, by using a custom-made osteotomy-instructor and custom-made plate.
2.4.4 Distal forearm fractures

Fractures of the distal radius are the most common fractures in children. They often occur during sports and play due to falls. The complete fractures are most usually apex volar fractures, and the treatment is frequently non-operative with a short arm splint immobilization (Randsborg et al., 2013). The exact anatomic reduction is not always required due to high remodeling capacity around the distal metaphysis (Rodríguez-Merchán, 2005). Some authors accept even 20 to 30° of dorsal angulation in non-operative treatment if the patient is young with satisfactory remaining growth. The growth plates of the distal forearm can restore the angular
deformity as much as 10° per year before skeletal maturity. The remodeling
capacity decreases with age (Mehlman, Wall, Beaty, & Kasser, 2006).

The immobilization time of unstable fractures is generally three to four weeks
depending on the patient’s age. The follow-up visits with radiographs are arranged
at week one and week two in case of risk for worsening reduction. In child patients,
physiotherapy is seldom necessary. Routine clinical follow-up is usually not needed
after cast removal.

In the case of irreducible or greatly displaced radius fractures, surgical

treatment is preferred (Zamzam & Khoshhal, 2005). If surgical treatment has been
chosen, intramedullary Kirschner-wire fixation is preferred instead of ESIN, which
may worsen the displacement due to awkward optimal positioning (Lieber &
Schmittenbecher, 2013). Metaphyseal fractures and SH I- II fractures are primarily
treated by closed reduction and percutaneous pinning. Intra-articular SH III and IV
fractures are usually primarily openly reduced and surgically fixed. The pins are
usually removed when satisfactory bony stabilization has occurred.

The treatment of USP fractures is mostly based on the fixing of the radius.

There is no specific treatment established for USP fractures (Zoetsch et al., 2013).
Some clinicians may fix the fractured USP during the same operation while they
fix the radius (Belloti, Moraes, Albers, Faloppa, & Dos Santos, 2010). However,
many prefer the fixation of the radius, leaving the ulna untreated even if the ulnar
fracture is evident (Buijze & Ring, 2010; Zoetsch et al., 2013).

The overall complication rate is low in distal forearm fractures, however, a
frequent follow-up of some types of fractures is essential. The risk for the re-
displacement is high during the first weeks, before bone ossifying. Growth plate
disturbances such as bone bridging and partial or complete growth arrest are
possible complications (Pannu & Herman, 2015). The wrist fractures may associate
with injuries in soft-tissue and ligaments. In adults, as much as 70% of the distal
radius fractures associate with USP fracture but the incidence in children is smaller,
about 11%–33% (Zoetsch 2013; Stansberry, Swischuk, Swischuk, & Midgett,
1990). The fracture in USP has been associated to DRUJ instability (Zoetsch 2013).
In addition, the risk of USP non-union is markedly high as compared with other
pediatric fractures, but the clinical long-term importance is not known (Cannata,
De Maio, Mancini, & Ippolito, 2003).
2.4.5 The forearm shaft fractures

The incidence of forearm shaft fractures has increased since the beginning of the 21st century (Sinikumpu et al., 2012). The incidence of their operative treatment has also increased as an alternative to non-operative treatment. In particular, ESIN has become a more common procedure (Alrashedan et al., 2018; Sinikumpu et al., 2012).

Indirect injury is the leading cause of forearm fractures. The injury typically occurs when falling onto outstretched hands. While the forearm shaft is mostly cortical bone, it needs high trauma energy to break (Pace, 2016; Sinikumpu & Serlo, 2015). The radius usually breaks first because it transmits more energy and the trauma energy first reaches the radius bone, resulting in dorsal angulation.

In contrast to distal forearm fractures, the shaft fractures remodel poorly and tend to re-displace even after successful reduction (Alrashedan et al., 2018; Sommerfeldt & Schmittenbecher, 2014). The fractures are farther away from the metabolically active growth plates, and the remodeling capacity is markedly smaller in the shaft than in distal fractures. In the shaft area, about one degree per year of angular remodeling is to be expected (Lascombes et al., 2006). Generally, girls go through puberty earlier and have less remodeling capacity left than boys of the same age. Therefore, the cut-off point for recommendations on whether to correct a deformity or not is suggested to be eight years old for girls and ten for boys (Noonan & Price, 1998; Ploegmakers & Verheyen, 2006). Maximal accepted angulation before intervention is 10 to 15° for younger children and 5 to 10° for anatomic reduction is recommended for older children (Fernandez, Eberhardt, Langendorfer, & Wirth, 2009).

The rotational deformities do not remodel (Noonan & Price, 1998; Wilkins, 2005). The guidelines on whether to accept a rotational deformity vary between 0 and 45°, and less deformity is accepted in older children (Mehlman et al., 2006). An anatomic reduction should be aimed for patients who have less than one to two years of growth remaining (Pace, 2016). The rotational deformity is difficult to judge accurately with plain radiographs. The diameter of the fragments at the level of the fracture may help assessment (Figure 6). A difference of diameters of the bone parts between both sides of the fracture line suggests a rotational deformity. The comparison with similar radiographs of a healthy extremity may also be used (Creasman, Zaleske, & Ehrlich, 1984), but these are rarely taken and therefore, scarce.
Loss of reduction occurs in as many as one-third of the conservatively treated forearm shaft fractures; therefore, the fractures are often fixed operatively. Recently, due to the complications and increasing expectations of the patients and their parents, the incidence of operative treatment has increased (Kapila et al., 2016).

![Forearm shaft fracture in 15-years old male patient. The fracture has rotational displacement, which is understood by different diameters in the radius bone fragments. The patient was treated with ESIN.](image)

2.5 Operative treatment of forearm shaft fractures

The operative treatment of pediatric forearm fractures has increased over 60% during the first decade of the 21st century; re-displacement is the most common complication in non-operative treatment and occurs in 5 to 30% of patients (Alrashedan et al., 2018; Baldwin, Morrison, Tomlinson, Ramirez, & Flynn, 2014; Sinikumpu et al., 2012), which explains and justifies the increasing trend of operative fixation.

Both-bone forearm fractures are usually unstable. Many factors affect treatment choice (see Table 1). Operative treatment is particularly indicated in patients older than ten years of age if the fracture position is not acceptable (Alrashedan et al., 2018).

There are many operative treatment methods for unstable forearm shaft fractures in children, such as K-wires, plate and screw fixation, external fixation, and intramedullary nailing. As the main difference, childhood fractures do not require as rigid fixation as the fractures in the mature skeleton (Helfet et al., 2003). The outcomes of both intramedullary nailing and plate fixation have been reported to be positive (Baldwin et al., 2014). Because the intramedullary nailing is minimally invasive, it has benefits regarding the cosmetic outcome. K-wires should
be used in fractures near the distal dia-metaphyseal transition (Schmittenbecher, 2005).

The AO and Orthopaedic Trauma Association (OTA) have together announced the classification system of long bone fractures. The classification is based on the anatomical segments, fracture form and type, and concomitant injuries. It is a comprehensive aid in determining childhood fractures and their potential natural history (Joeris et al., 2019; Meinberg et al., 2018).

Table 1. The table represents the indications for operative treatment and the features that increase instability in forearm shaft fractures.

<table>
<thead>
<tr>
<th>Indications of operative fracture treatment</th>
<th>Features increasing fracture instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irreducible fracture</td>
<td>Oblique fractures greater than transverse fractures</td>
</tr>
<tr>
<td>Unstable fracture</td>
<td>Fractures are in the same level in the radius and ulna</td>
</tr>
<tr>
<td>Open fracture</td>
<td>Greater primary dislocation</td>
</tr>
<tr>
<td>Remarkable soft tissue injury and forearm compartment syndrome</td>
<td>Higher age</td>
</tr>
<tr>
<td>High trauma energy and multiple fractures (e.g., floating elbow)</td>
<td></td>
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<tr>
<td>Fractures that loose alignment during the follow-up</td>
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</tr>
<tr>
<td>Monteggia fracture-dislocation</td>
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</tbody>
</table>

Adopted from Garg, Ballal, Malek, Webster, & Bruce, 2008; Kruppa et al., 2017; Schmittenbecher, 2005; Sun et al., 2001

2.5.1 Plate and screw fixation

The OA is a society of orthopedic and trauma surgeons that has announced the main principles of fracture treatment and classification in 1996. These principles are still valid to this day:

- Fractures should be reduced in the anatomic position.
- A stable operative fixation needs to be achieved by using such implants that the bone healing can be secured, e.g., plate and screws.
- The blood supply and soft tissues must be protected.

AO is mostly focusing on the treatment of adult fractures, but the rigid plate and screw fixation is an essential option in pediatric forearm shaft fractures, particularly for older children.
2.5.2 ESIN

ESIN was first introduced in its current form in the late 1970s (Lascombes et al., 2006; Ligier, Metaizeau, Prévote, & Lascombes, 1988; Sommerfeldt & Schmittenbecher, 2014). Since then, it has become a popular and well-accepted treatment method for forearm shaft fracture repair in children (Hunter, 2005; Schmittenbecher, 2005). This technique is usually minimally invasive leading in good cosmesis: long incisions in fracture site are no longer needed, as opposed to the plating option. The periosteal stripping is minimized, especially if the fracture is reduced carefully (Hunter, 2005). Growth plate injuries are avoided if the implants are introduced beyond the physis, and postoperative infections are rare (Lascombes et al., 2012). Even if a minimal open reduction is needed (Malek, Webster, Garg, Bruce, & Bass, 2012; Patel, Li, & Anand, 2014) the functional outcomes of ESIN have been satisfactory (Baldwin et al., 2014; Hunter, 2005).

In theory, relatively high elasticity of the nails allows micro-motion between the fragments, promoting rapid and strong callus formation (Hunter, 2005) as compared with rigid fixation methods that can result in hypertrophic nonunion. Theoretically, ESIN works in the long bones as an internal splint aligning the bone fragments (Johnson et al., 2009).

When performing ESIN, the patient is positioned in the supine position, i.e., dorsal decubitus, with the affected forearm on the radiotransparent table. The fracture is reduced under fluoroscopic control (Lascombes et al., 2006). The bone that is easier to reduce is usually fixed first. Therefore, the radius is usually treated first (Cosma & Vasilescu, 2014). For the radius, the entry point for the nail is in the distal metaphysis, above the distal growth plate, and usually on the radial side. The lateral radial vein and the sensory branch of the radial nerve must be avoided. Dorsal entry is another option.

The cortical hole is drilled by an awl and enlarged by circular movements of the instrument. The nail is then inserted into the medullary canal and introduced by oscillating movements. A hammer is seldom needed. The reduction is achieved at least at the time when pushing the nail beyond the fracture line under fluoroscopy control. In case of unsuccessful reduction, two or three attempts are allowed, and then a minimal open reduction through a small incision with conventional instruments is made (Cosma & Vasilescu, 2014).

The nails are inserted in the medullary cavity of the ulna and radius in opposite directions and turned in opposing concavities in the bone under tension to cause a three-point force, thus aiming to promote the alignment of the bone. The apex of
the bow is placed at the fracture level. In the forearm, only one nail can be inserted in one bone (Kaiser et al., 2012; Lascombes et al., 2006; Narayanan, Hyman, Wainwright, Rang, & Alman, 2004; Shaha et al., 2017).

The nail is usually introduced until it reaches the metaphysis of the bone fragment. One author has suggested that sufficient stability is achieved if the nail length over the fracture line is at least three times the diameter of the bone (Johnson et al., 2009). Finally, the tip of the nail is cut 5 to 10 mm outside the bone cortex, according to the procedure. Some clinicians cut and tap the nail at the level of the bone surface when no removal was planned to be done later (Lascombes et al., 2006).

The diameter of the nails varies between 1.5 mm and 3 mm (Cosma & Vasilescu, 2014). When evaluating sufficient thickness of the nail, the nail diameter (ND) is compared to the medullary canal diameter (MCD) (Shaha et al., 2017). The nails must be symmetrical in size, while different nails cause asymmetrical tension, which may displace the fracture (Lascombes et al., 2006). Not many studies have proven the optimal nail size for forearm fractures (Shaha et al., 2017), so the recommended thickness remains debatable.

According to some authors, a free postoperative mobilization is an advantage of ESIN, but the stability needs to be evaluated during the operation. Free mobilization without splint or cast improves functional rehabilitation (Lascombes et al., 2006; Schmittenbecher, 2005). However, some authors support the idea of short immobilization because the nails are not rigid (Skaggs D, 2014). The external immobilization also reduces pain and protects the forearm from new injuries during the healing period. If the forearm is immobilized postoperatively, the time of immobilization is usually shorter than in conservative treatment, in which 4 to 6 weeks is often recommended (Schmittenbecher, 2005).

The recommended age group for ESIN is between 5 to 16 years (Lascombes et al., 2006), while adolescents near to bone maturity should be considered for plate and screw fixation. Remodeling capacity tends to disappear in girls at the age of 12 to 14 years and a couple of years later for boys (Noonan & Price, 1998).

**Nail removal**

The long-term effects of ESIN in the forearm are not yet widely known. Therefore, the implants are traditionally removed approximately six months after the injury (Gorter, Vos, Sier, & Schipper, 2011; Mittal et al., 2004) under general anesthesia.
with a solid gripper. Still, later removal may be difficult, as the bone grows over the nail.

The removal has some disadvantages: it predisposes children to anesthesia and operation-related risks; moreover, it causes psychosocial stress. The cost of implant removal is estimated to be approximately 1900 USD in a developed country (Niemela, Uhari, Mottonen, & Pokka, 1999; van der Eng, D M, Schep, & Schepers, 2015). Some institutions prefer leaving implants or removing only symptomatic ones (Gorter et al., 2011; Molster, Behring, Gjerdet, & Ekeland, 2002; Schnittenbecher, 2013). When a child has remaining bone growth, the metallic implants may affect the natural modeling of the radius. In particular, the changes in lateral bowing during growth may limit the rotational movements. (Daruwalla, 1979; Firl & Wunsch, 2004). These problems do not occur if the implants are removed in an early phase of recovery. Until firm evidence is available, the removal of the ESIN is justified.

2.5.3 BIN

BIN has been developed to treat unstable forearm shaft fractures in children. The treatment indications are planned to be similar to ESIN (Sinikumpu et al., 2013). Biodegradable nails are designed to maintain mechanical strength but to be absorbed during bone healing in a couple of years. The implant was planned to be utilizable in both radial- and ulnar-shaft fracture repair.

The implant used in this study is an ultra-high-strength biodegradable intramedullary nail of poly(lactide-co-glycolide) (PLGA) with a tricalcium-phosphate (β-TCP) marker, designed and manufactured for the purpose of this study by Bioretec Ltd. (Hermiankatu 22, Tampere, Finland). It is mechanically based on the corresponding (short) pins that have been used in many indications in traumatology and produced by the same company. PLGA has previously been shown to be safe and biocompatible in preclinical work in animals (Krucinska et al., 2017; Xue et al., 2014). It is also used in the human body in medical use in many clinical indications (Rokkanen et al., 2000; Sinikumpu & Serlo, 2017; Waris, Konttinen, Ashammakhi, Suuronen, & Santavirta, 2004).

The study nails are of three diameters (2.0, 2.7, and 3.2 mm), each being 400 mm in length, and produced for use in children’s forearms. Hydrolytically activated memory effect causes the diameter of the implant to increase by about 1 to 2% while its length decreases by that same 1 to 2% in the human tissue (Sinikumpu &
Serlo, 2017). The thickening of the nail is assumed to increase the stability of the fixation still.

The BIN itself is straight, and there is no material-memory: the nail cannot be pre-bended. It will not provide much tension when applied in the medullary cavity. The tip of the nail is not curved, as opposed to the titanium nail that has a curved tip for wheeling. It also improves rotational stability when the tip is tapped against the cortices (Figure 7). Degradation of the PLGA-implant material occurs first by hydrolysis. After about 24 weeks macrophages and giant cells are noticed around fragmented implant material, and the degradation continues via enzymatic pathways (Tiainen, Soini, Törmälä, Waris, & Ashammakhi, 2004). Implant-related complications have been rare.

Fig. 7. Perioperative picture of Biodegradable Intramedullary Nail (BIN), where a special instrument is sometimes needed for introducing the implant.

The operative procedure of BIN is very similar to ESIN stabilization (Parikh et al., 2012; Sinikumpu et al., 2013). However, the nail is more flexible, and a high pushing force is not tolerated. Thus, reaming the whole medullary cavity until the end of the planned rodding is recommended. After reaming, the implant is
introduced by pushing gently while slightly tapping the nail into the cavity with a particular implant-specific instrument. A special lockable hammer instrument is sometimes needed (Figure 7).

The highly elastic nails are thought to reliably allow free physiological remodeling of the forearm bones after the healing of the fracture, thereby contributing to the function of the non-synovial forearm joint. The implant adapts to the natural form of the bone, and it cannot hold a curved alignment, similar to pre-bended titanium nails. Thus, external support by casting may be essential to hold the alignment.

Previously, biodegradable materials in the human body were used in many indications (Giannini et al., 2017; Hughes, 2006; Landes, Ballon, & Roth, 2006b; Partio et al., 1992; Prakasam et al., 2017; Rokkanen et al., 2000; Waris et al., 2004; Xue et al., 2014). There are many potential advantages to using implants that resorb spontaneously, making the removal unnecessary. Other benefits of these materials are the minimized artifact seen in MRI and CT scans (Landes et al., 2006b). The risk of infections or inflammatory responses may be reduced, and no biofilm is permanent in case of infection (Atkinson, Khan, Lashgari, & Ziegler, 2019; Randelli et al., 2014; Zheng et al., 2018). The lack of hardware removal precludes the risks of anesthesia complications and additional scarring. Also, the costs are reduced which is important, not only for the family but for society as well. However, there are some disadvantages. The learning curve involved in creating operative procedures using biodegradable (instead of metallic) implants is generally longer (Atkinson et al., 2019), and the material is also weaker than its counterparts; thus, some additional steps are needed during surgery. Moreover, some of these materials have also caused inflammation or osteolysis in human tissue (Balestro, Young, Maccioni, & Walch, 2015; Bergsma, de Bruijn, Rozema, Bos, & Boering, 1995; Prakasam et al., 2017).

Different polymers have been invented to be used alongside the metallic alloy nails, plates, and screws (Krucinska et al., 2017): poly-L-lactide acid (PLLA), poly(L-lactide-co-D,L-lactide) (PLDLLA) (Landes et al., 2006b; Landes, Ballon, & Roth, 2006a), poly(glycolic acid) (PGA), and poly(lactide-co-glycolide) (PLGA) (Sinikumpu & Serlo, 2017). Some polymers, such as PLLA and PLGA, may be used in orthopedic, craniomaxillofacial, and neurosurgical operations (Ashammakh & Serlo, 2007). The polymers have different properties regarding resorption time and material strength. Copolymers, such as PLGA, resorb faster than for example PLLA and are more suitable for children (Ashammakh & Serlo, 2007). PLGA has also lower crystallinity that PLLA, which degrades in about seven
years (Barber & Dockery, 2006). However, these biodegradable polymers have not yet been widely studied in children.

2.6 Follow-up of forearm fractures

The healing time of childhood fractures varies depending on the type of fracture and bone involved. Generally, pediatric bones heal quickly, so frequent follow-up is needed during the first weeks. Some injuries result in the need for prolonged follow-up. Furthermore, some complications of pediatric fractures will not be noticed until many years later, such as distal ulnar process fractures, which may show their outcomes no earlier than several years after the trauma.

The subjective experience of the patient’s disability guides the physician’s understanding regarding whether the treatment has been successful or not. The disabilities of the arm, shoulder and hand (DASH) questionnaire is a clinical tool introduced by the American Academy of Orthopedic Surgeons, and it is widely used for many upper extremity conditions (Hudak, Amadio, & Bombardier, 1996). The questionnaire is intended to aid the patients in self-reporting the evaluation of different symptoms and disability. The questionnaire yields a score: from 0 (no disability) to 100 (full disability). Studies have shown that a 10-point difference means a minimal clinically important change. The questionnaire has been translated into many languages and validated in several studies (Offenbaecher, Ewert, Sangha, & Stucki, 2002; Schwartz, Deborah A., OTR/L, CHT, 2010). The questionnaire can detect small and large changes in function (Gummesson, Atroshi, & Ekdahl, 2003). It is essential to understand the level of pain experienced by the patient. The visual analog scale (VAS) is a widely used tool for the measurement of pain. The patient can describe their pain on a scale from zero to ten (mm +/- SD).

2.6.1 Measuring ROM

Currently, the value of a well-restored function after a fracture treatment has been recognized as one of the primary treatment goals (Lee, St Louis, & Fowler, 2018). In the upper extremity, ROM of the joints is crucial for daily activities. Forearm shaft fractures particularly affect forearm pronation and supination. They may also disturb the normal function of the wrist and elbow.

The normal flexion-extension movement in the elbow is about 0 to 145°, and the pronation-supination ROM in the forearm is about 170° and flexion-extension ROM of the wrist is about 150° in healthy, uninjured forearms (Mittal, 2017). The
residual deformity following malunited forearm fractures is not always corrected by remodeling, especially in older children, which may lead to a loss of forearm ROM.

Cadaveric studies have shown that angular and rotatory deformities in both bones of the forearm of 10° result in significant loss of forearm rotation. In particular, the supination movement is vulnerable to angular and rotational deformities (Tarr, Garfinkel, & Sarmiento, 1984; Teoh et al., 2009).

In current clinical practice, functional measurements are usually made by a physician with a free-hand transparent goniometer. They are easy to use and widely available in clinics. Intra-rater reliability of the transparent goniometer is satisfactory when measuring ROM (Kolber & Hanney, 2012; Reese & Bandy, 2017). However, it is important that positioning of the instrument is consistent and the measurements are done according to the standardized protocols (Pratt & Burr, 2001).

Nevertheless, there are limitations in traditional measuring methods; e.g., the results of these measurements must be manually tabulated into clinical charts or hospital databases. Furthermore, the descriptive (range) and mathematical (e.g., mean) results of the repeated measurements must be manually calculated. There is a risk for human error in calculating and typewriting at every new stage needed after measuring. Thus, new devices have been developed to make the measurement process as accurate, fast, and safe as possible when investigating musculoskeletal conditions (Hirschhorn et al., 2015; Levanon, 2013; Remigio et al., 2017).

Computer-assisted and photography-based goniometers (Meals et al., 2017; Reese & Bandy, 2017; Trehan et al., 2017), fluid goniometers (Remigio et al., 2017), and cell phone application tools (Kim, Sung, Kang, Gaponov, & Jung, 2017; Lee et al., 2018) have been suggested to directly capture the quantitative values onto patient charts. The possible benefit would also be in decreasing the workload of surgeons involved in treatment. For example, occupational therapists (such as hand therapists) could be incorporated to follow up during outpatient visits. Improved job sharing between physicians and occupational therapists would impose economic benefits upon healthcare units, despite the higher purchase costs of technological measuring methods.

### 2.6.2 Measuring the grip strength

Muscle strength testing is another important part of clinical follow-up (Talsania & Kozin, 1998). The strength of the handgrip is thought to be an important
determinant of recovery after upper extremity trauma, and it is also a good overall measure of the patient’s condition (Beumer & Lindau, 2014). In the forearm, even slight malangulation, primarily those such as the decreased curve of the radius, may reduce the grip strength (Schemitsch & Richards, 1992). The hydraulic dynamometer is considered a valid instrument for maximal muscle strength assessment (Figure 8) (Gasior, Pawlowski, Williams, Dabrowski, & Rameckers, 2018; Kolber & Hanney, 2012; Reese & Bandy, 2017; Roberts et al., 2011), while it is deficient in distinguishing subtle differences in strength. New computer-assisted methods have been developed, and the main improvement is in their way of using the data, saving the results and making the mathematical calculations of repeated tests autonomously.

Fig. 8. The test subject demonstrates the sitting position and use of a computer-assisted dynamometer.
2.7 Complications of forearm fractures

2.7.1 Nonunion and delayed union

Disturbed bone healing is, in general, relatively rare in pediatric fractures (Fernandez et al., 2009), due to metabolically active bone tissue that is in the osteogenic stage during growth. However, in the forearm, USP fractures and ulna shaft fractures are at a particularly increased risk for nonunion. The nonunion of the radial shaft is rare but may occur (Sommerfeldt & Schmittenbecher, 2014). The older the patient, the more the risk for nonunion increases, so that the incidence rises as of the age of six, reaching the same level as adults by age ten (Arslan, Subasy, Kesemenli, & Ersuz, 2002). The nonunion in the forearm shaft is mostly associated with a comminute or open fracture, re-fracture, infections, or iatrogenic causes relating to fixation (Arslan et al., 2002; Schmittenbecher, Fitze, Godeke, Kraus, & Schneidermuller, 2008). The current understanding of the nature of USP fractures leading to nonunion is insufficient.

Bone healing is not a black and white deduction, but rather a gradual process leading to restored strength of the bone. Several mechanical and biological factors influence the formation of new bone tissue around the previous fracture. Histologically, bone regeneration happens by three routes, mimicking the embryonal bone growth: endochondral, intramembranous, and osseous remodeling. These happen in different parts of the bone: endosteum, periosteum and cortex, respectively. Even though a microscope could follow this process, the physician must estimate the healing by the radiographs and clinical examination such as pain, tenderness, function and palpable callus (Marsh, 1998).

The fixation method of a fracture affects the healing process. The radiographs, which are taken in two views, show callus formation in the fracture site during non-operative treatment with a splint (Figure 9). The same effect is seen in semi-rigid intramedullary nailing due to micro motion in the fracture line. After a rigid fixation with plate and screws, the process is different: it is followed by the disappearance of the fracture line (fracture line consolidation), and no bridging callus can be seen (Marsh, 1998). The physician’s estimation of the radiographs generally guides the healing process, but it may be standardized for research purposes. A widely used scoring system of bone union, in particular for research purposes, is Lane-Sandhu scoring (Lane & Sandhu, 1987). The scoring rates callus and fracture line visibility in different levels giving numerical estimates from zero to four.
Fig. 9. The patient had a forearm shaft fracture that was treated by splint immobilization. A callus formation can be seen in the ulna during the bone healing process. The fracture line is still visible in the ulna.

The delayed healing is diagnosed generally at three months after the primary injury following by a nonunion at six months’ (Fernandez, Langendorfer, Wirth, & Eberhardt, 2010; Mehlman et al., 2006). However, a final spontaneous fracture union may happen until one year (Schmittenbecher et al., 2008). The most common fractures associated with nonunion in the forearm are discussed separately below.

**USP fracture and nonunion**

USP fracture rarely occurs by itself; instead, it usually accompanies a distal radius fracture. The incidence is as high as 30 to 50% of distal radius fractures among the pediatric population (Abid et al., 2008; Gogna et al., 2014; Wijffels et al., 2014). The incidence in the adult population may be even higher (Kramer et al., 2013). However, the USP fracture may be under-diagnosed in children, while the distal ulnar epiphysis is cartilaginous and not appear before the ages of 5 to 9. MRIs are not usually performed in conventional wrist fractures.

The nonunion rate of USP fractures in the pediatric population is mostly unknown. The reported nonunion rate varies from 26 to 54% in adults (Kramer et al., 2013; Meyer et al., 2013). The risk factors for nonunion of USP are unknown. Some studies, performed in the adult population, suggest that the USP fracture type and primary dislocation of the USP are the leading indicators for nonunion, rather than the fracture in the radius (Meyer et al., 2013).

The importance of the USP regarding DRUJ stability is controversial (Logan & Lindau, 2008; Zenke, Sakai, Oshige, Moritani, & Nakamura, 2009). The DRUJ is stabilized by the ulnoradial ligament that is attached to the ulnar head and the base of the USP from where it extends to a sigmoid notch in the radius. This ligament is a primary dorsopalmar stabilizer of the DRUJ (Kazemian et al., 2011;
Palmer & Werner, 1984). However, the clinical findings and their association with USP fractures are unclear.

In adults, the USP fracture is mostly left without specific treatment even though it frequently fails to unite. The treatment in the pediatric population is mostly similar; the wrist fracture is immobilized in slight ulnar inclination (Abid et al., 2008; Gogna et al., 2014; Logan & Lindau, 2008). The fracture is sometimes treated operatively if the radius fracture requires surgical intervention (Chen et al., 2013; Souer et al., 2009; Zoetsch et al., 2013). However, the evidence for the optimal treatment in the USP fracture is missing.

The studies concerning the clinical importance of childhood USP nonunion are based on short-term outcomes (Gogna et al., 2014; Kramer et al., 2013; Mulders et al., 2018) and the understanding of long-term outcomes is insufficient (Cannata et al., 2003).

Nonunion in the forearm shaft

Delayed healing in the forearm shaft is reported in about 0.5% of non-operatively treated patients (Mehlman et al., 2006) The incidence is higher in operative treatment (Fernandez et al., 2009); delayed union is reported in about 0.1 to 3.2% (Fernandez et al., 2010; Lobo-Escolar et al., 2012; Schmittenbecher et al., 2008; Sommerfeldt & Schmittenbecher, 2014), while nonunion occurs in about 0.5 to 2.5% of the fractures treated by ESIN (Baldwin et al., 2014; Fernandez et al., 2005; Fernandez et al., 2009). The middle shaft of the ulna is affected most commonly (Schmittenbecher et al., 2008) while the risk increases with age (Lieber & Schmittenbecher, 2013; Lobo-Escolar et al., 2012) due to a slower healing process. Younger children rarely develop nonunion in the forearm.

It is known that open fractures and reductions compromise cortical blood supply, thus hindering bone healing; therefore, fractures with skin wounds and openly reduced fractures are at higher risk for nonunion (Sommerfeldt & Schmittenbecher, 2014). In addition, the intramedullary nailing may hinder the introsseous blood circulation, particularly in the ulna shaft (Wright & Glowczewskie, 1998). Despite the potential effects on bone healing, the intramedullary fixation with closed reduction is the preferred operative fixation method.
2.7.2 Limited ROM and grip strength

Normal ROM of pronation is 50 to 80° and 80 to 120° for supination, both in children and adolescents (Franklin et al., 2012; Sinikumpu & Serlo, 2015). However, the ROM that is required for daily living is about 50-0-50 pronation-supination (Franklin et al., 2012; Morrey, Askew, & Chao, 1981; Noonan & Price, 1998; Sinikumpu et al., 2012), even though some authors (Tarr et al., 1984; Youm, Dryer, Thambyrajah, Flatt, & Sprague, 1979) would require higher ROM (approximately 80% of the ROM of normal non-injured hand). The supination movement is thought to be more important than pronation because the shoulder abduction can be used to compensate for the loss of pronation in the forearm, but supination is hard to compensate with the shoulder.

It is known that the changes in radial curvature affect rotational movements (Tarr et al., 1984). Loss of forearm rotation that is clinically insignificant can be caused by 10° of angulation in any direction, whereas 20° of angulation causes clinically significant loss of forearm rotation (Schmittenbecher, 2005) Also, prolonged immobilization is associated with decreased ROM (Goldfarb, Ricci, Tull, Ray, & Borrelli, 2005). It is also suggested that grip strength may be weaker in cases with decreased radial bowing (Yorukoglu, Demirkan, Akman, Kitis, & Usta, 2017)

2.7.3 Loss of reduction

Loss of reduction is a relatively common complication after non-operative treatment of forearm shaft fractures (Sinikumpu et al., 2012). However, it is a rare but possible complication after ESIN (Cullen, Roy, Giza, & Crawford, 1998), and may be associated with technical errors in the initial surgery (Fernandez et al., 2010). The reported incidence of re-displacement after operatively treated forearm shaft fracture is about 1 to 3% in the early phases of recovery. Moreover, the reduction can also be lost while the nails remain in place if the trauma energy is high enough (Schmittenbecher, 2005).

In malunion, the normal physiologic healing process producing satisfactory stability is completed over the expected amount of time. However, the fracture has healed in an abnormal position due to loss of reduction, which is often a combination of angulation, rotation, and shortening. The position is not anatomical.

Crossunion, which is synostosis of the radius and ulna, is a rare complication. It affects the movement of the radius and ulna, preventing rotational movement.
Therefore, synostosis is usually resected to make rotation between forearm bones possible (Noonan & Price, 1998).

### 2.7.4 Re-fracture

Re-fracture is an uncommon complication of ESIN, as the incidence is reported to be 0.1 to 1.2% (Fernandez et al., 2010; Kelly, Shore, Bae, Hedequist, & Glotzbecker, 2016; Lascombes et al., 2012). Inadequate primary treatments, such as suboptimal primary reduction or poor operative technique, are associated with re-fractures (Price, Scott, Kurzner, & Flynn, 1990). The re-fracture risk is present up to six months after the initial injury when most re-fractures occur (Fernandez et al., 2010; Lascombes et al., 2012). Re-fractures are also possible with nails in place (O'Neill, Fitzgerald, Kaar, & Murphy, 2019). Upon the healing of the fracture, children no longer remember to be cautious with their fractured forearm. Further, the nail removal is usually performed six or even eight months after the injury (Noonan & Price, 1998; O'Neill et al., 2019). There is variation in the terms: a fracture that occurs at the same place during the first year after the initial injury is undoubtedly a re-fracture. On the other hand, a fracture at the same place in 2 years is a new fracture rather than a re-fracture.

### 2.7.5 Hardware-related complications in ESIN

The most common complications related to ESIN are nail prominence and irritation at the nail entry site, which may cause more severe complications such as skin breakdown, superficial or deep infection, bursitis, and early implant removal with the risk of re-fracture (Parikh et al., 2012). The tip of the nail has traditionally been left prominent for easier implant removal but, recently, some authors have recommended not to bend the nail tips and instead to leave them deep in the bone (Lascombes et al., 2006). Also, new tools have been invented to aid later nail removal (Parikh et al., 2012).

Implant-related infection and biofilm are uncommon complications after ESIN. Most of the inflammation is superficial wound inflammation. The reported incidence is between 0.9 to 7% (Fernandez et al., 2010; Mann, Schnabel, Baacke, & Gotzen, 2003). Also, hardware migration is reported (Cullen et al., 1998); and, the later radiographic imagining may be disturbed if the implants are left in place.
2.7.6 Compartment syndrome

Compartment syndrome may occur in the forearm, tibial, and femoral fractures, of which the forearm is the most common (Bae, Kadiyala, & Waters, 2001; Beniwal & Bansal, 2016). However, it is a rarely seen complication in pediatric forearm fractures. The risk is increased in high energy trauma and with significantly displaced fractures. Multiple attempts to achieve reduction causes increased soft-tissue injury and also increases the risk for compartment syndrome. That is the reason why no more than three attempts of closed reduction are suggested for the forearm (Bae et al., 2001; Parikh et al., 2012). The only treatment of evident compartment syndrome is the surgical opening of the muscle fascias, which releases the elevated intramuscular pressure and returns the circulation (Beniwal & Bansal, 2016).
3 Aims of the study

This doctoral thesis research aimed to investigate the treatment, follow-up, and long-term morbidity of bone fractures in the forearm of child patients, focusing on the forearm shaft and USP, which are known to have a risk for nonunion. Specifically, the study aimed to analyze the use of a new fixation method (BIN) in pediatric forearm shaft fracture repair and to understand if the clinical outcomes differ between the patient groups who received BIN versus ESIN treatment. The gold-standard operative fixation method, ESIN, was to be analyzed in order to uncover the quality of the tension metal frame construct. Thus, the technical deviations, including nail thickness and orientation and their association with poor outcomes, were to be studied as well. Furthermore, the electronic computer-assisted measurement method for ROM and grip strength measuring were to be compared to traditional methods. However, the overarching aim was to study USP fractures and the risk of their nonunion and possible long-term morbidity.

The specific study questions are presented below. They refer to the respective substudies I to IV:

1. Is there any difference in forearm ROM (pro-supination of the forearm, elbow flexion-extension) between patients treated with BIN and with ESIN after two years of follow-up? (I)
2. Which technical deviations of the tension metal frame construct in the ESIN method are associated with disturbed bone healing or instability in a short-term follow-up of forearm shaft fractures? (II)
3. Can the transparent goniometer, dynamometer (Jamar, Lafayette ltd), and computer-assisted measurement method (E-Link System Packages, Biometrics Ltd, U) be used interchangeably during the clinical follow-up of children’s upper extremity fractures? (III)
4. What is the long-term incidence of USP nonunion in patients with a previous distal forearm fracture in their childhood, and is USP nonunion associated with long-term morbidity? (IV)
4 Materials and methods

This study consists of four different sub-studies. The study population is described in detail below, with Roman numerals referring to the original articles and their study material (I to IV). As seen in Table 2, the baseline characteristics of each patient, including injury mechanism, clinical findings, and treatment, were collected (I to IV). Also, a radiographic analysis was performed in studies one, two, and four (I–II, IV).

Table 2. Baseline characteristics of study groups I to IV.

<table>
<thead>
<tr>
<th>Character</th>
<th>Study I</th>
<th>Study II</th>
<th>Study III</th>
<th>Study IV</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Retrospective observational study</td>
<td>Prospective comparative study</td>
<td>Retrospective follow-up study</td>
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<td>71</td>
<td>59</td>
<td>139</td>
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<td>17 (10–24)</td>
<td>21 (14–29)</td>
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<tr>
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<td>35 / 36</td>
<td>23 / 36</td>
<td>82 / 57</td>
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<tr>
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<td>14 m</td>
<td>10 y</td>
<td>11 y</td>
</tr>
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</table>

4.1 BIN versus ESIN

4.1.1 Patient enrolment (I)

Starting in November 2011, all children who suffered from forearm shaft fractures requiring operative fixation were screened for trial eligibility. The eligible participants were randomized into two groups to be treated by either BIN or ESIN. The patients’ age ranged between five and 15 years old. The enrolment continued until January 2015; the total enrolment time was three years and three months. The last follow-up visit was executed in January 2017. The patients were treated in Oulu University hospital and Päijät-Häme central hospital (Figure 10) (I).

The following were excluded from the study: non-shaft fractures, such as metadiaphyseal zone fractures; fracture-dislocations; fractures in patients with any metabolic bone or systemic disease; patients on any medication affecting bone quality or resistance to infection; and, fractures in patients with bone dysplasia or an underlying syndrome.
Fig. 10. Flow-chart of the patient allocation, to be treated by BIN or ESIN (I).

Stage 1: Assessment for eligibility
- Not meeting the criteria (n = 0)
- Declined to participate (n = 0)
- Other reasons (n = 3)

Stage 2: Randomization
- Intervention group (n = 19)
- Control group (n = 16)

Stage 3: Follow-up
- Control group: implant removal at 6 months

Stage 4: Analysis at 2 years mark
- Analysed (n = 31)
- Excluded from analysis (n = 4)

Intervention group:
- Adverse events (n = 2)
- Lost to follow-up (n = 2)
Also, patients with open fractures, other significant soft-tissue injuries, pathological fractures due to any background condition, a previous fracture or infection in the same forearm, or fractures older than seven days at the time of the appointment were excluded.

The mean age of the included patients was 10.1 years (range 5 to 15, SD = 2.5 years). Their mean height was 143.6 cm (range of 116 to 173 cm, SD = 16.0 cm) and mean weight was 36.3 kg (range of 20 to 67 kg, SD = 11.8 kg). The patients in the two study groups, BIN and ESIN, were of the same age (p = 0.569).

Among the fracture cases, 33 (94%) patients suffered from a diaphyseal both-bone fracture, and two had an isolated diaphyseal radius fracture, unstable enough to require osteosynthesis. Most of the fractures were classified as AO type 22r-D/4.1, 22u-D/5.1 (40%), or 22-D/5.1 (29%) and the rest were either 22-D/4.1 or 22r-D/5.1, 22u-D/4.1. The two single bone fractures were AO type 22r-D/4.1.

**Randomization (I)**

A study assistant provided by the sponsor was not involved in the treatment and was thus responsible for randomization, using varied block sizes to achieve 19 sealed envelopes per group. The envelopes were delivered to the study centers as required. Signed informed consent was obtained from all patients. A nurse at the ward, not involved in the treatment of the patients, opened one envelope for the operating surgeon. Parents and children were not blinded to the treatment. The radiographic analyses of all images, including the magnetic resonance images (MRI), in both study institutions, were performed by the same radiologist, specialized in pediatric radiology, to avoid inter-rater error in the measurements.

**Sample size (I)**

The mean ROM of forearm rotation after ESIN was taken to be 153° while the normal ROM in an unselected population in that age-group was taken to be 170° (Teoh et al., 2009). The latter was assumed to demonstrate ROM in the BIN patients, as BIN was thought to be elastic enough to contribute to the normal remodeling of the forearm after healing. It was calculated that 13 patients per group were needed, by using the abovementioned difference (17°) as the clinically important difference, and 15° as standard deviation (SD) and by using alfa level of 0.05 and power of 80%. In order to compensate for the possible drop-outs during the 2-year follow-
up in advance, it was decided that recruitment should continue beyond the satisfactory sample of 26 patients by exceeding the enrolment by a minimum of 20% in both groups. Therefore, the recruitment was interrupted only when it became inevitable that both had an excess of 20% in participation; however, at the time of interruption, one group out of these two had increased up to \( n = 19 \). The final excess was thus 35% \( (n = 35/26) \). The 35 cases comprised the primary study population.

### 4.1.2 Methods (I)

**Outcome variables (I)**

The primary outcome in the study was the forearm pro-supination ROM arch at the two-year mark (Franklin et al., 2012).

Other outcome variables included elbow flexion-extension ROM, radiographic bone healing and angulation, operation time from incision to casting, length of in-hospital treatment (in days), and complaints in daily living, as reported by the patients. The standardized questionnaire included elements of the DASH questionnaire regarding subjective satisfaction and pain. Pain levels were evaluated using the VAS-scale (with range 0 to 10 mm). Two-years was taken to be a standard interval for any general pain reported by the patient and local pain at the fracture site two years after the injury.

All surgery-related deep or superficial infections, intra-operative complications related to fixation hardware, osteolysis, potential bio-incompatibility reactions, and mechanical implant failure (loss of reduction) were registered to ensure the safety of the device. Drop-outs were analyzed in detail, and the reasons for the adverse events were to be analyzed.

All the patients in both patient groups were immobilized postoperatively by using the long arm splint, to standardize the study methods, according to the study plan. Metallic nails were routinely removed six months postoperatively.

**Trial follow-up (I)**

The patients were investigated at four weeks, three months, six months, and two years postoperatively and contacted by phone one year postoperatively. All information was collected via standardized questionnaires. Radiographic examinations were carried out in every follow-up visit. However, the primary study
outcomes were performed as per protocol by using, at a minimum, the two-year mark follow-up data.

4.2 ESIN (II)

4.2.1 Patient enrolment (II)

This population-based study included all consecutive patients aged less than 16 years, who had been treated for a shaft fracture of radius and ulna by using ESIN in Oulu University Hospital between 2009 and 2018. There were no other pediatric 24-hour emergency departments in the study area, with approximately 87,000 children-at-risk annually: the enrollment was thus taken to be inclusive. However, some individual cases may have been treated at other trauma units, e.g., during vacations abroad. The patients were initially captured by using the International Classification of Diseases (ICD), version 10, to include all potential patients. All primary and follow-up radiographs of the patients were reviewed to confirm the inclusion. The fractures were classified based on the AO-classification (Meinberg et al., 2018).

There were, altogether, 112 patients with a radius and ulna shaft fracture that were primarily reviewed, but 41 of them were excluded: 35 (31%) had been treated using another osteosynthesis such as Kirschner wires or biodegradable nails intramedullary, and four patients (3.6%) were non-operatively treated and thus excluded. Moreover, two patients had an isolated ulna fracture and thus excluded. Non-shaft fractures, fractures with a concomitant dislocation such as Monteggia fracture-dislocation, and fractures in patients with bone dysplasia or an underlying syndrome were to be excluded; however, there were none such cases among the primary cohort.

Patients (II)

The mean age of the patients who were treated by ESIN ($n = 71$) was 9.7 years (range 2 to 15, $SD = 2.6$); $n = 35$ (49%) were boys. A slight majority ($n = 39$, 54%) was classified as type 22-D/5.1, while $n = 15$ (21%) typed 22-D/5.2, and $n = 11$ (65%) presented type 22-D/4.1. The most common single cause of injury was caused by trampoline jumping (36%). Failed non-operative treatment preceded ESIN in $n = 12$ (17%) of the cases, while the other patients were treated with ESIN
as a preferred option. Two patients had repeated fractures in the same forearm but they both happened two years after the first injury. The first fractures of these patients were included in the study.

4.2.2 Methods (II)

Outcome variables

In this study, nonunion, delayed union, and re-fracture during the next 12 months postoperatively were the primary outcomes. Insufficient stability of osteosynthesis was chosen as a secondary outcome of the study. A change greater than 5° in alignment in any view in either the radius or ulna at any time during the postoperative out-of-hospital follow-up was taken as abnormal and evaluated via radiographs (Lascombes et al., 2013). Furthermore, changing alignment was analyzed not only with binary options (yes or no); instead, the change in alignment was further classified in three sub-groups: 5 to 10°, 10 to 15°, and 15 to 20°, to comprehensively analyze the potential change of alignment.

Explanatory variables of inferior outcomes

Technical deviations in the operative procedure, in particular, the unsatisfactory tension metal frame construct, as compared with the recommended operative technique and appreciated metal frame construction, were evaluated as the potential explanatory factors of poor outcomes. Several characteristics were recognized in the non-optimal operative fracture reduction and implant construction: more than 10 mm of residual re-displacement was taken as an unsatisfactory result. Anatomic medial angulation (lateral bowing) of a normal radius was taken to be 5 to 15°, according to the literature (Sinikumpu & Serlo, 2015). The opposite direction and curve of the nails were taken to refer to opposing concavities of the nails at the fracture site, yielding the correct tension for the IOM (Firl & Wunsch, 2004; Schemitsch & Richards, 1992). That kind of tension metal frame was appreciated while the lacking metal frame was taken as an explanatory factor.

The recommended length of interosseous space was taken to be at least 10%, compared with the length of the radius (Firl & Wunsch, 2004), demonstrating the satisfactory tension of the IOM: pre-bended nails are aimed to make tension to the IOM and thus to form a relatively stable construction to the forearm.
The size and number of the implants and the symmetry in their thickness were analyzed: asymmetric thickness was taken to be against the recommended technique. The impact of the nail thickness itself was investigated using two threshold values for the ND/MCD ratio: less than 40% versus equal to or greater than 40% and less than 70% versus equal to or greater than 70%. Thus, both nails which were too thin or too thick were taken to be explanatory factors of inferior outcomes.

The length of the nail introduced over the fracture site was measured, and less than 40 mm was not recommended. This cut point was determined by the suggestion that the two-fold thickness of bone width at the fracture segment would be a minimum length that the nails pass beyond the fracture line (Sinikumpu, 2015).

Furthermore, some fracture-related factors, such as the distal fracture site compared to proximal and mid-shaft, was considered as a potential risk factor for impaired bone healing and worsening alignment (Alrashdan et al., 2018). When determining the anatomical segments of the shaft, the total length of the radius was measured from the bicipital tuberosity in the proximal radius to the distal radial physis or—if absent—to the DRUJ.

### 4.3 Comparison of electronic, computer-assisted goniometer and -dynamometer to traditional measuring methods (III)

#### 4.3.1 Patient enrolment (III)

Comparison of computer-assisted goniometer and dynamometer (E-Link System Packages, Biometrics Ltd.) to standard, traditional measuring methods (plastic goniometer; Baseline® and hydraulic dynamometer; Jamar, Lafayette Ltd.) was performed as a prospective, observational study performed in Oulu University Hospital in Oulu, Finland. Patients with a former upper extremity fracture were included and supracondylar humerus fractures were taken to be representative for all patients with upper extremity fractures; thus, the patients who had suffered from the fracture during a study enrollment period were clinically examined during out-of-hospital follow-up visits at an average of 10 years after the initial injury, at an average age of 17 years old (10 to 24 years). All but one of the intended 60 cases participated (23 males and 36 females), resulting in the final population of 59 cases.
4.3.2 Methods (III)

Patients were investigated using both the study and the standard method. The measurements were independently performed during the same out-of-hospital visits by two thoroughly educated investigators (A.H. and J-J.S.) who were instructed about measurement details and the use of measurement devices in advance. Inter-observer reliability between the investigators was tested and found to be excellent (Cronbach’s alfa = 0.999).

4.4 Long-term incidence and morbidity of USP nonunion (IV)

4.4.1 Patient enrolment (IV)

The long-term incidence and late morbidity of USP nonunion were evaluated via clinical and radiographic follow-up at a mean of 11 years following the initial injury. Inclusion criteria were a previous distal radius fracture with or without a diagnosed concomitant USP fracture in patients less than 16 years of age. The patients had been treated in Vaasa Central Hospital, Finland, in 1992–1999. There are no other trauma centers in the area, and the cohort was taken to be population-based. All the patients were identified in the hospital database according to the diagnosis and operation codes; after confirming their final eligibility by reviewing the original radiographs, they were invited to a long-term follow-up visit through a postal letter. In cases of no-shows, another letter was sent. Throughout this process, the correct postal address was ensured by a nurse via a phone call, and information about the study and the invitation were given by phone as well.

Finally, 139 patients attended the clinical and radiographic follow-up out of 208 enrolled potentially eligible patients (participation rate 67%) at a mean of 11 years (9 to 15) after the injury (Figure 11). 39 out of 69 nonparticipants self-reported that they have no symptoms or reason to participate, while the other 30 declared no single reason for their decision to skip the study.

4.4.2 Methods (IV)

Original radiographs and hospital charts were re-reviewed to establish the baseline characteristics of all patients, their injury mechanism, clinical findings with admission, and primary treatment given at the trauma unit. The displacement and angular deformity of radius fractures were determined in the radiographs. The USP
fractures were classified as base and tip fractures, if visible. The rate of USP nonunion was evaluated, using the original numbers of the fractures. Additionally, possible risk factors of USP nonunion were evaluated.

Fig. 11. Flow-chart of patient enrolment.

In order to analyze current symptoms, the patients were asked about function, pain, their ability for physical activity, and daily-life-related complaints.

During clinical evaluation, distal RUJ instability decreased ROM, and lower grip strength as compared with the uninjured side were analyzed as primary outcome variables. Current symptoms were compared between the patients with USP nonunion and patients with the absence of USP nonunion, given that patients in both groups had suffered from distal radius fractures.

4.4.3 Radiographic analysis

Plain radiographs of the forearm included both the elbow and wrist in the captures. The AP and lateral projections were obtained for radiographic analysis. The elbow was in full extension and supination in AP radiographs and in a neutral rotation
with 90° flexion for the lateral view (Figure 5). The images were taken according to the study plan in every follow-up visit. In Study II, the follow-up radiographs were taken according to institutional practice. There were no special clinical or radiographic investigations for this study. The radiographs in Study IV were taken during the follow-up visit. Moreover, the initial radiographs were analyzed.

Fracture reduction and the potential residual re-displacement (mm), residual lateral, and dorsal angular deformity of the bones (degrees, SD) were analyzed. The angulation was determined by drawing the measuring lines that aligned with the axis of both proximal and distal bone fragments, after which the angle between these two lines was calculated (Figure 12). Forearm shaft fractures were classified based on the AO-classification (Meinberg et al., 2018). The stage of bone healing (I, II) was evaluated by using the Lane-Sandhu score: poor callus formation (in all cortexes of both bones), visible fracture lines, or absent cortical healing, i.e., lacking continuity of the cortical bone during three-month and six-month follow-up visits, was considered delayed union and nonunion, respectively (Fernandez et al., 2010; Mehlman et al., 2006).

The radiographs were analyzed by an experienced pediatric radiologist, familiar with childhood trauma (I), or by a medical doctor, familiar with the study questions (II, IV), thus using the established measuring landmarks. During the prospective trial, the radiographic examinations were carried out repeatedly not only to determine bone healing but also to note treatment-related complications (e.g., implant-related osteolysis and intramedullary nail (IM) failure) (I).

In addition to the conventional radiographs, a randomly selected sub-group of the patients, who were treated by BIN \( (n = 13) \), were analyzed by MRI to follow the biodegradation of the investigational implants. These images were also comprehensively analyzed by the same radiologist, familiar with pediatric trauma (I). In Study II, the proper axis of the radius and ulna could not be appropriately measured for four patients whose plain films were not large enough to analyze or otherwise insufficient. They were excluded from the analysis for changing alignment. In order to evaluate the radiographic outcomes of USP fracture in patients with a previous distal radius fracture, both left and right upper extremities were examined, excluding cases where the patient was pregnant. The presence of USP nonunion was recognized in radiographs, usually in AP projections: the displacement (mm), and possible ulnar shortening (mm) or lengthening (mm) in the injured extremity, were measured. Decreased joint space, osteophytes, and subchondral bone cysts were taken as signs of early degeneration. The USP fractures were classified as base and tip fractures, according to standard
descriptions. The radiographs were analyzed by an experienced radiologist, familiar with childhood trauma.

Fig. 12. Figure shows the measuring of angular deformity in forearm.

### 4.4.4 ROM and grip strength (I, III, IV)

The ROM of the wrist, forearm, and elbow were measured with the universal goniometer (Baselane®), which was made from transparent plastic and had two movable arms.

The patients were investigated while in a sitting position, with arms adducted against the torso. The elbows were at 90° flexion when the pronation, supination and wrist movements were measured. To measure pro-supination movement, the arm of the goniometer was set dorsally at the distal metaphysis of the radius (Figure 13). When elbow flexion-extension was measured, the forearm was in full supination again, while the patient was in the sitting position. The goniometer was placed laterally to the elbow. For wrist flexion-extension, the goniometer was placed laterally to the wrist. A similar procedure was performed with the computer-assisted goniometer (E-Link System Packages, Biometrics Ltd.). The ROMs were measured once, and the movements were based on the maximal active movement by the patient.

The motion ranges are reported with an accuracy of one decimal and, as mean values and SDs. The classification by Price was used for overall evaluation (Price et al., 1990).

Grip strength was measured using a hydraulic Jamar grip dynamometer (Sammons Preston, Bolingbrook, IL, USA) and in study three using also the
computer-assisted goniometer (Figure 8). The best of 3 attempts were recorded in this study setting (I, III, IV). Both the injured and uninjured sides were examined in the same manner. The handpiece of the dynamometer was fixed to fit the side of the patient’s hand before measuring.

The accuracy of data recording was decided for muscle strength as entire units (nm) and for movements as entire units and one decimal (degrees).

Fig. 13. The image shows the measuring of pronation, which is measured dorsally at the distal metaphyseal area of the radius bone. The measurement is done with the traditional goniometer, made of clear plastic.

4.4.5 Statistical analysis (I–IV)

In this study, several feasible statistical tests were used to evaluate the statistical significance of the findings. Differences in continuous variables were analyzed by Student's $t$-test for normally distributed variables and by the Mann-Whitney U test for skewed variables. The chi-square test or Fisher's exact test was used (in case of small groups with less than 5 cases) to compare the distribution between
categorical variables. Differences in proportions of independent variables were evaluated by using the binomial standardized normal deviate (SND) test. Independent samples t-tests were used to compare the differences between continuous variables. Continuous variables were described as mean ± standard deviation (SD) and categorical variables as frequency (n) and proportion (%). Odds ratios (ORs) were reported with their 95% confidence intervals (CIs).

All tests were two-sided, and 95% confidence intervals were used. Statistical analyses were performed by using SPSS version 24 software (IBM-SPSS Inc., USA) and StatsDirect Ltd. 2013 version 3.1 (Sale, Cheshire, England) (I–IV).

**Odds ratio, OR**

Binary logistic regression analysis and multivariate logistic regression were used to evaluate the potential predictive factors concerning the risk of USP nonunion (IV) and to analyze the association of potential risk factors of inferior tension metal frame construct and disturbed bone healing or changing alignment (II). ORs with their 95% CIs were determined.

The impact of nail thickness was analyzed using two threshold values for the ND/MCD ratio: less than 40% versus greater than 40% and less than 70% versus greater than 70% and by reporting the effect with an OR (II).

In Study IV, the analysis included age (per year of age), sex, severity of primary injury (greater than 2 mm displacement primarily or greater than 15° of angular deformity), concomitant ulnar fracture visible in radiographs, ulnar styloid fracture type (base versus tip), open fracture (no or yes), operative treatment of radius fracture (no or yes), junior versus senior operating surgeon and longer versus shorter time of immobilization (equal to or greater than 28 or less than 28 days), all of which were evaluated by their risk of predicting USP nonunion.

**Intra-class and inter-class reliability**

The intraclass correlation coefficient (ICC) was calculated based on the mean rating ($k = 2$), absolute agreement, and a two-way mixed effect model to evaluate interobserver validity in measurements and radiographic analysis.

Values greater than 0.90 indicate, in general, excellent reliability between different measurement results of one investigator (intra-rater) (I) or between two investigators (inter-rater) (III) (Koo et al., 2016). Less than 5% was considered to be the level of statistical significance (p less than 0.05).
For Study I, intra-rater validity was evaluated by measuring lateral angulation of the radius bone twice in the radiographs. The measurements were done in separate settings, and the radiologist involved in the study (Marja Perhomaa) was blinded to the previous measurements. Intra-rater reliability was excellent: the ICC was 0.941 (I).

For Study III, the inter-rater reliability was analyzed and was found to be 0.999, which is excellent. Both investigators independently performed a random selection of 25 measures on the same day using the same technique to evaluate interrater reliability between the investigators. The investigators were blinded during the revealing of their findings.

**Limits of agreement (III)**

The limits of agreement for ROM and grip strength, using the study and the reference methods, were examined using the Bland–Altman plot. The difference between the two measurements (Y-axis) for each patient was plotted against the mean of the same two measurements (X-axis). The limits of agreement were derived from the mean difference ± 1.96 SD. In the presence of agreement, most data points should have been contained between these intervals. If two methods are taken to be congruent, the mean of the differences is zero. The statistical significance of bias—the gap between the mean of the differences and zero—was tested using a one-sample t-test. The data were analyzed via differences in units rather than percentages. A linear trend among data points was evaluated using linear regression analysis.

**4.5 Ethical approval (I–IV)**

Study I’s plan was approved by the Medical Ethics Committee and the Hospital Ethics Committee of Tampere Hospital District, Tampere, Finland (§R09231/2009) and recorded in the annals of the Northern Finland Hospital District, Oulu, Finland. Study I is also registered with clinicaltrials.gov (NCT03474900) and the National Supervisory Authority for Welfare and Health (Valvira) approved the implant for use in the study. The Ethics Board of Vaasa Central Hospital approved studies III and IV in advance (§175/2008) and they were approved as an amendment by the Northern Finland Hospital District Ethical Committee.

Informed consent documents were obtained from all patients and their guardians, if under-aged; they had the right to interrupt participation at any time.
(I, III, and IV). All parts of this research were performed in compliance with the WMA's Declaration of Helsinki (I to IV).

The first potential patient in the prospective trial (I) was operated on using the study implant and technique to ensure the feasibility of the method and the implant in practice but was not included in the study, according to the study plan.

The biodegradable implants (I) were manufactured and provided by Bioretec Ltd., who also supported some practical arrangements of the study and in presenting the results. Financial support was also received from the Oulu University Hospital (public national study funding, VTR-funding) as well as from non-profit foundations (I, II, and IV). None of the funding bodies had a role in the investigation, data analyses, or writing of the manuscripts (I to IV).
5 Results

5.1 Treatment outcomes: BIN versus ESIN at the two-year mark (I)

5.1.1 ROM of the forearm, elbow, and wrist (I)

While injured sides in both BIN and ESIN groups were analyzed, there was no difference in any measured ROMs between the patients treated by BIN and ESIN. Also, the loss of ROM was compared with the patient’s uninjured side, and there was no difference in the outcomes between the groups.

The forearm rotational ROM had a mean of 162° (range 105 to 200°, SD = 22°) in the BIN group and 151° (range 90 to 180°, SD = 23°) in ESIN group (p = 0.201). Elbow flexion-extension ROM had a mean of 154° (range 132 to 175°, SD = 11°) in BIN patients and 148° (range 130 to 185°, SD = 15°) in the ESIN (p = 0.233) patients.

Flexion-extension ROM of the wrist was 150° (range 110 to 180°, SD = 20°) and 150° (range 95 to 110°, SD = 20°) in BIN and ESIN groups, respectively (p = 0.872). All cases achieved excellent or satisfactory results when classified according to Price (Noonan & Price, 1998). None of the movements differed significantly when compared to between study groups.

5.1.2 Pain (I)

Slight pain at the site of the fracture (VAS) was reported in three cases out of 16 cases during the year-two follow-up. All of these patients were treated with ESIN, compared with 0/16 in the BIN group (difference 19.0%, 95% CI: -4.1 to 43.4%, p = 0.113).

5.1.3 Radiographic findings (I)

The bone healing of the fracture was excellent in every study patient after the two years follow-up. The complete callus was seen in four out of four cortexes. The fracture line was invisible in every patient. During the follow-up time, no difference was found in the healing process between the groups (BIN and ESIN).

Mean residual dorsal angulation in the radius was 3.4° in the BIN group and 1.4° in the ESIN group (p = 0.225). In the ulna, mean dorsal angulation was 3.7°.
and 0.6° in these groups, respectively (p = 0.022). Mean residual lateral angulation in the radius was 3.3° for BIN, and 2.09° for ESIN (p = 0.046). In the ulna, mean lateral angulation was 5.1° for BIN, and 1.6° for ESIN (p = 0.063). No limb-length discrepancy was registered in either group.

5.1.4 Degradation of the study implants (I)

There was no harmful soft-tissue reaction in the fracture surroundings or osteolysis in the stabilized bone in the two-year MRI (n = 13). The biodegradable implants were still visible in all patients. However, the resorption was on-going, and the implants were partially (n = 3) or almost completely (n = 10) resorbed.

5.1.5 Operative procedure characteristics (I)

Seven patients (20.0%) were treated by stabilizing the radius only: four of them were in the BIN group, and three in the ESIN group (p greater than 0.999) [16,50,51].

The mean operation time from skin cut to complete casting was 66.9 min (range 18 to 170 min, SD = 33.2 min); 80 min in the BIN group and 53 min in the ESIN group (p = 0.014). All cases were included in these calculations, regardless of their single or both-bone fixation. A tourniquet was used in 20 cases (57.1%) according to the decision made by the operating surgeon. Open reduction with a short incision at the fracture site was performed in 12 cases (34%). The operating surgeon decided on open reduction for every individual case, seven of which were in the BIN group and five in the ESIN group (p greater than 0.999).

Prophylactic antibiotics were principally given for all initially, but finally, five patients were not given antibiotics: two of them were in the BIN group and three in the ESIN group. The patients stayed in the hospital for a mean of 2.7 days for the BIN group and 2.5 days for the ESIN group (p = 0.590). Above-the-elbow cast immobilization was carried out for four to six weeks for every study patient.

5.1.6 Recovery and drop-outs during the follow-up (I)

During the two years of follow-up, there were two implant failures among patients treated with BIN (2/19) versus none treated with ESIN (0/16). The re-fracture in these cases happened without any identified new injury (difference of 10.5%, with a 95% CI of 10.3 to 31.8%, p = 0.2445).
The first case with implant failure was a 14-year-old boy who suffered from a sudden pain in the forearm four weeks after the operative treatment. Both bones were re-angulated but not displaced. A 13-year-old girl who demonstrated delayed union at the follow-up suffered from re-fracture three months postoperatively from the initial operation. No technical issues were reported in the operations of these cases with complications, and initial results in both cases were promising.

There were two other patients in the BIN group (versus none in the ESIN group) who suffered from a new injury resulting in a secondary fracture (difference of proportions 10.5%, with a 95% CI of 10.3 to 31.8%, \( p = 0.2445 \)). The new re-fractures happened as a consequence of high external energy. The cases were taken out of the follow-up. Both cases were found to have had excellent clinical outcomes and complete union both in radiographs and MRI before the second fractures.

5.2 The quality of the tension metal frame construct of ESIN and the factors associated with poor outcomes (II)

5.2.1 The rate of disturbed bone union and re-fracture (II)

Of all 71 patients, seven (9.9%) suffered from disturbed bone healing, i.e., nonunion or delayed union. Two (2.8%) of them failed to unite at all and reoperation was needed for ossification. Five more cases had delayed (greater than 3 months) bone healing, but they all ossified after six months without any operative intervention.

Furthermore, two (2.8%) patients suffered from a secondary fracture over two years after the initial injury. Due to the long interval between the fractures, they were not counted as disturbed healing cases, but as new injuries. Therefore, they were not counted as a refracture. In one out of these two cases, the nails had been removed earlier, while in another patient, the nails remained in place (Figure 14).

5.2.2 The postoperative rate of change in alignment (II)

The stability of the fractures was evaluated by determining the possible change of bone alignment in the radiographs, taken at the out-hospital visits. Of all 71 patients, 67 (94%) had proper follow-up radiographs for evaluation. The mean change in the alignment of the radius was 2.5° (0 to 15°, \( SD = 2.6° \)) and 4.9° in the ulna (0 to 22°, \( SD = 4.6° \)) during the follow-up. Altogether, 24 (36%) cases out of the entire study
population presented a change greater than 5° in alignment during the out-of-hospital follow-up, despite the ESIN. Twelve (50%) of them presented 5 to 10° changes in alignment while the alignment worsened to 10 to 15° in one (4.2%) patient.

![Image](image.png)

**Fig. 14.** The patient fell on an outstretched hand two years after the initial injury and suffered from a re-fracture. The ESIN nails had not been removed.

### 5.2.3 Explanatory variables of metal frame construct (II)

All implants were of titanium alloy (Synthes DePuy ltd®, TEN™ or Stryker ltd®, T2Kids™), except one stainless steel nail (Stryker ltd®, T2Kids™).
The majority (n = 66, or 93%) of the fractures were stabilized with two implants, and five cases (7%) (all radius) with one nail only: this was understood as an improper technique.

Open reduction was performed in 56% (n = 40) of cases. Fourteen of these involved only the ulna. The radius was openly reduced in 13 cases; moreover, both bones were treated via an open reduction in 13 cases. Close to all fractures (n = 66, or 94%) were immobilized postoperatively by an above-the-elbow splint, for a mean of 4.1 (2 to 8) weeks. In two (2.8%) cases, the immobilization was longer than 42 days. Fifty-one (72%) of the fractures were in the midshaft, 15 (20%) were in the proximal third of the shaft and five (8%) were distal-third fractures. Ten (14%) of the patients had open fractures and 17 fractures were comminuted (24%).

The implants were cut or tapped inappropriately when more than 10 mm was left outside on the cortex surface: 39 times (55%) in radius (mean length of the nail outside the cortex was 11 mm, with a range of 0 to 26 mm, SD = 6.4 mm) and 39 (55%) in the ulna (mean 7.4 mm, with a range of 0 to 30 mm, SD = 5.7 mm).

Regarding fracture reduction, immediate postoperative residual displacement had a mean of 1.8 mm (range of 0 to 9 mm, SD = 1.9 mm) in the radius and 1.4 mm in the ulna (range of 0 to 6 mm, SD = 1.7 mm). The postoperative alignment was not anatomic in 50 (71%) patients, while the normal radial bowing of the radius (5 to 15°) was not reached.

The mean lateral angulation of the radius (radial bowing or apex radial) was 2.8° (range of 6° apex ulnar to 13° apex radial, SD = 3.5°) and dorsal angulation of the ulna was 1.8° (range of 1 to 2°, SD = 0.4°). Appropriate opposite concavities of the two nails were not achieved in 79% (n = 56) of the cases. The maximal pre-bent curve of the nail was placed at the fracture site, according to the recommended technique, in slightly more than half of the cases (for radius: n = 44, or 62%; and, for the ulna: n = 40, or 56%). The length of IOM was equal to or greater than 10% of the total length of the radius in almost all (n = 59, or 83%) patients.

Altogether, four (5.6%) patients had greater than 1.0 mm of a gap in the fracture line. Three of them were treated using thick (greater than 0.7 MCD) nails (p = 0.071). In the radius, the mean MCD was 0.61 (range of 0.33 to 0.95, SD = 0.14) and in the ulna, 0.62 (range of 0.40 to 0.93, SD = 0.13). In most (n = 61, 86%) cases, the nails were equal in size. The implants were introduced over the fracture line mean of 95 mm (range of 49 to 169 mm, SD = 31 mm) in the radius and 80 mm (range of 27 to 170 mm, SD = 27 mm) in the ulna. No implant was tapped deep enough to reach and disturb the physis. The closest distance to physis was 27 mm.
5.2.4 The link between explanatory factors and poor outcomes

Seven (9%) patients had disturbed bone healing (i.e., it was delayed or lacking) when evaluated by using radiographs. All patients who had disturbed bone healing had been treated with thicker nails (greater than 0.7x MCD), compared to other patients ($p = 0.021$). Four (25.0%) patients with thicker nails presented nonunion or delayed union, compared to the three (5.5%) patients who had thinner nails (difference of 19.2%, with a 95% CI of 17.4 to 44.6%, $p = 0.027$).

There was an increased risk, even a 5.4-fold risk (CI 95% of 1.1 to 27.6, $p = 0.041$) for delayed bone healing in the case of nails that were too thick ($nD$/MCD greater than 70%). Open reduction was associated with increased risk of ulna nonunion (OR of 9.7: 1.1 to 89, $p = 0.043$), but such a risk was not found for the radius (OR of 0.2: 0.02–2.9, $p = 0.271$). Five (24%) patients with open reduction (with ulna fractures) suffered nonunion or delayed union compared to one (2.3%) among the patients with closed reduction (difference of 20.0%, with a CI of 95% from 6.1 to 39.0%, $p = 0.02$). However, more significant primary displacement (with a mean of 7.7 mm, and $SD = 4.8$ mm) was found among the cases with open reduction, compared with 4.1 mm ($SD = 4.8$ mm) in closed reductions ($p = 0.003$). Other potential explanatory factors of this study did not link to the nonunion or delayed union.

Distal-third shaft fractures were associated with a 4-fold risk for greater than 5° changes in alignment (OR of 4.2: 1.1 to 14, $p = 0.027$) compared to mid- and proximal-third fractures. Two-third of the 12 (66.7%) cases of distal-third fractures changed alignment, compared to one in three of 17 (32.5%) among proximal or midshaft fractures (difference of 34.5%, with a CI of 95% from 44.9 to 57.8%, $p = 0.019$). Other explanatory factors were not linked with alignment.

5.3 Functional findings of the previously fractured upper extremities, by using the computer-assisted and traditional measuring methods (III)

The elbow flexion was measured as 138° using the study method (the computer-assisted E-Link) and 146° using the reference method (universal, transparent handheld goniometer). The following outputs were found for each mentioned movement function, using both the study method and the reference method, respectively: −8.8° and −9.8° for elbow extension, 87° and 85° for pronation, and 93° and 85° for supination.
Furthermore, the grip strengths were measured at 28 and 31 Nm using the computer-assisted study method and the reference method, respectively. There was a statistically significant difference in all mean values except for that of elbow extension.

5.3.1 Agreement between the computer-assisted and traditional measurement methods (III)

There were discrepancies between the two studied methods in all function categories except elbow extension. The measures achieved by the study method i.e., the computer-assisted method, were approximately 8.0° less (CI of 95% from 6.6 to 9.3°, \( p < 0.001 \)) in elbow flexion and 1.0° less in elbow extension (CI of 95% from 2.5 to 0.5°, \( p = 0.200 \)) than those results achieved using the traditional measuring method. The bias in pronation and supination between the two methods was 2.4° (with a CI of 95% from -4.3 to -0.4°, \( p = 0.017 \)) and 7.8° (CI of 95% from 9.7 to -5.8°, \( p < 0.001 \)), respectively. The computer-assisted method reported smaller values in flexion-extension and greater values in rotational movement ranges. Grip strength was 4 Nm less when evaluated using the computer-assisted method than the traditional, hydraulic dynamometer (CI of 95% from 2.7 to 5.5 Nm, \( p < 0.001 \)). Therefore, for all measures, except elbow extension, the study and reference methods were found not to agree on results.

When analyzing the correlations more closely, there was a positive linear trend found between data points in all categories except elbow flexion and grip strength. The regression coefficient \( \beta \) in elbow flexion and extension were 0.069 (CI of 95% from -18.72 to 15.24, \( p = 0.256 \)) and 0.332 (CI of 95% from 0.09 to 0.57, \( p = 0.008 \)), respectively. The regression coefficients \( \beta \) in forearm supination and pronation were 0.895 (CI of 95% from 0.49 to 1.30, \( p < 0.001 \)) and 0.485 (CI of 95% from 0.03 to 0.94, \( p = 0.036 \)), respectively. The regression coefficient \( \beta \) of grip strength was 0.11 (CI of 95% from -0.03 to 0.25, \( p = 0.120 \)).

5.4 The characteristics of distal forearm fractures with or without a USP nonunion in late follow-up (IV)

There were 139 distal forearm fractures, out of which four (3%) suffered from open fractures; two were Gustilo-Anderson type I fractures, and two were of type III. The fractures were complete in 12%, while the other fractures were greenstick fractures or other incomplete fractures. Twelve of the USP fractures were at the
base and ten at the tip. The initial radiographs were evaluated for all. The findings are shown below (Table 3).

Table 3. Findings in the radius evaluated from the initial radiographs.

<table>
<thead>
<tr>
<th>Findings in primary radiographs in the radius</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>High (equal to or greater than 15°) angular deformity</td>
<td>45</td>
<td>32%</td>
</tr>
<tr>
<td>Slight (less than 15°) angular deformity</td>
<td>42</td>
<td>30%</td>
</tr>
<tr>
<td>No angular deformity</td>
<td>52</td>
<td>37%</td>
</tr>
<tr>
<td>Anterior-posterior displacement equal to or greater than 2 mm</td>
<td>36</td>
<td>26%</td>
</tr>
<tr>
<td>Anterior-posterior displacement 0–2 mm</td>
<td>8</td>
<td>6%</td>
</tr>
<tr>
<td>Coronal plane displacement equal to or greater than 2 mm</td>
<td>11</td>
<td>8%</td>
</tr>
<tr>
<td>Coronal plane displacement 0–2 mm</td>
<td>6</td>
<td>4%</td>
</tr>
<tr>
<td>Comminuted</td>
<td>4</td>
<td>3%</td>
</tr>
</tbody>
</table>

5.4.1 The rate of USP nonunion

The rate of USP nonunion following childhood distal forearm fracture was 16% (22 in 139). Thirteen of the 22 fractures that failed to unite had been invisible in the initial radiographs. In 12 cases whose USP fractures were visible in the initial radiographs, nine did not unite.

5.4.2 Radiographic findings of USP nonunion (IV)

Seven cases out of the 22 with nonunion versus none in the reference group ($n = 117, p$ less than 0.001) showed the ulna minus (with a mean of 2.3 mm) when compared with the uninjured side. The respective rate of the premature growth plate arrest of the radius was 4% (5 in 139), and the mean ulna plus was 2.1 mm.

None of the nonunion patients showed degenerative radiographic findings. Osteophytes, degenerative subcortical cysts, and thin cartilage were taken as the potential degenerative findings. The mean displacement of the non-united fragments was 0.99 mm ($SD = 0.60$, with a range of 0.0 to 2.3 mm). Eight patients showed multi-fragmented USP nonunion in the radiographs.

5.4.3 Functional findings of USP nonunion (IV)

There was no decrease in wrist movement in flexion, extension, or ulnar deviation in patients with nonunion, compared with the respective movement on the uninjured side. Grip strength did not differ between the injured and uninjured.
wrist. Altogether, six patients in the entire cohort showed clinically unstable DRUJ, but the rates were similar between the nonunion and union groups. Five patients with USP nonunion and 18 in the reference group presented crepitation in the radiocarpal joint when moving and pressing the wrist passively on the investigator \((p = 0.4)\). Self-reported subjective symptoms did not differ between the patients with or without USP nonunion at long-term follow-up.

### 5.4.4 Effect of fracture type, treatment, and immobilization of the distal radius fractures on the risk of ulnar styloid nonunion (IV)

Displacement equal to or greater than 2 mm (OR of 1.6, CI of 95% from 0.52 to 4.9), angular deformity of greater than 15° (OR of 1.2, CI of 95% from 0.40 to 4.1), and a Salter-Harris fracture classification of two or higher in the radius (OR of 2.8, CI of 95% from 0.4 to 18) did not increase the risk of late USP nonunion. Furthermore, no increased risk was found in connection with longer immobilization time, equal to or greater than 28 days, (OR of 1.5, CI of 95% from 0.55 to 4.1), lower expertise of the treating physician (OR of 1.0, CI of 95% from 0.37 to 2.9), or male sex (OR of 1.02, CI of 95% from 0.36 to 2.9). Both base \((n = 12)\) and tip \((n = 10)\) fractures were associated with USP nonunion with similar risk \((p = 0.6)\). Nine of the 22 USP nonunion patients showed equal to or greater than a 2 mm anterior-posterior displacement of the radius primarily.

In the subgroup analysis, comparing the proportions of the base and tip fractures in patients with primarily diagnosed USP fractures, both types of fractures were found to be equally prevalent among the patients with healed USP fractures and USP nonunion.
6 Discussion

At birth, there are approximately 270 bones in the human body, and all of them have their typical characteristics. The fractured bone, site, type of the fracture, patient’s age, and the equipment in use, as well as the surgeon’s experience all, have a crucial influence on the method and result of the treatment (Schmittenbecher, 2005). The most important treatment goals are a painless life with proper function. ROM, muscular strength and bone healing are the best indicators of successful treatment (Beaty, 2006; Högström, Nilsson, & Willner, 1976). Also, the cosmetic outcome, cost-effectiveness and psychological burden are aspects that need to be taken into account when determining the course of treatment (Baldwin et al., 2014; Schmittenbecher, 2005).

Childhood forearm fractures have increased dramatically from 1967 to 2005 (Mayranpaa et al., 2010). In the study area, an up to four-fold increase in incidence was found in a population-based ten-year study period from 2000 to 2009 (Sinikumpu et al., 2012). Corresponding increasing numbers of incidence have been reported in the study country within the Helsinki capital area (Mayranpaa et al., 2010). The marked increase of forearm fractures is interesting, because the incidence of many other pediatric fractures has decreased over a similar period. The popularity of organized sports and recreational activities such as home trampolines (Cosma & Vasilescu, 2014; Sinikumpu, Antila, Korhonen, Ratty, & Serlo, 2012; Valerio et al., 2010) and trampoline parks has increased which may partly explain the increasing trend.

The operative management of long-bone shaft fractures (Cheng, Ng, Ying, & Lam, 1999; Sinikumpu et al., 2012) has become more popular in recent decades. The diaphyseal fractures are characterized by slower metabolic activity and limited potential for remodeling compared to metaphyseal and physeal fractures (Cosma & Vasilescu, 2014). One-third of non-operatively treated shaft fractures re-displace (Antabak et al., 2013; Sinikumpu, 2015). For these reasons, operative treatment may be justified in these fractures. Moreover, the increase in patients’ and parents’ requests for non-delayed interventions, voluntary insurances for accidents and better economic circumstances may have favored the complex and sometimes expensive procedures (Cosma & Vasilescu, 2014).

As much as half of the pediatric fractures occur in the forearm (Valerio et al., 2010). The distal forearm fractures usually happen as a consequence of a fall on the extended upper extremity (Sinikumpu & Serlo, 2015). A vast majority of these can be treated non-operatively, and fracture healing is usually great (Randsborg et al.,
2013). Not uncommonly, concomitant fractures of the USP are often ignored; however, no comprehensive understanding of its healing is available. Also, the children’s USP fractures are often chondral and may become visible upon mineralization of the chondral tissue. For that reason, the actual number of USP fractures has not been measured.

The USP fracture is seldom treated operatively. (Chen et al., 2013; Logan & Lindau, 2008; Souer et al., 2009; Zoetsch et al., 2013) Understanding that USP is a site for ligament attachment and thus contributing to the stability of the wrist joint, the healing rate of USP fractures and the effect of potential USP nonunion on clinical recovery needs to be clearly understood.

The distal radius fractures heal well, contrary to the fractures of the shaft of radius and ulna, where the treatment is remarkably more challenging (Garg, Ballal, Malek, Webster, & Bruce, 2008; Wall et al., 2012). Due to their high frequency, they are a challenge for both physicians and scientists to further develop and improve the treatment. There are some limitations to the present treatment methods. In addition to widely known disadvantages, such as nail removal and tissue reactions, it has been suggested that the present recommended treatment, ESIN, is not always performed according to technical recommendations (Lascombes et al., 2006). The importance of these recommendations is not widely known. Many surgeons may consider themselves competent to perform ESIN, even when the quality of the tension metal frame construct, performed in ESIN operation, is not widely known.

Unrestricted mobility of the forearm after a fracture is one of the most important treatment goals. The traditional handheld, plastic goniometers have been the method of choice when measuring the movement arcs: this is time-consuming and, in some respect, also a risk-bearing method as the results need to be observed and marked manually. The same problems are present with a traditional dynamometer.

6.1 BIN versus ESIN (I)

As the main finding of the RCT study (I), the rotational ROM was excellent in both study (160°) and control groups (150°), which is in agreement with the rotational arch of uninjured, healthy forearms (Teoh et al., 2009). Non-synovial joint stiffness is the most common and most important long-term complication of forearm shaft fractures (Beaty, 2006; Högström et al., 1976). The majority of daily activities can be performed with 100° of forearm rotation (Franklin et al., 2012; Morrey et al.,
1981). However, from a clinical point of view, a greater than 30° loss of ROM is usually taken as an unsatisfactory result. (Flynn, Jones, Garner, & Goebel, 2010). In this study, none of the patients showed such a decrease in either patient groups. In this respect, both methods, BIN and ESIN, are successful in restoring the required rotational movement of the forearm. Other vital movements in the elbow and wrist were analyzed as secondary outcomes. They were found to be similar in both patient groups.

There are pediatric trauma units that prefer to leave the intramedullary implants in place (Gorter et al., 2011; Molster et al., 2002; Schmittenbecher, 2013; Vos, Hanson, & Verhofstad, 2012). However, the titanium alloy implants may disturb the shape in the radius in the long-term, while the curve increases by age in a healthy skeleton (Firl & Wunsch, 2004). The titanium implants may also cause long term risk for infections and cause artifacts in the radiographs; thus, they are usually removed in a secondary operation. The advantage of BIN is in avoiding the later implant removal surgery.

The stability of biodegradable nails, together with a postoperative casting for four weeks, yielded satisfactory outcomes. Regarding the angular deformity, it has previously been determined that equal to or greater than 10° of angular deformity in forearm midshaft fractures is not acceptable (Ploegmakers & Verheyen, 2006; Price et al., 1990). There is no exact threshold for unacceptable angular deformity regarding the movements of the forearm, but any more significant deformity would have had disadvantageous effects on movements. The remodeling of the malunited forearm has been expected to happen if the child has equal to or greater than two years of growth remaining (Beaty, 2006; Younger et al., 1994). However, in this study population, all cases achieved proper alignment at a two-year follow-up. The radius was laterally angulated at a mean of 3.3° in connection with the BIN procedure, compared to 2.1° in the ESIN procedure, which was a statistically significant difference, but far from the suggested minimal clinical significance of 10°. There was also a statistically significant difference in dorsal angulation of the ulna in the BIN (3.7°) versus ESIN (0.6°) groups. That kind of a slight difference is not clinically significant either and probably does not affect the movements of the wrist or forearm.

The biodegradable implants are less rigid than titanium nails, giving less angular support in the bones until bone union. In younger children, the stability of the BIN tends to be satisfactory, while in older children, deforming forces by the surrounding muscles are higher and the alignment may worsen (Fernandez et al., 2010; Sommerfeldt & Schmittenbecher, 2014). The correction through remodeling
also diminishes by age. Therefore, due to their lower elasticity, titanium nails may be preferred implants in particular for older children and adolescents with more mature bones, instead of the PLGA nails (BIN).

Generally, the need for postoperative immobilization is considered on an individual basis (Skaggs D, 2014). Free mobilization of the forearm shaft after ESIN appears to be favored (Lascombes et al., 2006; Schmittenbecher, 2005) while some still support short immobilization (Fernandez et al., 2010). In this study, all patients were immobilized, to standardize the study methods.

The operation time was slightly longer in the BIN group. Reaming the medullary cavity, which is recommended for the BIN implant (Sinikumpu, 2015), is an extra step in the surgery.

Pain or discomfort is generally one of the most common symptoms during recovery (Fernandez et al., 2010). Among the study population, one-third of the patients experienced pain or discomfort during recovery, but, most often, the problems resolved spontaneously between follow-ups without intervention. The pain was more usual in the ESIN group. Children less than ten years of age complained of feelings of irritation at the fracture site more often than older children, but the reason remains unclear. Three patients in the ESIN group reported still experiencing pain at the two-year check. The pain was compared between the study groups and no additional subgroup analysis was performed regarding the link between pain and nonunion or open reduction.

Another critical factor affecting the subjective experience after the study versus reference methods is the need for later interventions. According to the recommended operative technique, titanium implants are left 4 to 6 mm above the bone surface for routine removal later on, which predisposes the patient to mechanical complications of the prominent implant (Fernandez et al., 2010) and also to anesthesia-related morbidity due to the removal-operation (Baldwin et al., 2014; Schmittenbecher, 2005). Neither of these problems were seen in the present study, however.

Because the intramedullary fixation may compromise the intra-osseous circulation, midshaft forearm-shaft fractures, and in particular in the ulna, have been considered vulnerable to nonunion. In this study, no problems in bone healing in either groups were found.

Despite overall good functional outcomes in this study, two patients treated by BIN experienced unexpected re-displacement of the fracture without proven re-injury. Moreover, no adverse technical issues during operations or the postoperative fracture reductions were found. It is still possible that these failures are linked to
the study implant. Adolescence (13 and 14 years of age) may also have influenced the healing process; so, more adult-type fixation with plates and screws should be considered for this age-group. An extensive study is needed to refine the correct indication for BIN in children versus adolescents.

6.2 Frame construct of ESIN (II)

It was found that the tension metal frame construct including nail pre-bending, the site of the maximal bow, or lacking concavity configuration of the nails, were not associated with impaired bone healing. Nonunion or delayed union occurred in seven (9.9%) cases. The ulna was involved in six of these. Such a high rate of impaired fracture healing is following the literature, while 4 to 7% of nonunion rates have been reported (Lascombes et al., 2013; Schmittenbecher et al., 2008; Sinikumpu, 2015). All cases with lacking or delayed radiographic bone healing were treated through open reduction. Three patients had suffered from open fractures. Specifically, the ulna is known to be vulnerable to nonunion after open reduction (Ballal, Garg, Bruce, & Bass, 2009; Fernandez et al., 2009; Sinikumpu, 2015). Altogether, 36% of the cases ($n = 24$) showed increased malalignment greater than $5^\circ$. However, only one patient needed re-reduction. The patient had been treated with asymmetrical implants.

The link between open reduction and disturbed bone healing arises from the impairment of periosteal blood supply, which interferes with callus formation (Fernandez et al., 2010; Greenbaum et al., 2001; Schmittenbecher et al., 2008; Sinikumpu et al., 2012; Wright & Glowczewskie, 1998). The findings warrant a gentle operative technique when dissecting the tissues in the forearm area. In our material, seven out of 40 patients (18%) with open reduction suffered from delayed union or nonunion. The study also showed that initial displacement was slightly higher in cases treated with open reduction. Fractures requiring open reduction are often more severe than these, per se (Makki et al., 2017). High trauma energy causing severe soft tissue damage (Trionfo, Cavanaugh, & Herman, 2016) also predisposes patients to impaired fracture union.

Interestingly, we also found that impaired fracture healing took place more often when thicker nails (greater than 70% of the medullary canal) were used. Thick intramedullary implants may cause distraction of the fracture during its introduction and cause a gap in the fracture line (Ballal et al., 2009). In the present study, four patients had greater than 1.0 mm of a gap in the fracture line, three of which were treated using thick (greater than 0.7 MCD) nails. According to the
literature (Lascombes et al., 2012; Lascombes et al., 2013) thinner nails (ND/MCD 40 to 70%) are not linked with nonunion, delayed union or changing alignment during the postoperative period. Thus, it may be concluded that nails that are too thick should be avoided.

Loss of alignment of the fracture during the healing period after intramedullary fixing (ESIN) of the forearm fractures was a secondary outcome in this study. Clinically significant malalignment in these fractures is preferably greater than 10° rather than greater than 5° (Alrashedan et al., 2018; Lascombes et al., 2012). However, we chose 5° as the cut-point of worsening to evaluate the satisfactory stability of the osteosynthesis method. In our material, 24 fractures (36%) showed increased malalignment of more than 5°, and over 10° change was seen in two of the patients. Only one patient was re-operated due to malalignment indicating that worsening of the alignment may not be a clinical concern in the short term. ESIN is an elastic method and it is not intended to be a rigid osteosynthesis. Accordingly, angular reduction changed for some amount in all our cases. Principally, the normal lateral curve in the radius is crucial for forearm motions. Also, narrowing and scarring of the IOM may limit rotation movement (Sinikumpu et al., 2012; Yasutomi, Nakatsuchi, Koike, & Uchiyama, 2002). The possible instability of the fracture due to thin nails was not analyzed because very thin nails (less than 30% of MCD) were not used in this population.

We also found that the distal-third location of the fracture was associated with a higher risk for changing alignment when compared with mid- or proximal shaft fractures, which follows current literature (Schmittenbecher, 2005). In particular, the distal metaphyseal-diaphyseal junction zone of the radius is vulnerable to radial malalignment (Sinikumpu & Serlo, 2013) and should not be treated by ESIN at all but rather by cast immobilization or by K-wire fixation (Miller et al., 2005). Cast immobilization was an additional treatment in 94% of the study patients, according to the institutional practice. It remains unclear if the fractures would have been stable enough without postoperative casting because of the lack of prospective comparative aspects in this research. We understand that avoidance of postoperative external immobilization is one of the reported advantages of ESIN (Fernandez et al., 2009; Lascombes et al., 2006).

Four (17%) patients out of 24 with changed postoperative alignment had been treated with different thickness implants, which is absolutely against recommendations (Lascombes et al., 2013). One of them required re-operation. Even though the equal-sized implants were not statistically significantly better in bone healing or keeping alignment in this study, we do not recommend using
asymmetric nails as this is against the recommendations (Alrashedan et al., 2018). An appropriate configuration of two nails of equal thickness, one in the radius and one in the ulna, is crucial in creating tension in the IOM (Lascombes et al., 2012).

6.3 Functional measurements (III)

In this study, the two measurement methods used in the patient follow-up were compared. Both methods seemed feasible for clinical use in adolescents. However, when compared with each other, discrepancies between these two methods were found.

The rotational ROM values were larger when measured with the computer-assisted tool. Flexion and extension ROM of the elbow and handgrip strength, in contrast, seemed to be smaller when measured with the computer-assisted tool. The difference increased along with higher measurement values. Nevertheless, the difference between the two measuring methods of ROM was 8° at its highest, which seemed to be under minimum clinically significant difference and therefore not clinically important (Flynn et al., 2010).

The measuring methods did not give exactly similar results; however, there is also natural variation in the traditional free-hand measurements (Carter et al., 2009). Analyzing the difference between the studied methods with Bland Altman’s analysis by defining the statistical intervals of agreement (Bland & Altman, 1999; Giavarina, 2015), statistically significant differences were found. However, despite the incongruence and lack of agreement between the study and reference methods, those findings may be beyond clinical significance. The loss of forearm rotational ROM greater than 30° (Flynn et al., 2010; Guven et al., 2015) and the loss of greater than 15 to 10° in the flexion-extension ROM in the elbow have been defined as clinically relevant and unsatisfactory findings (Flynn et al., 2010; Teoh et al., 2009; Tuomilehto, Sommarhem, & Nietosvaara, 2018). Also, normal pronation-supination movements in the forearm were greater than 160° in healthy, uninjured cases (Teoh et al., 2009). In this regard, it seems clear that both the computer-based and traditional methods can be used to investigate the motion capacity of the elbow and forearm in children during follow-up in clinical practice.

The traditional goniometer has been defined as a validated measuring tool in clinical use (Mittal, 2017). Although, in cadaveric studies, the freehand measurements generally differed up to 7° for flexion and 10° for extension when compared with the measurements by fluoroscopy (Carter et al., 2009). For this reason, some studies have recommended that surgeons should use radiographic
measuring rather than the goniometer as a gold standard to measure joint movements (Chapleau, Canet, Petit, Laflamme, & Rouleau, 2011; Enwemeka, 1986; Reese & Bandy, 2017). However, radiographic measuring of ROM—particularly in children—is not acceptable due to the radiation. Neither is it feasible due to high time consumption. Currently, the goniometer is the most commonly used method for measuring movements and it is also used for study purposes (Cimatti, Marcolino, Barbosa, & De Cássia Registro Fonseca, Marisa, 2013; Colaris et al., 2010; Gerhardt & Rondinelli, 2001; Reese & Bandy, 2017).

We recognize that there are many possibilities for measuring errors in a clinical setting. The position of the goniometer may change, and the sitting position of the patient may vary which may result in measurement result variations. The dynamometer may give more accurate values because the position of the device does not vary as much as with the goniometer. However, the gripper must be suitable for the patient’s hand. Therefore, some small differences in the results may be rather suggestive than absolute differences, albeit the minimal clinically significant difference is not clear.

The final reason for the statistically significant difference between the study and reference methods remains unknown. When using the universal goniometer, the central black line and the circular degree scale are placed along the midline of the patient’s extremity (Reese & Bandy, 2017). The computer-assisted tool, however, lacks these qualities, which may complicate positioning the sensor along the upper- and lower-arm axis, which hinders the measuring process. Furthermore, there is no clear central point in the computer-based handle, and the hinge area is not transparent: this may be an essential feature for positioning the instrument precisely in the mechanical central point of the movement. We suggest that adjusting the design of the study measure would improve the agreement with the reference method.

### 6.4 Distal forearm fractures and USP nonunion (IV)

The incidence of USP nonunion was 16% in all distal radius fractures. Only one-fourth of the primarily recognized USP fractures successfully progressed to ossification during the extended 11-year follow-up. Such a low rate of bone union is exceptionally unusual in childhood fractures (Fernandez et al., 2009; Schmittenbecher, 2005). Clinical outcomes of USP fractures were useful regardless of bone healing. The associated risk factors of USP nonunion remain unclear.
Fractures of the USP are linked to 20% of all distal radius fractures in children and the nonunion rate is markedly high (Abid et al., 2008). The patients with USP nonunion showed good clinical long-term outcomes. Many investigators have suggested an increased risk of DRUJ instability in patients who have distal radius fractures with concomitant USP fractures due to lesions in the TFCC (Daneshvar, Chan, MacDermid, & Grewal, 2014; Gogna et al., 2014; Kazemian et al., 2011). However, DRUJ instability was found only in a few patients in this study. The instability was as common in both groups: normal USP and USP nonunion.

One-third of nonunion patients showed ulnar shortening, which may predispose them to later degenerative processes. There may be a temporary overgrowth of the radius after a fracture as a result of the fracture healing process. Temporarily increased longitudinal growth is a known phenomenon after a femur fracture (Edvardsen & Syversen, 1976). Ulnar shortening has been associated with ligament disruption (Ramos-Escalona, Garcia-Bordes, Martinez-Galarza, & Yunta-Gallo, 2010) and early-stage joint degeneration (De Smet, 1994; Kristensen & Soballe, 1987). Premature radius growth arrest occurred in 4% of our patients, which was expressed as ulnar lengthening, using the uninjured side as a reference. Such a low rate of radius growth plate arrest is in agreement with the previous literature (1 to 7%) (Abzug, Little, & Kozin, 2014; Buterbaugh & Palmer, 1988; Cannata et al., 2003). It also needs to be kept in mind that radius and ulnar length discrepancy is not a static but a dynamic condition and the relationship changes during forearm rotation and grip loading (Schuurman, Maas, Dijkstra, & Kauer, 2001).

An interesting finding was that a majority of the patients with USP nonunion were primarily diagnosed with isolated distal radius fractures but showed USP nonunion in the long-term follow-up. In children, the real incidence of USP nonunion can only be evaluated after ossification of the ulnar styloid, if MRI is not available. Thus, there may be an under-diagnosis of acute USP fractures in young children, which may explain the previously suggested higher incidence of USP nonunion in adults (Abid et al., 2008; Stansberry et al., 1990; Wijffels et al., 2014).

In this study, the patients were, on average 21 years of age (14 to 29) at the time of follow-up. In that age group, the USP is ossified and visible in radiographs (Gilsanz & Ratib, 2005) even though physeal closure usually occurs at the age of 16 to 19 years (Egol, Koval, & Zuckermann, 2010). Possibly, the open physis of the ulna would have made radiographic evaluation more difficult in the youngest study patients. However, reference imaging of the uninjured wrist was undertaken.
in all cases in order to support radiographic analysis. Routine MRI or CT scans were not included in the study plan because they have not been reported to be superior in diagnosing USP fractures, compared with plain radiographs in patients with a mature skeleton (Spence, Savenor, Nwachuku, Tilsley, & Eustace, 1998; Welling et al., 2008).

The associated risk factors of USP nonunion remain unclear. Previous studies have suggested the base type of USP fractures to be a risk factor (Abid et al., 2008; Zenke et al., 2009), which was not found in this study. A comprehensive risk analysis was performed of patient-related information including sex, radiographic displacement and angular deformity, the severity of the radius fracture according to Salter-Harris classification, treatment method, and the length of immobilization time to evaluate the risk of USP nonunion. None of these were associated with a greater risk of USP nonunion in this long-term study.

6.5 Strengths and limitations (I–IV)

This prospective clinical, randomized trial (I) of a new, intramedullary nailing technique was important to begin openly discussing the issue. The strength Study I lies in its prospective randomized design. Albeit being a small series, the study pioneered research on the use of these implants providing level-A evidence. The study protocol was settled precisely in advance. The patients were treated by educated surgeons in recognized trauma units with appreciated operation room facilities and resources. All radiographs were of high quality and they were analyzed by the same, specialized radiologist, familiar and educated in pediatric trauma. Most patients reached the two-year follow-up and were eligible for final analyses. The noted adverse events were analyzed in detail and their root reasons were comprehensively investigated. The two implant-failure cases warrant further studies. As a weakness, the technique was new in both institutions involved, which may have increased the operation time. The patients and their parents were not blinded to the treatment, which may have affected the subjective results. Single blinding could be an option to eliminate this source of error. Still, a longer follow-up is needed to ensure full resorption of the biodegradable implants. The range of age of the patients was broad and the cases were heterogeneous in that regard. A more comprehensive study is needed to confirm appropriate patient selection in children versus adolescents. Also, more understanding of the need for postoperative immobilization in this method should be acquired.
As a strength, Study II was population-based, including all consecutive patients with operatively (ESIN) treated forearm shaft fractures in the geographically defined recruitment area. Radiographs of the primary injury were available in all cases, and fulfillment of the inclusion criteria was confirmed by reviewing all images. An adequate number of cases were recruited. They all presented diaphyseal both-bone fractures of the forearm and the findings are precise and thus generalizable. Radiographically impaired bone union (nonunion or delayed union) was considered the primary outcome, and it was determined by using validated scoring. Malangulation greater than 5° during the follow-up was taken as a sign of instability because full rigidity is not required for ESIN and slight angular deformity may not affect the ROM or patient satisfaction (Tarr et al., 1984). All analyzed variables were radiographic findings. That information was inclusively available, and the findings are thus generalizable. A limitation of the study is its retrospective design. However, the purpose was to analyze the effects of limited metal frame construction on radiographic bone healing. Also, there was no systematically collected data regarding functional outcomes or patient satisfaction. According to institutional practice, the follow-up was short; therefore, bone remodeling that is a time-consuming process (Wilkins, 2005) could not be evaluated in this study. Regarding the statistical analyses, there may have been confounding factors, while open fractures, open reductions and other potential risk factors may have mutual links.

Study III’s strength was that the adolescents and children patients presented a homogeneous group of upper extremity fractures. Due to this authentic study population, the findings may be generalized for use within injury units. The actual measuring with the two methods was familiar for both investigators, therefore the intra-rater reliability was not measured. This is a weakness of the study, and maybe should have been done in advance. The interobserver reliability of the two educated personnel was excellent.

The study’s purpose was also highly appreciated because upper extremity fractures are the most common fractures in children, and many new methods have been developed recently to improve their treatment (Reese & Bandy, 2017; Remigio et al., 2017; Trehan et al., 2017).

The long period between the initial injury in childhood and the follow-up visit is a strength of Study IV, and the participation rate was satisfactory. The 60 to 80% participation rate has been recommended in epidemiologic long-term follow-up studies (Fewtrell et al., 2008; Galea & Tracy, 2007; Kristman, Manno, & Cote, 2004). Furthermore, distributions of age, sex, and treatment were similar among
participants and non-participants, which strengthens the findings. As a weakness, it is probable that some of the non-participants had fewer symptoms than participants and were thus not interested in the follow-up examination. A majority of non-participants reported full recovery on their own when they declined their participation. As another limitation, the primary data were based on hospital registers and not all interesting particulars were available. And so, we found only 22 patients with USP nonunion and a more extensive study would be necessary to confirm possible causal links between the primary injury, its treatment and the risk of USP nonunion.

### 6.6 Future aspects (I–IV)

This research raises several questions for future research:

- What is the optimal age group for the patients to be treated by BIN?
- Is postoperative immobilization necessary after BIN fixation?
- What is the late clinical and radiographic outcome of BIN, several years after the injury?
- Could the BIN material be further developed to increase the stability but to hold its degradation ability?
- Are clinical outcomes of ESIN good also in long term, regardless the inappropriate tension metal frame construct?
- Can the computer-based measuring method be used in acute injuries?
- Does USP nonunion cause degenerative processes in the wrist area?
- Would child patients get benefit of immediate operative fixation of recognized acute USP fracture?
- Is there any situation in which operative fixation of USP is required?
7 Conclusions

Biodegradable intramedullary nailing (BIN) using a PLGA implant for fixing the forearm shaft fractures in children was researched. Elastic stable intramedullary nailing (ESIN) was the reference method in the prospective, randomized clinical trial. Most of the known benefits of intramedullary nailing were available with BIN, as compared with ESIN. The method is mini-invasive and further implant removal is not needed. Two unexpected re-fractures occurred in the study group versus none in the reference group, which justifies further studies for appropriate patient selection for this technique.

The current gold standard method of forearm shaft fracture treatment (ESIN) was analyzed, paying special attention to the tension metal frame construct, made by pre-bending the nails and having them set opposing to each other. In the majority of the cases, the tension metal frame was not achieved entirely according to the recommendations. However, the clinical results were good and the fundamental idea of a tension metal frame as necessary construct for forearm stability requires further research. Thicker nails (greater than 70% of the intramedullary diameter) and open reduction were associated with disturbed bone healing. Loss of alignment occurred more often in fractures of the distal third of the shaft.

Joint movements and grip strength are essential in evaluating the recovery of upper extremity bone fractures. As compared with the traditional goniometer, the computer-assisted study method was not congruent. However, all differences in movements were less than 10° and thus probably beyond clinical importance. The computer-assisted study method also resulted in slightly lower grip strength, when compared with a traditional hydraulic dynamometer. However, this difference also seemed to be beyond clinical importance. The computer-assisted method has advantages in recording the outcomes to electronic charts, avoiding the risk of human error in type-writing, and when making mathematical estimations. The studied computer-assisted method is a potential technique in performing the follow-up of pediatric upper extremity fractures.

Distal USP is another fracture site in the forearm that is prone to nonunion. The rate of nonunion was 16% among the cases with a previous distal forearm fracture. Only in half of the USP nonunion cases were the fractures visible in the initial radiographs. The long-term clinical results were good. One in three had ulnar shortening, which may predispose an individual to degenerative processes later in life.
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Original publications


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