

Diploma Thesis

**Comparison of Ponseti versus Pantalar Release
Treatment for Idiopathic
Clubfeet – from Birth to Adulthood**

submitted by

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Klagenfurt am Wörthersee, 26.07.2022

Statutory Declaration

I declare on my honour that I have written this thesis independently and without outside help, that I have not used any sources other than those indicated, and that I have marked the passages taken verbatim or in substance from the sources used as such.

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Abbreviations

AOFAS	American Orthopaedic Foot & Ankle Society
AP	Anteroposterior
CI	Confidence interval
COM	Centre of mass
COP	Centre of pressure
CTEV	Congenital talipes equinovarus
DF	Dorsiflexion
FF	Forefoot
FRS	Functional Rating System
GC	Gait cycle
GDI	Gait deviation index
GDI-k	Gait deviation index-kinetic
GRV	Ground reaction vector
HF	Hindfoot
HHD	Handheld dynamometry
HX	Hallux
ICFSG	International Clubfoot Study Group
LMJA	Longitudinal midtarsal joint axis
MAX	Maximum
MIN	Minimum
ML	Mediolateral
OFM	Oxford Foot Model
OMJA	Oblique midtarsal joint axis
PF	Plantarflexion
PODCI	Pediatric Outcomes Data Collection Instrument
ROM	Range of Motion
SD	Standard deviation
SF-36	Short-Form-36

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Zusammenfassung

Einleitung: Der Klumpfuß ist, mit einer Häufigkeit zwischen 0,6 und 2,57 pro 1000 Lebendgeburten, eine der häufigsten angeborenen Fußfehlbildungen. Frühere Studien der Grazer Kinderorthopädie (Zwick et al. und Švehlik et al.) konnten bereits die Überlegenheit der Ponseti-Methode im Vergleich zur operativen Methode (pantalar release) in der Behandlung von Klumpfüßen deutlich machen. Dennoch gibt es nur wenige Studien, welche die Langzeitergebnisse beider Methoden vergleichen. Ziel dieser Studie war es daher, einen prospektiven Langzeitvergleich zwischen den beiden Therapiegruppen durchzuführen, um neue Erkenntnisse über die Fußbeweglichkeit, die Lebensqualität sowie anatomisch-morphologischen Unterschiede zu erlangen.

Material und Methoden: Es handelt sich um eine prospektive, nicht verblindete, initial randomisierte Studie. Neun PatientInnen der Ponseti-Gruppe (n=12 Füße) und fünf PatientInnen der operativen Gruppe (n=9 Füße) wurden zu einer dritten Nachuntersuchung – nach Wachstumsabschluss - eingeladen. Neben der Durchführung einer klinischen Untersuchung wurden das Functional Rating System (FRS), das Protokoll der International Clubfoot Study Group (ICFSG), der Adolescent Outcomes Fragebogen (PODCI), der Short-Form-36 (SF-36) Fragebogen und die American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot and midfoot Skalen verwendet, um die beiden Gruppen in Bezug auf Fußfunktion, Morphologie, Lebensqualität sowie auch hinsichtlich der radiologischen Ergebnisse zu vergleichen. Außerdem wurden eine 3D-Ganganalyse und eine Kraftmessung (HHD) durchgeführt, um die kinematischen und kinetischen Daten der Füße zu bewerten.

Ergebnisse: Es konnten signifikante Unterschiede zugunsten der Ponseti Gruppe hinsichtlich Dorsalflexion ($p=0,043$), der erreichten Punkteanzahl im FRS ($p=0,0001$) und dem ICFSG-Protokoll ($p=0,001$) festgestellt werden. Darüber hinaus schnitt die Ponseti-Gruppe auch statistisch signifikant besser in der „ankle-hindfoot“- ($p=0,0003$) und „midfoot“ ($p=0,001$) - Skala des AOFAS ab. Auch im Gangbild unterschieden sich die beiden Gruppen deutlich. Die PODCI- und SF-36-Ergebnisse konnten zudem das häufigere und stärkere Auftreten von Schmerzen in der chirurgischen Gruppe aufzeigen.

Diskussion: Die Ergebnisse unserer Studie zeigen, dass die Ponseti-Gruppe auch im Langzeitvergleich hinsichtlich Funktionalität, Schmerzfreiheit und Beweglichkeit sowie im Gangbild der chirurgischen Gruppe überlegen ist, und untermauert die Ponseti Methode als therapeutischen Goldstandard.

Abstract

Introduction: The clubfoot, also referred to as congenital talipes equinovarus (CTEV), is one of the most common musculoskeletal deformities and the most common foot deformity at birth, with incidences between 0.6 to 2.57 per 1000 live births. Previous studies by Zwick et al. and Švehlik et al. have shown that conservative treatment (Ponseti method), including a combination of gentle manual manipulation and "toe-to-groin" plaster cast of idiopathic clubfoot is superior to surgical treatment (pantalar release). However, a prospective randomised long-term comparison is still missing. Therefore, the aim of this follow-up study was to compare the longterm-outcome of two treatment methods (Ponseti and pantalar release) in terms of mobility and function of the ankle joint. Furthermore the morphological and radiological results, as well as the individual improvement in quality of life, were evaluated.

Material and Methods: The design of this trial is a long-term, previously randomised, non-blinded, prospective single-centre study. Nine patients of the Ponseti group (n=12 feet) and five patients of the surgical group (n=9 feet) from the previous studies were invited to a third follow-up 17-19 years after the initial treatment. In addition to a clinical examination, the Functional Rating System (FRS), the International Clubfoot Study Group (ICFSG) protocol, the Adolescent Outcomes Questionnaire (PODCI), Short-Form-36 (SF-36) questionnaire and the American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot and midfoot Scales were used to compare the two groups in terms of foot function, morphology, quality of life and radiological outcomes. Furthermore, a 3D gait analysis and a handheld dynamometry (HHD) were performed to evaluate the kinematic and kinetic data of the foot.

Results: Significant differences in dorsiflexion ($p=0.043$), FRS ($p=0.0001$) and ICFSG protocol ($p=0.001$) were found in favour of the Ponseti group. Moreover, the Ponseti group also performed statistically significantly better in the AOFAS ankle hindfoot ($p=0.0003$) and midfoot ($p=0.001$) scale. In the 3D gait analysis, differences were found in ankle power ($p=0.002$) and range of motion ($p=0.004$) as well as in kinetic parameters ($p=0.005$). The PODCI and SF-36 results highlight the more frequent and more severe occurrence of pain in the surgical group.

Discussion: Our study was able to show the superiority of the Ponseti method in terms of functionality, freedom from pain and ankle mobility as well as kinetic properties compared to the surgical group in a long-term comparison (mean follow-up time: 18 years).

1 Introduction

1.1 Historical Overview

Since time immemorial, the idiopathic clubfoot (=congenital talipes equinovarus) has shaped the image of the lame and crippled and is mentioned in numerous historical traditions and ancient finds. For example, the deformity, among others, was already described in the Old Testament as a "curse of God". Also in Greek mythology, the description of the foot and gait of Hephaestus, the god of the blacksmiths, indicates that he suffered from a bilateral clubfoot (Figure 1).

Even Hippocrates already mentioned clubfeet in his work "Corpus Hippocrates". He also laid the foundation for modern clubfoot treatment by recommending that the foot should be continuously brought into position over a longer period of time by manipulation and subsequent fixation with firm bandages.

Ambroise Pare described the clubfoot deformity again in the Renaissance period after about 2000 years without literary mention. With regard to treatment, in addition to the methods of Hippocrates, Pare used special footwear.

From the middle of the 18th century until the early 19th century, Cheselden's method was used. (19) The talipes was wrapped with cloths and then dipped in egg white and flour. The cloths were left to dry to fix the foot in the previously corrected position. This whole process was repeated until the foot was in the desired position.

(Figure 2) (6)

From 1803 onwards, Antonio Scarpa tried to bring the clubfoot into its normal shape through forceful manipulation with his apparatus, later known as "Scarpa's shoe" (Figure 3). However, his method never caught on due to the lack of treatment success. (19)



Figure 1: Greek amphora depicting the club-footed Hephaistos on a horse (6)

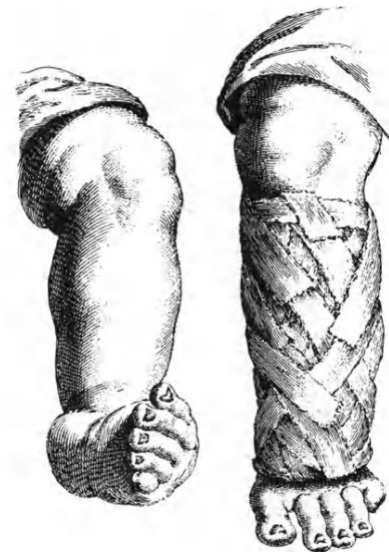


Figure 2: Cheselden's method (6)

The 19th century heralded the turning point in the treatment of clubfoot: Conservative and manipulative methods were gradually replaced by surgical interventions. Georg Friedrich Louis Stromeyer from Hanover performed the first successful subcutaneous tenotomy on a 14-year-old clubfooted schoolboy in 1831. His idea was to cut the Achilles tendon subcutaneously to reduce the risk of infection. His method corrected the equinus component of clubfoot so well that 400 tenotomies were performed as early as 1833. (6)

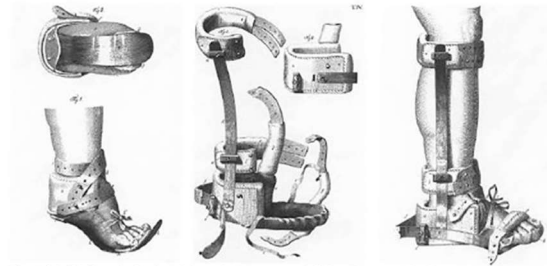
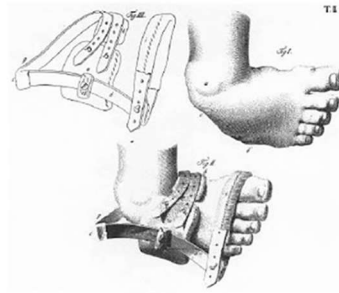


Figure 3: Scarpa's shoe (1)

To better understand the causes and pathology of the congenital talipes equinovarus, William Adams, an English surgeon, dissected newborns with clubfeet and published his results in 1875. (20) Furthermore, he carried out microscopic examinations of the muscles of clubfoot patients for the first time. However, he could not detect any structural abnormalities either with the naked eye or microscopically. (19)

In 1891, Abel Mix Phelps developed a method, in which not only a tenotomy of the Achilles tendon was performed, but also a medial release of the soft tissue, an elongation of the tibialis posterior and a surgical sectioning of the flexor hallucis longus, abductor hallucis, short flexors, plantar fascia, the deltoid ligament. Eventually, a wedge resection of the calcaneus and osteotomy of the neck of the talus were also performed. (21)

During the 20th century, only the details of existing surgical approaches were modified. (19) Surgical methods from this time that are still used today are the "posteromedial release" by Turco (22), the release according to McKay, (23) and the "medioposterior release" also called "à la carte release" described by Bensahel. (24)

At the same time, conservative, non-surgical methods made significant progress. (19) In the mid-20th century, Kite realised that the forceful manipulation used in the treatment of talipes resulted in stiffened joints and cartilage damage. Therefore he developed a method using continuous, repeated manipulation and plaster casts. (6) In the late forties, Ponseti developed a special conservative method for the treatment of clubfoot, thanks to his unique understanding of the functional anatomy of the (club)foot and based on Kite's findings. Unlike Kite, Ponseti corrected all components of clubfoot simultaneously, while Kite tried

to correct each one separately. Ponseti was of the opinion that many orthopaedists would rather choose surgical procedures, due to their lack of knowledge of clubfoot anatomy and its kinematics, which led to disastrous treatment results. (25) His treatment successes proved him right: The Ponseti method became the gold standard in the treatment of congenital talipes equinovarus and still is today. (19, 25, 26)

1.2 Definition and Epidemiology

The clubfoot, also referred to as congenital talipes equinovarus (CTEV), is one of the most common musculoskeletal deformities and the most common foot deformity at birth. (25, 27) The incidence varies greatly, depending on the population. For example, US studies have found incidences between 0.6 to 2.57 per 1000 live births. Males were affected twice as often as females. (13-15) In comparison to the US, studies conducted in Japan and Sweden came up with an estimated incidence of 0.5-0.64 per 1000 live births, while the incidence in Western Australia, Uganda and Spain was 1.2 to 1.65 per 1000. Much higher incidences, almost 6-7/1000, were found among the Hawaiian natives and the Māori in New Zealand. (28) In about half of the cases, both feet were affected, which is called bilateral clubfoot. (29, 30) However, unilateral clubfeet tend to be on the right side. (31) The talipes is a complex three-dimensional deformity consisting of equinus, hindfoot varus, forefoot adductus, cavus, and supination of the foot. It can already be detected in utero by ultrasound. (25, 32) The feet of CTEV patients are turned inwards and the navicular bone is in contact with the medial malleolus, which makes the big toe look like as if it is shortened. The foot appears convex from the lateral side and concave from the medial side ("*medial crease*") (Figure 4). Furthermore, the limb affected by clubfoot looks slightly shorter and the calf looks smaller due to the atrophied musculature. (33) The deformity can range from mildly stiff to rigid. A rigid clubfoot, for example, is difficult or impossible to manipulate. (27) Therefore, two common systems are used for the initial assessment of severity: the Pirani score (34) and the classification system according to Dimeglio et al. (35)



Figure 4: Bilateral clubfoot before treatment (36)

CTEV can be roughly divided into two subtypes: the “idiopathic clubfoot” (IC)/ “isolated clubfoot” and the “syndromic clubfoot”. Approximately 80% of clubfoot cases are IC which indicates an isolated birth defect without any evidence of other abnormalities or causes. The remaining 20% are “syndromic clubfeet” associated with genetic syndromes, neurological disorders, and other malformations. (37, 38)

This thesis mainly addresses idiopathic clubfoot.

1.3 Aetiology

The aetiology of clubfoot is still unknown and is heatedly debated. (38) Over the years, numerous theories for pathogenesis of idiopathic clubfoot have been proposed, including the maternal age (31), high maternal body mass index (39), maternal diabetes (40), season of birth (41, 42), nerve lesions (43), vascular or muscular abnormalities (37), too early amniocentesis in pregnancy week 11-14 (37, 44, 45), neuromuscular defects (46) and either a genetic component alone (47) or a combination of genetic environmental factors, like maternal smoking. Some of the factors mentioned above, such as the influence of the birth season, could not be sufficiently proven. (48)

For environmental factors, maternal smoking seems to be the most consistent and strongest risk factor associated with idiopathic clubfoot.

Nowadays, it is widely accepted that the cause of idiopathic clubfoot is a combination of genetic and intrauterine factors. The idea that genetic factors are responsible for the development of clubfeet is supported by the fact that almost 25% of cases are familial. (27, 49)

Not only are men twice as likely to be affected by the deformity (28), but women are also more likely to transmit the CTEV to their children than men, which again suggests a genetic component to be causal. (50)

In contrast to idiopathic clubfoot, syndromic clubfoot occurs secondary to other disorders such as central nervous system abnormalities (meningomyelocele, spina bifida), myotonic

dystrophy (Steinert disease), distal arthrogyriposis, TBX4 mutation and TARP syndrome (=talipes equinovarus + atrial septal defect). (37) The syndromic type also shows less response to treatment. (51)

Although some genes have already been associated with clubfoot deformity, the pathways and exact factors leading to CTEV are still unknown. (37)

1.4 Functional and structural anatomy of the foot and ankle

“The human foot and ankle contain 28 bones and 55 articulations” and the foot can be roughly divided into three sections: the hindfoot, the midfoot and the forefoot. (Figure 5) (52)

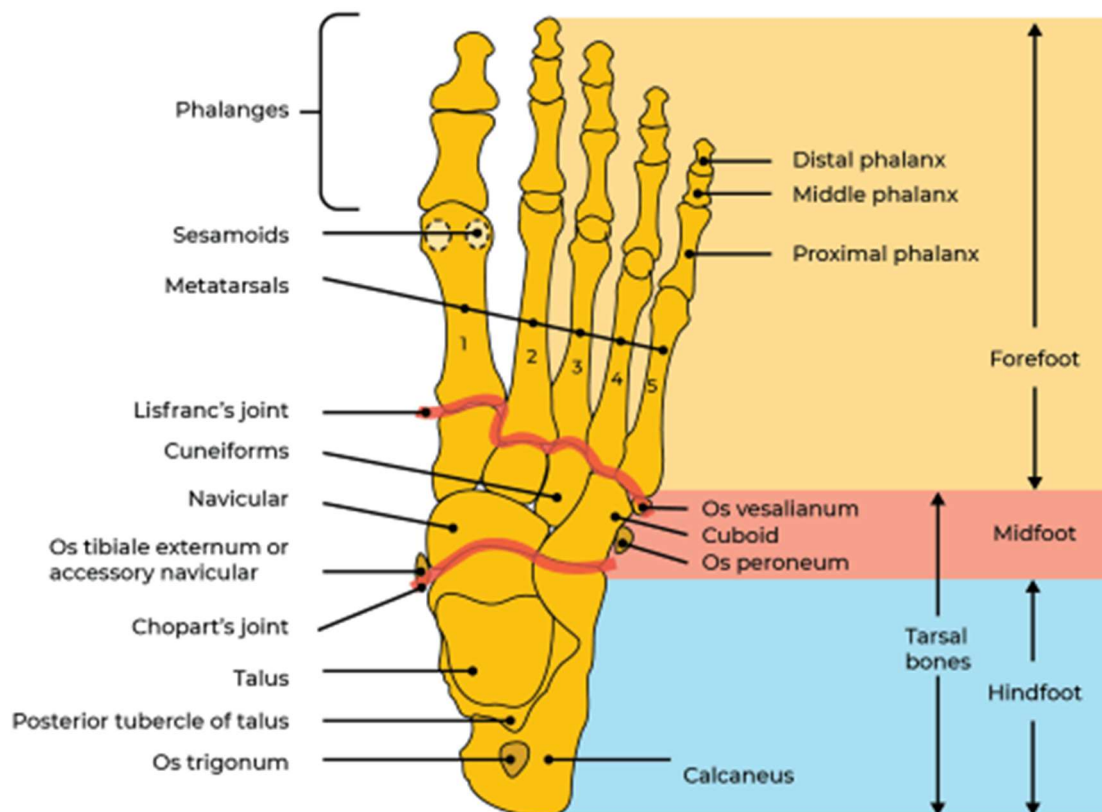


Figure 5: Osseous anatomy (53)

The ankle joint, also known as the talocrural joint, is the articulated connection between the lower leg bones (tibia and fibula) and the tarsal bones (talus). It is designed as a very firmly guided joint that tolerates high compression forces. It is the only joint that bears the entire body weight and is also exposed to the kinetic energies during gait, running and jumping. (54)

As already mentioned, the ankle joint is the articulation between the talus (more precisely the talar trochlea) and the distal tibia and fibular. Numerous authors describe that the joint

axis can be constantly repositioned with movement in the ankle joint, due to the curvilinear contour of the medial talus. (52, 54) The movement axis of the talocrural joint is transverse and is located directly under both malleoli. “As the lateral malleolus extends further distally, it is inclined laterally by 82° with respect to the tibial axis” (Figure 6). (55) Moreover, it is inclined 20 to 30 degrees to the frontal plane (Figure 7). (52)

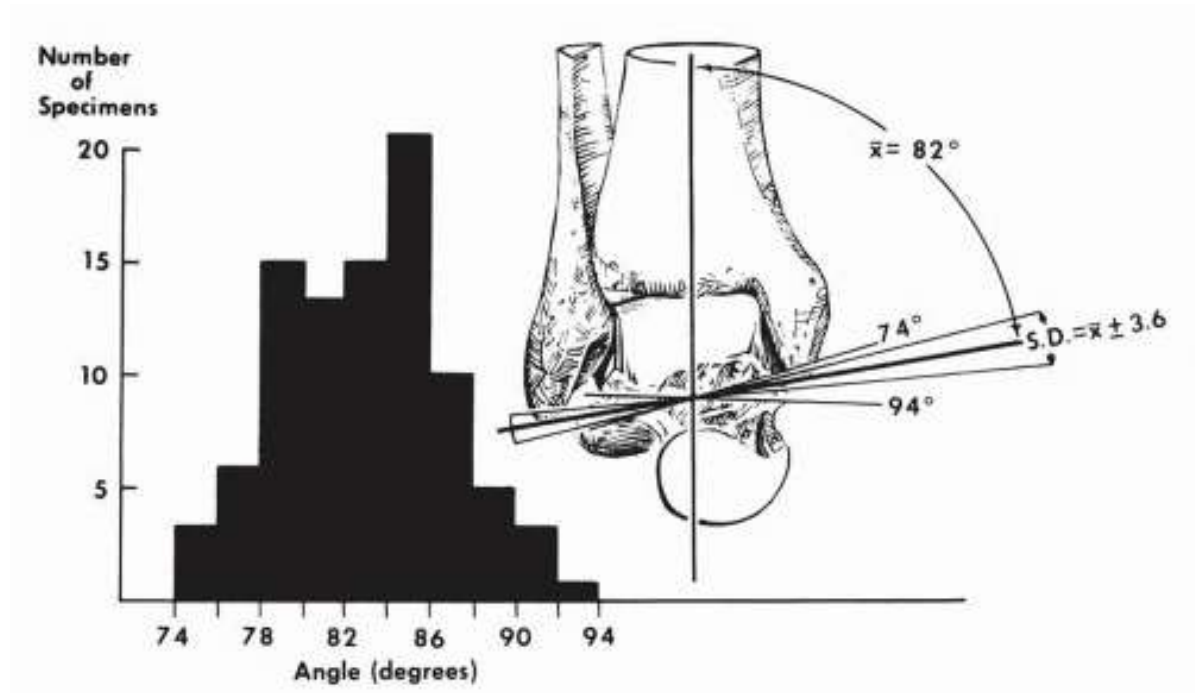


Figure 6: Illustration of the angle of inclination (82°) of the ankle joint axis (56)

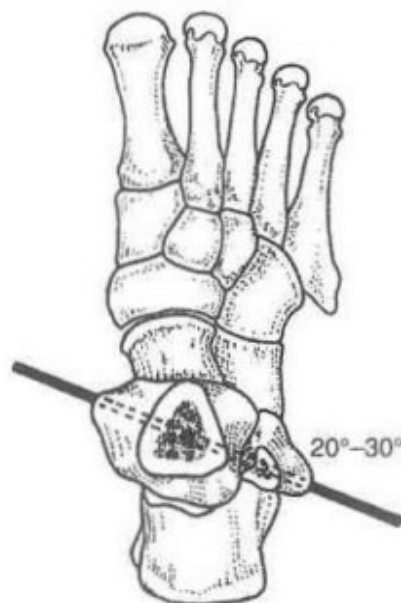


Figure 7: Average axis of motion for the ankle (superior view) (52)

From a plantigrade foot position, about 20-30° of dorsiflexion and about 40-50° of plantarflexion can be achieved in the ankle joint. While walking, the lower leg can be flexed approx. 50° backwards (plantarflexion) and about 30 degrees forwards (dorsiflexion) (Figure 8). (55, 57)

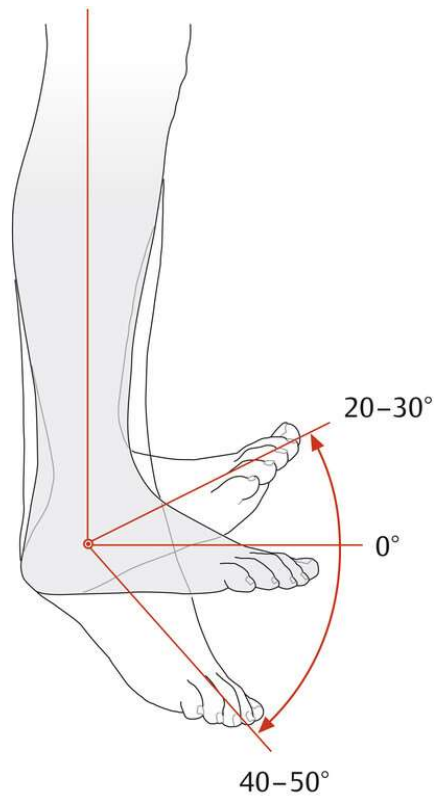


Figure 8: Illustration showing the range of motion (ROM) for ankle dorsiflexion (20-30°) and plantarflexion (40-50°) in the free leg (57)

The range of motion of plantar- and dorsiflexion is limited by bones, muscles, ligaments, and parts of the joint capsule. At maximum dorsiflexion, the neck of the talus abuts the anterior edge of the tibia, the dorsal part of the capsule and the posterior talofibular ligament are tense and resistance is created by the muscle tone of the triceps surae. This results in inhibition of movement and further dorsiflexion is no longer possible. Motion in direction of plantarflexion are limited by tension created by the anterior talofibular ligament and the anterior part of the capsule and “*by an osseous block produced when the posterior tubercle of the talus contacts the posterior margin of the articular surface of the tibia.*” (52, 54)

However, the foot consists of numerous and complex joints that connect the bones of the hindfoot, midfoot and forefoot. The following joints can be differentiated from each other:

the subtalar joint, Chopart's joint (transverse tarsal joint or midtarsal joint), the cuboideonavicular and cuneonavicular joints and Lisfranc's joint (tarsometatarsal joint). These joints are helping to form the shape of the foot and its longitudinal arch and therefore to compensate for unevenness in the ground. Furthermore, they provide a shock-absorbing effect between the body weight and the floor and thus ensures a soft gait. With the exception of the metatarsophalangeal joint of the hallux, which is important for ensuring the natural rolling movement of the foot, the other metatarsophalangeal and interphalangeal joints play a subordinate role. (54)

Biomechanically, the foot can be divided into a flexible medial and a rigid lateral column (Figure 9). (58) The medial column consists of the first through third metatarsals, all three cuneiforms, the navicular and the talus. Fourth and fifth metatarsals, cuboid and calcaneus form the lateral column. (59)

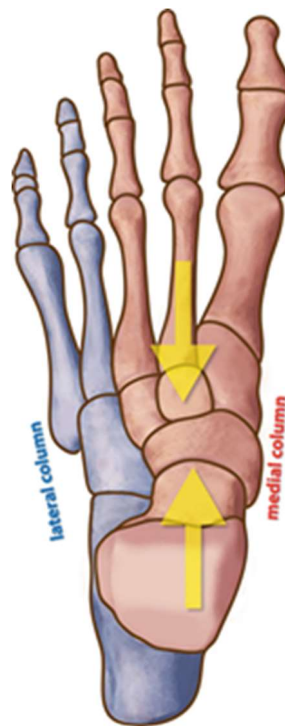


Figure 9: Illustration of the medial (red) and lateral (blue) columns of the foot(9)

„The distal positioning of the medial and lateral column next to each other and proximally on top of each other creates a longitudinal and transverse arch on the plantar surface.“
(57)

Although the subtalar joint and the talocalcaneonavicular joint are anatomically two separate joints, they are considered as one functional unit. While the subtalar joint articulates between the talus and calcaneus, the talocalcaneonavicular joint articulates

between the talus, calcaneus, navicular and the plantar calcaneonavicular ligament (also known as spring ligament). (4, 55) The movements of these two joints are often used inconsistently both in literature and in clinical practice. In old textbooks in the German-speaking world, the movements of these two joints were often referred to as supination and pronation, whereas in more recent literature and in the English-speaking world, they are referred to as eversion/inversion. (4, 60, 61) In standing (supporting leg), lifting the lateral edge of the foot corresponds to eversion and raising the medial edge of the foot corresponds to inversion (Figure 10). The inversion can be performed by up to 20° and the eversion by up to 10°. Although the rotational movement of the calcaneus is measured. (4, 57)

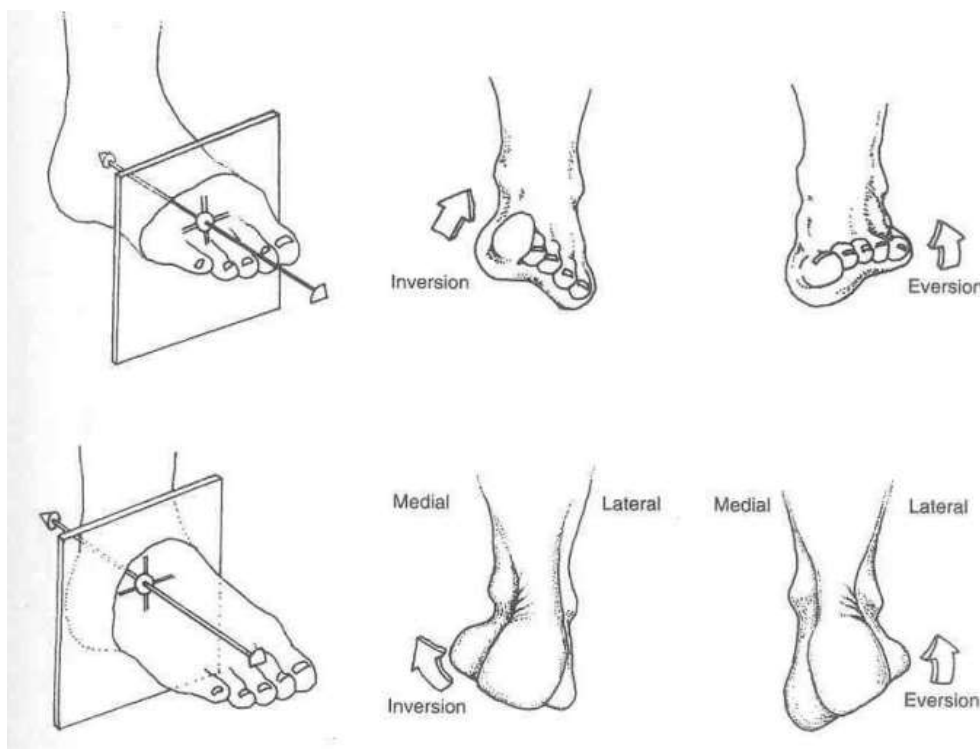


Figure 10 Motion in the subtalar joint and talocalcaneonavicular joint as a functional unit (52)

Since the subtalar joint forms a multiaxial joint together with the talocalcaneonavicular joint, a compromise axis was introduced. *"It leads from the lateral end of the posterior edge of the back of the calcaneus obliquely through the tarsal sinus and finally leaves at the medial-distal neck of the talus"*. (61)

Further distally located is the midtarsal joint (also referred to as chopart's joint or transverse tarsal joint), which is comprised of two joints, namely the talocalcaneonavicular and the calcaneocuboid joints. In the chopart's joint, movement in the direction of pro- and supination can be performed by twisting the mid- and forefoot against the hindfoot. The

normal range of motion for supination is approx. 35° and that for pronation 15° . Thereby it is important to fix the hindfoot when measuring. (4, 55, 57)

Not to be confused with this, are the pronation and supination of the entire foot, which can be performed with the non-weight-bearing leg (free leg). Supination of the whole foot is a combination of plantarflexion (ankle), inversion (subtalar and talocalcaneonavicular joint) and supination (chopart's joint), whereas pronation of the entire foot is formed by the opposite movements (dorsiflexion, eversion and pronation). (4, 52)

The main functions of the foot are the transfer of body weight to the ground and the contact between the underground and the rest of the body. Moreover, it plays a key role in locomotion. (55) The plantar vault is formed by three bony arches which are in contact with the ground at three points (Figure 11). The longest arch, the medial longitudinal arch, is formed by the following bones: first metatarsal bone, medial cuneiform bone, navicular bone, talus and calcaneus, with the head of the first metatarsal bone and the calcaneus in contact with the ground. Its shape is maintained by numerous plantar ligaments and muscles, most notably the tibialis posterior, peroneus longus, flexor hallucis longus and the abductor hallucis muscles.

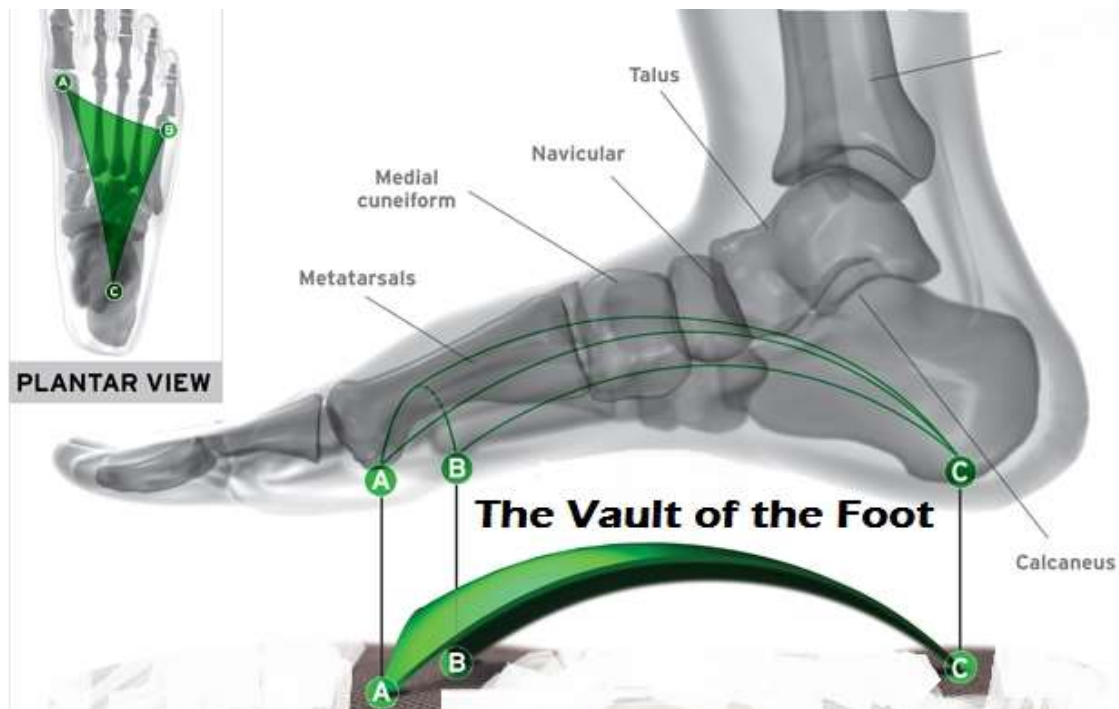


Figure 11: The vault of the foot (medial and plantar view) formed by the medial longitudinal arch (A-C), lateral longitudinal arch (B-C) and anterior transverse arch (A-B) (62)

The lateral longitudinal arch is formed by the head of the fifth metatarsal bone, the cuboid bone and the calcaneus. Due to the long plantar ligament, the lateral longitudinal arch is significantly more rigid than the medial arch and thereby enables the rolling motion in cooperation with the triceps surae. The fibularis longus, fibularis brevis and abductor digiti minimi muscles prevent the lateral longitudinal arch from collapsing.

Contrary to the longitudinal arches, the anterior transverse arch is located in the coronal plane (also referred to as frontal plane) of the foot. The anterior arch is formed by the heads of all five metatarsal heads, the cuboid, and the three cuneiform bones and continues proximally as a transverse arch.

Therefore, in a healthy non-deformed foot, the longitudinal and transverse arches lead to weightbearing like a tripod. (54)

1.5 Foot development from birth to adolescence

The paediatric foot grows and changes during childhood in terms of length, width, proportions, function and shape. It differs from the adult foot in functional anatomy as well as biomechanically. During growth, various influencing factors can significantly affect the development of the foot. In infants, the hip and knee are typically in a flexed position. (63, 64) The lower limb appears in the genu varum position. Genu varum is the Latin term for bow legs. Up to the age of two years, genu varum is considered physiological and results in intoeing. This condition disappears without treatment and is part of normal development. (65-67)

The infant feet are in supination, the forefoot is adducted and the hallux protrudes from the other toes. Plantar flexion is limited, while dorsal extension is unrestricted. Longitudinal and transverse arches are already present. (63, 64) In comparison to the adult foot, the arches are flatter and less well defined in infants. Moreover, the range of motion is greater in the infant foot and the *"end point of range of motion"* is difficult to estimate, whereas it is well defined in the adult. The *"amount of subcutaneous fat tissue"* is also greater in the infant foot than in the adult. (68)

The upright human gait requires the morphological and functional development of the lower limb, which consists of several components. The typical genu varum position in infancy transitions temporarily into a physiological genu valgum when the toddler starts to stand up and finally transforms into a straight leg at around six to seven years of age. (Figure 12). (69)

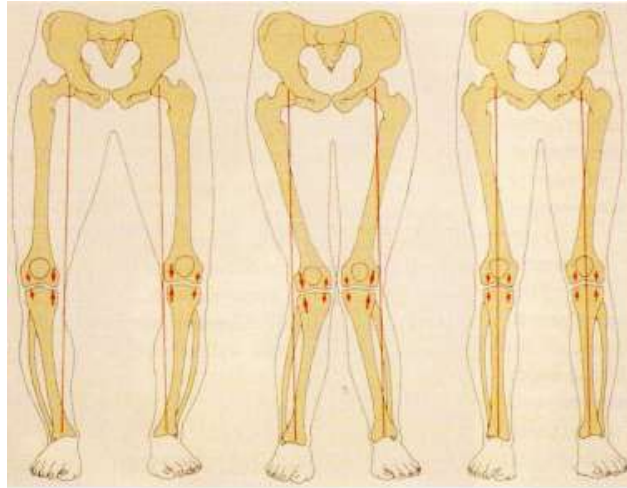


Figure 12: Development of the leg axes: from left to right: genu varum, genu valgum, straight leg (70)

Other developmental components that are required to ensure an upright gait are the erection of the hindfoot, the pronation of the forefoot and external rotation of the ankle mortise.

In contrast to adult feet, the talus in newborn's feet is positioned more medially to calcaneus and pronated. Furthermore, the dome of the talus is inclined medially. In the course of development, the calcaneus moves further under the talus through a pronation movement around its longitudinal axis, while the talus supinates. This movement in the opposite direction finally brings the calcaneus under the talus in adulthood. (63)

On an X-ray of a newborn's foot, only the ossification centres of the cuboid, talus, calcaneus, metatarsal bones and those of the proximal and middle phalanges are visible. Finally at the age of three years, the navicular bone also forms an ossification centre. (71) Due to the growth stimulus caused by the higher mechanical stress on the inner forefoot and outer hindfoot, ossification begins there first. (63)

At about six years of age, most of the bones of the metatarsus and hindfoot have been ossified. (72) The epiphyseal-diaphyseal fusion, on the other hand, is not completed until the age of about 17. (73)

Within the first few years of life, fatty tissue is stored in the area of the longitudinal arch, which then disappears again during childhood. (74) These fat pads on the plantar surfaces protect the arches of the foot. Due to the continuous reduction of the plantar fatty tissue, the arches appear at the age of about five to six years. (75) In principle, the development of the longitudinal arch is completed before the end of the second year of life. (76)

In terms of foot length, the feet of girls are considered fully grown at 13 years of age and those of boys at 14-15 years of age. (77)

1.6 The gait cycle

The upright gait serves as human locomotion and is unique. No other living creature on earth can walk upright. Although there are animals that can stand up on their hind paws, this is not a normal form of locomotion for any of them. (54) Normal gait is supported by the interaction of different systems in the body, such as the musculoskeletal system, postural reflexes, sensomotor function, balance and the cardiopulmonary system. (78) A complete gait cycle is measured from heel-strike to the next ipsilateral heel-strike. It starts with the initial contact of the heel with the ground and ends when the same heel touches the ground again. This description of the gait cycle focuses entirely on the most common gait pattern, in which the heel strike is the initial contact with the ground. For the purpose of completeness, it should be mentioned that a small percentage of the population strikes first with the forefoot. Looking at the gait cycle from a temporal perspective, it can be divided into two different phases: the stance phase and the swing phase (Figure 13), which make up approximately 60% and 40% of the gait cycle. (52, 78)

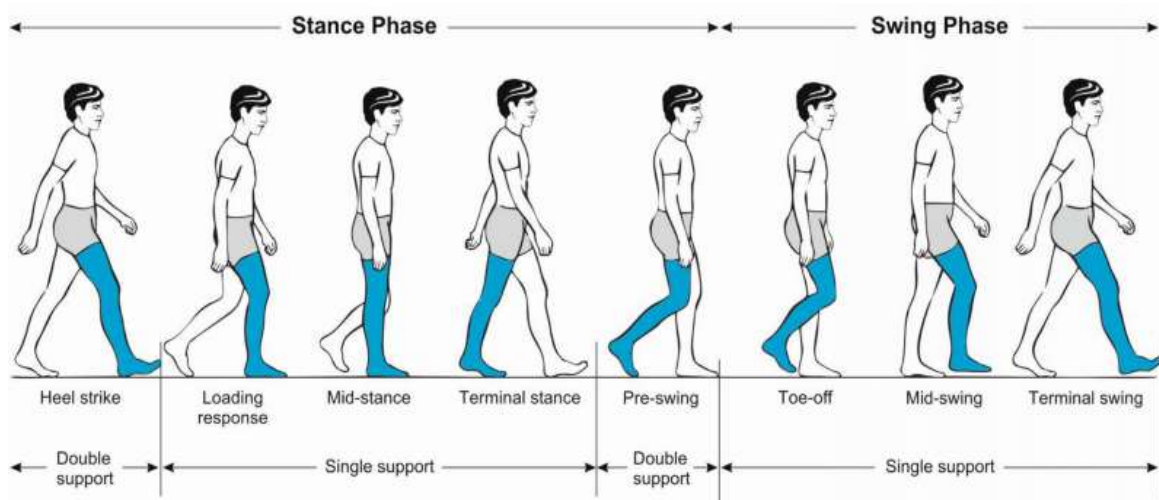


Figure 13: Functional divisions of the gait cycle (78)

A walking person needs approximately 1 second for one gait cycle, therefore the stance phase lasts 0.6 and the swing phase 0.4 seconds. (52) The stance phase is divided into five subphases and the swing phase into three subphases (Figure 13). During a gait cycle, both feet are on the ground twice at the same time (double support). This happens during heel strike and pre-swing. The movement sequence can be described as follows (52, 79, 80):

- (1) During **initial contact**, also called **heel strike**, the heel touches the ground. The hip is flexed 30° and the knee is almost fully extended. Thereby the vastus muscles and the iliotibial tract are active and keep the knee joint stable in this position.

Furthermore, the ankle is slightly dorsiflexed. Meanwhile, the subtalar joint is slightly supinated, while the midtarsal joint is inverted about its longitudinal axis and fully pronated about its oblique axis (Figure 14).

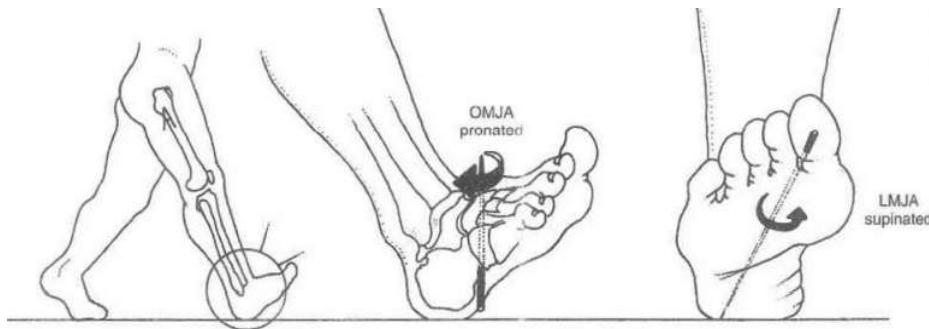


Figure 14: joint positions at heel strike. OMJA= oblique midtarsal joint axis; LMJA= longitudinal midtarsal joint axis (52)

- (2) In the **loading response** period, the load is transferred to the supporting leg. By rolling the foot and moving the tibia forward, the body's centre of mass (COM) moves behind the transverse axis of the knee. This flexes the knee joint and it absorbs the weight load as a shock absorber. Flexion in the knee joint is limited by the quadriceps femoris muscle. As a result, the knee joint is dynamically stabilised.
- (3) In the **mid stance** period the entire body weight is transferred to the supporting leg. As the contralateral leg begins to swing forward, the knee joint of the stance leg is increasingly extended and the body's centre of mass is shifted towards the knee joint.
- (4) In the **terminal stance** period, the knee joint is further extended by the forward movement of the body, preparing the heel off of the supporting leg. The phase ends with the initial contact of the contralateral leg.
- (5) In the **pre-swing** phase, active flexion in the hip joint occurs by the iliopsoas muscle, which passively flexes the knee joint. This lifts the foot off the ground, which in turn initiates the swing phase.
- (6) The **initial swing**, called **toe off**, is the first subphase of the swing phase. Increased active flexion in the hip joint leads to further passive flexion of the knee joint. This causes the toe off.
- (7) In the **mid swing** phase the swing limb continues to swing forward through hip flexion and reaches its maximum flexion at the knee joint. As it continues, the leg begins to extend due to gravity, ending with the leg in a vertical position to the ground.

- (8) The **terminal swing** initiates the end of the gait cycle. The quadriceps femoris muscle causes extension in the knee joint and prepares the limb for the subsequent stance phase, which again starts with the heel strike.

Simultaneously to the movement of the lower limbs, the upper limb also moves to balance displacements of the barycentre. *“The human gait includes flexion of the upper limb on the side opposite to the swinging lower limb.”* These balancing movements of the upper extremities are mostly automatic. In neurological diseases such as Parkinson's disease, this counterbalancing is no longer possible. It is a fact that walking is more difficult if both upper limbs are immobile. That is also the reason why prisoners are handcuffed behind their backs. That way it is more difficult for them to run away. (54)

1.7 Kinetics and kinematics of the foot during gait

“The term kinematics simply means a description of the gait in terms of the angles, positions (displacements), velocities and accelerations of the body segments and joints.”(2) Among other tools, gait kinematics can be measured with 3D motion analysis systems, which are explained in more detail in the “Material and Methods” section of this thesis. In normal gait, most movement takes place in the forefoot and hindfoot, while relatively little movement occurs in the midtarsal joint. Both the individual body segments and the body have a *centre of mass* (COM) in which the mass is concentrated. The centre of mass of the body is impacted by the movement of COM of the individual body segments. During normal gait the COM falls during double support and rises during single support. (2)

Kinematics can be well assessed visually in the clinic and in the laboratory, but they do not reflect the cause of individual movements. In contrast, kinetics can be used to make a statement about why individuals move the way they do, by measuring forces, power and energy. (81)

The average of all the pressure exerted on the plantar surface of the foot is called the centre of pressure (COP), which moves from the lateral border to the centre of the foot to the hallux during the gait cycle.

While the forces act vertically when standing, additional forces occur when walking, the so-called shear forces, which are caused by the friction between the ground and the foot (Figure 15).

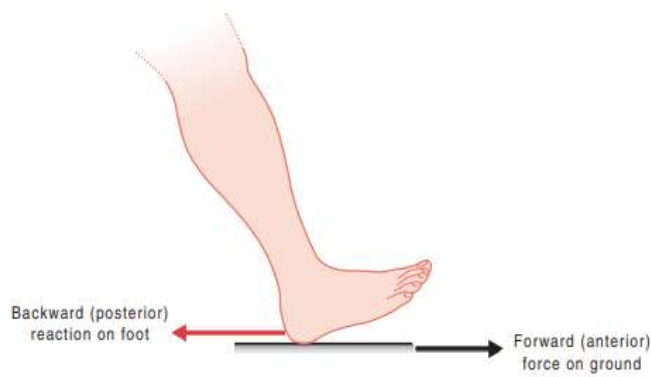


Figure 15 Shear force (2)

The ground reaction vector (GRV) is the geometric sum of the shear components and the load (Figure 17).

Force platforms, a device imbedded in the ground or treadmill that uses either piezo-electric crystals or strain gauges to measure ground reaction forces, can be used to quantify the individual components of GRV (Figure 16). (2)

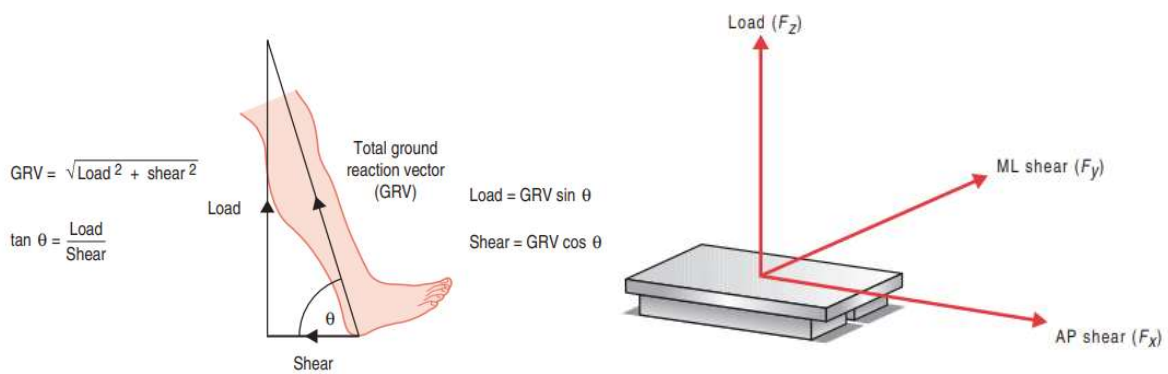


Figure 17: components of the ground reaction vector (GRV) (2)

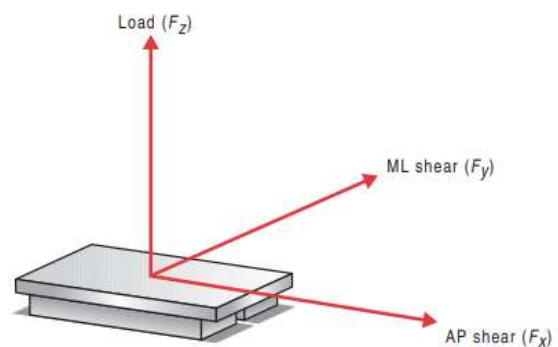


Figure 16 Measuring the components of GRV with a force platform; mediolateral (ML), anteroposterior (AP) (2)

1.8 Pathoanatomy of idiopathic clubfoot

The clinical inspection of the clubfoot of a newborn clearly shows that it is a complex deformity. It is characterised by several components such as equinus, hindfoot varus, forefoot adductus, cavus, and supination of the foot. (Figure 18 & 19) (25, 35)



Figure 18 bilateral clubfoot, indicating the components of the deformity: equinus, hindfoot varus, forefoot adductus, cavus, and supination of the foot (4)

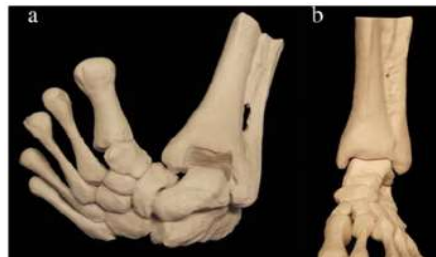


Figure 19 a) deformation of the bones in a clubfoot and b) normal foot (12)

The bony deformation of the clubfoot (Figure 19) includes a medial tilt of the calcaneus and inversion under the talus, a medial displacement of the navicular and an abnormally shaped talus. (82-85) The deformity of the talus is caused by the torsion between neck and body. In combination with the rotation of the calcaneus, it causes the forefoot to be held in adduction and pronation. (35, 86) The adduction and supination of the forefoot typical of clubfoot can therefore be explained by the subtalar malrotation. (5) This malrotation moves the navicular bone closer to the medial malleolus and the calcaneus bone closer to the lateral malleolus. (43)

The aforementioned medial rotation of the calcaneus underneath the talus and the plantarflexed position of both the calcaneus and talus result in a varus deformity of the hindfoot. (83, 85, 87, 88) This derotation between calcaneus and talus results in a decreased talo-calcaneal (TC) angle on plain radiographs. The distal part of the calcaneus underneath the head of the talus prevents the talus from dorsiflexion and pronation. Thereby the talus is blocked in an equinus position. (82)

The malformation affects not only the bones but also the soft tissue including tendons, ligaments and some muscles. (4) Due to adduction malalignment of the forefoot bones, the soft tissue structures are shortened on the medial side of the foot and lengthened on the lateral side. Whereas in a normal foot the ratio of supinators and pronators is balanced, in clubfoot there is a muscular imbalance. (43) The tibialis posterior muscle exerts a three-dimensional effect on the clubfoot. It causes the foot to be held in equinus, supination and in medial rotation. The muscle bellies of the soleus muscle and gastrocnemius muscle are atrophied (Figure 20).

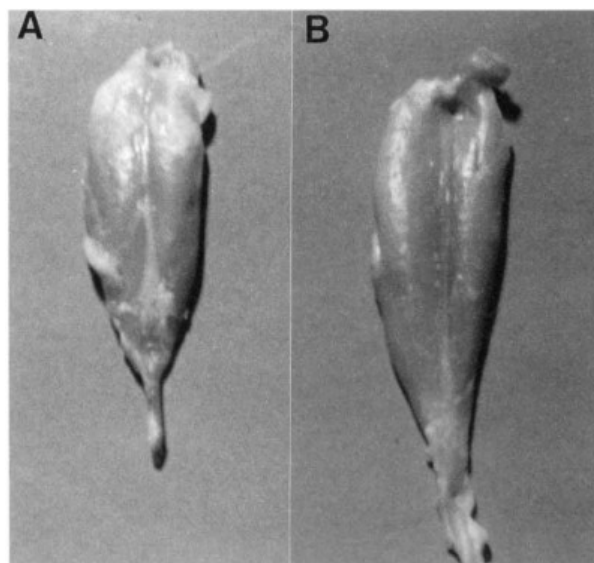


Figure 20: Comparison of the gastrocnemius muscles from a 6-month old baby with unilateral clubfoot. A) hypotrophic muscle and B) normal muscle (25)

Fibrosis was also detected at the muscle insertions and the tendons of both muscles. (83, 89) The Achilles tendon is usually shortened. (90)

In anatomical dissections of clubfoot, tight and thickened tibio-navicular and calcaneo-navicular ligaments and tendon sheath of the tibialis posterior muscle were found on the medial and plantar side of the foot. This medial tie has a crucial influence on the midfoot part of the deformity. (82, 83) The fibulo-calcaneal ligament on the lateral side of the foot is fibrotically altered. Together with the peroneal tendon sheaths, it forms a thick fibrotic mass. (91, 92)

Further abnormalities such as leg length discrepancy and shortness of the foot, as well as peroneal nerve dysfunction and joint hyperlaxity have been described. (93-96)

1.9 Disease severity classification and clinical examination of clubfoot

Congenital talipes equinovarus (CTEV) presents with different levels of severity at birth. It is essential to have a consistent classification system in order to grade the initial deformity and for prognostic purposes, as the malformation can vary significantly. The two most widely used classification systems are the protocols of Pirani (34) and Dimeglio (35) which have both proven to be reliable and valid. (97)

In our previous studies we used the classification system by Pirani to grade the initial deformity. The Pirani score evaluates six clinical signs, three parameters of the midfoot (medial crease, curvature of the lateral border and position of the talar head) and three parameters of the hindfoot (emptiness of the heel, rigidity of the equinus and posterior crease). Each parameter is scored as normal (0), moderate (0.5), or

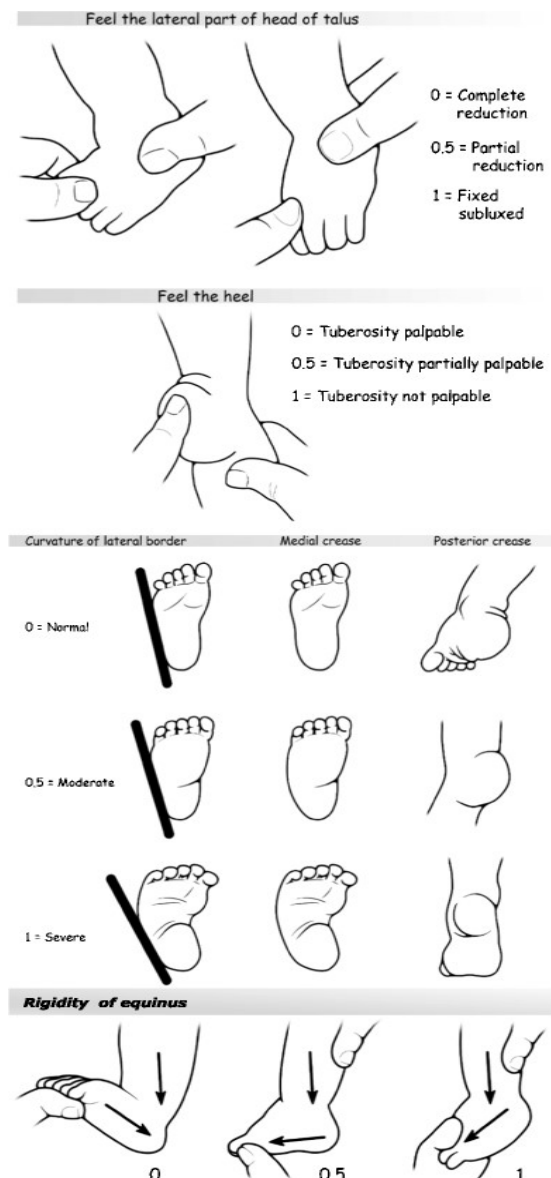


Figure 21 Pirani score for clubfoot (10)

severe (1), with a total score of six points (severe deformity). (Figure 21) (34)

Whereas the Dimeglio score evaluates four parameters (varus, equinus, derotation of the calcaneo-forefoot block and forefoot adduction) in terms of stiffness with a total score of 16 points. (35) “Additional points are added for deep posterior crease (1 point), deep medial crease (1 point), cavus (1 point) and muscle abnormalities (1 point). The sum of these parameters constitutes a total on a 20-point scale, where a higher score indicates a more severe deformity. The clubfoot is classified as benign (< 6 points), moderate (6–10 points), severe (11–15 points) and very severe (> 15 points)” (Figure 22) (10)

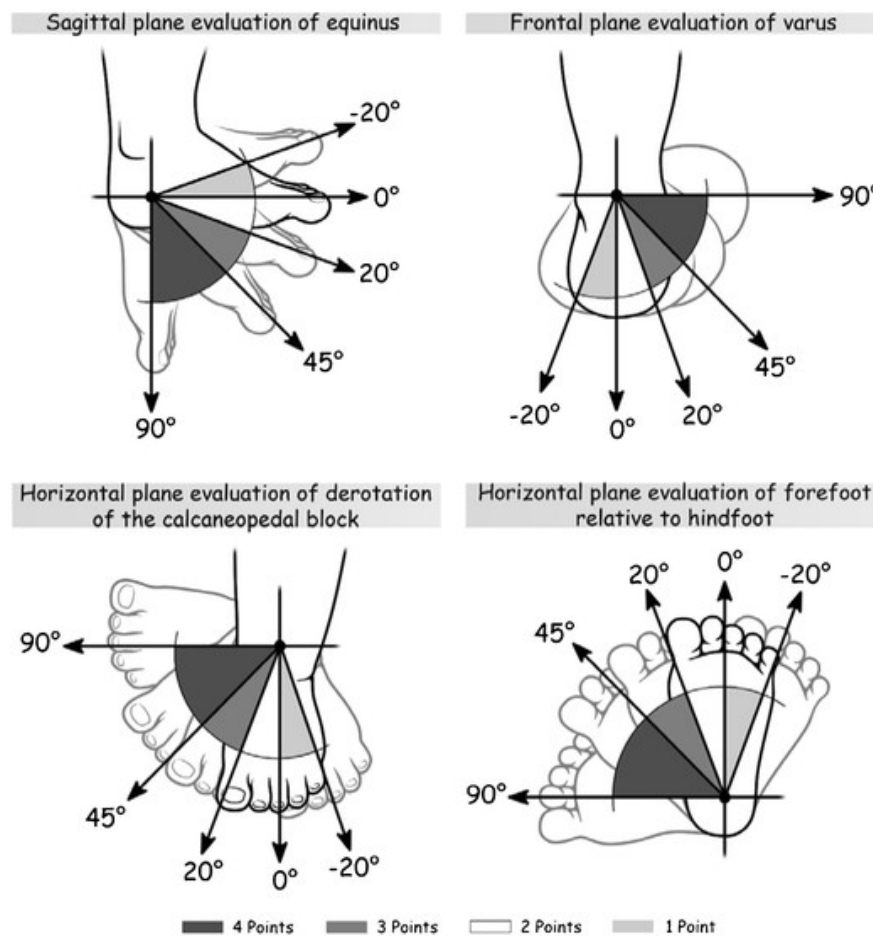


Figure 22: Dimeglio score for clubfoot (10)

1.10 Clubfoot treatment

The aim of the treatment is to achieve a mobile, pain-free foot with normal function, a good cosmetic result and load-bearing capacity. Furthermore, the patients should be able to wear normal shoes. The treatment mainly focuses on restoring the anatomy of the hindfoot and thus achieving the correct alignment between the ankle joint and the tarsal bones.

The difficulty after treatment is to maintain the corrected clubfoot during growth. To do this, it is also necessary to create a muscular balance. (25, 98) Nevertheless, despite all the progress in treatment, it must be noted that a clubfoot will never be a normal foot, no

matter how good the treatment success may look. Therefore, realistic goals should be set at the beginning of treatment. (99)

Since we compare a non-surgical approach (Ponseti) with a surgical approach (McKay) in our follow-up study, only these two treatment methods will be discussed in more detail in the following sections.

1.10.1 Conservative approach - Ponseti method

Nowadays, the Ponseti method is probably the most used treatment method worldwide and can be considered the gold standard. Due to its cost-effectiveness, relative ease of implementation and with a success rate of about 90 per cent, it has replaced all surgical methods. It is important to start the therapy in the first weeks of life. (5) The Ponseti method is basically a combination of gentle manual manipulation and "toe-to-groin" plaster casts. (18) The plaster treatment is then followed by years of treatment with a foot abduction orthosis, also referred to as Denis-Brown-Bar. (5)

The Ponseti method consists of two phases – the initial correction phase and the maintenance phase:

The initial correction phase involves weekly manipulation of the clubfoot with repeated serial casting for the first weeks of life. While the joint capsules, ligaments, and tendons become stretched, and the bone deformity is corrected by manipulations, the plaster casts ensure the degree of correction. During manipulation, all clubfoot components (cavus, varus and adductus) except for equinus are treated simultaneously. (25)

The manipulation last about 30 seconds. Then the plaster is applied. During the first cast, the first metatarsal bone is slightly raised to align the forefoot and hindfoot and reduce the cavus.

This is followed by pure abduction of the forefoot under lateral counterpressure at the head of the talus. (3) In order to maintain this corrected position, the "talus, the ankle, and the leg are stabilized by a toe-to-groin plaster cast while the knee is in 90-degree flexion" (Figure 23). (25)



Figure 23 Toe-to-groin plaster cast after manipulation for bilateral clubfeet (5)

As a rule, about six casts are necessary until complete correction is achieved, depending on the severity of the clubfoot. (5)

The equinus must be treated separately after all other components have been corrected. For this purpose, an Achilles tenotomy in most of the cases must be performed as soon as the heel is in valgus position and abduction of the foot is achieved. (3)



Figure 24 Foot abduction orthosis (i.e. Dennis-Brown-Bar) (5)

After the percutaneous Achillotomy, the foot is plastered again in a plantigrade position for three weeks. This allows the divided Achilles tendon to heal. (5)

The initial correction phase is followed by the maintenance phase, which involves years of treatment with a foot abduction orthosis (i.e. Dennis-Browne-Bar) (Figure 24) to “*hold the foot in the same degree of abduction as it was in the last plaster cast.*” (5, 25). First the foot abduction brace should be worn full time for two to three months and thereafter only at night and during naps until four years of age. (3, 5, 25) The splint should be set at 70 degrees external rotation for clubfeet and 45 degrees for the healthy foot (for unilateral clubfeet) to prevent the recurrence of adduction, varus of the calcaneus and in-toeing.(3, 25) If foot abduction orthosis is not worn consistently, there is an increased risk of relapse.(100)

1.10.2 Surgical approach - Pantalar release

Nowadays, surgical therapy (i.e. pantalar release or complete subtalar release) is only used for clubfeet for which conservative therapy has failed or for recurrent clubfeet. (3, 101, 102) Some authors also consider open surgery as the method of choice for extremely rigid clubfeet (Dimeglio IV), as forceful manipulation and prolonged plastering can cause more harm than good. (101, 102)

In principle, surgical therapy is always based on the respective deformity. (3) The operation requires a minimum age of twelve weeks and the foot should have a size of at least 10 cm. (101) From about the age of eight the pantalar release is no longer recommended due to the advanced ossification of the deformity. (102)

All surgical approaches of the pantalar release include extensive soft-tissue release. (101)

At our department, the McKay-Simons surgical approach (Figure 25) is used, as this procedure best respects the complex deformity of the subtalar joint. (23) First, a transverse skin incision (Cincinnati incision) is made, which starts at the base of the first metatarsal bone, continues around the heel and ends at the cuboid fifth metatarsal joint. (101) Next, the calcaneofibular ligament is divided and the subtalar joint is opened, up to the calcaneocuboid joint. Afterwards, the talonavicular

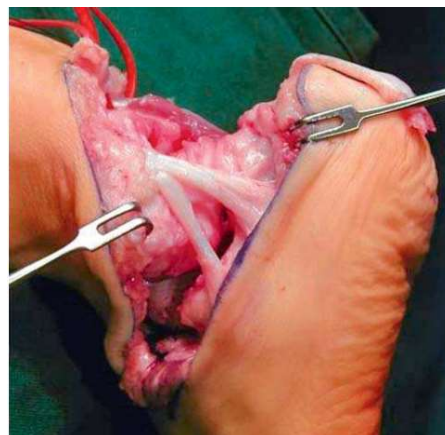


Figure 25 Subtalar release according to McKay-Simons (3)

joint is opened. Attention should now be given to the neurovascular bundle under the flexor retinaculum. Subsequently, the Achilles tendon is lengthened in coronal plane, to correct the equinus. (3, 101) After that, “*the abductor hallucis is detached from its origin*” and a Z-lengthening of the posterior tibial tendon is performed. (101) This is followed by a further opening of the talonavicular and subtalar joint medially, whereby the interosseous talocalcaneal ligament must not be cut. Finally, the reduced talonavicular joint is fixed centrally with a Kirschner wire. After surgery, the foot is in a plaster cast for six weeks. After removal of the cast, therapy is continued with a foot abduction orthosis. (3) While Henn et al. (103) found good foot function including dorsiflexion in all patients after subtalar release, several other authors were able to demonstrate a significant reduction in functionality. (16, 17, 104)

1.10.3 Relapse

Relapse (or recurrence) describes the regression of one or more components of the clubfoot (cavus, varus, adductus, and equinus) after complete correction. (105) Inconsistent wearing of the foot abduction orthosis is the main risk factor for relapse. (106, 107) In one study, wireless sensors were used to document how often the braces were used. The conclusion was that the splints were used only 62% of the recommended time. (108)

Relapse is rare after the age of five years and virtually no longer occurs after the age of seven. When discovered at an early stage, recurrence is often easily and effectively treatable with two to three repeated casts. (15, 105) This is sometimes followed by a tibialis anterior tendon transfer as a part of the Ponseti protocol. (106, 109)

Severe and persistent deformities may require repeated soft-tissue release, resulting in increased stiffness and complication rates. (110, 111)

Since non-compliance to the brace is the biggest risk factor, patient and parent adherence should be encouraged to prevent relapse. (112)

1.11 Aims

Previous studies by Zwick et al. (16) and Švehlik et al. (17) have shown that conservative treatment (Ponseti method) of idiopathic clubfoot is superior to surgical treatment (pantalar release).

The 2017 follow-up study by Švehlik et al. showed that the Ponseti group was now superior even in the initially comparable treatment outcomes. (17) However, a prospective randomised long-term comparison is still missing. Therefore, the aim of our follow-up study was to compare the two treatment methods (Ponseti and pantalar release) from the newborn to the adult foot. The main focus of the study was on the mobility and function of the ankle joint. Based on the findings of previous studies by Zwick et al. (16) and Švehlik et al. (17) we hypothesised that the Ponseti group would perform better than the surgical method (pantalar release) in terms of ankle function and mobility. Furthermore, the morphological and radiological results, as well as the individual improvement in quality of life, were also compared between the two treatment groups.

2 Material and Methods

2.1 Participants

The first trial conducted by Zwick et al. included 19 patients with a total of 28 clubfeet. Only otherwise healthy infants with unilateral or bilateral clubfeet younger than two weeks were included in the clinical trial. Out of these, ten patients were assigned to the surgical group (Mc Kay approach) with a total of 16 clubfeet and nine subjects with a total of 12 clubfeet were assigned to the Ponseti group (Figure 26).

A power analysis was conducted in which a sample size of 23 feet per treatment group was calculated assuming group proportions of 25% and 75%, respectively, to exceed the statistical power of 0.9. The reason that a total of only 19 subjects took part in the study was that the local ethics committee demanded a recruitment stop in 2003 after an interim report. This interim evaluation showed that more surgical procedures than simple tenotomies were performed in the surgical group.

Participants in the surgical group underwent initial manipulation and casting (according to the Johann Bösch approach) followed by posteromedial release at six to eight months of age. (16) In the Ponseti group, the clubfeet were treated with weekly manipulations and

above knee casts. After the percutaneous Achilles tenotomy, the subjects received the final cast for three weeks. Management with the foot abduction brace was started as soon as the optimal correction was achieved.(17) First follow-up was conducted at an average age of 3.5 years. (16) At the time of the second follow-up conducted by Švehlík et al., only 15 subjects (with a total of 24 clubfeet) were still participating in the study since the other four subjects either could no longer be contacted or no longer wished to participate. At that point, the patients were between eight and ten years old.

Only three patients in the Ponseti group (n= 4 feet) needed revision surgery compared to four people in the surgical group (n= 6 feet). In the surgical group, anterior tibial tendon transfer was performed in three patients (n=4 feet) and major revision surgery with partial release in one patient (n=2 feet). Furthermore, one patient of the surgical group (n=2 feet) even required an "opening wedge medial cuneiform osteotomy and closing wedge cuboid osteotomy" after the anterior tibial tendon transfer. (17) In contrast, in the Ponseti group, two patients (n=2 feet) underwent anterior tibial tendon transfer and one subject (n=2 feet) required a second achillotomy. With the exception of one patient, all patients with bilateral clubfeet received the same treatment for both feet. Therefore, one person with bilateral clubfeet appears in both groups because one foot was treated with Ponseti therapy and the other foot was treated surgically.

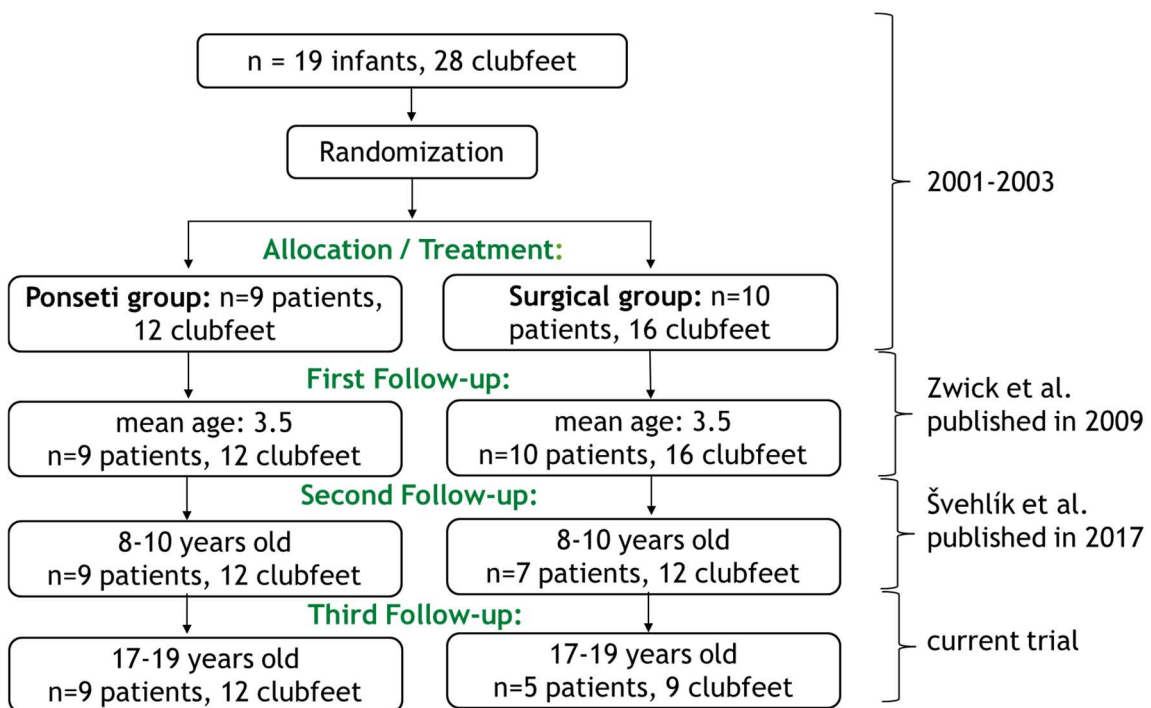


Figure 26 Consort flow chart

For the current trial, all 15 patients (four females and eleven males) with 24 clubfeet included in the previous study of Švehlík et al. were invited. Out of these, only 13 patients (four females and nine males), a total of 21 clubfeet participated in the current trial (third follow-up). (Figure 26) One patient could not be contacted due to a change in address data, another patient refused to participate - both assigned to the surgical group. All adult participants aged 18 years or older had to give their written informed consent to the study. For minors (<18 years of age), the parents also had to sign the informed consent. The exclusion criterion was refusal to participate in the trial.

2.1.1 Study design

This trial is designed as a long-term, previously randomised, non-blinded, prospective single-centre study. As mentioned above, the patients from the studies conducted by Zwick et al. and Švehlík et al. were invited to a new follow-up 17-19 years after the initial treatment. In the current study, the participants had to answer questionnaires about their quality of life and were clinically examined. Furthermore, they took part in a gait analysis and X-rays of their feet were taken.

The current study was approved by the local ethical committee (EK No. 32-624).

2.2 Assessment instruments

2.2.1 Outcome Evaluation in Clubfoot - ICFSG (International Clubfoot Study Group) score (Appendix I)

In order to compare treatment results internationally, the ICFSG score was published by Bensahel et al. in 2003. Its intention was to standardise the "language" of paediatric orthopaedists who treat clubfeet. (113)The great advantage of this score is that the morphological, functional and radiological treatment results of clubfeet can be both evaluated and compared. (114) "Scores are from 0 for a perfect result to 60 for the worst result". (113) Feet with a total score between 0 and 5 are considered "excellent", between 6 and 15 points "good", whereas a score between 16 and 30 is interpreted as "fair" and above 30 as "poor".

According to the ICFSG protocol, measurements for clubfoot morphology shall be taken with a goniometer in, or almost in neutral position. The following morphological parameters are recorded: hindfoot (varus/valgus, equinus/calcaneus), midfoot (supination/pronation, adduction/abduction) and global alignment of the foot (medial or lateral rotation of the sole of the foot, pes cavus/flat foot). Each of these individual

parameters is scored with a number of points between 0 and 2. A maximum of 12 points in total are possible for morphology.

The functional evaluation of the ICFSG score includes the analysis of different aspects of gait, footwear, passive motion in three joints (ankle, subtalar joint and midtarsal joint), as well as muscle function and pain assessment. In this section, 36 points can be achieved as worst possible outcome.

Finally, radiological measurements are taken. Six angles are assessed in anteroposterior views and six angles in lateral views. Each one is scored 0 (normal) or 1 (abnormal), with a total maximum score of 12 achievable in this section. (113)

2.2.2 FRS (Functional Rating System) (Appendix II)

With the functional rating system (FRS), we used another tool to assess foot function - mainly to allow comparison with our data from previous studies as this was the main outcome measure in our previous trials. (16, 17)

This rating system was first described by Laaveg and Ponseti in 1980. In addition to function, this score also assesses satisfaction, pain sensation, heel position, gait and three passive motions (dorsiflexion, varus/valgus-motion of the heel and anterior inversion-eversion). The total score can be interpreted as follows: 90-100 points as „excellent“, 80-89 points as „good“, 70-79 points as “fair” or as “poor” for feet with less than 70 points. (18)

2.2.3 AOFAS Midfoot Scale (Appendix III)

The American Orthopaedic Foot and Ankle Society (AOFAS) Midfoot Rating System was first published in 1994 to standardise the evaluation of the clinical status of the midfoot.

The scale ranges from 0 to 100, with a total of 100 points representing a healthy midfoot.

The score consists of three subscales including “Pain”, “Function” and “Alignment”.

However, the individual questions are rated differently. While the subcategory "Pain" contains only one item with four possible answers, which can be rated from 0 to 40, the “Function” section contains five items, which can be rated either from 0 to 10 or 0 to 5.

Furthermore, the "Alignment" is also evaluated with 0 to 15 points. (115)

The AOFAS score is the most widely used outcome instrument used by ankle and foot specialists (116) and “conveys acceptable validity regarding conditions affecting the foot and ankle”(117)

2.2.4 AOFAS Ankle-Hindfoot Scale (Appendix IV)

The Ankle-Hindfoot Scale consists of nine items divided in three subscales, including pain (with a total of 40 points achievable), function (with a total of 50 points achievable), and alignment (with total of 10 points achievable). The scale ranges from 0 to 100, with a total of 100 points representing a healthy ankle and hindfoot. (115, 118)

About 40% of the assessment can be answered through examination done by the examiner (mobility in ankle and subtalar joint, gait pattern, hindfoot stability and foot orientation) and 60% are answered by the patient. (115)

We have decided to use the two tools AOFAS Midfoot Scale and AOFAS Ankle-Hindfoot Scale in the current follow-up to make our treated clubfeet comparable, as these scores are widely used especially in the Anglo-American world. (116)

2.2.5 Three-dimensional gait analysis

As the main focus of our study is on the mobility in the ankle joint, we again performed a 3D gait analysis in this follow-up. For this purpose, the "Vicon motion capture system" consisting of 14 Vicon Vue infrared cameras was used in combination with the "Oxford Foot Model" (OFM). (17)

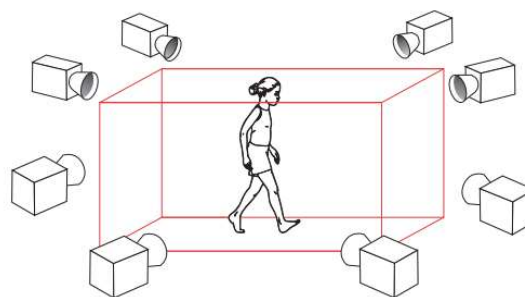


Figure 27 Scheme of camera positioning for 3D gait analysis (2)

In 3D gait analysis, retro-reflective markers are attached to the patient, which are seen by the cameras mounted in the gait laboratory (Figure 27). Due to the position of the cameras, all markers are always seen by at least two cameras simultaneously. The markers reflect the infrared light emitted by the cameras. This reflection appears as a bright spot on the individual images and is reconstructed as 3D trajectories. In order to produce accurate kinematic measurements of the individual body segments, it is important to position the markers correctly on the patient's body. (2) The markers are applied to the subject's body according to the Davis protocol, as shown in Figure 28. (119)

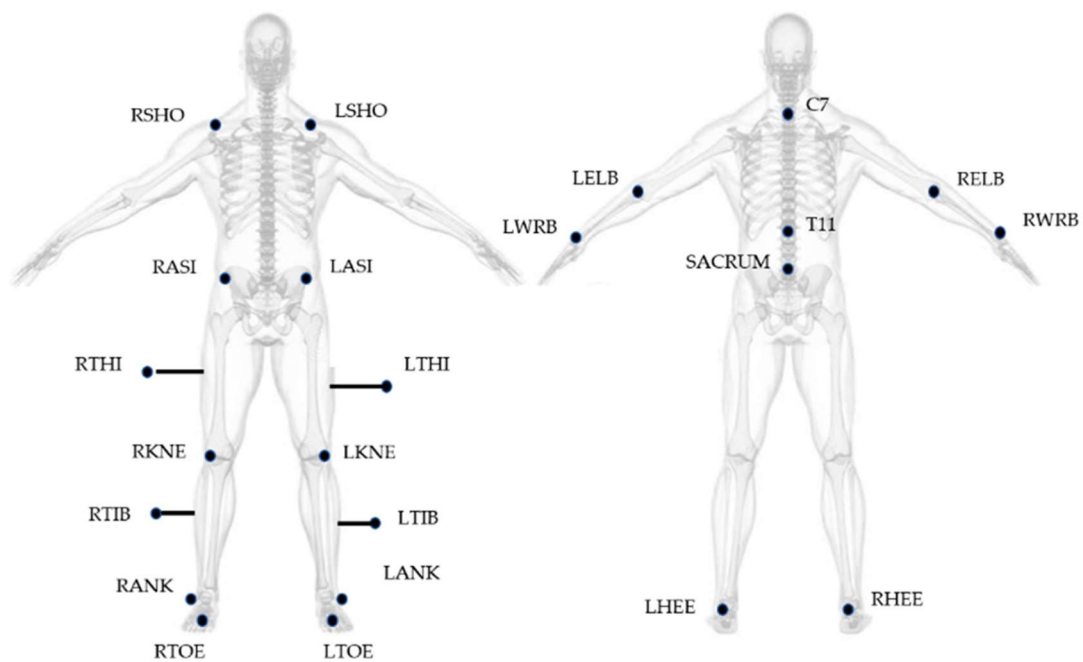


Figure 28 Position of markers according to the Davis Protocol: RSHO + LSHO = right + left acromioclavicular joint; RASI + LASI = right + left anterior superior iliac spine; RTHI + LTHI = right + left thigh; RKNE + LKNE = right + left lateral epicondyle; RTIB + LTIB = right + left tibia; RANK + LANK = right + left lateral malleolus; RTOE + LTOE = right + left second metatarsal head; C7 = 7th cervical vertebrae; T11 = 11th thoracic vertebrae; LELB + RELB = left + right elbow; LWRB + RWRB = left + right wrist bar pinkie side; LHEE + RHEE = left + right calcaneus (8)

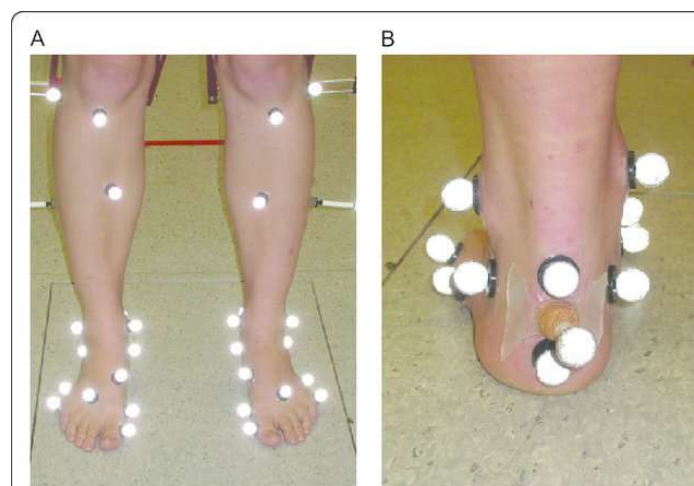


Figure 29 Positioning of the OFM markers in the anterior view (A) and the posterior view (B) (7)

Furthermore, we used the oxford foot model (OFM) extension (Figure 29) to capture and evaluate foot kinematics according to the recommendations of Stebbins et al (120) and Carson et al(11), as it “*is a multi-segment model for calculating hindfoot and forefoot motion.*” (121).

With the OFM, motion measurements between different sections of the foot (tibia, hind- and forefoot and hallux) are possible (Figure 30). (11)

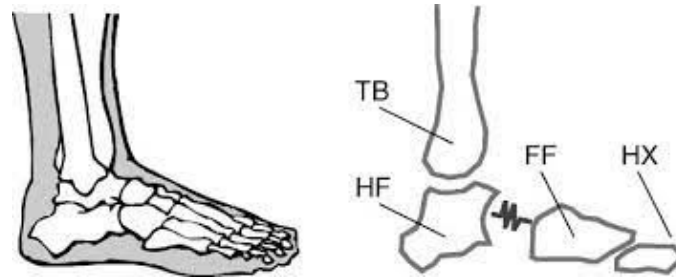


Figure 30 OFM by Carson with “TB Tibial segment (tibia and fibula), HF-Hindfoot (calcaneus and talus), HX-Hallux (hallux proximal phalanx)”(11)

The repeatability of OFM has been adequately demonstrated for adults and children, as well as for healthy individuals and patients with disorders/pathologies. (122)

The kinematic and kinetic data of the subjects were collected over at least five gait cycles. From this data, the average values were then calculated. The range of motion (ROM) values were measured during a whole gait cycle, while in the stance phase, minimum, mean and maximum values were collected in the sagittal, frontal and transversal plane. Taking into account the determined centre of pressure (COP), the ground reaction forces (GRF) and the joint kinematics, the joint kinetics (joint moments and forces) were calculated.

2.2.6 Handheld dynamometry

Since clubfoot deformity is often associated with muscular atrophy of the legs, which increases with growth (123), ankle strength was measured for the first time in our study participants, to determine if there are differences in muscle strength between the two groups. A handheld dynamometer (HHD) was used to compare the dorsal- and plantar flexion torques between the two groups. The HHD measures the force exerted on it in Newtons [N]. The HHD was placed plantar to the metatarsal heads to measure force during plantar flexion and dorsal to the metatarsal heads to measure dorsiflexion. During the plantar flexion force measurement, the subjects were in a supine position with their feet facing the wall to which the HHD was attached. In contrast, the force in the direction of dorsiflexion was measured in a seated position with the feet flat on the floor. The examiner then placed the HHD on the dorsum of the foot above the metatarsal heads. For each direction of movement (dorsiflexion and plantar flexion), three attempts were performed in which the patient was asked to try to build up maximum force within five seconds. Each patient had an additional attempt if one failed. Before each attempt, care was taken to ensure that the angle between the foot and lower leg was always 90 degrees.

The torque in Newton*meter [NM] for each direction of movement (plantar and dorsiflexion) was calculated by multiplying the moment arm (distance between the centre of the ankle and the metatarsal heads) by the isometric force [N].

Currently, force measurement with an isokinetic dynamometer (ID) is the gold standard. However, in comparison, the HHD is cheaper, portable, and also provides reliable and valid test data. (124)

One limitation of hand dynamometry is that the examiner must be stronger than the patient when holding the device in hand in order to be able to hold the dynamometer in exactly the same position. (125)

2.2.7 Short-form-36 (SF-36) questionnaire (Appendix V)

The SF-36 questionnaire is a measurement instrument to assess subjectively perceived health-related quality of life. There have been a variety of iterations of this questionnaire.

The version used in our study is better known as RAND SF-36.

As the name suggests, the SF-36 questionnaire contains 36 questions on eight health-related categories: Physical functioning, physical pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue and general health perception. Scores for each category range from 0 to 100 with a higher score indicating a better health condition. (126, 127)

Originally developed as part of an insurance study, the SF-36 has now become the most widely used measurement instrument internationally for assessing subjective health and quality of life. (128) The SF-36 was evaluated using the “Free online SF-36 score calculator” provided by OrthoToolKit. (129)

2.2.8 PODCI: Adolescent Outcomes Questionnaire (self reported) (Appendix VI)

The Pediatric Outcomes Data Collection Instrument (PODCI) was first published in 1998 by Daltroy et al. to measure changes after orthopaedic treatment. (130) The questionnaire is especially designed for adults and children with musculoskeletal problems. Changes in pain, ability to participate in normal daily activities, activity level and overall health are assessed with this questionnaire.

Depending on the patient collective, 86 or 83 questions are asked about the following scales:

- global functioning
- happiness

- pain/comfort
- transfer and basic mobility
- upper extremity
- sports/physical functioning

A distinction is made between the following three PODCI questionnaires, adapted to the respective age of the patients:

- Pediatric Outcomes Questionnaire (parent reported): It consists of 86 items and is intended for children up to the age of 10.
- Adolescent Outcomes Questionnaire (parent reported): It also consists of 86 items and is used for patients aged 11-18 years.
- Adolescent Outcomes Questionnaire (self-reported): It consists of 83 items and is also used for patients aged 11-18 years (Appendix VI). The answer options available in the Pediatric Outcomes Questionnaire, which should indicate that the child is too young for certain activities, do not exist in this questionnaire. (131)

Since our patients were between 17 and 19 years old, we used the last questionnaires in the current follow-up. The subjects therefore had to answer the questions by themselves.

Although the Adolescent Outcomes Questionnaire (self-reported) is only intended for persons up to 18, we decided to use it for our two 19-year-old subjects as well, in order to be able to make comparisons with the previous studies. In our previous trials, parents answered the Pediatric Outcomes Questionnaire on behalf of their children, which is almost identical in content to the Adolescent Outcomes Questionnaire. After data collection, the data was entered into the analysis sheet (Microsoft Excel 2003) created by the AAOS to analyse the Adolescent Outcome Questionnaire.

“The majority of items are scored using a 1–5 range with 1 indicating the most positive response”. Therefore, higher scores indicate higher levels of disability and lower scores indicate better functioning for most items. (131)

Per scale the number of points for the standardised score can range from 0-100, higher scores representing less disability and better function. Since the interpretation of a standardised score between scales is not consistent, data from the US population was transformed for each scale so that the normative score for each scale is 50 (mean) with a SD of 10. This means that a patient who scores higher than 50 on a scale is above the average of the general health of the US population. Under 50 the patient is below the population health average. (131)

2.3 Statistics

For continuous parameters, mean, standard deviation, median, minimum and maximum was calculated and for categorical parameters, frequencies and relative frequencies.

Statistical analysis was performed by using Statistica (Statsoft, USA). Because of low number of participants, a non-parametric Mann-Whitney-U test was used to compare the results between the study groups. P-values of less than 0,05 were considered as statistically significant.

3 Results

Due to dropouts, already described in detail above, the number of participants in the surgical group was reduced to five people and nine clubfeet. In comparison, the number of participants and the number of clubfeet in the Ponseti group remained the same since the last follow-up. The mean follow-up time for both groups was 18 years with a SD of ± 0.764 in the Ponseti group and a SD of ± 0.292 in the surgical group, with a p-value of 0.943 indicating no statistical difference between these two treatment groups.

3.1 Examination

The physical examination showed that significantly higher dorsiflexion was possible in the Ponseti group, regardless of whether the knee was in an extended ($p=0.043$) or flexed position ($p=0.043$).

		Ponseti group (n=12)			Surgical group (n=9)		
	p-value	Mean (\pm SD)	Median	5% CI/ 95% CI	Mean (\pm SD)	Median	5% CI /95% CI
Max. ankle DF (extended knee)	0.043	9.6 (± 4.7)	10.0	3.4/8.0	4.4 (± 4.5)	3.0	3.0/8.6
Max. ankle DF (flexed knee)	0.043	13.9 (± 5.1)	15.0	3.6/8.7	10.1 (± 11.9)	10.0	8.0/22.8
Max. ankle PF (extended knee)	0.972	50.3 (± 15.3)	50.0	10.8/26.0	50.1 (± 16.2)	50.0	10.9/31.0
Max. ankle PF (flexed knee)	0.594	54.8 (± 16.9)	52.0	11.9/28.6	48.3 (± 24.6)	50.0	16.6/47.1

Table 1: Results of goniometry of the ankle joint; DF= dorsiflexion, PF= plantarflexion

3.1.1 FRS – Functional Rating System

In the Ponseti group, no subject scored less than 86 points in the FRS total score. Thus, all but two subjects in this group achieved "excellent" results (90-100 points). The remaining two patients achieved "good" results (80-89 points).

In the surgical group, on the other hand, not a single subject was able to achieve the grade "excellent"; in fact, only two participants achieved the grade "good", all others were below it.

As shown in Table 2, the Ponseti group was superior to the surgical group in the FRS total score and in the categories "satisfaction", "function", "pain" and "passive motion".

		Ponseti group (n=12)			Surgical group (n=9)		
	Maximum FRS score	Mean (± SD)	Median	5% CI/ 95% CI	Mean (± SD)	Median	5% CI /95% CI
Satisfaction (p= 0.012)	20	20.0 (± 0.0)	20.0	0/0	16.0 (± 4.0)	16.0	2.7/7.7
Function (p=0.012)	20	20.0 (± 0.0)	20.0	0/0	16.0 (± 3.5)	16.0	2.3/6.6
Pain (p=0.003)	30	28.5 (± 2.7)	30.0	1.9/4.6	18.7 (± 7.6)	18.0	5.1/14.6
Position Heel standing (p=0.859)	10	9.2 (± 1.9)	10.0	1.4/3.3	8.9 (± 2.2)	10.0	1.5/4.2
Passive motion (p=0.012)	10	5.9 (± 2.1)	7.0	1.5/3.6	3.0 (± 2.4)	2.0	1.6/4.6
Gait (p=0.619)	10	9.7 (± 1.2)	10.0	0.8/2	9.1 (± 1.8)	10.0	1.2/3.4
Total (p<0.001)	100	93.3 (± 3.8)	93.5	2.7/6.4	71.7 (±12.9)	73	8.7/24.6

Table 2: Results of the FRS. The statistically significant categories are marked in bold. The total score can be interpreted as follows: 90-100 points as „excellent“, 80-89 points as „good“, 70-79 points as “fair” or as “poor” for feet with less than 70 points.

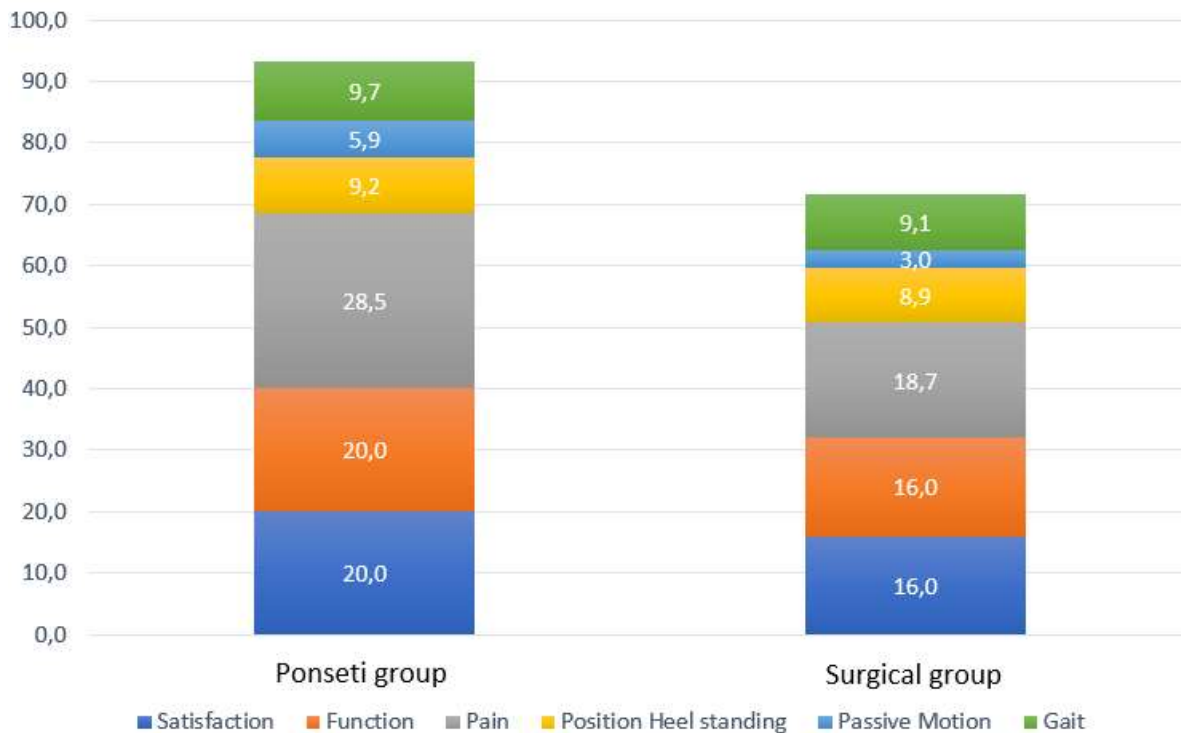


Figure 31 Illustration of FRS results (mean values) showing the superiority of the Ponseti group in each subcategory compared to the surgical group.

As shown in figure 31, the biggest difference between the groups was found in the FRS subcategory "pain". With a mean of 28.5 (± 2.7), the Ponseti group performed significantly better than the surgical group with a mean of 18.7 (± 7.6). In the surgical group, only one person reported being pain-free. All others claimed at least intermittent pain or pain during certain activities. All patients in the Ponseti group reported that they could manage their daily life without any problems, while only two people in the surgical group (n=3 CTEVs) had no difficulties with their clubfeet at all in everyday life.

3.1.2 ICFSG

None of the patients in both groups received an "excellent" (0-5 points) or "poor" (over 30 points) result in the ICFSG total score. Nevertheless, there was a statistically significant difference in favour of the Ponseti group (Table 3). In the Ponseti group, no patient scored worse than "good" (6-15 points), while in the surgical group 2 patients (n=4 CTEVs) scored "fair" (16-30 points). A statistically significant difference ($p=0.004$) between the groups was also found in the functional evaluation of the ICFSG protocol. This can be explained on the one hand by the fact that in the surgical group only one patient reported being pain-free, and on the other hand that in the Ponseti group only two patients reported having pain, and that only during physical activity or sport. In addition, two subjects (n= 3 CTEVs) in the surgical group showed limitations in dorsiflexion, while only one patient in

the Ponseti group was limited in this movement. Another patient in the surgical group had a significant reduction of strength in the triceps surae muscle due to atrophy.

In regard to morphology, fewer flat foot and pes cavus deformities occurred in the Ponseti group compared to the surgical group. In addition, no midfoot supination/pronation was observed in the Ponseti group, whereas this occurred in two patients (n=4 CTEVs) in the surgical group. Although there was no significant difference between the two groups in the ICFSG categories "radiological evaluation", the radiographs of the surgical group showed a flat-top talus significantly more often (p= 0.016, surgical group: $\emptyset=0.9 \pm 0.5$, Ponseti: $\emptyset=0.3 \pm 0.3$).

	p-value	Ponseti group (n=12)			Surgical group (n=9)		
		Mean (\pm SD)	Median	5% CI/ 95% CI	Mean (\pm SD)	Median	5% CI /95% CI
Functional evaluation	0.004	0.8 (\pm 1.3)	0.0	0.9/2.3	3.7 (\pm 2.1)	3.0	1.4/3.9
Morphology	0.014	2.3 (\pm 1.2)	2.0	0.8/2.0	3.9 (\pm 1.4)	4.0	0.9/2.6
Radiologic evaluation	0.145	5.0 (\pm 1.8)	5.0	1.3/3.1	6.7 (\pm 2.3)	5.0	1.6/4.5
Total	0.001	8.2 (\pm 2.2)	7.5	1.6/3.8	14.2 (\pm 3.7)	12.0	2.5/7.0

Table 3: Results of the ICFSG. Statistically significant categories are marked bold; the total score of ICFSG can be interpreted as follows: “excellent” (0-5 points), “good” (6-15 points), “fair” (16-30 points) and “poor” (>30 points).

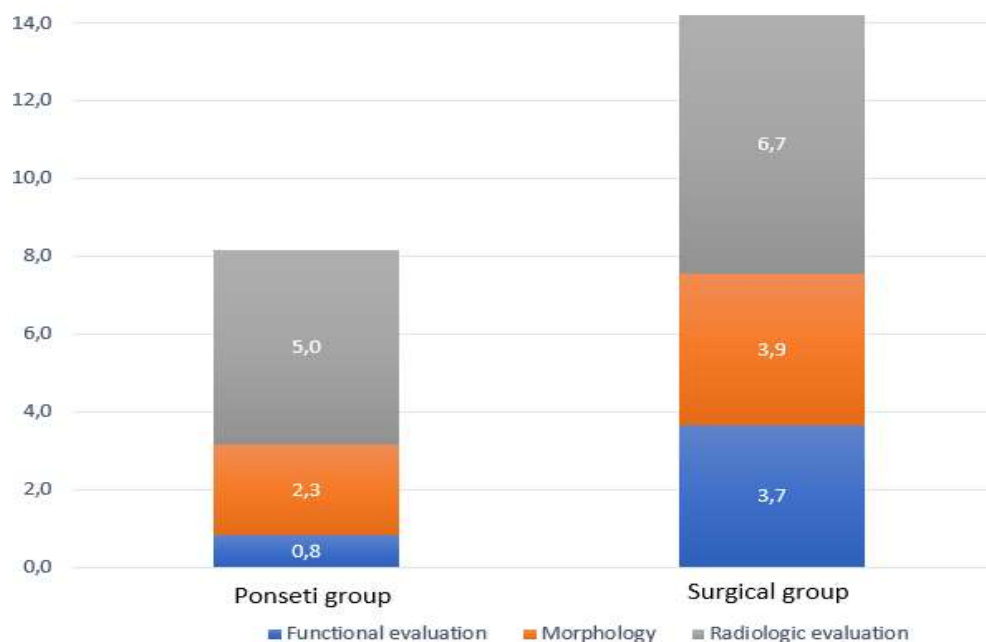


Figure 32 Illustration of ICFSG results (mean values) showing the Ponseti group scoring better (=lower) in each subcategory compared to the surgical group.

3.1.3 AOFAS Midfoot Scale

In the surgical group, no subject achieved the full score of 100 on the AOFAS midfoot scale, while this was achieved by 4 subjects in the Ponseti group (n= 5 CTEVs). This is mainly due to the fact that all but one patient in the surgical group reported pain. As already mentioned above all patients in the Ponseti group reported that they could manage their daily life without any problems, while most of the surgical group participants had some sort of limitations in their everyday life. As a result, the Ponseti group performed better in terms of function.

		Ponseti group (n=12)			Surgical group (n=9)		
	Max. AOFAS score	Mean (± SD)	Median	5% CI/ 95% CI	Mean (± SD)	Median	5% CI /95% CI
Pain (p=0.006)	40	37.5 (± 4.5)	40.0	3.2/7.7	25,6 (±11.3)	30.0	7.6/21.7
Function (p=0.039)	45	43.4 (± 2.2)	45.0	1.6/3.7	39.1 (± 5.6)	40.0	3.8/10.8
Alignment (p=0.060)	15	11.5 (±3.7)	11.5	2.6/6.2	8.0 (± 0.0)	8.0	0.0/0.0
Total (p=0.001)	100	92.4 (± 8.4)	94.0	6.0/14.3	72.7 (±14.2)	77.0	9.6/27.1

Table 4: Results of the AOFAS Midfoot Scale. The statistically significant categories are marked in bold.

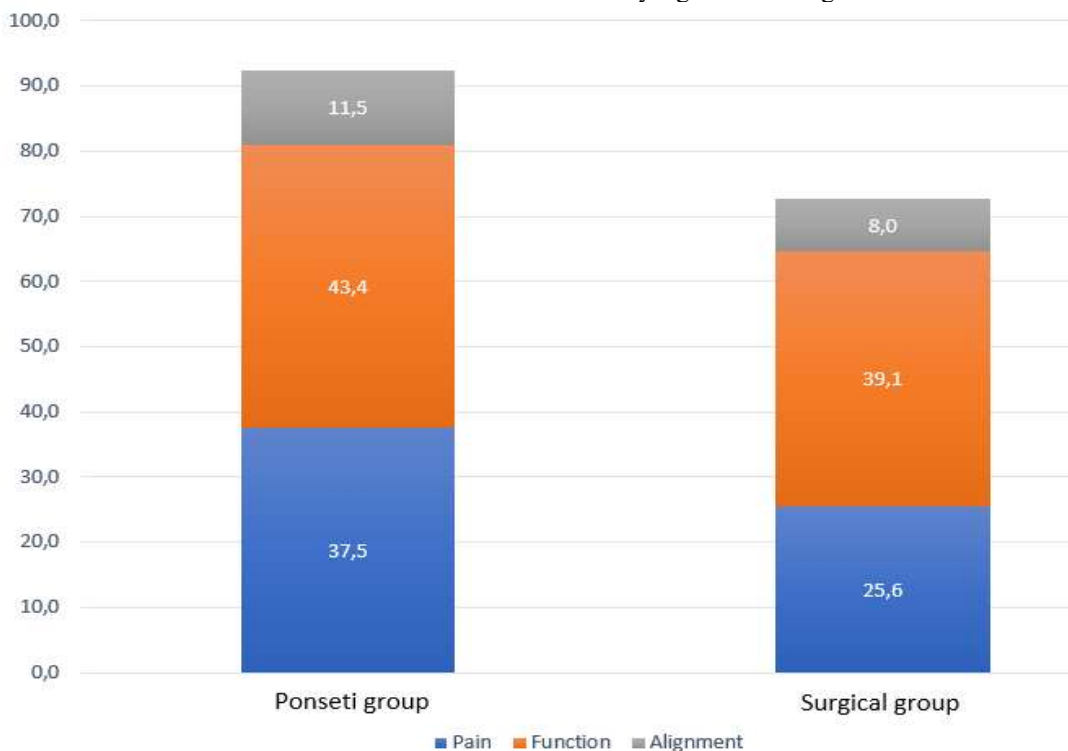


Figure 33: Graph of AOFAS Midfoot scale results (mean values) showing that the Ponseti group is superior in each subcategory compared to the surgical group.

3.1.4 AOFAS Ankle-Hindfoot Scale

In the AOFAS scale for the ankle and hindfoot, 5 patients (n= 6 CTEVs) reached the total score of 100 points, while none in the surgical group could reach the maximum score. The reasons for this are the same as for the AOFAS midfoot scale results.

	Max. AOFAS score	Ponseti group (n=12)			Surgical group (n=9)		
		Mean (± SD)	Median	5% CI/ 95% CI	Mean (± SD)	Median	5% CI /95% CI
Pain (p=0.006)	40	37.5 (± 4.5)	40.0	3.2/7.7	25.6 (±11.3)	30.0	7.6/21.7
Function (p=0.006)	50	49.5 (± 1.2)	45.0	1.6/3.7	43.0 (± 5.7)	32.0	3.9/10.9
Alignment (p=0.060)	10	7.5 (± 2.6)	11.5	2.6/6.2	5.0 (± 0.0)	5.0	0.0/0.0
Total (p=0.0003)	100	94.5 (± 6.8)	94.0	6.0/14.3	73.6 (±12.5)	76.0	8.4/23.9

Table 5 Results of the AOFAS Ankle-Hindfoot Scale. The statistically significant categories are marked in bold.

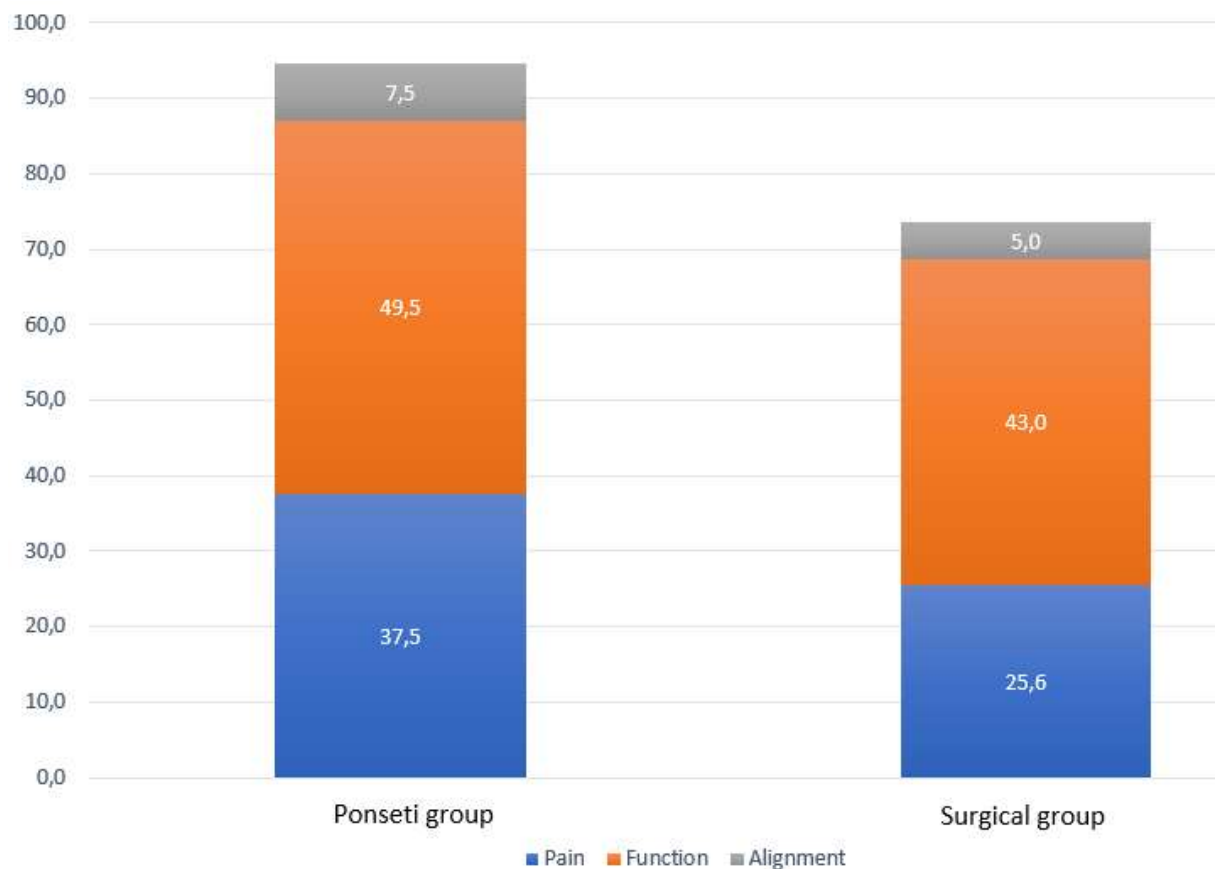


Figure 34 Illustration of AOFAS ankle-hindfoot results (mean values) showing the superiority of the Ponseti group in each subcategory compared to the surgical group.

3.2 3D gait analysis- Oxford Foot Model and Plug-in Models

In stance, hardly any differences could be found between the two groups in terms of movements (Table 7). However, as shown in table 6, during gait there were statistically significant differences in favour of Ponseti, including range of motion (ROM) of hindfoot rotation (HF) (p=0.031), ROM of ankle dorsi- and plantar flexion (p=0.004) and Gait Deviation Index Kinetic (GDI-k) (p=0.005). The GDI-k includes 9 kinetic gait curves: the moments from the ankle in the frontal and sagittal planes, as well as from the knee and hip, and the total joint force from the ankle, hip and knee. In addition, significantly higher maximum ankle power during walking was observed in the Ponseti group compared to the surgical group (p=0.002).

The ROM of plantar flexion/dorsiflexion of the forefoot in relation to the hindfoot during the gait cycle was statistically significant (p=0.003; surgical group: $\bar{\theta}=9.9 \pm 3.1$, Ponseti: $\bar{\theta}=16.9 \pm 2.8$).

	Ponseti group				Surgical group			
	n=	Mean (\pm SD)	Median	5% CI/ 95% CI	n=	Mean (\pm SD)	Median	5% CI /95% CI
Max. ankle power over GC (p= 0.002)	11	3.0 (\pm 0.7)	2.9	0.5/1.2	7	1.7 (\pm 0.6)	1.5	0.4/1.2
GDI (p=0.052)	11	91.2 (\pm 11.5)	94.4	8.1/20.2	8	79.9 (\pm 11.6)	75.0	7.7/23.7
GDI-k (p=0.005)	11	94.0 (\pm 6.9)	94.2	4.8/12.0	7	83.4 (\pm 5.4)	80.9	3.5/12.0
ROM of ankle dorsi- /plantarflexion over GC (p=0.004)	11	32.7 (\pm 7.1)	22.5	2.6/7.9	8	22.5 (\pm 3.9)	33.4	4.9/12.4

Table 6 Kinetic and kinematic parameters of the 3D gait analysis over the gait cycle, statistically significant results are marked in bold; ROM=range of motion, GC= gait cycle, GDI =Gait Deviation Index, GDI-k: Gait Deviation Index Kinetic

	Ponseti group				Surgical group			
	n=	Mean (± SD)	Median	5% CI/ 95% CI	n=	Mean (± SD)	Median	5% CI /95% CI
Max. HF dorsiflexion in stance (p= 0.651)	11	4.4 (± 6.9)	6.1	4.8/12.0	6	9.9 (± 16.6)	6.4	10.4/40.8
Mean HF rotation in stance (p= 0.451)	11	8.8 (± 8.0)	11.5	5.6/14.0	6	1.4 (± 19.4)	7.9	12.1/47.5
Mean HF inversion in stance (p= 0.248)	11	-6.3 (±5.6)	-5.5	3.9/9.9	6	-4.3 (± 8.9)	-1.8	5.6/21.9
ROM HF dorsiflexion/plantarflexion over GC (p= 0.291)	11	22.0 (± 4.8)	21.3	3.4/8.5	6	19.7 (± 2.4)	20.1	1.5/5.8
ROM HF rotation over GC (p= 0.031)	11	15.6 (± 5.6)	14.7	3.9/9.9	6	10.1 (± 2.3)	10.2	1.5/5.7
ROM HF inv./eversion over GC (p= 0.393)	11	9.8 (± 2.9)	9.7	2.0/5.1	6	8.7 (± 2.5)	8.4	1.5/6.1
Max. FF dorsiflexion in stance (p=0.960)	11	16.5 (± 5.2)	16.3	3.6/9.1	6	16.5 (± 4.2)	16.4	2.6/10.4
Mean FF adduction in stance (p=0.514)	11	6.8 (± 8.2)	8.4	5.7/14.3	6	7.0 (± 16.0)	13.3	10.0/39.3
Max HX dorsiflexion in stance (p=0.802)	11	10.5 (± 8.7)	6.7	6.0/15.2	6	20.7 (± 35.0)	10.9	21.8/85.8

Table 7: Stance parameters of 3D gait analysis using Oxford Foot Model and plug-in gait model; statistically significant results are marked in bold; ROM= range of motion, HF= hindfoot, FF= forefoot, HX=hallux

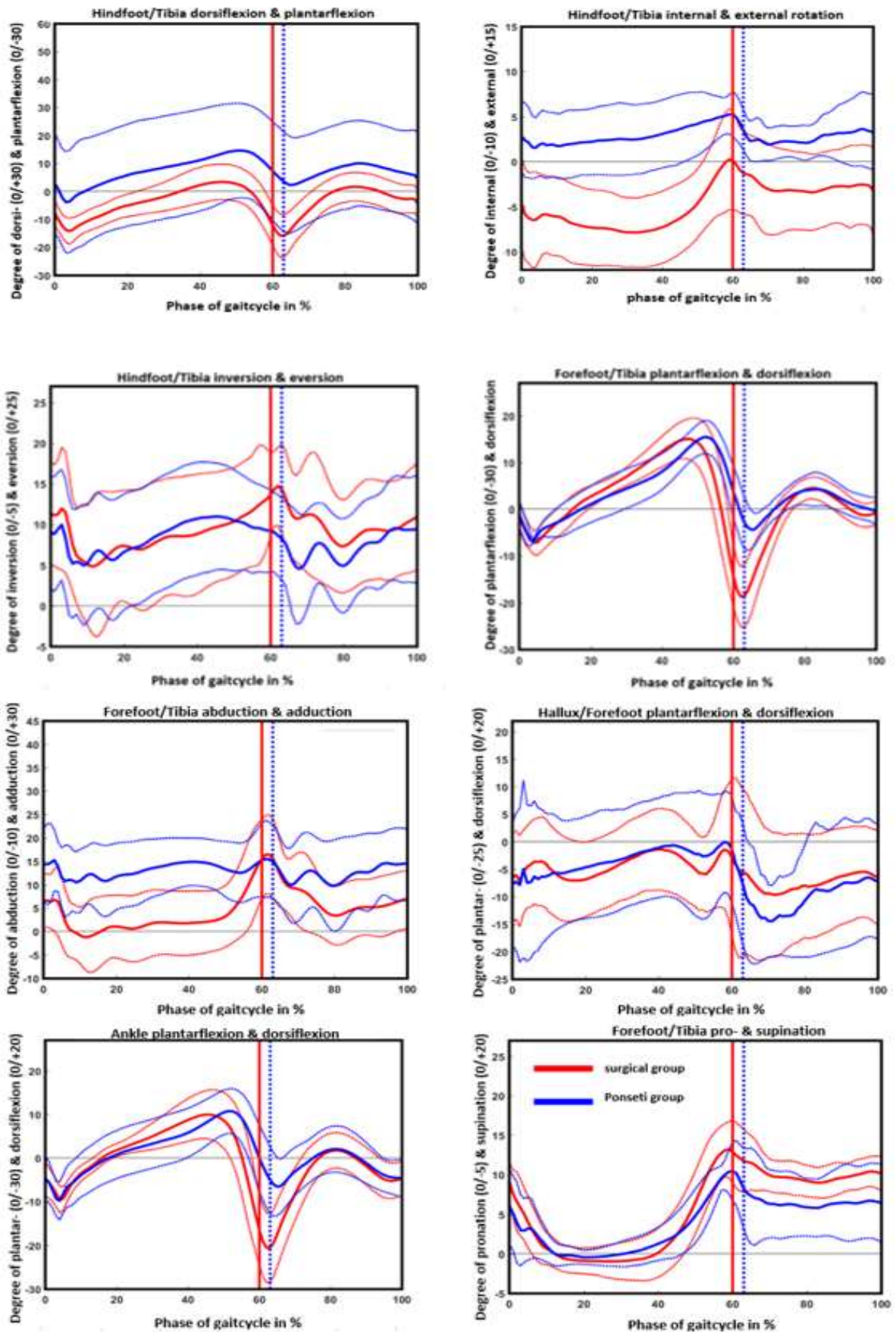


Figure 35: Graphical results of Oxford foot model data comparing Ponseti and surgically treated clubfeet (mean \pm SD). The motion of ankle joint, subtalar joint, Chopart joint line and hallux are illustrated separately.

3.3 Handheld dynamometry (HHD)

No statistical significance was found when comparing the dorsiflexion torque and the plantar flexion torque between the two groups. The standard deviation of the mean value of the plantar flexion moment of the Ponseti group is increased with SD= 25.3, which indicates a higher statistical spread. This can be explained by the fact that one patient (n= 2 CTEVs) of the Ponseti group is to be considered a statistical outlier due to his job-related better physical constitution (carpenter). This subject achieved an average plantarflexion torque of 92.4 Nm (=maximum of Ponseti group) with one leg and 72.6 Nm with the other leg.

	p-value	Ponseti group (n=12)			Surgical group (n=9)		
		Mean (± SD)	Median	5% CI/ 95% CI	Mean (± SD)	Median	5% CI /95% CI
Plantar flexion torque	0.070	43.8 (± 25.3)	37.8	17.9/42.9	21.8 (± 4.9)	22.3	3.3/9.4
Dorsal flexion torque	0.594	21.3 (± 9.8)	20.7	7.0/16.7	22.5 (± 6.5)	24.4	4.4/12.5

Table 8: Results of HHD in Nm

3.4 Questionnaires

3.4.1 *PODCI: Adolescent Outcomes Questionnaire (self reported)*

The PODCI questionnaire shows better results in favour of the Ponseti group, especially in terms of happiness (p=0.005; surgical group: Ø=77.8 ±10.6, Ponseti: Ø=93.3 ±10.1) and pain/comfort (p=0.007; surgical group: Ø=73.4 ±29.6, Ponseti: Ø=99.1 ±3.2) for the reasons already mentioned above regarding the increased pain and limitations in daily life in the surgical group.

		Ponseti group (n=12)			Surgical group (n=9)		
	p-value	Mean (± SD)	Median	5% CI/ 95% CI	Mean (± SD)	Median	5% CI /95% CI
Happiness: Std. Mean	0.005	93.3 (± 10.1)	97.5	7.1/17.1	77.8 (± 10.6)	80.0	7.2/20.4
Pain Comfort: Std. Mean	0.007	99.1 (± 3.2)	100.0	2.2/5.4	73.4 (± 29.6)	89.0	20.0/56.7
Transfer, basic mobility Std. Mean	0.414	100 (± 0.0)	100.0	0.0/0.0	98.9 (± 2.2)	100.0	1.5/4.2
Sports Physical Functioning Std. Mean	0.776	95.4 (± 4.7)	95.0	3.3/7.9	90.8 (± 13.2)	94.0	8.9/25.4
Upper extremity Std. Mean	0.972	100.0 (± 0.0)	100.0	0.0/0.0	100.0 (± 0.0)	100.0	0.0/0.0
Global Functioning: Mean of Std. Means	0.055	98.7 (± 1.6)	99.0	1.1/2.7	90.6 (± 11.2)	95.0	7.5/21.4
Global Functioning Scale: Norm. Score	0.065	55.3 (± 2.1)	56.0	1.5/3.5	44.6 (± 15.3)	51.0	10.3/29.3

Table 9 Results for PODCI questionnaire; statistically significant headings are marked bold.

3.4.2 SF-36

The Short Form-36 questionnaire shows a statistically significant better result in favour of the Ponseti group in the categories "general health" (p= 0.036; surgical group: \bar{X} =77.8 ±17.3, Ponseti: \bar{X} =91.7 ±12.1), "health change" (p= 0.017; surgical group: \bar{X} =38.9 ±13.2, Ponseti: \bar{X} =60.4 ±16.7) and "pain" (p= 0.023; surgical group: \bar{X} =78.3 ±32.0, Ponseti: \bar{X} =99.2 ±2.9).

	p-value	Ponseti group (n=12)			Surgical group (n=9)		
		Mean (± SD)	Median	5% CI/ 95% CI	Mean (± SD)	Median	5% CI /95% CI
General health	0.036	91.7 (± 12.1)	100.0	8.6/20.6	77.8 (± 17.3)	85.0	11.7/33.2
Health change	0.017	60.4 (± 16.7)	50.0	11.8/28.4	38.9 (± 13.2)	50.0	8.9/25.2
Pain	0.023	99.2 (± 2.9)	100.0	2.0/4.9	78.3 (± 32.0)	90.0	21.6/61.3
Physical functioning	0.070	97.5 (± 7.2)	100.0	5.1/12.3	92.2 (± 10.0)	95.0	6.8/19.2
Role limitations due to physical health	0.414	100.0 (± 0.0)	100.0	0.0/0.0	88.9 (± 22.9)	100.0	14.9/42.2
Social functioning	0.456	89.6 (± 24.9)	100.0	17.6/42.3	86.1 (± 17.1)	100.0	11.5/32.7
Role limitations due to emotional problems	0.546	86.1 (± 33.2)	100.0	23.5/56.4	100.0 (± 0.0)	100.0	0.0/0.0
Emotional well-being	0.670	75.3 (± 21.4)	80.0	15.2/36.4	81.8 (± 10.0)	80.0	6.8/19.2
Energy/fatigue	1.000	59.6 (± 24.5)	70.0	17.4/41.7	59.4 (± 19.9)	55.0	13.5/38.1

Table 10 Results for SF-36 questionnaire in percentage calculated with the “Free online SF-36 score calculator” provided by OrthoToolKit(129); statistically significant headings are marked bold.

4 Discussion

Numerous studies (16, 17, 104, 132, 133) have already compared the results of the Ponseti method with those of the surgical method, but most of them only referred to childhood. Only a few studies examined the long-term comparison of the two methods. Studies comparing the outcome of Ponseti treatment and surgical treatment in adulthood are a rarity. Most of the studies conducted on this topic concluded that the Ponseti method is superior to the surgical method. (16, 17, 132, 133).

The aim of this study was to compare two therapy methods (Ponseti vs. pantalar release) in terms of mobility and function of the ankle joint as well as in terms of morphology, radiological aspects, and quality of life approximately 18 years after the start of therapy.

Our trial (third follow-up), now conducted in patients with adult feet, has shown that the Ponseti method is superior to the surgical method (pantalar release). Participants in the Ponseti group not only suffered from pain less frequently and less severely (FRS, ICFSG, AOFAS Ankle-Hindfoot and Midfoot Scale, PODCI, SF-36), they also showed a better outcome in terms of morphology (ICFSG, X-rays) and functionality (physical examination, FRS, ICFSG, OFM, AOFAS Ankle-Hindfoot and Midfoot Scale). In addition, participants treated according to the Ponseti method were happier overall (PODCI) and had better general health (SF-36) than participants in the surgical group. Moreover, a flat-top talus was found more frequently in patients from the surgical group. In the gait analysis, the Ponseti group showed higher ankle power, a more flexible ankle and better kinetic parameters than the surgical group.

In the physical examination, maximum dorsiflexion was significantly reduced in the surgical group compared to the Ponseti group. Nevertheless, the Ponseti group also had a decreased dorsiflexion with an average of $9.6^{\circ} (\pm 4.7^{\circ})$ compared to the foot of a healthy peer of the same age with about $20.9^{\circ} (\pm 7.1^{\circ})$ observed by Bok et al. (134)

Comparable results were also obtained by Smith et al. (132) in their surgical group (n=37 feet) regarding the measurement of dorsiflexion with the knee extended. Compared to their Ponseti group (n=29 feet), an average of 6.6 degrees less dorsiflexion was measured than in our group. (132) The mean ankle dorsiflexion of 11 degrees in patients (mean follow-up: 14.5 years) treated with the Ponseti method obtained in the systemic review by Rastogi et al. (135) is consistent with our measurements.

Smith et al. (132) also compared the two therapy groups (Ponseti vs. surgery group) with the feet of healthy subjects (control group with n=20 feet). In the physical examination, they were able to show that in both therapy groups, the dorsiflexion of the ankle joint as well as the eversion and inversion of the hindfoot were significantly reduced compared to the control group. In addition, Smith et al. observed greater plantar flexion of the ankle in the Ponseti group compared to the surgical group. (132) In the physical examination, we could not find any statistically significant differences in plantarflexion between the two groups that would fit to the findings of Smith et al. However, we observed a significant difference in ROM of ankle dorsiflexion and plantarflexion during walking between the Ponseti and surgical group. More detailed explanation follows in the discussion section on 3D gait analysis (OFM).

The evaluation of the Functional Rating System (FRS) results also showed that the Ponseti method was superior to the surgical group. Better results were achieved especially in the subcategories "satisfaction", "function", "pain", "passive movement" and in the total score. In the first follow-up study by Zwick et al., in which they examined the patients of our current trial at an average age of 3.5 years, it was shown that the patients in the Ponseti group performed better in the FRS subcategories "satisfaction" and "passive movement" than the patients of the surgical group of the same age. (16) In the second follow-up study by Svehlik et al. our patients (mean age: 9.8 years) showed a superiority in the FRS total score and the subcategory "pain" in favour of the Ponseti group. (17)

In our current trial, 78% of our participants in the Ponseti group achieved the rating "excellent", while no one in the surgical group was able to achieve this FRS top rating. Our findings were consistent with the results of the meta-analysis by Lykissas et al.. (133) They were able to show, although not in a statistically significant way, that patients in the Ponseti group achieved "excellent"/"good" results more often than patients with soft tissue release.

Dobbs et al. evaluated 73 clubfeet that were treated surgically, and none of them achieved an "excellent" result - as in our study. (104)

Using the International Clubfoot Study Group (ICFSG) protocol, significant differences were found between the two groups. With the exception of the subcategory "radiological evaluation", the Ponseti group performed significantly better than the surgical group in all other ICFSG categories. Due to the lower dorsiflexion in the patients who were treated surgically and the fact that only one subject in this group reported complete freedom from pain, the result in the "functional evaluation" was significantly worse than in the Ponseti group. The increased occurrence of pain in long-term comparison after soft tissue release has already been described by several authors. (17, 104, 136) In addition to pain, increased stiffness and a tendency to residual deformity due to scarring are observed in clubfeet treated surgically. (137)

Graf et al. (136) found a correlation between foot morphology and pain in young adults. Therefore, compared to the Ponseti method, surgical release resulted in long-term deformity to a greater extent. We also found that the patients who underwent a pantalar release more often had a pes cavus or flat foot, which in turn explains the poorer performance in the morphological subcategory of the ICFSG protocol.

Although the patients in our group hardly differed statistically in the radiological evaluation, a higher incidence of flat-top talus was observed in the surgical group. Several reports have shown that a flatter talus leads to a lower range of motion in the ankle joint. (138, 139) Furthermore, Kolb et al. (140) identified the flat deformity of the talus as a risk factor for development of arthrosis. In their study, Dobbs et al. found ankle and foot arthritis in 56% of their subjects aged 31 who had undergone surgery. (104)

The American Orthopaedic Foot and Ankle Society (AOFAS) midfoot and ankle-hindfoot scales were used to compare pain, satisfaction, function including activity level and alignment between the two groups. The Ponseti group showed better functionality in the midfoot, but especially in the ankle and hindfoot, and significantly less pain. Our results are in line with those of Smith et al (132), who also compared a Ponseti group with a surgical group comparable to our patient cohort, in terms of therapeutical approaches and age. Like us, they found a lower score on the AOFAS scales for the ankle hindfoot and midfoot to the disadvantage of the surgical group in the categories of pain and ankle-hindfoot function. The poorer functional scores in our surgical group can be explained by the already described limitation in sagittal motion (plantar flexion plus dorsiflexion) as well as by the increased occurrence of activity limitations. While most patients in the surgical group described at least some kind of limitation, the subjects in the Ponseti group had no limitations in daily life.

In contrast to our groups, Smith et al. (132) also found a significant decrease in alignment in the surgical group. Although the difference in alignment between our two treatment groups was not statistically significant, the Ponseti group scored on average 2.5 points higher on the AOFAS ankle-hindfoot and 3.5 points higher on the midfoot scale than the surgical group. However, the Ponseti group could not reach the score of healthy individuals, neither in the AOFAS midfoot nor in the ankle-hindfoot scale.

The Oxford Foot Model (OFM) can be used to obtain valid information about the gait kinematics and kinetics and thus also about forefoot and hindfoot movements in clubfoot patients. (11, 141) Compared to our last follow-up study conducted by Svehlik et al. (17) at an mean age of 9.8 years, no significant difference in maximum hindfoot dorsiflexion (tibia in relation to hindfoot) was found between the two groups in the current study with adult feet (mean age: 18 years). On the one hand, this can be explained by the significantly lower number of participants in the surgically treated group compared to the surgical group

at the last follow-up. In the study by Švehlik et al. seven subjects (n=12 clubfeet) of the surgical group were examined by using gait analysis. In the current follow-up study there were only five participants (n=6 clubfeet). Actually, gait analysis data of nine clubfeet of the surgical group should have been collected in the current study, but unfortunately data of three clubfeet are missing for inexplicable reasons.

On the other hand, the large standard deviation (± 16.6 with a mean of 9.9) in the surgical group in the current study causes the previously existing difference in maximum hindfoot dorsiflexion between the two groups (Ponseti vs. surgical group) to no longer be statistically significant.

Furthermore we could not confirm the increase in dorsiflexion of the forefoot in relation to the hindfoot in clubfeet as compensation for the reduced hindfoot dorsiflexion described by Theologis et al. (142) However, the lack of ankle power throughout the gait cycle, but especially during push-off, was remarkable in the surgical group compared to the Ponseti group. We suspect that this result is due to an insufficient lever arm for push-off caused by the greater instability of overcorrected clubfeet.

Although there were no statistically significant differences in the plantar flexion moment in our HHD measurements, considerable weakness of the plantar flexors was observed in the surgery group. The reduced ankle power of the surgical group is also reflected in a lower gait deviation index (GDI-k) of the same group. Gait deviation index (GDI) and GDI-k are used to quantify how far the kinematic (GDI) and kinetic (GDI-k) gait curves of the examined group deviate from the healthy norm population (100 points). (143, 144)

With an average kinetic gait deviation index of 94 points, our Ponseti group scored closer to the norm population than the surgical group with an average GDI-k of 83.4 points.

Therefore, our study has shown that the Ponseti group is superior in terms of gait kinetics (GDI-k).

Lööf et al. (145) found comparably high kinematic and kinetic values in patients treated according to the Ponseti protocol. For GDI data in patients treated surgically, we could only find one study conducted by Duffy et al. (146) They found a GDI of 91 in the Ponseti treated children and a GDI of 84 points in the surgical group. In comparison to the Ponseti group, our surgical group scored on average 4.1 points lower on the GDI. However, our two Ponseti groups were comparable in terms of gait kinematics. Nevertheless, both groups are below the kinetic and kinematic gait curves of the normal population. The assessment of the gait deviation index for kinematics and kinetics could be useful to get an overview of gait pathology in CTEVs. Our study also showed that the Ponseti group had a

significantly higher ankle range of motion (dorsiflexion + plantarflexion) over the gait cycle compared to the surgical group. This result is consistent with our data from the clinical examination, the ICFSG and FRS protocols.

As mentioned above, with the use of handheld dynamometry (HHD), we were able to determine that the subjects in the surgical group had worse values for the plantar flexion torque compared to the Ponseti group. Our results are consistent with the measurements of Smith et al. (132), who also found greater plantar flexor weakness in the surgical group compared to the Ponseti group. Moraux et al. (125) measured the plantar- and dorsiflexion torque of the ankle in healthy subjects aged 15 to 19 years. On average, healthy individuals in this age cohort achieved a torque of 36.9 Nm for dorsiflexion and 114.6 Nm for plantar flexion. Neither our surgical group nor the Ponseti group could reach the strength values of the healthy subjects. However, the most striking difference is in the plantar flexion torque of the ankle, with the Ponseti group achieving 70.8 Nm less on average and the surgical group 92.8 Nm less. We attribute this difference mainly to muscle atrophy and the resulting weakness of the plantar flexion muscles, as this phenomenon has already been described for clubfeet in various studies. It was found that mainly the posterior tibialis muscle and the triceps surae muscle are affected by atrophy and shortening. Since congenital talipes equinovarus is a genetic disease, the muscle change could be caused by the expression of pathological genes. However, further research is needed. (147)

Although the Pediatric Outcome Data Collection Instrument (PODCI) is not a specific questionnaire for patients with clubfeet, it is a quick and useful tool for detecting changes in pain, ability to participate in normal daily activities, activity level and overall health after orthopaedic treatment. (131) We used this instrument again to compare our results with those of our previous trials conducted by Zwick et al. (16) and Švehlik et al. (17). In the last two follow-ups, the parent-specific PODCI questionnaire was used, in which parents were asked questions about their children. In the current study, patients were self reported using the Adolescent Outcomes Questionnaire. While Zwick et al. (16) could not find any significant differences between the two groups in the PODCI, Švehlik et al. (17) found significant differences in favour of the Ponseti group. *“The most important statistically significant differences were found within the PODCI section of “sports and physical functioning”, “pain and comfort” and “happiness”.*” (17) In our current trial, the two therapy groups only show statistically significant differences in the categories

"happiness" and "pain, comfort", due to the already mentioned increased pain and limitations in daily life in the surgical group. When interpreting the results of the PODCI subcategory "happiness", it should be taken into account that our study was conducted in the middle of the COVID-19 pandemic and that especially adolescents were more vulnerable to depression, anxiety and stress during this time. (148) Despite this psychologically challenging time, the subjects in the Ponseti group were more satisfied than those in the surgical group. This finding was already evident in the last follow-up study by Svehlik et al. in which the subjects in the Ponseti group (regardless of the pandemic) also achieved better scores in the PODCI subcategory "happiness". Furthermore, we did not find any other clubfoot study with a similar patient group using the Adolescent Outcomes questionnaire with which we could compare our results.

In order to be able to compare the health-related quality of life of our subjects with that of the norm population and other study groups with clubfoot patients, we used the widely used Short Form 36 (SF-36) questionnaire. The Ponseti group also scored better on the SF-36 compared to the surgical group, especially in the headings "general health", "health change" and "pain". In the study by Smith et al. (132), the Ponseti group was significantly better than the surgical group only in the "pain" category. They also found that the patients who had undergone surgery were far more affected by pain. In their study, Ponseti was on par with the healthy group, except in the subcategories of "general health" and "physical functioning". Dobbs et al. (104) measured below the normative data mean in all SF-36 categories in the patient population that underwent surgery. This stands in contrast to the data of Hsu et al. (149) whose cohort with surgically treated clubfeet was above the norm of the general population in all SF-36 scales.

This study has numerous limitations: Firstly, the small number of study participants. The reason that a total of only 19 subjects took part in the study was that the local ethics committee demanded a recruitment stop in 2003 after an interim report showed that more surgical procedures than simple tenotomies were performed in the surgical group. (16) Originally, a sample size of 23 clubfeet per treatment group was calculated. For the reasons mentioned above, this could not be kept. However, the study by Zwick et al. (16) led to a change in the treatment protocol at our centre. The surgical approach was replaced by the Ponseti method as the gold standard therapy in clubfoot treatment. Unfortunately, by the time of the current study, the already small number of subjects had been reduced to 13

patients (four women and nine men) with 21 clubfeet. The reasons for this were, on the one hand, the move to a region far away from our centre and, on the other hand, the unwillingness to participate in the study again. In addition, 2 patients dropped out of the Ponseti group at that time because the parents decided against the treatment and the children received a posteromedial release.

Another aspect that should be considered when interpreting the results of this study is that three patients in the Ponseti group (n= 4 feet) and four subjects in the surgical group (n= 6 feet) required revision surgery.

In the surgical group, anterior tibial tendon transfer was performed in three patients (n=4 feet) and major revision surgery with partial release in one patient (n=2 feet). Furthermore, one patient of the surgical group (n=2 feet) even required an "*opening wedge medial cuneiform osteotomy and closing wedge cuboid osteotomy*" after the anterior tibial tendon transfer. (17) In contrast, in the Ponseti group, two patients (n=2 feet) underwent anterior tibial tendon transfer, and one subject (n=2 feet) required a second achillotomy. With the exception of one patient, all patients with bilateral clubfeet received the same treatment for both feet.

Another limitation is that it was unfortunately not possible to blind the investigators of the current study because the surgical scars were clearly visible.

Furthermore, the unequal number of group participants should be considered when interpreting the gait analysis data. Unfortunately, this is due to an unexplained loss of data. As a result, the automatically stored gait analysis data of one clubfoot in the Ponseti group and most of the data of three clubfeet in the surgical group are missing. Since gait analysis is very time-consuming and some of the subjects had to travel very long distances to our centre, we decided not to repeat the gait analyses that resulted in data loss for the benefit of the patients.

All these factors should be considered when interpreting the results of this study.

Nevertheless, our trial shows that even the adult foot treated with the Ponseti method at the time is superior to the surgically treated clubfoot in terms of functionality, pain, ankle strength, morphology, quality of life, gait kinematics and kinetics. Furthermore, the use of the Ponseti method leads to less frequent and less invasive revision procedures compared to the pantalar release. The Ponseti method is therefore rightly considered the gold standard therapy, as it is a less invasive and relatively inexpensive procedure that can be

used in a wide range of patients, even if it does not perform better in all studies. (16, 17, 132, 136, 150)

Unfortunately, there are still very few long-term studies that focus primarily on the adult former clubfoot. However, this would be necessary to ensure good and evidence-based care for patients with congenital talipes equinovarus beyond childhood.

Although most paediatric orthopaedic specialists agree that the Ponseti method should be the first therapy of choice, it should not be forgotten that the treated clubfoot does not (yet) approach the healthy foot in some aspects. At this point, the question must be asked whether this will ever be possible?

Using standardised classification systems and 3D gait analysis, data can be collected from early childhood to adulthood to modify the Ponseti method and achieve the best possible outcome at each stage of life. Some authors recommend 3D gait analysis as early as possible (e.g. at the age of five) in order to detect possible deformities or gait pathologies at an early stage. (145)

The pathophysiology of muscle weakness or atrophy associated with clubfeet is also not yet fully understood. Further research is needed in this field as well (147), in order to be able to better compensate for muscle weakness through modified therapies in the future. Since clubfoot patients are more likely to develop osteoarthritis in adulthood (151), the risk factors for the development of arthritis should be identified even more precisely in order to prevent it in the best possible way.

Currently, the Ponseti method is the best possible treatment option of congenital talipes equinovarus.

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6 Appendices

Appendix I: Outcome Evaluation Rating System by the ICFSG (International Clubfoot Study Group) (113)

Rating system listing

I. Morphology

	Score		
A. Hindfoot			
1. Varus or valgus	0	1 (10°)	2 (>10°)
2. Equinus or calcaneus	0	1 (10°)	2 (>10°)
B. Midfoot			
1. Supination or pronation	0	1 (10°)	2 (>10°)
2. Adduction or abduction	0	1 (10°)	2 (>10°)
C. Global alignment of the foot			
1. Rotation: medial or lateral (thigh-knee foot angle)	0	1 (10°)	2 (>10°)
2. Pes cavus or flat foot	0	1 (10°)	2 (>10°)
Maximum			12

II. Functional evaluation

	Score		
A. Passive motion:			
1. Ankle			
i. Dorsiflexion	0	1 (0°)	2 (negative)
ii. Plantar flexion	0	1 (10°)	2 (0° or negative)
2. Subtalar varus-valgus	Flexible/stiff	0	1
3. Midtarsal joint motion: pronation-supination	Flexible/stiff	0	1

B. Muscle function

	Normal	Moderate	Severe
Jones' classification	(5,4)	(3)	(2,1,0)
1. Triceps surae	0	1	2
2. Toe flexors	0	1	2
3. Extensors	0	1	2
4. Anterior tibia tendon	0	1	2
5. Extensor Hallicis Longus	0	1	2
6. Posterior tibia tendon	0	1	2
7. Peroneal tendon	0	1	2
8. Flexor Hallicis Longus	0	1	2

C. Dynamic function

	None	Positive	
1. Gait			
i. Intoeing (medial rotation)	0	1 (10°)	2 (>10°)
ii. Calcaneus	0	1 (10°)	2 (>10°)
iii. Equinus	0	1 (10°)	2 (>10°)
iv. Dynamic supination	0	1 (10°)	2 (>10°)
v. Limping	0	1	
vi. Ability to run	1	0	
vii. Ability to jump	1	0	
2. Shoe wear	Normal 0		Abnormal 1
3. Heel walking or toe walking	Yes 0		No 1

D. Pain

1. No pain	0		
2. Pain with activity	1		
3. Pain with sports	2		
4. Constant	3		
Maximum			36

III. Radiologic evaluation

	Score	
	Normal	Abnormal
A. Standing anteroposterior views (in weight bearing position)		
1. Talo-calcaneal angle	0	1
2. Cuboid-calcaneo alignment	0	1
3. Cubo-M5 axis	0	1
4. Talo-M1 angle	0	1
5. Talo-navicular position	0	1
B. Standing lateral views (foot in weight bearing position)		
1. Talo calcaneal angle	0	1
2. Tibio-calcaneal angle	0	1
3. Talo-navicular position	0	1
4. Talo-M1 axis	0	1
5. Calcaneo-M5 axis	0	1
6. Flat top talus	0	1
C. Ankle anteroposterior standing (Posterior border of medial and lateral malleoli lined up at same plane when taking radiograph)	0	1
Maximum		12

Scores are from 0 for a perfect result to 60 for the worst result.

Classification of results

'Excellent'	0-5
Good	6-15
Fair	16-30
Poor	>30

Appendix II: FRS (Functional Rating System) by Laaveg and Ponseti (18)

FUNCTIONAL RATING SYSTEM FOR CLUB FOOT

Category	Points
Satisfaction (20 points)	
I am	
a) very satisfied with the end result	20
b) satisfied with the end result	16
c) neither satisfied nor unsatisfied with the end result	12
d) unsatisfied with the end result	8
e) very unsatisfied with the end result	4
Function (20 points)	
In my daily living, my club foot	
a) does not limit my activities	20
b) occasionally limits my strenuous activities	16
c) usually limits me in strenuous activities	12
d) limits me occasionally in routine activities	8
e) limits me in walking	4
Pain (30 points)	
My club foot	
a) is never painful	30
b) occasionally causes mild pain during strenuous activities	24
c) usually is painful after strenuous activities only	18
d) is occasionally painful during routine activities	12
e) is painful during walking	6
Position of heel when standing (10 points)	
Heel varus, 0° or some heel valgus	10
Heel varus, 1-5°	5
Heel varus, 6-10°	3
Heel varus, greater than 10°	0
Passive motion (10 points)	
Dorsiflexion	1 point per 5° (up to 5 points)
Total varus-valgus motion of heel	1 point per 10° (up to 3 points)
Total anterior inversion-eversion of foot	1 point per 25° (up to 2 points)
Gait (10 points)	
Normal	6
Can toe-walk	2
Can heel-walk	2
Limp	-2
No heel-strike	-2
Abnormal toe-off	-2

Appendix III: American Orthopaedic Foot and Ankle Society (AOFAS) Midfoot Scale (115) provided by orthotoolkit (152)



AOFAS Midfoot Scale

Patient Name: _____

Patient MRN: _____

Date: _____

I. Pain (40 points)

<input type="checkbox"/> None	+40
<input type="checkbox"/> Mild, occasional	+30
<input type="checkbox"/> Moderate, daily	+20
<input type="checkbox"/> Severe, almost always present	+0

II. Function (45 points)

Activity limitations, support requirements

<input type="checkbox"/> No limitations, no support	+10
<input type="checkbox"/> No limitation of daily activities, limitations of recreational activities, no support	+7
<input type="checkbox"/> Limited daily and recreational activities, cane	+4
<input type="checkbox"/> Severe limitation of daily and recreational activities, walker, crutches, wheelchair	+0

Footwear requirements

<input type="checkbox"/> Fashionable, conventional shoes, no insert required	+5
<input type="checkbox"/> Comfort footwear, shoe insert	+3
<input type="checkbox"/> Modified shoes or brace	+0

Maximum walking distance, blocks

<input type="checkbox"/> Greater than six	+10
<input type="checkbox"/> Four-six	+7
<input type="checkbox"/> One-three	+4
<input type="checkbox"/> Less than one	+0

Walking surfaces

<input type="checkbox"/> No difficulty on any surface	+10
<input type="checkbox"/> Some difficulty on uneven terrain, stairs, inclines, ladders	+5
<input type="checkbox"/> Severe difficulty on uneven terrain, stairs, inclines, ladders	+0

Gait abnormality

<input type="checkbox"/> None, slight	+10
<input type="checkbox"/> Obvious	+5
<input type="checkbox"/> Marked	+0

III. Alignment (15 points)

<input type="checkbox"/> Good, plantigrade foot, midfoot well aligned	+15
<input type="checkbox"/> Fair, plantigrade foot, some degree of midfoot malalignment observed, no symptoms	+8
<input type="checkbox"/> Poor, nonplantigrade foot, severe malalignment, symptoms	+0

IV. Total Score (100 points):

_____ Pain Points +

_____ Function Points +

_____ Alignment Points =

_____ Total Points/100 points

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Appendix IV: American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale (115) provided by orthotoolkit (153)



AOFAS Ankle-Hindfoot Scale

Patient Name: _____

Patient MRN: _____

Date: _____

I. Pain (40 points)

<input type="checkbox"/> None	+40
<input type="checkbox"/> Mild, occasional	+30
<input type="checkbox"/> Moderate, daily	+20
<input type="checkbox"/> Severe, almost always present	+0

Sagittal motion (flexion plus extension)

<input type="checkbox"/> Normal or mild restriction (30° or more)	+8
<input type="checkbox"/> Moderate restriction (15° - 29°)	+4
<input type="checkbox"/> Severe restriction (less than 15°)	+0

II. Function (50 points)

Activity limitations, support requirements

<input type="checkbox"/> No limitations, no support	+10
<input type="checkbox"/> No limitation of daily activities, limitations of recreational activities, no support	+7
<input type="checkbox"/> Limited daily and recreational activities, cane	+4
<input type="checkbox"/> Severe limitation of daily and recreational activities, walker, crutches, wheelchair, brace	+0

Hindfoot motion (inversion plus eversion)

<input type="checkbox"/> Normal or mild restriction (75% - 100% normal)	+6
<input type="checkbox"/> Moderate restriction (25% - 74% normal)	+3
<input type="checkbox"/> Marked restriction (less than 25% of normal)	+0

Maximum walking distance, blocks

<input type="checkbox"/> Greater than six	+5
<input type="checkbox"/> Four-six	+4
<input type="checkbox"/> One-three	+2
<input type="checkbox"/> Less than one	+0

Ankle-hindfoot stability (anteroposterior, varus-valgus)

<input type="checkbox"/> Stable	+8
<input type="checkbox"/> Definitely unstable	+0

Walking surfaces

<input type="checkbox"/> No difficulty on any surface	+5
<input type="checkbox"/> Some difficulty on uneven terrain, stairs, inclines, ladders	+3
<input type="checkbox"/> Severe difficulty on uneven terrain, stairs, inclines, ladders	+0

III. Alignment (10 points)

<input type="checkbox"/> Good, plantigrade foot, ankle-hindfoot well aligned	+10
<input type="checkbox"/> Fair, plantigrade foot, some degree of ankle-hindfoot malalignment observed, no symptoms	+5
<input type="checkbox"/> Poor, nonplantigrade foot, severe malalignment, symptoms	+0

Gait abnormality

<input type="checkbox"/> None, slight	+8
<input type="checkbox"/> Obvious	+4
<input type="checkbox"/> Marked	+0

IV. Total Score (100 points):

_____ Pain Points +

_____ Function Points +

_____ Alignment Points =

_____ Total Points/100 points

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Appendix V: SF-36 (Short Form 36) questionnaire (154)

SF-36 QUESTIONNAIRE

Name: _____ Ref. Dr: _____ Date: _____
ID#: _____ Age: _____ Gender: M / F

Please answer the 36 questions of the **Health Survey** completely, honestly, and without interruptions.

GENERAL HEALTH:

In general, would you say your health is:

- Excellent Very Good Good Fair Poor

Compared to one year ago, how would you rate your health in general now?

- Much better now than one year ago
 Somewhat better now than one year ago
 About the same
 Somewhat worse now than one year ago
 Much worse than one year ago

LIMITATIONS OF ACTIVITIES:

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

- Yes, Limited a lot Yes, Limited a Little No, Not Limited at all

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Lifting or carrying groceries

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Climbing several flights of stairs

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Climbing one flight of stairs

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Bending, kneeling, or stooping

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Walking more than a mile

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Walking several blocks

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Walking one block

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Bathing or dressing yourself

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

PHYSICAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Cut down the amount of time you spent on work or other activities

- Yes No

Accomplished less than you would like

- Yes No

Were limited in the kind of work or other activities

- Yes No

Had difficulty performing the work or other activities (for example, it took extra effort)

- Yes No

EMOTIONAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Cut down the amount of time you spent on work or other activities

- Yes No

Accomplished less than you would like

- Yes No

Didn't do work or other activities as carefully as usual

- Yes No

SOCIAL ACTIVITIES:

Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- Not at all Slightly Moderately Severe Very Severe

PAIN:

How much bodily pain have you had during the past 4 weeks?

- None Very Mild Mild Moderate Severe Very Severe

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- Not at all A little bit Moderately Quite a bit Extremely

ENERGY AND EMOTIONS:

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

Did you feel full of pep?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you been a very nervous person?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt so down in the dumps that nothing could cheer you up?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt calm and peaceful?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Did you have a lot of energy?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt downhearted and blue?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Did you feel worn out?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you been a happy person?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Did you feel tired?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

SOCIAL ACTIVITIES:

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

- All of the time
- Most of the time
- Some of the time
- A little bit of the time
- None of the Time

GENERAL HEALTH:

How true or false is each of the following statements for you?

I seem to get sick a little easier than other people

Definitely true

Mostly true

Don't know

Mostly false

Definitely false

I am as healthy as anybody I know

Definitely true

Mostly true

Don't know

Mostly false

Definitely false

I expect my health to get worse

Definitely true

Mostly true

Don't know

Mostly false

Definitely false

My health is excellent

Definitely true

Mostly true

Don't know

Mostly false

Definitely false

Appendix VI: Pediatric Outcomes Data Collection Instrument (PODCI): Adolescent (self reported) Outcomes Questionnaire (155)

Adolescent (self reported)

Outcomes Questionnaire

Developed by:

American Academy of Orthopaedic Surgeons®
Pediatric Orthopaedic Society of North America
American Academy of Pediatrics
Shriner's Hospitals

To be completed by adolescents 11 – 18 years old

Based on the Version 2.0 Pediatrics-Adolescent Outcomes Instrument

Also commonly referred to as the PODCI ("Pediatric Outcomes Data Collection Instrument")

Revised, renumbered, reformatted August 2005

Adolescent Health Assessment (self-reported)

FOR OFFICE USE ONLY

Clinic ID _____ First six letter of patient's last name _____
 Physician ID _____ Office Chart # _____

	Diagnosis & ICD-9 Code*	Procedure & CPT Code	CPT Date	Side of body procedure was performed on:
Primary DX	DX _____ ICD-9 _____	Tx _____ ICD-9 _____		<input type="checkbox"/> Right <input type="checkbox"/> Left <input type="checkbox"/> Both <input type="checkbox"/> N/A
Secondary DX	DX _____ ICD-9 _____	Tx _____ ICD-9 _____		<input type="checkbox"/> Right <input type="checkbox"/> Left <input type="checkbox"/> Both <input type="checkbox"/> N/A
Secondary DX	DX _____ ICD-9 _____	Tx _____ ICD-9 _____		<input type="checkbox"/> Right <input type="checkbox"/> Left <input type="checkbox"/> Both <input type="checkbox"/> N/A
Secondary DX	DX _____ ICD-9 _____	Tx _____ ICD-9 _____		<input type="checkbox"/> Right <input type="checkbox"/> Left <input type="checkbox"/> Both <input type="checkbox"/> N/A
Secondary DX	DX _____ ICD-9 _____	Tx _____ ICD-9 _____		<input type="checkbox"/> Right <input type="checkbox"/> Left <input type="checkbox"/> Both <input type="checkbox"/> N/A

Adolescent Health Assessment (self-reported)

Today's Date / /

Thank you for completing this questionnaire!

This questionnaire will help us to better understand your general health and any problems related to bone and muscle conditions.

Your completion of this questionnaire is completely voluntary and your responses will be held in the strictest confidence.

Please answer every question. Some questions may look like others, but each one is different.

There are no right or wrong answers. If you are not sure how to answer a question, just give the best answer you can. You can make comments in the margin. We do read all your comments, so feel free to make as many as you wish.

Your Birth Date / /

Your Social Security Number _____

Your Father or Mother's
Social Security Number _____

Adolescent Health Assessment (self-reported)

Some kind of problems can make it hard to do many activities, such as eating, bathing, school work, and playing with friends. We would like to find out how you are doing. (Circle one response on each line.)

During the **last week** was it easy or hard for you to:

		Easy	A little hard	Very hard	Can't do at all
1.	Lift heavy books?	1	2	3	4
2.	Pour a half gallon of milk?	1	2	3	4
3.	Open a jar that has been opened before?	1	2	3	4
4.	Use a fork and spoon?	1	2	3	4
5.	Comb your hair?	1	2	3	4
6.	Button buttons?	1	2	3	4
7.	Put on your coat?	1	2	3	4
8.	Write with a pencil?	1	2	3	4

9. On average, **over the last 12 months**, how often did you miss school (camp, etc.) because of your health?

1. Rarely
2. Once a month
3. Two or three times a month
4. Once a week
5. More than once a week
6. Do not attend school, etc.

During the **last week** how happy have you been with: (Circle one response on each line.)

		Very happy	Somewhat happy	Not sure	Somewhat unhappy	Very unhappy
10.	How you look?	1	2	3	4	5
11.	Your body?	1	2	3	4	5
12.	What clothes or shoes you can wear?	1	2	3	4	5
13.	Your ability to do the same things your friends do?	1	2	3	4	5
14.	Your health in general?	1	2	3	4	5

Adolescent Health Assessment (self-reported)

During the **last week**, how much of the time:
(Circle one response on each line.)

		Most of the time	Some of the time	A little of the time	None of the time
15.	Did you feel sick and tired?	1	2	3	4
16.	Were you full of pep and energy?	1	2	3	4
17.	Did pain or discomfort interfere with your activities?	1	2	3	4

During the **last week**, has it been easy or hard for you to:
(Circle one response on each line.)

		Easy	A little hard	Very hard	Can't do at all
18.	Run short distances?	1	2	3	4
19.	Bicycle or tricycle?	1	2	3	4
20.	Climb three flights of stairs?	1	2	3	4
21.	Climb one flight of stairs?	1	2	3	4
22.	Walk more than a mile?	1	2	3	4
23.	Walk three blocks?	1	2	3	4
24.	Walk one block?	1	2	3	4
25.	Get on and off a bus?	1	2	3	4

26. How often do you need help from another person for walking and climbing? (Circle one response.)

1 Never 2 Sometimes 3 About half the time 4 Often 5 All the time

27. How often do you use assistive devices (such as braces, crutches, or wheelchair) for walking and climbing? (Circle one response.)

1 Never 2 Sometimes 3 About half the time 4 Often 5 All the time

During the **last week**, has it been easy or hard for you to:
(Circle one response on each line.)

		Easy	A little hard	Very hard	Can't do at all
28.	Stand while washing your hands and face at a sink?	1	2	3	4
29.	Sit in a regular chair without holding on?	1	2	3	4
30.	Get on and off a toilet or chair?	1	2	3	4
31.	Get in and out of bed?	1	2	3	4
32.	Turn door knobs?	1	2	3	4
33.	Bend over from a standing position and pick up something off the floor?	1	2	3	4

Adolescent Health Assessment (self-reported)

34. How often do you need help from another person for sitting and standing? (Circle one response.)

- 1 Never 2 Sometimes 3 About half the time 4 Often 5 All the time

35. How often do you use assistive devices (such as braces, crutches, or wheelchair) for sitting and standing? (Circle one response.)

- 1 Never 2 Sometimes 3 About half the time 4 Often 5 All the time

36. Can you participate in **recreational outdoor activities** with other kids the same age? (For example: bicycling, skating, hiking, jogging) (Circle one response.)

- 1 Yes, easily 2 Yes, but a little hard 3 Yes, but very hard 4 No

If you answered "no" to Question 36 above, was your activity limited by: (Circle yes to all that apply)

	Yes
37. Pain?	1
38. General Health?	1
39. Doctor or parent instructions?	1
40. Fear the other kids won't like you?	1
41. Dislike of recreational outdoor activities?	1
42. Activity not in season?	1

43. Can you participate in **pickup games or sports** with other kids the same age? (For example: tag, dodge ball, basketball, softball, soccer, catch, jump rope, touch football, hop scotch) (Circle one response.)

- 1 Yes, easily 2 Yes, but a little hard 3 Yes, but very hard 4 No

If you answered "no" to Question 43 above, was your activity limited by: (Circle yes to all that apply)

	Yes
44. Pain?	1
45. General Health?	1
46. Doctor or parent instructions?	1
47. Fear the other kids won't like you?	1
48. Dislike of pickup games or sports?	1
49. Activity not in season?	1

Adolescent Health Assessment (self-reported)

50. Can you participate in **competitive level sports** with other kids the same age?
 (For example: hockey, basketball, soccer, football, baseball, swimming, running [track or cross country], gymnastics, or dance) (Circle one response.)

- 1 Yes, easily 2 Yes, but a little hard 3 Yes, but very hard 4 No

If you answered "no" to Question 50 above, was your activity limited by: (Circle yes to all that apply)

	Yes
50. Pain?	1
52. General Health?	1
53. Doctor or parent instructions?	1
54. Fear the other kids won't like you?	1
55. Dislike of competitive level sports?	1
56. Activity not in season?	1

57. How often in the **last week** did you get together and do things with friends? (Circle one response.)

- 1 Often 2 Sometimes 3 Never or rarely

If you answered "sometimes" or "never or rarely" to Question 57 above, was your activity limited by: (Circle yes to all that apply)

	Yes
58. Pain?	1
59. General Health?	1
60. Doctor or parent instructions?	1
61. Fear the other kids won't like you?	1
62. Friends not around?	1

63. How often in the **last week** did you participate in **gym/recess**? (Circle one response.)

- 1 Often 2 Sometimes 3 Never or rarely 4 No gym or recess

If you answered "sometimes" or "never or rarely" to Question 63 above, was your activity limited by: (Circle yes to all that apply)

	Yes
64. Pain?	1
65. General Health?	1
66. Doctor or parent instructions?	1
67. Fear the other kids won't like you?	1
68. Dislike of gym/recess?	1
69. School not in session?	1
70. I don't attend school?	1

71. Is it easy or hard for you to make friends with kids your own age? (Circle one response.)

- 1 Usually easy 2 Sometimes easy 3 Sometimes hard 4 Usually hard

Adolescent Health Assessment (self-reported)

72. How much pain have you had during the **last week**? (Circle one response.)

- 1 None 2 Very mild 3 Mild 4 Moderate 5 Severe 6 Very severe

73. During the **last week**, how much did pain interfere with your normal activities (including at home, outside of the home, and at school)? (Circle one response.)

- 1 Not at all 2 A little bit 3 Moderately 4 Quite a bit 5 Extremely

What expectations do you have for your treatment?

As a result of my treatment, I expect:

(Circle one response on each line.)

	Definitely yes	Probably yes	Not sure	Probably not	Definitely not
74. To have pain relief.	1	2	3	4	5
75. To look better.	1	2	3	4	5
76. To feel better about myself.	1	2	3	4	5
77. To sleep more comfortably.	1	2	3	4	5
78. To be able to do activities at home.	1	2	3	4	5
79. To be able to do more at school.	1	2	3	4	5
80. To be able to do more play or recreational activities (biking, walking, doing things with friends).	1	2	3	4	5
81. To be able to do more sports.	1	2	3	4	5
82. To be free from pain or disability as an adult.	1	2	3	4	5

83. If you had to spend the rest of your life with your bone and muscle condition **as it is right now**, how would you feel about it? (Circle one response.)

- 1 Very satisfied 2 Somewhat satisfied 3 Neutral 4 Somewhat dissatisfied 5 Very dissatisfied