Comparison of long-term outcome of Ponseti versus surgical treatment for idiopathic clubfoot

Vergleich der Langzeitergebnisse der Ponseti- und chirurgischen Behandlung des idiopathischen Klumpfußes

University clinic for pediatric and adolescent surgery;
Division of pediatric orthopedics

Diploma thesis to obtain the academic degree
"Doctor medicinae Universae (Dr. med. Univ.)"

May 19, 2014

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TABLE OF CONTENT

GLOSSARY

ABD	Abduction
ADD	Adduction
ADL	Activity of Daily living
AP	Anterior-Posterior
ASIS	Anterior Superior Iliac Spine
B.C.	Before Christ
CF	Clubfoot
CI	Confidence interval
CTEV	Congenital Talipes Equinovarus
DF	Dorsifelxion
EV	Eversion
EXT	External
FF	Forefoot
FRS	Functional Rating System
HF	Hind foot
HX	Hallux
ICFSG	International Clubfoot Study Group
INT	Internal
INV	Inversion
LAT	Lateral
MAX	Maximum
MIN	Minimum
OFM	Oxford Foot Model
PF	Plantarflexion
PODCI	Pediatric Outcome
PRO	Pronation
PSIS	Posterior Superior Iliac Spine
ROM	Range of Motion
ROT	Rotation
SD	Standard deviation
SUP	Supination
TIB	Tibia
TSP	Temporal-spatial Parameter

TABLE OF FIGURES

LIST OF FIGURES

ABSTRACT

Background

Finding the right course of treatment in order to assure best quality of life for affected children is an essential aim in children´s orthopedics. Clubfoot is a rather common deformity in newborn. There is still a lack of randomized data comparing long-term outcomes of surgical versus the Ponseti treatment. We hypothesized that the conservative approach by Ponseti is the superior treatment to ensure best possible mobility in the ankle joint and therefore better functionality of the foot and higher life satisfaction of the affected children.

Method

The design is a single center, non-blinded, randomized, controlled analysis. Patients treated for idiopathic clubfoot from 2001 to 2003 by the Ponseti or the surgical treatment and participated in the previous study at our center in 2009 were invited. They underwent a medical examination, gait-analysis, x-ray examination of the foot and answered a questionnaire about life satisfaction. We used the Functional Rating System (FRS) as well as the Rating System by the International Clubfoot Study Group (ICFSG) to compare the morphology and functionality to the mobility, measured by 3D gait analysis, of the ankle joint. The Pediatric Outcomes Data Collection Instrument (PODCI) was used to rate the level of satisfaction.

Results

The physical and radiological examination according to the ICFSG & FRS protocols revealed a significantly better outcome within the Ponseti group. The Ponseti group excelled in terms of morphology and functionality and also showed better radiological outcomes compared to the surgically treated one. In the 3D gait analysis better maximal hind foot dorsiflexion and a more physiological gait pattern has been proven in the patients who received the conservative treatment according to Ponseti. Within the PODCI questionnaire this group also reported better physical functioning, less pain and a greater amount of happiness. The superior long-time outcome as well as the reduced need for additional surgery makes the Ponseti technique the treatment of choice.

ABSTRACT

Hintergrund

Ein grundsätzliches Ziel bei der Behandlung von Klumpfüßen ist es, die bestmögliche Behandlung zu finden, um betroffenen Kindern eine größtmögliche Lebensqualität zu ermöglichen. Trotz der Häufigkeit dieser Erkrankung, mangelt es nach wie voran randomisierten Vergleichen der Langzeitergebnisse zwischen der Behandlung nach der Ponseti und der chirurgischen Methode. Wir vermuten, dass die konservative Methode nach Ponseti die beste Methode ist um größtmögliche Mobilität im Sprunggelenk und daher beste Funktionalität und eine hohe Lebensqualität zu garantieren.

Methode

Es handelt sich um eine monozentrische, offene, randomisiert, kontrollierte Studie. Patienten, die aufgrund eines idiopathischen Klumpfußes zwischen 2001 und 2003 mittels Ponseti-Methode oder chirurgisch behandelt wurden und an der Vorstudie unserer Klinik 2009 teilgenommen haben, wurden erneut eingeladen. Diese Patienten wurden einer physikalischen und radiologischen Untersuchung, sowie einer Ganganalyse unterzogen. Außerdem beantworteten sie einen Fragebogen zur Lebensqualität. Dabei wurde die Morphologie und Funktionalität des Fußes mittels des “Functional Rating System” (FRS) und dem Protokoll der “International Clubfoot Study Group” (ICFSG) gemessen. Die Mobilität hingegen wurde mit einer 3D Ganganalyse gemessen. Anschließend wurden beide Ergebnisse miteinander verglichen.

Ergebnisse

Die physikalische und radiologische Untersuchung nach ICFSG- & FRS-Protokoll ergab signifikant bessere Ergebnisse innerhalb der Ponseti-Gruppe. Diese Patienten übertrafen die chirurgisch behandelten Patienten in Morphologie, Funktionalität sowie in der radiologischen Evaluierung. Die 3D Ganganalyse zeigte eine bessere maximale Dorsiflexion im Rückfuß. Im PODCI-Fragebogen berichtete die Ponseti-Gruppe über eine bessere Funktionalität, weniger Schmerzen und mehr Lebensfreude. Die deutlich besseren Langzeitergebnisse und der geringere Bedarf an zusätzlichen chirurgischen Maßnahmen machen die Behandlung nach Ponseti zur bestmöglichen Ersttherapie.

1. INTRODUCTION

1.1 Relevance of the topic

Clubfoot is a rather common congenital foot deformity in newborn. Finding the right treatment is a key to assure the best possible quality of life for children born with clubfoot and is therefore an essential aim in children's orthopedics. Leonard F. Peltier described clubfoot malformations in his book "Orthopedics: A History and Iconography" as one of the "two most frequent congenital deformities whose diagnosis and treatment contributed to the development of the specialty of orthopedic surgery." (1) The clubfoot deformity has repeatedly been described for centuries, which underlines the importance of this handicap. References where found in Greek mythology as well as in the Old Testament. Hippocrates was among the first to analyze and elaborate on the "concepts of causation" and "principles of treatment". (2)

The primary problem of a clubfoot is the inability to place the sole of the foot flat on the ground. As a result, the patient has to walk on the side of the foot, which will lead to further deformation and calluses with a need to customize special shoe wear.(3)The impairment in uncorrected clubfoot dramatically affects the patient's life. In addition to the stigmatizing look and gait the patient might not be able to attend sports classes or walk longer distances. This especially causes children to face a decreased motoric development when handicapped with a clubfoot. (4)

To prevent this abnormal development from proceeding, several treatment regimens evolved over the centuries. Early methods included manual manipulation to correct the deformity. Only a few hundred years ago surgical techniques for the treatment of congenital talipes equinovarus were developed. Today, a trend back to traditional and more conservative therapy methods can be seen. This includes the combination of casting and, if needed, the lengthening of the Achilles tendon. Over the last century decent results for the common surgical treatments, as well as the nonsurgical approaches were reported.(5,6)However, comparisons of the different techniques revealed that the clubfoot treatment according to Ponseti leads to significantly better results (in terms of morphology and functionality) compared to a posterior medial release or other non-operative methods. (7-21)

1.2 Aims

This study aims to clarify whether the non-surgical approach by Ponseti is the superior treatment method to ensure best possible mobility in the ankle joint. It is believed that the joint has a major influence on the functionality of the foot and, therefore, on life satisfaction of the affected children. (17) Furthermore, the study aims to reveal differences in the long term outcome between the surgical treatment and the nonsurgical approach described by Ponseti by illustrating the personal level of satisfaction with the results of the approach in each group.

Our study is a follow-up study of the published work of Zwick et al. in 2009. This clinical study evaluates two randomized groups in which one group received the traditional surgical treatment while the second group was treated with the Ponseti method. Zwick´s study was conducted at our hospital between 2001 and 2009.It showed, that3.5 years after the treatment, Ponseti´s method is superior compared to the surgical treatment in terms of upper ankle joint mobility. (20)We believe that the long term outcome will show similar results.

There is still a lack of data comparing the long term outcome of those two very common forms of treatment in a randomized setting. (17,19,22) Due to the superior outcome the Ponseti treatment produces and its less invasive character (11,17,19,23,24), ethical aspects will make randomized study setups rare in the future. Because the participants in our study were treated during a period when the Ponseti method was implemented as the new “Gold-Standard” at our institution, a randomized prospective study protocol could be set up and the same group could be re-evaluated now. To ensure that the approach used at our facility is the best possible form of treatment available, and to adapt our modus operandi if necessary, we initiated this study.

1.3 Hypothesis

Based on the study by Zwick, et. al.(20)we believe that the Ponseti method is superior to the surgical method described by McKay in 1983 in terms of ankle joint mobility.

2. THEORETICAL PART

2.1 Anatomical characteristics

Clubfoot is a complex disorder that negatively affects the bones, joints, ligaments and muscles of the foot. Clubfoot can also be called “Pes equinovarus excavatus et adductus”. The name describes the combination of deformities resulting in this type of deformity.

A classical clubfoot (Figure 1 & 2) deformity shows equinus, adduction and inversion in both, the hind foot and forefoot. (25) Different authors tried to explain the 3D complexity associated with this disease. (25-30) The calcaneus is rotated internally and is inverted under the talus. The posterior end of the calcaneus is deviated upward and laterally, which forces the talus into equinus and therefore the tip of the foot points downwards. The head and neck of the talus are rotated medially. Different authors described an abnormal torsion between the neck and the body of the talus. (25,31) This abnormal torsion, accompanied by the rotation of the calcaneus, leads to an adduction and pronation of the forefoot. Because of the rotation of the talocalcaneal joint in the horizontal and coronal plane, a proximity of the tuber of the calcaneus to the fibular malleolus can be seen. In clubfeet, the talus and the calcaneus show a parallel architecture. This can be explained with the navicular´s moves around the head of the talus causing the talonavicular joint to be inverted. This subtalar malrotation can sometimes lead to the development of a new articulation (Ne-Arthros) between the navicular and the medial malleolus. The

Figure 1: Bilateral Clubfoot deformity in a 6 week old infant (30)

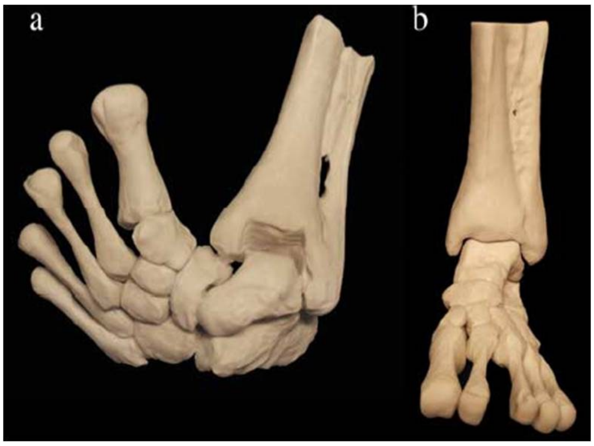


Figure 2: Bony deformation in a clubfoot (a) and a normal foot (b) (26)

cuboid is located medially on the calcaneus. In severe clubfoot an internal tibial torsion can be seen. (28)

Soft tissue anomalies, like contractures of specific ligaments, result in further deformation in the untreated foot or can compromise the correction of the bony deformity. A hindrance to the realignment of the talocalcaneal or talonavicular joint is the fibrous thickening and contraction of different ligaments, e.g. the calcaneofibular ligament or the deltoid ligament. The posterior tibial ligament, for example, enforces the medioplantar location of the navicular and the massive thickening and contracture of the Achilles tendon promotes equinus. (32)

Another common feature of congenital talipes equinovarus (CTEV) is a hypotrophic anterior tibial artery and an obvious atrophy of the surrounding musculature. Figure 3 shows two gastrocnemius muscles from a premature baby with unilateral CTEV. The muscle of the leg of the clubfoot is hypotrophic. (33)

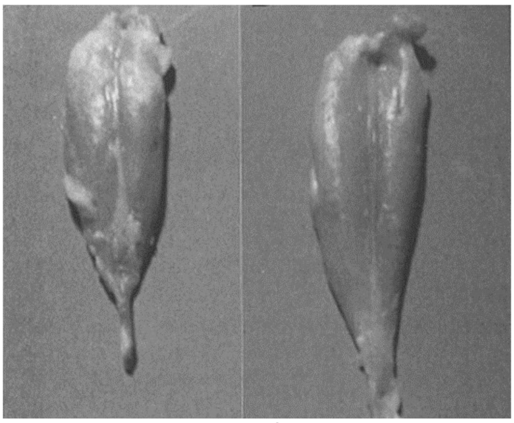


Figure 3: Hypotrophic (left) and normal (right) Gastrocnemius muscles (30)

The appearance of clubfoot can range from very severe, with a high arch (Pes cavus) causing an even further complication of the deformity, to a less severe or mild clubfoot, with “only a mild equinus and varus position.” (28)

Finding a proper classification system to categorize the severity of the deformity, make a prediction of the probable outcome and to find the best course of treatment has been attempted by different authors. Although numerous classification systems emerged, only a few are commonly used because of the poor results the prediction of the prognosis shows. (34)

In this study we used the classification system by Pirani. The Pirani score compares three parameters of the midfoot, resulting in the midfoot contracture score, and three parameters of the hind foot, resulting in the hind foot contracture score. The curvature of the lateral border, the medial crease and the position of the talar head are used to describe the severity of the deformity in the midfoot. To describe the severity of the deformation in the hind foot the posterior crease, the emptiness of the heel and the rigidity of the equinus are being evaluated. Each parameter is rated on a scale of 0 to 1 in half point increments, where “0” describes “no deformation” and “1” stands for “severe deformation”. The overall score for clubfoot in the Pirani scoring system varies between “0” (=”no clubfoot”) and “6” (“very severe clubfoot”). (28) “In a study to predict the need for tenotomy, Scher et al. found that patients with a Pirani score of 5 […] are very likely to require tenotomy. At the end of cast treatment, however, there was no significant difference between patients with and without tenotomy.” (28)

There are basically two types of clubfeet with very different treatment options – the positional-type and the congenital clubfoot. The positional-type clubfoot can be corrected manually instantly and possible arises from uterine constraint, while the congenital clubfoot (structural-type)needs a proper treatment repeatedly after birth. (35) This study concentrates on the structural-type clubfoot and its treatment. If clubfoot remains untreated, late adaptive changes, such as spontaneous fusion of joints or degenerative changes to the joints can occur which will ultimately worsen the patients situation.(28)

2.2 Pathophysiology & Biomechanics

“The average person takes between 5,000 and 15,000 steps per day – that´s about 2-5 million per year – on average 27,000 km, or a complete circuit of the earth.” (36) Gait requires a complex interaction of physical and coordinative abilities, such as adequate biochemical processes for a sufficient energy supply, a healthy locomotor- and neuromuscular system, postural control and other capabilities.“Normal” gait patterns differ due to influential factors like age, sex, body dimensions, configuration of the ground and even purpose of walking, why no strict description of “normal” gait can be given. Still, the sequence of gait and its kinematics (stride length, cadence) can be analyzed, as described in Gotz-Neumann´s book. (37)

The Gait Cycle

During one gait cycle only one foot is being observed. The cycle starts with the initial contact of the heel on the ground and ends when the same foot treads on the ground again. The cycle can be divided into a stance phase, where the observed foot touches the ground and a swing phase in which it is moving forward without contact.

As shown in figure 4(38), the gait cycle can also be divided into phases with double support, meaning the interval when both feet are on the ground, and the single support phase, describing the phase in which one foot is lifted without contact to the ground. The exact composition of stance and swing phase depends on the speed of gait. While double supported phases dominate in slow gait, these do not exist while running. (37)
The gait cycle can roughly be divided into eight sequences: (37)

(1) The “initial contact” phase, in a former terminology described as “heel strike”, it usually starts when the heel of the observed foot touches the ground.
(2) “Loading response ”describes the interval of shock absorption. This phase takes place with the abrupt transfer of the body’s weight into the observed leg. During this phase stability has to be granted.
(3) The “Mid stance ”starts when the contra lateral leg is lifted from the ground. This is also called “toe off”.
(4) The phase of “terminal stance” starts with lifting the observed foots’ heel and ends with the initial contact of the contra lateral leg on the ground.
(5) During the “pre-swing” period the body weight is being transferred to the contra lateral leg while the observed leg is lifted to prepare for the next swing.
(6) The “initial swing” starts with “toe off” of the observed leg.
(7) The “mid swing” is marked by decussating of the tibia of the observed and the contra lateral leg and ends when the tibia of the observed leg is vertical to the ground.
(8) The “terminal swing”, which denotes the end of the gait cycle, starts with the vertical tibia and ends with the next “initial contact” of the observed leg.

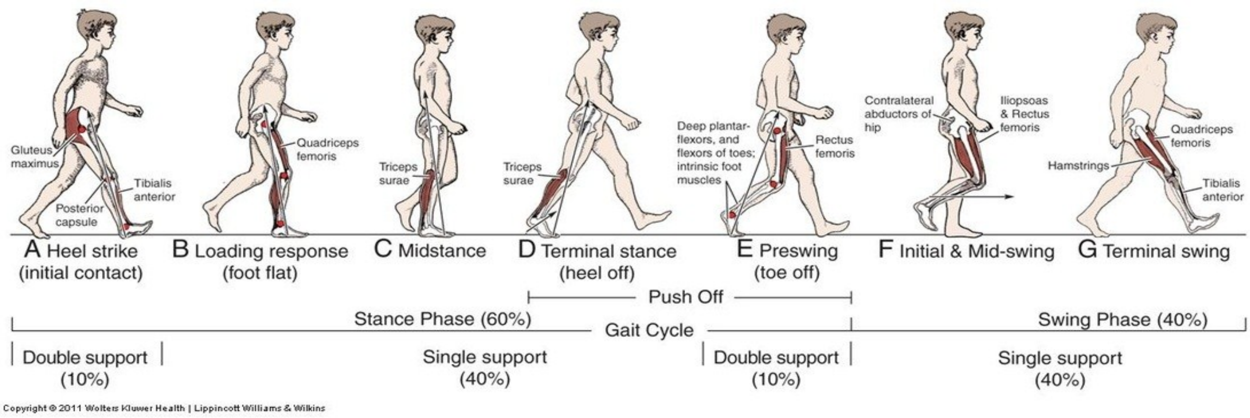


Figure4: Gait cycle (38)

Time-distance parameters

Additional gait parameters of importance are the walking speed, cadence and stride length. The walking speed is defined as distance per time (m/sec) while the stride length represents the length of two steps or one gait cycle. The cadence is defined as the number of single steps taken in one minute. Adults usually have a stride length of approximately 1.4 meters while the cadence is about 120/min. “Together, the walking speed, cadence and stride length are called the temporal-spatial parameters (TSPs) of gait, and their measurement forms the basis of any gait assessment.” (36) Children usually start to walk with about12-18 months, but their temporal-spatial parameters stabilize when they reach the age of four to five years. For younger children it is therefore necessary to normalize the TSPs (gait variables) by converting them into dimensionless quantities. Since this normalization is not always possible in a clinical setting the broad rule, that a child´s natural stride length is approximately 90% of its height should be kept in mind. (36)

Kinematics

“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.” (36) In his book about clinical gait analysis, C. Kirtley described the joint kinematics in normal gait as followed: the hip joint flexes at initial contact of the observed foot and turns into extension at initial contact of the contra lateral foot.

Meanwhile the knee joint shows two peaks in flexion, one during the stance phase and a larger one during the swing phase. “The ankle angle is neutral (0°) at initial contact.” (36) In his study Carson also described the kinematics of the foot. He explained the hind foots´ dorsiflexion during midstance which then progresses into inversion and internal rotation during terminal stance and plantarflexes at toe off. During midstance also the forefoot dorsiflexes while the longitudinal arch of the foot flattens. The arch of the foot restores during terminal stance when the forefoot plantarflexes, supinates and adducts before toe off. During the same phase the hallux dorsiflexes “with respect to the forefoot as the heel comes off the ground.”(39)

Gait in Clubfoot

If children with successfully treated clubfoot are observed their gait might appear quite normal. Modern videoanalysis might still reveal differences in gait patterns due to the pathological changes of the musculoskeletal system. Common findings are reduction in overall motion at the ankle in the sagital plane and reduced functional range of motion (ROM) especially during gait, which might be even less than measured from the physical examination. In some cases diminished ankle push-off power and walking speed is present and reduced step length can be seen. (11,40)

2.3 Epidemiology

Clubfoot is a common deformity of the foot in newborn. Its incidence varies from 0.5 per 1,000 newborn in Japan to 7 per 1,000 live births in the south pacific, depending on race and geography. In Caucasians the incidence is about 1 per 1,000 live births. An approximately 2:1 male predominance is seen. (41) This could probably be explained through the Carter Effect, described by Kruse et al in 2008. This effect describes the phenomenon, that females need a greater genetic liability to express the malformation but are more likely to conduct the disease to their children than affected men. (42) The disease occurs bilaterally in 50% of the cases. (25,41)

2.4 Etiology

In clubfoot, congenital and acquired forms can be found. The acquired clubfoot deformities develop as a result of trauma or neurological damage. The congenital clubfoot is further divided into idiopathic and non-idiopathic forms. Non-idiopathic clubfoot occurs secondary to genetic syndroms, teratologic anomalies, neurological disorders or myopathies. This type usually shows a poor response to treatment. (43) Although the idiopathic form usually responds well especially to conservative treatment it shows a tendency to late recurrence. (7) In most cases, the idiopathic clubfoot occurs isolated, without accompanying diseases. (7) Today, most authors agree that the idiopathic deformity probably results from a combination of multifactorial polygenic predispositions and some intrauterine environmental factors. (25)
Genetics play a role in this disease as well as maternal consumption of alcohol and smoking during pregnancy and maternal BMI. (35,44,45)Different authors found different causes for the development of congenital talipes equinovarus over time. Hippocrates, for example, emphasized on the hypothesis that intrauterine pressure leads to the development of congenital equinovarus adductus. (1,46) This theory, however, is nowadays only one among a few etiological explanations, and does not come into consideration as sole reason, as a higher prevalence is not seen in twins or children born large for gestational age. (7)Theories range from an arrest of fetal growth after the fibular phase leading to the formation of clubfoot described by V. Diaz (47), to germplasm defects of the head of the talus as is described by Walsingham and Hughes up to hereditary factors as an explanation. (25) But still, the etiology has not yet been fully identified.

2.5 Therapy

Over the past years many treatment techniques were developed. All of them follow either one of the two principles to treat clubfoot: the surgical correction and the conservative, non-surgical treatment. Both therapies start with a gentle manipulation and casting or splinting shortly after birth. After that initial phase the courses of treatment diverge. While the conservative method uses the force of a brace to obtain correction, the surgical method uses more or less extensive surgery.

2.5.1 Historical overview

According to the paper “Treatment of idiopathic Clubfoot: An Historical Review” by Dobbs et al., the first conservative approach has already been described 1,000 B.C. in India and the first written description of clubfoot came from Hippocrates around 400 B.C.. (5,48) He described a casting method, quite similar to Ponseti´s treatment and pointed out “two important principles in the treatment of clubfoot”.(5) He “emphasized on an early start of the treatment with repeated gentle stretching. Strong bandages were used during manipulative correction and shoes for the maintenance of correction.” (25) Hippocrates also stated that, in order to maintain correction, the foot needs to be overcorrected and held in that position to prevent recurrence. (1) These two principles accompanied the conservative treatment throughout the ages.

Until the early 19th century, different manipulative therapies were used. They differentiated in the degree of force used for manipulation as well as the way the foot was held in place. The first clubfoot orthosis, the so called “scarpa´s shoe” (Figure 5) was invented to maintain the correction after forceful manipulation. The innovator of the shoe elaborated on the importance of treating varus deformity before equinus. (49)

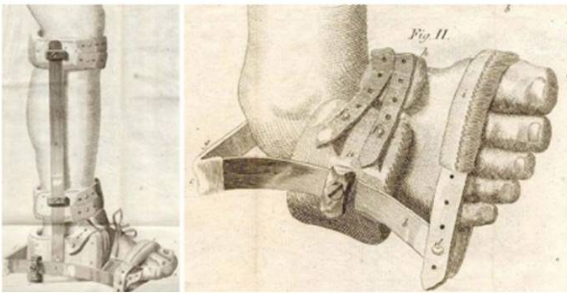


Figure 5: Scarpa´s shoe (50)

Then, the era of surgical treatment began. The first percutaneous Achilles tendon tenotomys were performed which led to sepsis and death of the patients. Stromeyer was the first one to repeat this surgery successfully. Since that time the clubfoot treatment developed rapidly. The use of anesthesia began in 1846 and led to an increase of operative clubfoot treatment. (49) Also, the introduction of antiseptic principles by Lister in 1867, and the Esmarch ischemia in 1873 promoted good change in the surgical treatment. During the decades surgeons invented a variety of new and different approaches to correct the deformity. While some favored a radical approach, e.g, the talectomy or the transfer of the tibialis anterior tendon to prevent relapse, other surgeons emphasized on a more limited surgical approach followed by immobilization in a “plaster of Paris” cast until correction was established. (5,50)

Until the late 20th century the majority of literature about clubfoot treatment concentrated on technical details of the operative treatment. Still, very well-known procedures are the “posteriomedial release” described by Turco, the “partial or complete release” by McKay and the “a la carte approach” introduced by Bensahel. (49)

At the same time, the nonsurgical methods evolved. The use of “plaster of Paris” and the “Thomas wrench” hustled on the conservative approach. While the “Thomas wrench” used strong forces to correct the clubfoot deformity, which according to Dobbs et al. “could easily detach the foot from a cadaver” (5), others used gentle manipulation, e.g. the manipulation and casting method by Kite, who “corrected each component of the deformity separately instead of simultaneously.” (5) “The French functional method for the nonoperative treatment of clubfoot originated in the 1970s with Masse” (6), and was refined over the next several decades. It uses continuous passive motion through physical therapy and splinting. Despite their good functional outcomes, Kite´s and Bensahel´s methods did not gain much popularity probably due to the amount of time and expenses needed. (6)

The Ponseti method was developed by Ignacio Ponseti in the late 1940´s but was first published in 1963. (13,16,49)Although it showed good results even then, it was not established until the late 1990´s when parent groups and the internet helped bringing attention to his method. (49) Today, Ponseti’s method still finds great recognition and is used in many centers all around the world. (24)

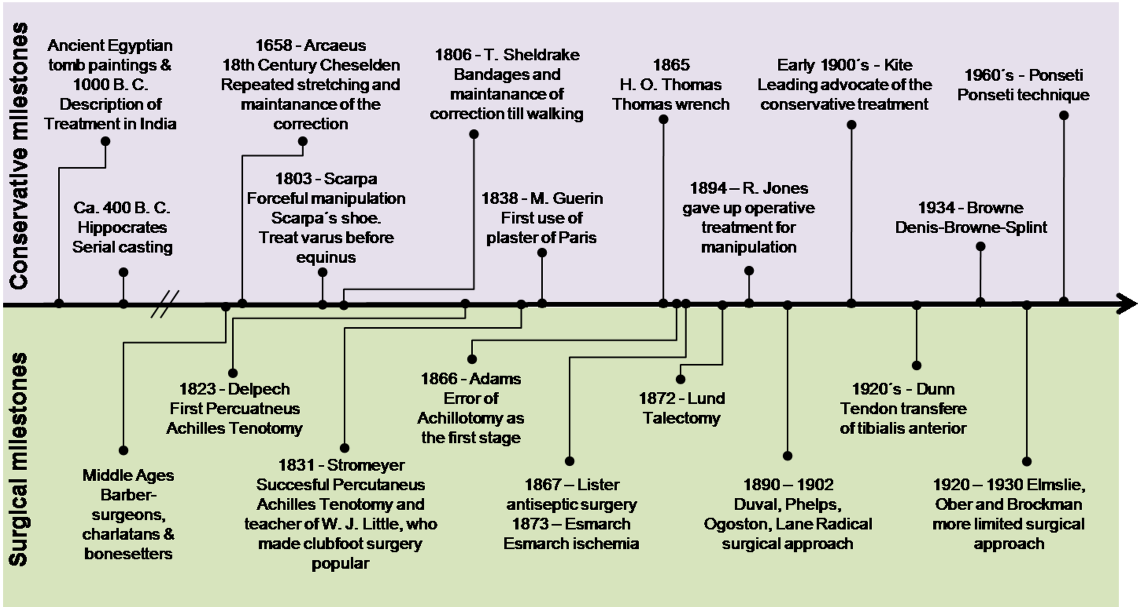


Figure 6: Milestones of Clubfoot Treatment -author´s illustration (5,48-50)

2.5.2 Nonsurgical approaches

Among all conservative techniques available today, the Ponseti method of serial casting is the first choice. Nowadays many centers believe that most clubfeet can be “cured” through Ponseti casting rather than surgery. Success rates up to 98% are reported. (28)

The treatment “involves gentle manual manipulation of the foot without anesthesia as soon as possible after birth. The manipulation is followed by the application of a toe-to-groin plaster cast.” (16) After several cast changes and repeated manipulation a modified Denis-Browne-Bar is customized to prevent recurrence. (16)

The process of the Ponseti method can be divided into two phases. The “treatment phase” includes the manipulation, serial casting and, if needed a tenotomy of the Achilles tendon. In the second and so called “maintenance phase”, the infant has to wear an orthosis to maintain correction. (51)

The treatment usually starts within the first week of life. Gentle manipulation and casting is done in weekly intervals. (28) The components of the clubfoot deformity (cavus, adduction, pronation) except for the ankle equinus, are corrected more or less simultaneously. Attempts to correct the equinus first may break the foot causing a so called “rockerbottom foot”. (52) The casts are applied to hold the foot in the corrected position, so that the foot can reshape gradually.

The first cast corrects the cavus deformity by aligning the forefoot with the hind foot, supinating the forefoot and elevating the first metatarsal. At time of the first cast change the foot is abducted around the head of the talus. By pressure onto the talar head the navicular reduces around the same. Then the second plaster cast will be applied. It is important to avoid any pronation and manipulation directly to the heel. While manipulation and casting is continued over the next weeks, the amount of supination is gradually decreased until the forefoot is in a neutral position relative to the longitudinal axis of the foot. Normally, five to six long leg casts are necessary to correct the alignment of the foot and ankle (Figure 7A,B). In the last cast change, the foot is brought into the final position of approximately 70 degrees of abduction and 15 degrees of dorsiflexion for three weeks. (28,51-53)

In most cases, a consecutive percutaneous tenotomy of the Achilles tendon is required to finally correct the equinus. In this way a sufficient lengthening of the Achilles tendon is achieved. One last additional cast needs to be applied during surgery to ensure that the foot heals without forming new contractions, before the “maintenance phase” begins.

During the “maintenance phase” the patient wears a foot abduction brace, comparable to the “Denis-Brown-Bar” shown in figure 7C by Gibbons et al. (54) This orthosis consists of open-toed straight-laced shoes attached to a bar, on which the affected foot is abducted to 70 degrees of external rotation and 15 degrees of dorsiflexion while the unaffected foot is fixed in a 45 degree abducted

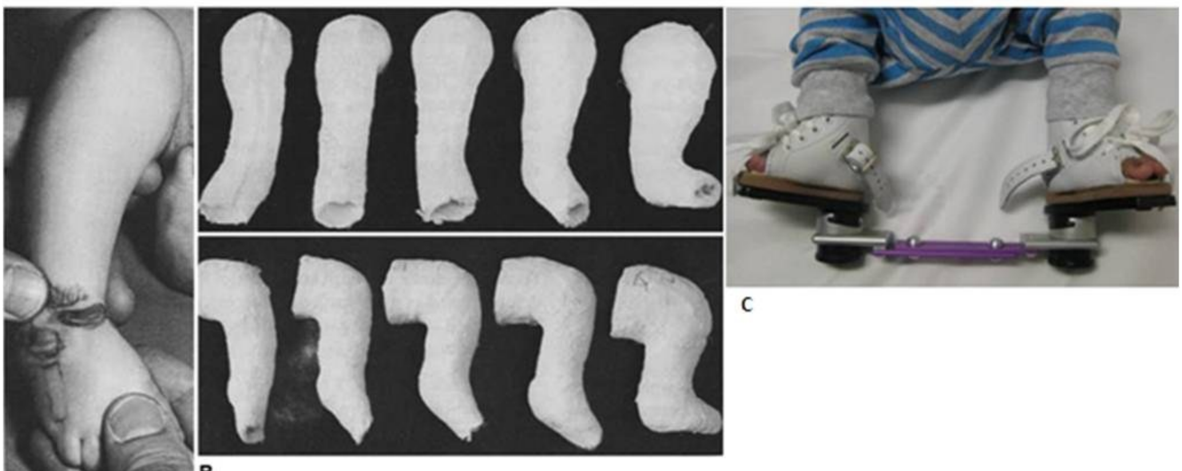


Figure 7: Manually manipulation (A), casts to correct a right CF deformity (B) anda foot abduction brace (C) (30,54)

position. These shoes are worn for 23 hours per day for three months and while sleeping for the next three to four years. (52) The patient's compliance is especially important during this phase of the treatment. If the orthosis is not worn as indicated, recurrence of the clubfoot is quite likely. (19,24,53)

Recurrence rates after Ponseti casting vary from 10% to 30%. Recurrence is reported infrequent if the treatment protocol is followed closely and will not occur after 6 or 7 years of age. (33,41) Most authors believe that the most important factor in prevention of recurrence is the patient's compliance in wearing the orthosis. (9,41,55-57) Upon others Dobbs et al. even described that the parental educational level is of significant importance. (19,24,28,57) Opposing, a recent study falsified this association between poor bracing compliance and the family´s educational level, also no association to income or cultural origin was found.(58)Another predominance of recurrence can be seen in secondary clubfoot. According to Canale, factors such as the severity of the deformity, the age of the patient, the beginning of treatment and previous treatment do not seem to have a significant impact on the risk of recurrence. (28) In the case of an early recurrence, long leg casts are applied in two week intervals, and the sequence of initial treatment (cavus, adductus, supination) is followed. If ankle dorsiflexion is insufficient by the end of the second treatment ,a lengthening of the Achilles tendon will be performed. (28)

Operative steps are needed occasionally. Authors describe the necessity of Achilles tenotomy in 70% to 97% of the cases. (9,28,52,52) Scher et al. described a correlation between the Pirani score and the probability of required tenotomy. The success of treatment, however, cannot be derived from this correlation.

There are a few complications related to the Ponseti treatment. Through very tight applied casts, circulatory disorders can occur. This can result in a swelling and shortage of blood flow. Therefore, it is necessary to regularly check the re-capillarization time after each change of the cast. Additionally, pressure sores can develop in tight casts and result in an infection. As mentioned earlier, the correction of the equinus before the correction of the adduction and pronation will result in a "rockerbottom foot" by dorsiflexing the foot through the midfoot rather than the hind foot. (28) Yoshioka & Huisman reported peroneal nerve dysfunction in severe clubfeet after the Ponseti treatment was applied and recommended very careful cast placements in severe cases to avoid this complication. (59)

2.5.3 Surgical approaches

Surgical treatment in clubfoot nowadays is reserved for those feet, which do not respond well to conservative treatment. In most cases those children present with a very rigid clubfoot and only some correction can be achieved in the forefoot, while the hind foot remains fixed in equinus and varus throughout the Ponseti treatment. (28) In the surgical therapy an initial "manipulation phase" is followed by a surgical intervention when the patient is between six and eight months old,the foot had the chance to re-shape and no further change can be seen. Although there are variations within the surgical methods, extensive soft-tissue release of the foot, as shown in figure 8 by Rab et al. (60), is almost always part of the treatment. (28,52)
Furthermore, in every surgery the correction is held with wires at the talocalcaneal and the talonavicular joint or with a plaster-cast, and the foot requires splintage in appropriate footwear for six to twelve months. (52)
Various procedures are still in use. Most important is, that the surgery is "tailored to the age of the child and to the deformity". (28) The procedure described by Mc Kay, was the surgical approach of choice at our center, as it

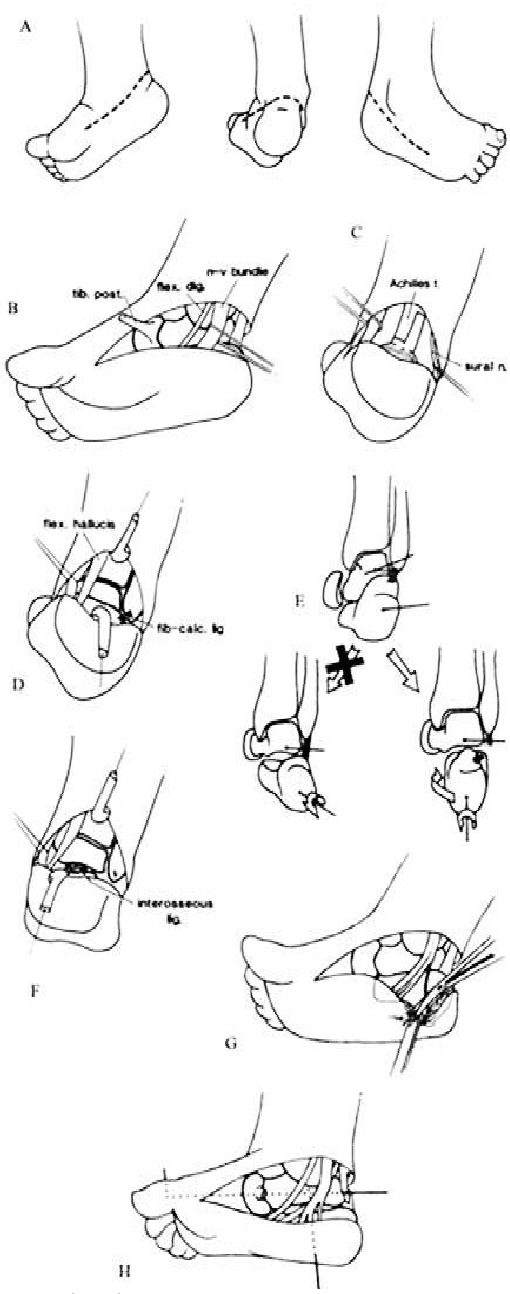


Figure 8: Clubfoot surgery (60)

takes account of the three-dimensional deformity of the subtalar joint. In this approach the Skin is incised through a circumferential (Cincinnati) incision (Figure 8A). The veins as well as the sural nerve are protected carefully, as the Achilles tendon is lengthened through a Z-shaped-tendoplasty (Figure 8C, D). Some ligaments fixating the talocalcaneal joint (e.g. calcaneofibular-, posterior calcaneotalar ligament, etc.) are dissected and the capsule of the ankle joint is incised, “At this point, the talus should roll back into the ankle joint” (Figure 8E). (28)

Incising the capsule of the talonavicular joint and the bifurcated ligament should correct the horizontal rotation of the calcaneus (Figure 8E). The medial side of the talus and the medial side of the cuneiforms are lined up. Before suturing the tendons the proper positioning of the foot should be checked. The longitudinal plane of the foot should be 85 to 90 degrees to the bimalleolar ankle plane, and the heel under the tibia should be in slight valgus. In a maximum of 20 degrees of dorsiflexion all tendons are sutured and their sheaths are repositioned over them. After surgery the foot is placed in an over knee cast, holding the foot in a neutral or slightly plantar flexed position to reduce tension on the suture line. At two weeks the cast is changed, and the foot placed in the correct position. Usually this is done with sedation or general anesthesia. After six weeks another cast change should be planned and all pins should be removed. Casting ends ten to twelve weeks after surgery. (28,52)

The surgical treatment of clubfoot is reported to sometimes result in overcorrection or generalized joint laxity. (61,62) In 2006 Haslam et al. reported 40 out of 70 clubfeet included in his study and treated surgically developed generalized joint laxity and 28 feet where assumed to be overcorrected. As a consequence the authors recommended a limited surgical release. (61) Besides over- and undercorrection Magone et al. also found avascular necrosis of the talus, navicular and calcaneus, and talar dome flattening to be complications of clubfoot surgery. (63)

3. METHODS

3.1 Therapy

The current trial is designed as a single center, non-blinded and randomized study. Those patients that have been treated for idiopathic clubfoot in the years 2001 to 2003 with the Ponseti method or the surgical treatment and took part in a previous study done by Zwick et al. are invited for a new follow-up 8-10 years after the treatment. During this visit, the patients answer questionnaires about their life satisfaction, participate in a clinical examination and gait-analysis as well as an x-ray examination of the foot.

3.2 Study participants

In the previous study nineteen patients with a total number of 28 clubfeet were included in the clinical trial. “Nine infants (with a total of 12 clubfeet) were assigned to the Ponseti treatment group, and 10 patients (with a total of 16 clubfeet) were assigned to a group with initial casting and posteromedial release at the age of 6 to 8 months.” (20) Two of those patients could not be invited to the current trial due to a change of their contact data, and two other refused their participation resulting in a total of fifteen patients (with a total of 24 clubfeet) that were included in our study. Of those 24 clubfeet, twelve were treated surgically while the other twelve received the Ponseti treatment. Within the surgical group six feet needed eight revision surgeries; in most cases a transfer of the anterior tibial tendon was performed. Within the Ponseti group only four out of twelve feet received additional surgical treatment other than a simple tenotomy of the Achilles tendon, two of those feet needed re-achillotomy and two needed transfer of the anterior tibial tendon.

Those children that were affected bilaterally received the same course of treatment on both feet. The participating children were 8 to 10 years old at the time of the current trial. The affected children as well as their legal guardian received an elucidation before they filled out an informed consent form. Both had to agree to be enrolled in the study. Only four of the fifteen children enrolled were female, the ratio between female and male feet was 1:3.

The severity of the clubfeet measured with the Pirani score in both groups was comparable. The detailed demographic description of both groups can be found in Table 1.

	Surgical Treatment	Ponseti Treatment
Sample size (Clubfeet)	12	12
Unilateral : Bilateral	2:5	6:3
Sex (f:m)	1:11	5:7
Age (mean) (±SD)	9.25	9.3
Pirani Score at birth (median)	3.75	3.25
Pirani Score at birth (mean) (±SD)	3.67 (±0.91)	3.46 (±1.89)
Additional surgical procedures (other than achillotomies)	8	4

Table 1: Description of the study groups

3.3 Examination

3.3.1 Medical examination following the protocol of the International Club Foot Study Group (ICFSG) and the Functional Rating System (FRS)

Medical examination is a simple, favorable and painless approach to test the mobility of the foot. In our study we used the assessment protocol by the ICFSG, established in 2003, to meet the latest standard of evaluation, as well as the functional rating system as used in the previous study by Zwick et al.(20)For optimal comparability it is necessary to use the same protocol lto gather information about the participants at follow-up.

Outcome Evaluation (International Clubfoot Study Group (ICFSG) and Bensahel) (Appendix A)

The ICFSG was founded in order to consolidate the massive amount of literature available on clubfoot and its treatment and to standardize the “language” used in pediatric orthopedists. In 2003 Bensahel and the ICFSG developed an evaluation tool to assess the morphological, functional and radiological outcome in treated clubfeet. (64) According to their protocol the morphology of the foot is analyzed and measured in a neutral position using a goniometer. varus/valgus and equinus/calcaneus deformity is measured in the hind foot while supination/pronation as well as ad-/abduction is measured in the midfoot. The overall alignment of the foot is examined in terms of rotation of the thigh-knee foot angle and the presence of cavus or flat foot is noted. Each parameter of the morphology is assessed on a scale between 0 and 2 points. A maximum of 12 points indicates the worst possible outcome in morphology. (64)

The functional assessment includes an evaluation of the passive motion (ankle, subtalar and midtarsal joint), the muscle function, the dynamic function and the experienced level of pain. A total of 36 points indicates the worst possible score in the functionality section. An x-ray analysis is used to determine residual misalignments in the bones of the foot. Six angles are evaluated in anteroposterior view radiographs (e.g. the talo-calcaneal angle, talo-M1 angle, ankle alignment etc.) and six in a standing lateral view (e.g. talo-calcaneal angle, tibio-calcaneal angle, etc.). Each angle is rated normal or abnormal. A score of maximal12 points can be reached and indicates that all angles appear abnormal. (64)
According to the ICFSG protocol all feet with an overall score between 0 and 5 are rated as “excellent”, between 6 and 15 as “good”, while scores between16 and 30 points are rated as “fair” and exceeding 30 points as “poor”. (64)

Functional Rating System (FRS) (Laaveg and Ponseti) (Appendix B)

For an optimal comparability the FRS is also used in our study to assess the long-term outcome in treated clubfeet. The FRS was first described by Laaveg and Ponseti in 1980 when they assessed 104 clubfeet, treated at the Department of Orthopedic Surgery at the University of Iowa Hospital between 1950 and 1976. (16) “A rating system for functional results was designed, with 100 points indicating a normal foot. This included a maximum score of 30 points for amount of pain; of 20 points each for level of activity and patient satisfaction; and of 10 points each for motion of the ankle and foot, position of the heel during stance and gait”. The total scores were classified as excellent (90-100 points), good (80-89 points), fair (70-79 points) or poor (<70 points). (16)

3.3.2 3D gait analysis

To assess the ankle joint mobility a 3Dgaitanalysis was performed. For this analysis we used the "Vicon MX Motion Capture System" and the Oxford Foot Model. As shown in figure 9, the cameras are positioned around the capture area so that at least two see each marker at any given time. They are equipped with a powerful infrared light. Retro-reflective markers reverse the light and result in a corresponding bright spot in each image. (36)

For an optimal positioning of the cameras a calibration needs to be undertaken so that every camera can localize the marker as a spot. The spots are then reconstructed to generate the 3D trajectories. (36)

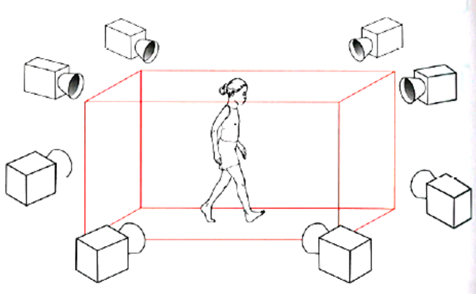


Figure 9: Position of the cameras in 3D gait analysis (36)

The objective of a gait analysis is to capture the movement of body segments. Whereas in a 2D analysis two markers are necessary to define the location of a segment, three markers are needed to define the segment in a 3Danalysis. The correct position of the markers is essential to produce accurate measurements. Certain reference points are defined for each gait analysis model. To measure the kinematics of the pelvis, hip, knee and ankle the marker placement followed a standard protocol (Figure 10) described by Davis et al. (65) in 1991. (36)

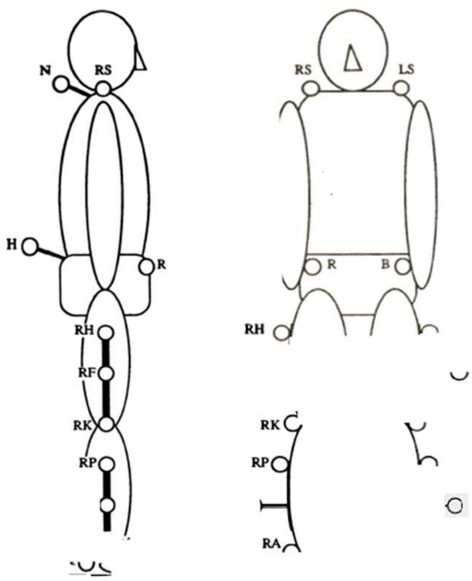


Figure 10: Marker config.employed at the Newington Children´s Hospital (65)

Viewing the foot as one single rigid vector was prevalent in almost all gait analysis models for a long time. This limited the diagnostic relevance of the gait analysis in foot deformities. (36,39,66)

According to Kirtley basically three problems led to this limitation: (36)

1) The foot is formed by 26 separate bones. To observe the motion between them, it would be necessary to put markers on each bone. Even if very small markers would be used, advanced camera technologies would be required to distinguish between the markers and reconstruct a proper image.
2) The second limitation arises due to the skin-bone interface artifact.
3) The third problem arises out of the complexity of articular surfaces and the fact that the joints between the bones of the foot do not act as simple hinge joints.

These problems subsided over the last decade, as video technology improved and made it possible to observe the foot´s functional segments more detailed. Thanks to these improvements several multi-segment models evolved.

In 2001 Carson et al. referred to their limitations in comparability and started a study in order to “develop a multi-segment foot model and measurement protocol applicable to gait analysis for clinical and research applications” and to “evaluate the reliability of the protocol and model”. (39) During his attempt to develop the later called “Oxford Foot Model (OFM)” he measured the motion between the tibia, the hind- and the forefoot as well as the hallux (Figure 11). Two testers performed repeated gait analysis on two participants in their mid-twenties. (39) Therefore, in 2006 the Oxford Foot Model was re-evaluated by Stebbins et al., to modify it for the use in children. Figure 12 shows the markers used in Stebbins’ trial and their position on the lower extremity. “Five variations of the default model were tested for anatomical feasibility and repeatability.” (66) Changes were made to the default model, like using anatomical markers on the tibia itself instead of using the knee joint center to define the longitudinal axis of the tibia, eliminating

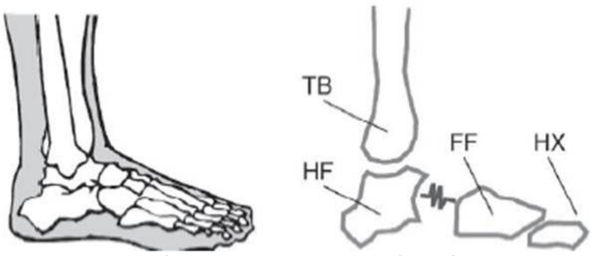
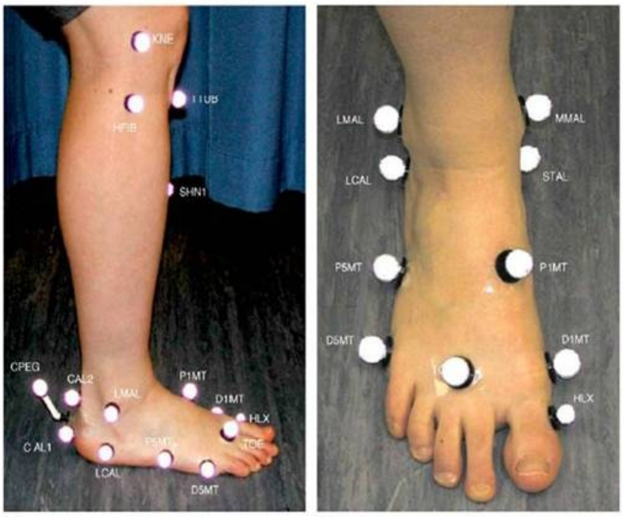


Figure 11: Three functional segments of the foot used in the OFM (39)



Names and positions of markers used in the foot model

Marker name	Position	Segment
KNE	Femoral condyle	Femur
TTUB	Tibial tuberosity	Tibia
HFIB	Head of fibular	Tibia
LMAL	Lateral malleolus	Tibia
MMAL	*Medial malleolus*	*Tibia*
SHN1	Anterior aspect of shin	Tibia
CAL1	Posterior distal aspect of heel	Hindfoot
CAL2	*Posterior medial aspect of heel*	*Hindfoot*
CPEG	Wand marker on posterior calcaneus aligned with transverse orientation	Hindfoot
LCAL	Lateral calcaneus	Hindfoot
STAL	Sustentaculum tali	Hindfoot
P1MT	Base of first metatarsal	Forefoot
P5MT	Base of fifth metatarsal	Forefoot
D1MT	*Head of first metatarsal*	*Forefoot*
D5MT	Head of fifth metatarsal	Forefoot
TOE	Between second and third metatarsal heads	Forefoot
HLX	Base of hallux	Hallux

Names in italics are used in the static trial only and are removed for dynamic trials.

Figure 12: Position of markers on the leg and foot (Oxford Foot Model) (66)

the wand marker on the posterior calcaneus (CPEG) only in dynamic trials to potentially reduce the source of variability when it is knocked, or eliminating it in static calibration.

As Stebbins et al. compared the variability between the different variations they found that the only change contributing to a better repeatability was the elimination of the CPEG during static calibration as it significantly reduced the standard deviation for hind foot rotation. Stebbins also concluded that the “results in kinematic patterns were found to be more consistent than the absolute values. Absolute measurements in the transverse plane were found to be the least consistent” and stated that “a significant factor is the consistency of marker placement between days on small feet. Therefore, clear protocols and practice in marker placement are crucial.” (66)

Following the recommendations by Stebbins et al. we used the same experienced gait lab technician and orthopedic surgeon throughout our study to position the markers according to the protocol of the Oxford Foot Model. And because modern “gait analysis instrumentation is now capable of detecting multiple small markers on the foot as well as those on the rest of the body” (67), we supplemented some markers on the upper legs and hip.

The angular relationships in joint kinematics seem to be expressed as Euler angles in the majority of 3D gait analysis models. (67,68) These are angles between three axes which define the position of a solid body (e.g. segment) in the three-dimensional space. In our study, we used the angles and terminology according to the study by Carson et al. from 2001. (39) (Table 2)

Segment Pairs	Axes	Motion
Hind foot/Tibia (HF/TB)	Mediolateral axis of TB	Plantar-/Dorsiflexion
	Post./Ant. axis of HF	Inversion/Eversion
	Perpendicular axis	Internal/External Rotation
Forefoot/Hind foot (FF/HF)	Mediolateral axis of HF	Plantar-/Dorsifelxion
	Post./Ant. axis of FF	Supination/Pronation
	Perpendicular axis	Ab-/Adduction
Hallux/Forefoot (HX/FF)	Mediolateral axis of FF	Plantar-/Dorsiflexion
	Plantar/Dorsal axis of HX	Ab-/Adduction
	Perpendicular axis	Axial Rotation

Table 2: Rotational axes and Motion in OFM (39)

3.4 Pediatric Outcomes Data Collection Instrument (PODCI)

To analyze the patient´s individual satisfaction with the treatment and life satisfaction, we used the "Pediatric Outcomes Data Collection Instrument (PODCI)" (Appendix C). This tool was first published by Daltroy in 1998 and is used to assess the patient's overall health, ability to participate in activities of daily living (ADLs) as well as more vibrant activities and pain, in children under the age of 19 years. (69) PODCI's "target populations are children and adolescents with general health problems, specifically any problems related to bone and muscle conditions." (70)

Daltroy designed three sets of questionnaires: The first was the "Adolescent Outcomes Questionnaire (self report)" which is used for adolescents in the age between 11 and 18 years and in which the outcome is self-reported by the adolescents. The second questionnaire – the "Adolescent Outcomes Questionnaire (parent report)" - was designed for parents to report the outcome of their children between 11 and 18 years. The third report was the "Pediatric Outcomes Questionnaire" which was designed for the parents to report the outcome of their children between 2 and 10 years. (70) This questionnaire was used in our trial and contained 86 questions to be completed by a parent or guardian of the child.

The questionnaire included questions about:

- The upper extremity and physical function
- Transfers and mobility
- The child's abilities to participate in sports and its physical functions
- Pain & comfort
- Individual happiness
- Treatment expectations as well as satisfaction with his symptoms

The majority of the items were scored on a 1 to 5 scale "with 1 indicating the most positive response." (70) Some questions also included the option to indicate that the child was too young and the question therefore not applicable. In this case the response was marked as "missing" and omitted from the score.

The score ranged from 0 to 100 where a higher score represented a better functionality. In the United States, the healthy adult population achieved an average score of 50 (mean) with a standard deviation of 10 for each scale. Every standardized score above this average represents an even better functionality while a score below 50 represents a reduced mobility compared to the healthy population's average. (70)

3.5 Statistics

For the statistical analysis a software package Statistica was used. After independency of our study groups was assured, the p-levels were calculated using the non-parametric Mann-Whitney-U Test due to low sample sizes. A descriptive statistics (mean, median and confidence intervals) was used to describe the differences between the groups.

4. RESULTS

The two treatment groups were comparable in terms of Pirani score at birth, sample size, and age. For the Pirani score at birth in the Ponseti group we calculated a mean of 3.46 (±1.89) and a median of 3.25, in the surgical treated suspects we found a mean of 3.67 (±0.91) and a median of 3.75. The Mann-Whitney U test showed no significant difference in both treatment groups evaluated for the pirani score at birth (p=0.624). The average time of follow up was 9.8 years.

4.1 Examination - ICFSG and FRS

When the classification system, developed by the ICFSG was applied, no study participant presented with either “excellent” or “poor” results. While all subjects in the Ponseti group showed “good” results with scores ranging from 7 to 13 points; in the surgical group only 5 out of the 12 participants received “good” scores (9 – 11 points), the other 7 participants only showed “fair” results (18 – 25 points).
The statistical analysis of the ICFSG-examination´s results revealed significantly better results for the Ponseti treatment group within all sections of the evaluation (Table 3). Within the morphology section the average suspect treated by the Ponseti protocol scored about 2out of 12 points better than an average surgically treated study participant. This was especially seen in the fact, that children treated by the Ponseti method show significantly less cavus or flat foot deformity (p=0.002; OP: Ø=1.17, Ponseti: Ø=0.25 out of 2 points). Also a significant difference of about 3.4 out of 36 points was noted for the functional evaluation scores, as well as 1.9 out of 12 points for the radiologic evaluation in favor of the Ponseti treatment. Within the functional evaluation we found no difference between the groups for subtalar varus or valgus deformity, also only few cases with intoeing during gait, and again, no significant difference between the groups was seen. However, we found significantly more cases showing dynamic supination in the surgically treated children (p=0.008; OP: 1.08, Ponseti: 0.17 out of 2 points), also significantly more often pain was described by those who were treated surgically (p=0.01; OP: Ø=1.58, Ponseti: Ø=0.42 out of 3 points). Within the radiological assessment 1 point was given for each abnormal angle noticed. The radiographs

did not show significant differences in the Talo-calcaneal angle, neither on the lateral nor on the anterior-posterior views. On the lateral radiographs we found the Talo-navicular angle to significantly differ between the groups (p=0.045; OP: Ø=0.75 points, Ponseti: Ø=0.33 points).

The above mentioned differences led to the fact, that the average total ICFSG-Score for the Ponseti group outranked the average score measured in the surgical group by 7.3 out of 60 points.

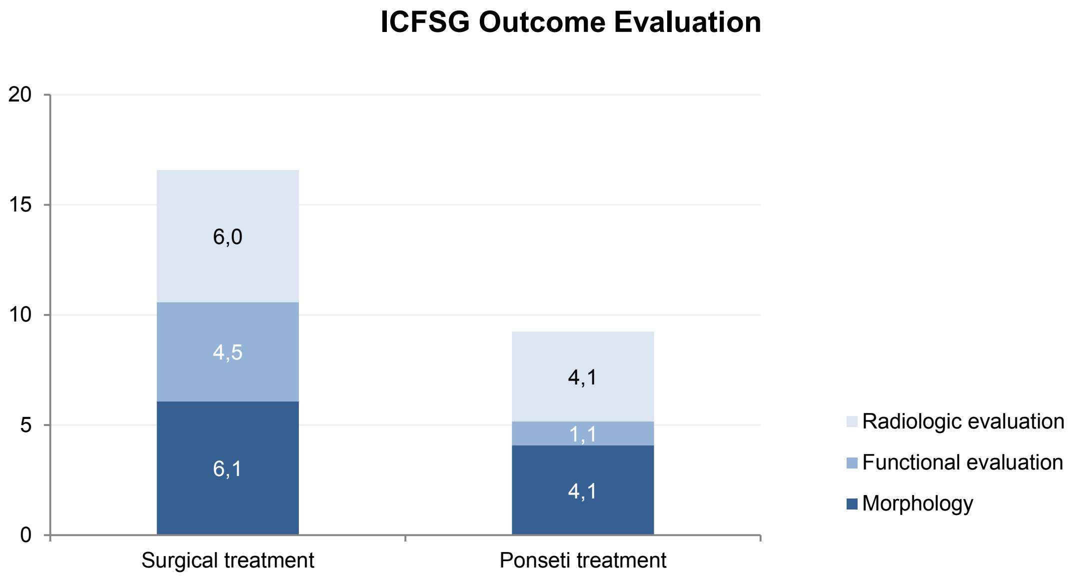


Figure 13: Comparison of outcomes according to the ICFSG protocol

ICFSG Outcome Evaluation						
	Ponseti Treatment (n=12)			Surgical Treatment (n=12)		
	Mean (±SD)	Median	5%CI/ 95%CI	Mean (±SD)	Median	5%CI/ 95%CI
Morphology (p=0.021)	**4.083 (±0.1)**	**4.0**	**3.5/4.7**	**6.083 (±2.15)**	**6.0**	**4.7/7.5**
Functional (p=0.005)	**1.083 (±0.1)**	**1.0**	**0.5/1.7**	**4.500 (±3.37)**	**4.5**	**2.4/6.6**
Radiologic (p=0.020)	**4.083 (±2.11)**	**3.0**	**2.7/5.4**	**6.000 (±1.6)**	**7.0**	**5.0/7.0**
Total (p=0.004)	**9.250 (±2.26)**	**9.0**	**7.8/10.7**	**16.583 (±6.07)**	**19.0**	**12.7/20.4**

Table 3: Statistics regarding the ICFSG outcome evaluation. Outcomes written in bold letters found to be significantly different between the groups.

Although not recommended by the ICFSG, we also measured the lateral Calcaneo-M1 angle (p=0.004; OP: Ø=159.8°, Ponseti: Ø=149.4°) as well as the Calcaneal-Pitch (p=0.006; OP: Ø=6.8°, Ponseti: Ø=14.4°), which both showed significant differences between both groups.

Even the FRS total score proofed the Ponseti treatment, to be superior to the surgical treatment (p=0.0045) at 10 year follow up (Table 4). We found a difference of 9.25 points for the average total FRS score (100 points) between both groups, indicating the Ponseti treatment to be the treatment of choice. While 100% of the Ponseti patients showed "excellent" results with scores above 90 points, in the surgical group only 25% presented with "excellent", 50% with "good" (80-90 points), 17% with "fair" (70-80 points) and one foot (8%) with "poor" (<70 points) outcome. Our study showed that measured by the FRS, the Ponseti treatment exceeded the surgical treatment in terms of pain. Within that section we found a difference of 5.8 out of 30 points. (Table 4)

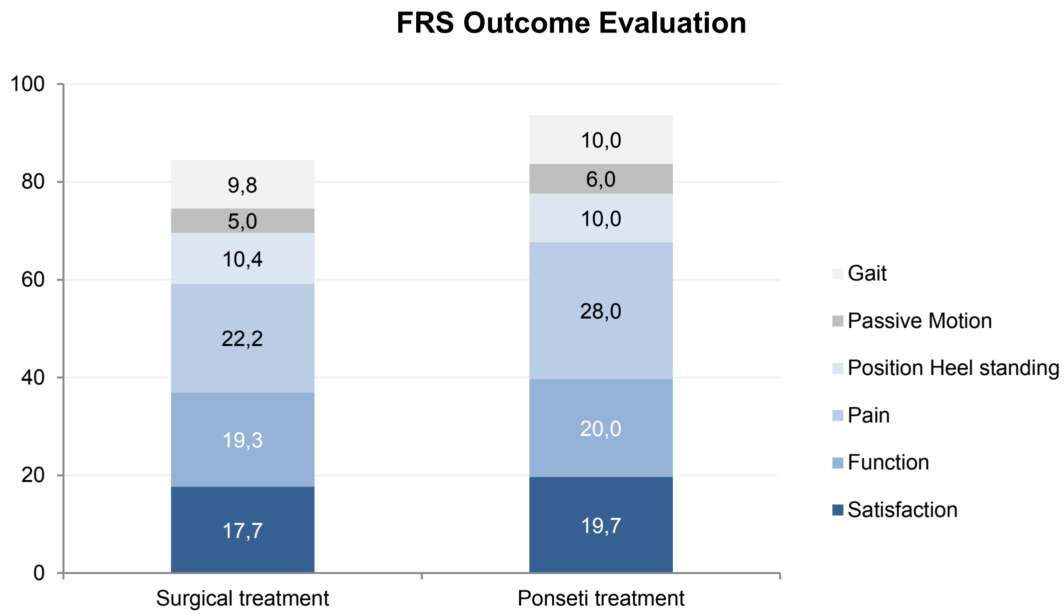


Figure 14: Comparison of outcomes according to the FRS

Functional Rating System						
	Ponseti Treatment (n=12)			Surgical Treatment (n=12)		
	Mean (±SD)	Median	5%CI/ CI95%	Mean (±SD)	Median	5%CI/ 95%CI
Satisfaction (p=0.23)	19.67 (±1.16)	20.0	18.9/20.4	17.67 (±4.33)	20.0	14.9/20.4
Function (p=0.317)	20.0 (±0)	20.0	20.0/20.0 (min/max)	19.33 (±2.31)	20.0	17.9/20.8
Pain (p=0.003)	**28.0 (±2.90)**	**30.0**	**26.1/29.9**	**22.17 (±4.55)**	**22.0**	**19.3/25.1**
Position heel standing (p=0.317)	10.0 (±0)	10.0	10.0/10.0 (min/max)	10.42 (±3.34)	10.0	8.3/12.5
Passive motion (p=0.094)	6.0 (±1.41)	6.0	5.1/6.9	5.0 (±1.54)	5.0	4.0/6.0
Gait (p=0.317)	10.0 (±0)	10.0	10.0/10.0 (min/max)	9.83 (±0.58)	10.0	9.5/10.2
Total (p=0.005)	**93.67 (±2.71)**	**94.0**	**92.0/95.4**	**84.412 (±11.6)**	**87.5**	**77.1/91.8**

Table 4: Statistics regarding the FRS. Outcomes written in bold letters found to be significantly different between the groups.

4.2 3D gait analysis

The appraisal of the 3D gait analysis data showed physiological motion in the ankle joint of the children treated by the Ponseti method and their results were found to be closer to normal feet. Children of the Ponseti group showed significantly bigger maximum dorsiflexion at the ankle joint (max. HF dorsiflexion) than operatively treated children (p=0.039; OP: Ø=-3.38°, Ponseti: Ø=4.71°). Also within the surgically treated group the maximal dorsiflexion occured significantly later in the gait process than within the group of the conservatively treated children (p=0.002; OP: Ø=49.67%, Ponseti: Ø=39.44%). Another significant difference between the groups was found in the max. dorsiflexion of the hallux (HX) (p=0.047). In the metatarsophalageal joint of the hallux we saw a greater max.

dorsiflexion in the children treated by the Ponseti method (Ø=37.44°) compared to the surgically treated children (Ø=28.06°).There was not found any statistically significant difference between the groups in terms of dorsiflexion, adduction or pronation of the forefoot (FF) to the tibia (TIB). Also, rotation, inversion and range of motion (dorsi-/plantarflexion, rotation, in-/eversion) of the hind foot (HF) in the ankle joint did not proof to be significantly different between both groups.

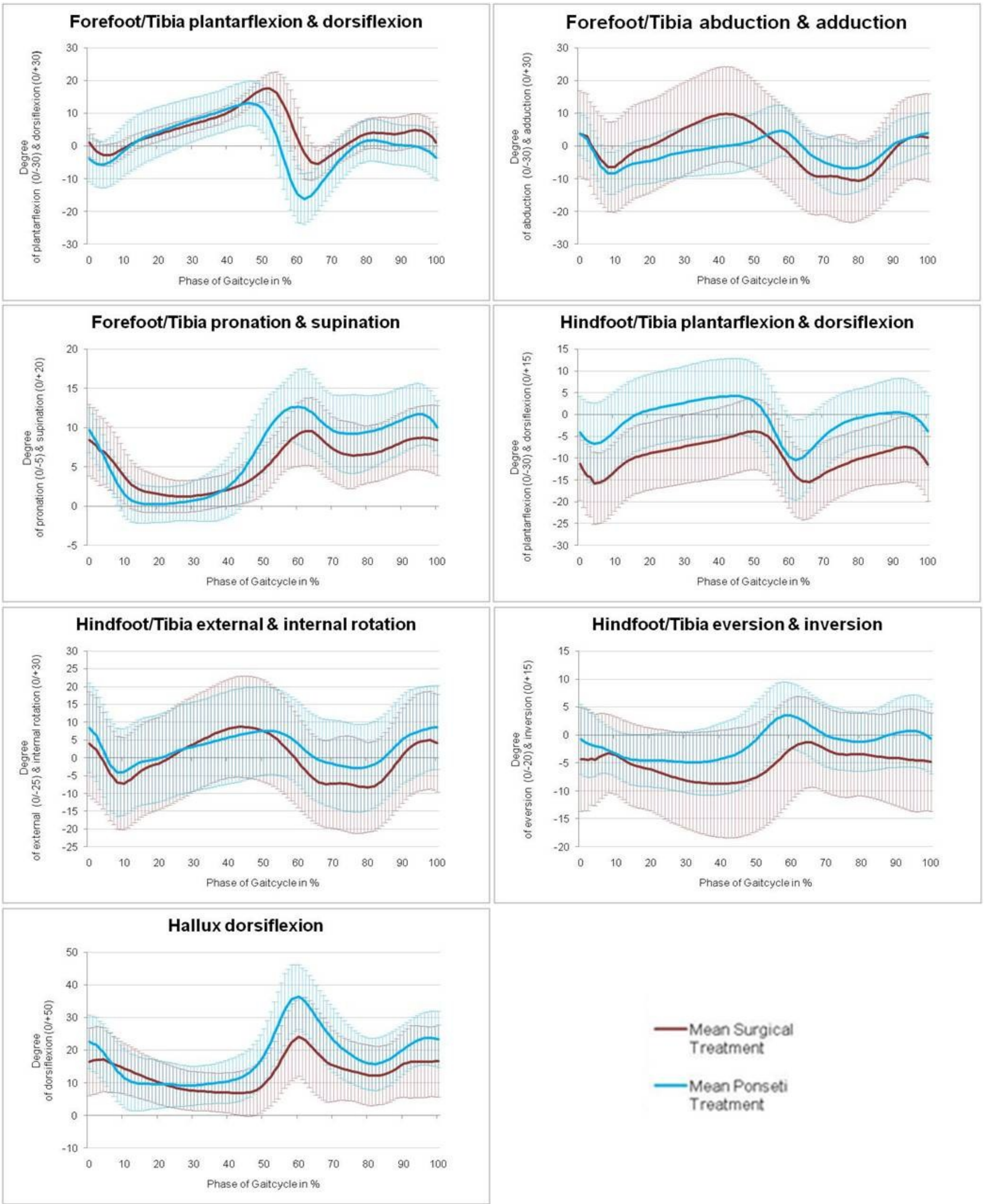


Figure 15: Comparison of gait analysis data (Mean and SD)

3D gait analysis						
	Ponseti Treatment (n=12)			Surgical Treatment (n=12)		
	Mean (±SD)	Median	5%CI/ 95%CI	Mean (±SD)	Median	5%CI/ 95%CI
Max. FF dorsiflexion (p=0.088)	13.93 (±7.22)	14.7	8.4/19.5	18.39 (±4.23)	19.0	15.7/21.1
Mean FF adduction (p=0.2)	-2.31 (±6.88)	-4.3	-7.6/3.0	3.7 (±13.58)	5.6	-4.9/12.3
Mean FF pronation (p=0.722)	2.74 (±3.26)	3.0	0.2/5.2	1.85 (±2.3)	1.7	0.4/3.3
Max. HF dorsiflexion (p=0.039)	**4.71 (±8.54)**	**4.46**	**-1.9/11.3**	**-3.36 (±7.24)**	**-2.9**	**-8.0/1.2**
Timing max. HF dorsiflexion (p=0.002)	**39.44 (±10.04)**	**43.0**	**31.7/47.2**	**49.67 (±4.77)**	**51.0**	**46.6/52.7**
Mean HF rotation (p=0.394)	2.15 (±11.20)	-2.2	-6.5/10.8	2.51 (±12.95)	4.0	-5.7/10.7
Mean HF inversion (p=0.256)	-3.51 (±5.11)	-3.67	-7.4/0.4	-7.21 (±8,51)	-7.0	-12.6/-1.8
Max. HX dorsiflexion (p=0.047)	**37.44 (±9.46)**	**36.1**	**30.2/44.7**	**28.06 (±9.35)**	**29.0**	**22.1/34.0**
ROM HF dorsiflexion/ plantarflexion (p=0.477)	15.54 (±3.72)	14.0	12.7/18.4	14.01 (±2.75)	13.7	12.3/15.8
ROM HF rotation (p=0.177)	16.42 (±2.36)	16.3	14.6/18.2	20.11 (±5.81)	21.1	16.4/23.8
ROM HF inv./ eversion (p=0.67)	9.57 (±2.02)	10.1	8.0/11.1	8.72 (±2.99)	8.9	6.8/10.6

Table 5: Statistics regarding the 3D gait analysis. Outcomes written in bold letters found to be significantly different between the groups.

4.3 Pediatric Outcomes Data Collection Instrument (PODCI)

The Pediatric Outcomes Data Collection Instrument questionnaire showed preferable results for the Ponseti group. The global function score (Mean of Std. Means), with not more than 100 points attainable, showed 7.8points better results within the patients treated by the Ponseti protocol. This difference resulted due to 6.4 points better results within the section of "sports & physical functioning", 25.6 points in "pain & comfort" and 11.7 points better results regarding the "Happiness" section for the Ponseti children.

PODCI	Ponseti Treatment (n=12)			Surgical Treatment (n=12)		
	Mean (±SD)	Median	5%CI/ 95%CI	Mean (±SD)	Median	5%CI/ 95%CI
Upper Extremity (p=0.317)	99.0 (±3.46)	100.0	96.8/101.2	100.0 (±0)	100.0	100.0/100.00 (min/max)
Transfer, basic mobility (p=0.317)	99.42 (±2.02)	100.0	98.1/100.7	100.0 (±0)	100.0	100.0/100.0 (min/max)
Sports, physical functioning (p=0.002)	**98.75 (±2.38)**	**100.0**	**97.2/100.3**	**92.33 (±5.93)**	**92.5**	**88.6/96.1**
Pain, comfort (p=0.033)	**96.67 (±5.25)**	**100.0**	**93.3/100.0**	**71.08 (±35.4)**	**91.0**	**48.6/93.6**
Happiness (p=0.018)	**96.25 (±9.32)**	**100.0**	**90.3/102.2**	**84.58 (±23.59)**	**95.0**	**69.6/99.6**
Global func. Mean of Std. Means (p=0.010)	**98,42 (±2.02)**	**100.0**	**97.1/99.7**	**90.58 (±10.01)**	**95.5**	**84.2/97.0**
Global function Norm. Score (p=0.018)	**58.08 (±8.89)**	**58.0**	**52.4/63.7**	**45.67 (±13.53)**	**52.5**	**37.1/54.3**

Table 6: Statistics regarding the PODCI. Outcomes written in bold letters found to be significantly different between the groups.

5. DISCUSSION

Our study revealed that the long term outcome of patients treated with the Ponseti method is superior compared to those treated surgically with the McKay method. Besides the fact, that the children in the Ponseti group needed notably less additional invasive surgery the Ponseti group showed significantly better results in terms of pain (PODCI, FRS), functionality (OFM, ICFSG, PODCI) and morphology (ICFSG). Also, the assessment of the angles in the radiographs of those patients proved to be significantly closer to the angles expected in normal feet. Furthermore, the gait analysis showed a significantly greater flexibility especially for dorsiflexion and plantarflexion of the ankle joint. Our findings matched with the hypothesis stated at the beginning of the thesis.

By applying the International Clubfoot Study Group (ICFSG) outcome evaluation protocol (Appendix A) to both study groups we were able to collect relevant information about the patients. The Ponseti group showed superior results within all sections of the protocol. The ICFSG Scores showed 100% “good” results for those patients treated by the Ponseti method. Compared to these results the surgical treatment seemed to be less effective, with only 41.7% “good” and 58.3% “fair” results. The average total score for the ICFSG was approximately 7.3 out of 60 points better in the Ponseti group than in the surgically treated group. The largest difference could be seen within the morphology section. Although the radiological differences in our trial appeared smaller between both study groups than the morphological varieties, different authors described the radiological angles as an important outcome measure. (40) The recently published work by Graf et al about functional outcome measures and their value in the assessment of clubfoot treatment described that abnormal radiographic measurements may correlate with the degree of residual deformity, like parallelism of the talus and the calcaneus and/or a reduction of the talocalcaneal angle (AP or lateral). (40) The latter may correlate with the functional outcome, as is mentioned by Lykissas. (17) Also, especially in surgically treated feet a diminished calcaneal pitch may be seen. (40) However, some authors also questioned the correlation of radiographic angles and functionality and its predictive value. (17,19,71,72)

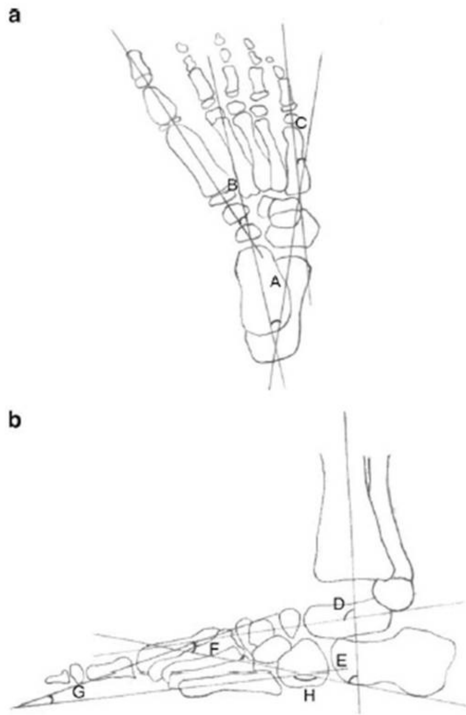


Figure 16: Angles used in our study I (76)

Radler et al. published their findings concerning interobserver reliability in 2010. They described measurement discrepancies of up to 30° but still described good interobserver reliability for the talocalcaneal (AP and lateral) and the AP calcaneus-fifth metatarsal angle. (73) Other authors also described good interobserver reliability and stated that minor errors of positioning cause only small angle variances. (74,75) In our study the assessment of the radiographs was complicated by the fact that when the ICFSG scoring system was introduced by Bensahel et al. in 2003, no instructions for the radiographic angle measurements were provided. As some of the angles are not commonly used in foot radiographs, finding proper instructions was a challenge. This could lead to some measurement bias and partially limit the validity of our results.

The radiographic angles suggested by the ICFSG were taken according to recommendations by Prasad et al. and Escobedo. (76,77) The measurement techniques used in this study can be found in Figures 15-16, the calcaneocuboid alignment was measured by the Thometz grading system. (78)

Figure 15 shows:
- (A,F) Talo-calcaneal AP and lat.
- (B) Talo-1st Metatarsal AP
- (E) Tibiocalcaneal lat. Angles
- (H) Calcaneo-5th Metatarsal axis

Figure 16 shows:
Upper row left to right (AP):
- Talocalcaneal angle
- Talo-1st Metatarsal angle
- CYMA Line
- Talo-navicular position
Lower row left to right (Lat.):
- Talocalcaneal angle
- Talo-1st Metatarsal angle
- CYMA Line
- Calcaneal Pitch

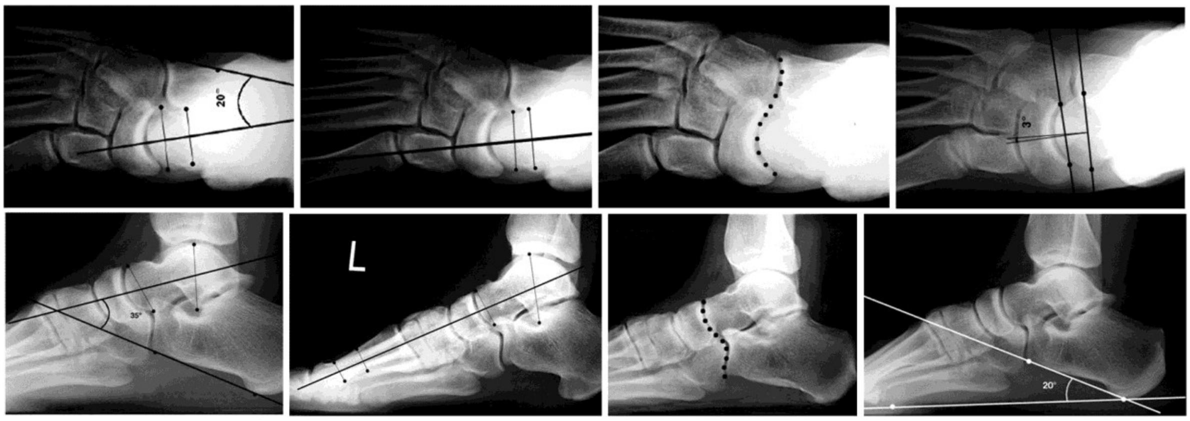


Figure 17: Angles used in our study II (77)

As these techniques may differ slightly in other studies using the ICFSG´s protocol as an outcome measure the radiological scores can only be compared with caution. Because the angles were only rated normal or abnormal and no exact degrees were given, this difference might only be minor. Another obstacle for the application of the ICFSG protocol was a wrong scoring system within pain measurement. Bensahel et al. recommended a scoring system where “no pain” receives 0 points, “pain with activity” receives 1 point and “pain with sports” receives 2 points. (64) In our opinion, however, the two categories “pain with activity” and “pain with sports” should be exchanged, as “sports” is of greater intensity and therefore leads earlier to pain than “activity”. In our study we rated those two increments vice versa to achieve appropriate scores.

The results of the evaluation using the FRS (Appendix B) also revealed significantly better results for those patients who have received repeated manipulation and serial casting after Ponseti. Zwick et al. found that 3.5 years after the initial treatment the total score for the FRS as well as the sub-categories “satisfaction” and “passive motion” (dorsiflexion and ant. inversion/eversion) were significantly better for those patients treated with the Ponseti method. (20) However, six years later our study revealed that the same children showed significantly better results for the Ponseti group within the sub category “pain” as well as the total FRS score. In our study 100% of the Ponseti patients showed “excellent” FRS scores compared to 25% within the surgical group. One patient of the surgical treatment group who presented with a bilateral clubfoot received an overall FRS score of 54 points for his left and 95 points for his right foot. While his left foot could only be rated as “poor” the right foot received an “excellent” rating. A possible reason for the large difference within this patient´s scores may be also the rating system´s major limitation: it depends heavily on the patient's subjective response. (16)

Our findings matched with the results of the meta-analysis study performed by Lykissas et al., which analyzed the outcomes of 12 studies comparing the primary management of patients with CTEV with either soft-tissue release or the Ponseti method. The analysis revealed a higher rate of "excellent" or "good" FRS results for those patients treated by the Ponseti method (although this difference was not statistically significant). (17) Several other authors also found high rates of "good" to "excellent" results for the patients treated with the Ponseti method in the past. While in 2011 Porecha et al. found "good" to "excellent" FRS scores in 89.3% of the cases (79), Pavone et al. even described that 95.6% of the patients within the Ponseti group scored above 80 points in the FRS. (80) The average FRS total scores for the patients treated surgically were described in the literature in a range from 65.3 points (81) to 87,5 points (16). Lykissas et al. could furthermore confirm what also Laaveg and Ponseti found in 1980: that a larger talocalcaneal angle is correlated with a better functional outcome. (16,17)

The 3D gait analysis showed that the participants treated by Ponseti´s approach showed significantly more dorsiflexion in the ankle joint than those children who underwent primary corrective surgery. By using the Oxford foot model we were able to observe the difference in ankle joint flexibility between our study groups. As it was not possible to make observations regarding the movement of one particular joint of the foot in older gait analysis models, our finding was very revealing. Recently Smith et al published their results using another mutisegmental foot and ankle motion analysis (Millwaukee foot model) comparing surgically treated adult clubfoot patients with patients who were treated by the Ponseti method and to a control group without clubfoot. They described similar findings, for example that subjects in the Ponseti group more closely resembled subjects in the control group. The surgically treated patients showed diminished peak plantarflexion during preswing and in both clubfoot groups showed reduced dorsiflexion during swing phase. (82) While we could not compare the results of our study groups to those of a control group, we also observed that the results of the ponseti group appeared closer to results of the OFM in children with “normal” feet described by other authors. (66) Compared to the results described by Stebbins et al. (66) we saw, that children treated by the Ponseti approach show viewer difference to normal feet than children treated surgically. This difference was especially seen in the maximum dorsiflexion of the hind foot as well as in the maximum dorsiflexion of the forefoot. Usually the maximum dorsiflexion in the hind foot is bigger and dorsiflexion in the forefoot is smaller in children with healthy feet than in children with clubfoot. This led us to believe, that in older gait analysis models, were the foot was treated as a single rigid body, the difference between surgically and conservatively treated feet in ankle dorsiflexion was underestimated. Because the surgically treated children could compensate the lack of hind foot dorsiflexion by increased dorsiflexion in the forefoot, and this foot models were not able to distinguish between those two joints, the studies using such models could probably not reveal that difference.

Smith et al. also described decreased hind foot ROM for both groups because of a plantar flexion shift in the hindfoot and a corresponding dorsiflexion shift in the forefoot kinematics. Compared to the their control group he reported, that only the surgically treated patients had significant different ROM of the hind foot (82), which supports the assumption, that children treated by the Ponseti protocol show better results.

In 2009 Zwick et al. could not find significant differences between the two study groups measured by the Pediatric Outcome Data Collection Instrument (PODCI) 3.5 years after initial treatment. (20) Opposite to Zwick, about 10 years after the treatment, we were able to observe that the total (“global functioning”) scores for the PODCI within the Ponseti group excelled the average total scores of those patients treated surgically. The subgroups of “sports & physical functioning”, “pain & comfort” as well as “happiness” showed significantly better results for the group that was not treated surgically. Our findings are consistent with the findings by Church et al., who also found the scores within the sections of “global functioning” as well as “pain& comfort” to be significantly higher in the Ponseti group compared to the group that received the surgical treatment. (11) These differences in the functional outcomes maybe explained with the average time of follow-up. As

illustrated by previous studies by Centel, Dobbs, Ippolito and others, surgical treatment mostly provides satisfactory short-term clinical results, but long-term results based on questionnaires, examinations and imaging turned out to be disappointing. (11,17,81,83,84)
Although the Pediatric Outcome Data Collection Instrument (PODCI) was not designed specifically for the use in children with congenital equinovarus deformity, it shows adequate sensitivity to change. It is easily understandable and only takes about 15 minutes to answer all questions. (70) On the other hand, a major challenge in using the PODCI was that it had to be translated into German before it could be used by the patient´s parents (Appendix C). Since the language used in the PODCI questionnaire is quite simple (70) most questions could be translated easily into German language. Some questions used Anglo-American specific measures to which the Austrian participants could most likely not relate. Those measures had to be adapted to fit our setting ("gallon"/"liter", "block"/"meter"). Another limitation stems from the fact, that although, "the standardized scores are all in the range of 0-100, the interpretation of a single standardized score is not consistent between scales due to differences in how the general, healthy population is scored." (70) Therefore, in the original study the PODCI scores were standardized by comparing them to data of the general, healthy and adult US population. These transformed scores were not used in our study and therefore, the comparability of the results with results of other studies is limited.

Apart from the fact that we found beneficial outcomes in favor of the Ponseti method in the results of all measurement tools, also considerable less revision surgeries were necessary in those feet. As mentioned by Zwick et al. their recruiting process needed to be discontinued because of the different necessity of additional surgical procedures. (20) The children from the Ponseti group mainly needed only a transfer of the anterior tibial tendon, which is considered a standard part of the Ponseti treatment. The additional surgeries needed in the surgically treated group were more invasive. Of the twelve surgically treated feet eight (4 children) needed an additional surgery. Of those feet two were revised with a partial release to correct the residual deformity, four surgeries were limited to a simple transfer of the tibialis anterior tendon and two feet subsequently underwent an open/close wedge osteotomy to correct the forefoot adduction. From the Ponseti group only two feet needed a transfer of the tibialis anterior tendon and two feet (one child) underwent a re-achillotomy at the age of 1½ years. Tenotomy of the Achilles tendon, which is part of the initial Ponseti treatment, was necessary in nine out of twelve feet. A study conducted by Halanski et al. in New Zealand in 2010 supports our findings. They described significant less need of revision surgery for clubfeet treated by the Ponseti method, also they noticed less major recurrence leading to major surgery in the conservatively treated feet. (14)

While reviewing our results it should be kept in mind, that in the former study, by Zwick et al. the local ethics committee required an interim evaluation of the extent of surgery required to achieve correction of the deformity after a minimum of 12 feet was assigned to each group. Recruitment of patients stopped in 2003 when this evaluation revealed that a higher number of consecutive surgical procedures was required within the surgical treatment group. (20) Although the initial calculated sample size of 23 clubfeet per treatment group could not be retained, the study led to a change in the local treatment protocol at the Department of Pediatric and Adolescent Surgery at the Medical University of Graz from the traditional surgical to the Ponseti treatment. Because of the limited study size in the previous study and missing contact data, our follow-up study had to be done on even lower sample sizes.
Due to this low number of study participants, in bilateral clubfeet both feet were treated as separate study subjects. However in bilateral clubfeet the possibility of disregarded confounders can distort the results. As mentioned by Gray in 2012, in “bilateral cases each limb does not respond independently of the other and therefore violates the underlying independence assumption of statistical analysis.” (22) These limitations must be considered when our results are interpreted.

Beside its limitations, this thesis comes to the conclusion that the best initial treatment for an idiopathic clubfoot is the Ponseti method. Our results are consistent with the results of many authors, who describe the Ponseti method as the preferred treatment modality. Even if the outcome between surgical and Ponseti treatment did not differ significantly in some studies, the authors still stated, that due to its less invasive nature, the Ponseti treatment should be of first choice. (11,14,16,17,19,20,23,24,30,54,82,85,86)

Future perspectives

A lot of studies compare the number of casts applied, recurrence rates, Pirani score, brace compliance, complications of treatment and other individual outcome measures. (14,79,80) But there is still a low number of studies comparing outcomes of different clubfoot treatment regimes, especially the Ponseti and surgical treatment, using standardized measurement tools. (17,19,22,40,62,64,78) This leads to poor comparability and difficulties to draw conclusions for the daily practice. Furthermore, the large number of outcome measures can lead to confusion and therefore they are easily missed. A recently published research by Graf et al. (40) addressed this issue and recommended data collection parameters that are most appropriate for a comprehensive functional analysis. They reviewed classification systems like the Dimeglio and the Pirani scoring systems, outcome evaluations like the Turco classification, the rating systems by Laaveg and Ponseti (FRS) and the International Clubfoot Study Group (ICFSG). They also assessed parameters used in gaitanalysis and pedobarography and its role in the evaluation of Talipes equinovarus, as well as common functional and quality of life questionnaires (Short Form-36, disease specific instrument & Foot function index). The last section of the article was dedicated to future assessment tools like the fluoroscopic Imaging system for foot and ankle motion analysis during walking, future kinetic foot models and finite element modeling (biomodeling). For future assessment of the clubfoot deformity the authors recommended: (40)

- Hands-on physical examination to provide information about foot stiffness, range of motion, and strength;
- Plain radiographs to inspect bony alignment and osteoarthritis;
- Gait analysis to measure lower extremity joint kinematics, kinetics, and temporal-spatial parameters;
- Heel raises to assess gastrocnemius strength;
- ICFSG Outcome evaluation;

- Short Form-36 as it profiles functional, physical and mental health and well-being and the disease specific instrument as a short feedback on foot pain, shoe wear, social acceptance, disabilities, and personal satisfaction.

Further research is also needed for the use of radiographic measurements in clubfoot treatment. There is still discordance about the prognostic value of radiographic measurements or their correlation with the functional outcome of the clubfoot. The literature revealed that while some authors found correlation of certain angles with functionality of the foot (17), others repeatedly doubted it or at least could not find an association within their studies. (19,71,78-80) Considering that people with clubfoot demonstrate higher degrees of arthritis during adulthood (40), to be able to predict and intervene in an early stage or prevent this development at all would be definitely beneficial for the patients. This would probably help to prevent pain and loss of function, correlating with severe arthritis or other consecutive impairment.

To further improve the process of the Ponseti method, analysis of the correlation of compliance with brace application and recurrence should be continued. Different opinions are found in the literature. While some authors state explicitly that non compliance is a significant risk factor for recurrence of idiopathic pes equinovarus (9,41,55-57), Halanski (14) disagrees to this correlation. Until this dilemma is resolved parents should be encouraged to adhere to the brace application protocol and should be supported when doubts occur.

The Ponseti method of clubfoot treatment seems to be the best possible care at this time. However, there is still room for improvement and a chance to enhance functional and morphological outcomes and quality of life for the patient.

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APPENDICES

Appendix A – Evaluation Protocol by the International Clubfoot Study Group (ICFSG) (64)

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 Hallicus Longus	0	1	2
6. Posterior tibia tendon	0	1	2
7. Peroneal tendon	0	1	2
8. Flexor Hallicus Longus	0	1	2
C. Dynamic function			
1. Gait	None	Positive	
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 B – Functional Rating System (FRS) by Laaveg and Ponseti (16)

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 C – Pediatric Outcomes Data Collection Instrument (PODCI) used in this study (Translation: Ulrike Floh)

Pädiatrie

Messung der Behandlungsergebnisse

Entwickelt von:
American Academy of Orthopaedic Surgeons®
Pediatric Orthopaedic Society of North America
American Academy of Pediatrics
Shriner´s Hospitals

Auf der Basis der Version „2.0. Pediatrics-Parent/Child Outcomes Instrument“

Siehe auch: PODCI („Pediatric Outcomes Data Collection Instrument“)

Überarbeitet, neuformatiert im August 2005

Pädiatrische Gesundheitsbeurteilung (Elternfragebogen)

Nicht vom Elternteil auszufüllen

Identifikationsnummer Krankenhaus: ____________ Ersten sechs Buchstaben des Familiennamens (Patient): ____________

Identifikationsnummer Arzt: ____________ Büronummer: ____________

	Diagnose & ICD-9 Code	Prozedur & CPT Code	CPT Datum	Beh. Körperseite
Erstdiagnose	DX ICD-9	Tx ICD-9		O Re. O Li. O Bds. O N/A
Zweitdiagnose	DX ICD-9	Tx ICD-9		O Re. O Li. O Bds. O N/A
Zweitdiagnose	DX ICD-9	Tx ICD-9		O Re. O Li. O Bds. O N/A
Zweitdiagnose	DX ICD-9	Tx ICD-9		O Re. O Li. O Bds. O N/A
Zweitdiagnose	DX ICD-9	Tx ICD-9		O Re. O Li. O Bds. O N/A

Seite**2** von **11**

Pädiatrische Gesundheitsbeurteilung (Elternfragebogen)

Datum: ____________________

Vielen Dank, dass Sie an dieser Befragung teilnehmen.

Dieser Fragebogen wird uns dabei helfen allgemeine Erkrankungen und Störungen des Bewegungsapparats besser zu verstehen.

Die Teilnahme an dieser Befragung ist absolut freiwillig und Ihre Angaben werden selbstverständlich vertraulich behandelt.

Bitte beantworten Sie jede Frage. Einige Fragen mögen gleich erscheinen sind jedoch anders.

Es gibt keine richtigen oder falschen Antworten. Wenn Sie sich nicht sicher sind wie Sie eine Frage beantworten sollen, wählen Sie einfach jene Antwort die am ehesten zutrifft. Sie können am Seitenrand beliebig viele Kommentare hinzufügen. Wir werden alle Ihre Anmerkungen lesen.

Geburtsdatum Ihres Kindes:____________________

Versicherungsnummer Ihres Kindes:________________

Ihre Versicherungsnummer:____________________

Seite**3** von **11**

Pädiatrische Gesundheitsbeurteilung (Elternfragebogen)

Manche Probleme können bestimmte Aktivitäten erschweren, wie zum Beispiel essen, baden, Schulaufgaben machen und mit Freunden spielen. Wir würden gerne herausfinden wie es Ihrem Kind dabei geht. (Markieren Sie eine Antwort pro Zeile)

Während der **letzten Woche**, war es einfach oder schwierig für Ihr Kind: (Markieren Sie eine Antwort pro Zeile)

	Einfach	Eher schwer	Sehr schwer	Nicht möglich	Zu Jung für diese Aktivität
1. Schwere Bücher zu heben?	1	2	3	4	5
2. Einen Liter Milch einzuschenken?	1	2	3	4	5
3. Ein bereits zuvor geöffnetes Marmeladeglas öffnen?	1	2	3	4	5
4. Eine Gabel oder einen Löffel zu benutzen?	1	2	3	4	5
5. Sich seine/ihre Haare zu kämen?	1	2	3	4	5
6. Knöpfe zu knöpfen?	1	2	3	4	5
7. Sich seinen/ihren Mantel anzuziehen?	1	2	3	4	5
8. Mit einem Stift zu schreiben?	1	2	3	4	5

9. Wie oft konnte Ihr Kind aufgrund gesundheitlicher Probleme in den **letzten 12 Monaten** die Schule (Kindergarten, Tagesbetreuung, etc.)nicht besuchen? (Markieren Sie die zutreffende Antwort)

1. Kaum
2. Einmal pro Monat
3. Zwei bis drei Mal pro Monat
4. Einmal pro Woche
5. Häufiger als einmal pro Woche
6. Geht nicht zur Schule, etc.

Seite**4** von **11**

Pädiatrische Gesundheitsbeurteilung (Elternfragebogen)

Wie zufrieden war Ihr Kind **innerhalb der letzten Woche mit**: (Markieren Sie eine Antwort pro Zeile)

	Sehr zufrieden	Eher zufrieden	Nicht sicher	Eher unzufrieden	Sehr unzufrieden	Kind zu jung
10. Seinem/Ihrem Aussehen?	1	2	3	4	5	6
11. Seinem/Ihrem Körper?	1	2	3	4	5	6
12. Mit der Kleidung die er/sie tragen kann?	1	2	3	4	5	6
13. Mit seiner/ihrer Fähigkeit die gleichen Dinge tun zu können wie seine/ihre Freunde?	1	2	3	4	5	6
14. Seiner/Ihrer Gesundheit im Allgemeinen?	1	2	3	4	5	6

Wie häufig **innerhalb der letzten Woche**: (Markieren Sie eine Antwort pro Zeile)

	Meistens	Manchmal	Selten	Nie
15. Fühlte sich Ihr Kind krank und müde?	1	2	3	4
16. War Ihr Kind aktiv und voller Tatendrang?	1	2	3	4
17. Hat Schmerz und Unwohlsein Ihr Kind von Aktivitäten abgehalten?	1	2	3	4

Seite**5** von **11**

Pädiatrische Gesundheitsbeurteilung (Elternfragebogen)

Konnte Ihr Kind **innerhalb der letzten Woche** folgenden Aktivitäten nachgehen: (Markieren Sie eine Antwort pro Zeile)

	Einfach	Ein bisschen schwer	Sehr schwer	Unmöglich	Zu jung für diese Aktivität
18. Kurze Strecken laufen?	1	2	3	4	5
19. Rad oder Dreirad fahren?	1	2	3	4	5
20. Drei Stockwerke zu Fuß hinauf gehen?	1	2	3	4	5
21. Ein Stockwerk zu Fuß gehen?	1	2	3	4	5
22. Mehr als 1 km gehen?	1	2	3	4	5
23. Dreihundert Meter gehen?	1	2	3	4	5
24. Hundert Meter gehen?	1	2	3	4	5
25. In einen Autobus ein- bzw. aussteigen?	1	2	3	4	5

26. Wie häufig benötigt Ihr Kind Hilfe von anderen Personen zum Gehen oder Klettern? (Markieren Sie die zutreffende Antwort)

1. Nie 2. Manchmal 3. Die Hälfte der Zeit 4. Häufig 5. Immer

27. Wie häufig benötigt Ihr Kind Hilfsmittel (wie z.B. Orthesen, Krücken oder Rollstuhl) zum Gehen oder Klettern? (Markieren Sie die zutreffende Antwort)

1. Nie 2. Manchmal 3. Die Hälfte der Zeit 4. Häufig 5. Immer

Seite**6** von **11**

Pädiatrische Gesundheitsbeurteilung (Elternfragebogen)

Konnte Ihr Kind **innerhalb der letzten Woche** folgenden Aktivitäten nachgehen: (Markieren Sie eine Antwort pro Zeile)

	Einfach	Ein bisschen schwer	Sehr schwer	Unmöglich	Zu jung für diese Aktivität
28. Selbstständig stehen, während er/sie sich die Hände oder das Gesicht am Waschbecken wusch?	1	2	3	4	5
29. Auf einem Sessel sitzen ohne sich festzuhalten?	1	2	3	4	5
30. Sich auf einen Sessel bzw. Toilette setzen oder davon aufstehen?	1	2	3	4	5
31. Ins Bett gehen bzw. aus dem Bett aufstehen?	1	2	3	4	5
32. Türschnallen-drücken?	1	2	3	4	5
33. Sich aus dem Stand zu bücken um etwas vom Boden aufzuheben?	1	2	3	4	5

34. Wie häufig benötigt Ihr Kind Hilfe von anderen Personen zum Sitzen oder Stehen? (Markieren Sie die zutreffende Antwort)

1. Nie 2. Manchmal 3. Die Hälfte der Zeit 4. Häufig 5. Immer

Seite**7** von **11**

Pädiatrische Gesundheitsbeurteilung (Elternfragebogen)

35. Wie häufig benötigt Ihr Kind Hilfsmittel (wie z.B. Orthesen, Krücken oder Rollstuhl) zum Sitzen oder Stehen? (Markieren Sie die zutreffende Antwort)

1. Nie 2. Manchmal 3. Die Hälfte der Zeit 4. Häufig 5. Immer

36. Kann ihr Kind an Freizeitaktivitäten im Freien mit anderen gleichaltrigen Kindern teilnehmen? (Wie z.B. Radfahren, Dreiradfahren, Skaten, Wandern, Laufen) (Markieren Sie die zutreffende Antwort)

1. Ja, ohne Probleme 2. Ja, aber mit Einschränkung 3. Ja, aber sehr schwer 4. Nein

Wenn Sie die Frage 36 zuvor mit „Nein" beantwortet haben, war die Aktivität Ihres Kindes eingeschränkt durch: (Markieren Sie alle zutreffenden Antworten)

	Ja
37. Schmerz?	1
38. Allgemeiner Gesundheitszustand?	1
39. Ärztliche oder elterliche Anweisung?	1
40. Angst, die anderen Kinder könnten ihn/sie nicht mögen?	1
41. Eine Abneigung gegen die Freizeitaktivität?	1
42. Zu jung?	1
43. Falsche Jahreszeit für diese Aktivität?	1

44. Kann Ihr Kind an Ballspielen oder Sport mit gleichaltrigen Kindern teilnehmen? (wie z.B. Fußball, Basketball, Völkerball, Seilspringen, Fangen, etc.) (Markieren Sie die zutreffende Antwort)

1. Ja, ohne Probleme 2. Ja, aber mit Einschränkung 3. Ja, aber sehr schwer 4. Nein

Wenn Sie die Frage 44 zuvor mit „Nein" beantwortet haben, war die Aktivität Ihres Kindes eingeschränkt durch: (Markieren Sie alle zutreffenden Antworten)

	Ja
45. Schmerz?	1
46. Allgemeiner Gesundheitszustand?	1
47. Ärztliche oder elterliche Anweisung?	1
48. Angst, die anderen Kinder könnten ihn/sie nicht mögen?	1
49. Eine Abneigung gegen das Spiel oder die Sportart?	1
50. Zu jung?	1

Seite**8** von **11**

Pädiatrische Gesundheitsbeurteilung (Elternfragebogen)

51. Falsche Jahreszeit für diese Aktivität? 1

52. Kann Ihr Kind an Hobbywettkämpfen mit gleichaltrigen Kindern teilnehmen? (wie z.B. Fußball, Basketball, Schwimmen, Wettlauf, Gymnastik, Tanz, etc.) (Markieren Sie die zutreffende Antwort)

1. Ja, ohne Probleme 2. Ja, aber mit Einschränkung 3. Ja, aber sehr schwer 4. Nein

Wenn Sie die Frage 52 zuvor mit „Nein" beantwortet haben, war die Aktivität Ihres Kindes eingeschränkt durch: (Markieren Sie alle zutreffenden Antworten)

	Ja
53. Schmerz?	1
54. Allgemeine Gesundheit?	1
55. Ärztliche oder elterliche Anweisung?	1
56. Angst, die anderen Kinder könnten ihn/sie nicht mögen?	1
57. Eine Abneigung gegen den Wettkampf oder die Sportart?	1
58. Zu jung?	1
59. Falsche Jahreszeit für diese Aktivität?	1

60. Wie oft **innerhalb der letzten Woche** traf sich Ihr Kind mit Freunden zu gemeinsamen Aktivitäten? (Markieren Sie die zutreffende Antwort)

1. Häufig 2. Manchmal 3. Nie bzw. fast nie

Wenn Sie die Frage 60 zuvor mit „Manchmal" oder „Nie bzw. fast nie" beantwortet haben, war die Aktivität Ihres Kindes eingeschränkt durch: (Markieren Sie alle zutreffenden Antworten)

	Ja
61. Schmerz?	1
62. Allgemeine Gesundheit?	1
63. Ärztliche oder elterliche Anweisung?	1
64. Angst, die anderen Kinder könnten ihn/sie nicht mögen?	1
65. Die Freunde waren nicht in der Nähe?	1

Pädiatrische Gesundheitsbeurteilung (Elternfragebogen)

66. Wie häufig **innerhalb der letzten Woche** hat Ihr Kind am Sportunterricht/Sportaktivitäten während Schulpausen teilgenommen? (Markieren Sie die zutreffende Antwort)

1. Häufig 2. Manchmal 3. Nie bzw. fast nie 4. Kein Sportunterricht oder Pausen

Wenn Sie die Frage 66 zuvor mit „Manchmal" oder „Nie bzw. fast nie" beantwortet haben, war die Aktivität Ihres Kindes eingeschränkt durch: (Markieren Sie alle zutreffenden Antworten)

	Ja
67. Schmerz?	1
68. Allgemeine Gesundheit?	1
69. Ärztliche oder elterliche Anweisung?	1
70. Angst, die anderen Kinder könnten ihn/sie nicht mögen?	1
71. Eine Abneigung gegen den Sportunterricht/Pausen?	1
72. Schule ist zur Zeit geschlossen?	1
73. Mein Kind geht nicht zur Schule?	1

74. Fällt es Ihrem Kind einfach oder schwer neue Freunde im gleichen Alter zu finden? (Markieren Sie die zutreffende Antwort)

1. Meistens einfach 2. Eher einfach 3. Eher schwer 4. Meistens schwer

75. Hatte Ihr Kind **innerhalb der letzten Woche** Schmerzen? (Markieren Sie die zutreffende Antwort)

1. Kein 2. Sehr leicht 3. Leicht 4. Mittelmäßig 5. Stark 6. Sehr stark

76. Wie sehr hat Schmerz Ihr Kind **innerhalb der letzten Woche** in seinen/ihren normalen Aktivitäten beeinflusst? (zu Hause, außerhalb des Wohnorts, in der Schule) (Markieren Sie die zutreffende Antwort)

1. Kein 2. Sehr leicht 3. Leicht 4. Mittelmäßig 5. Stark 6. Sehr stark

Pädiatrische Gesundheitsbeurteilung (Elternfragebogen)

Was erwarten Sie sich von der Behandlung Ihres Kindes?

Als Behandlungsergebnis erwarte ich, für mein Kind: (Markieren Sie eine Antwort pro Zeile)

	Auf jeden Fall	Eher Ja	Nicht sicher	Eher nein	Auf keinen Fall
77. Schmerzlinderung.	1	2	3	4	5
78. Verbesserung des Aussehens.	1	2	3	4	5
79. Dass es zufriedener mit sich selbst wird.	1	2	3	4	5
80. Besser zu schlafen.	1	2	3	4	5
81. Tätigkeiten im häuslichen Bereich machen zu können.	1	2	3	4	5
82. In der Schule besser mithalten zu können.	1	2	3	4	5
83. Mehr Spielen bzw. Freizeitaktivitäten machen zu können.	1	2	3	4	5
84. Mehr Sport machen zu können.	1	2	3	4	5
85. Als Erwachsener keine Schmerzen oder Behinderung mehr zu haben.	1	2	3	4	5

86. Wie zufrieden sind Sie mit der Vorstellung, dass Ihr Kind den Rest seines/ihres Lebens mit dem jetzigen Zustand von Muskulatur und Knochen leben müsste? (Markieren Sie eine Antwort)

1. Sehr zufrieden   2. Eher zufrieden   3. Neutral   4. Eher unzufrieden   5. Sehr unzufrieden

Seite**11** von **11**