An Innovative design for the treatment of Talipes equinovarus utilizing dynamic tri-planar stretching rather than static positioning: a call to researchers

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INTRODUCTION

The purpose of this paper is to present information about an alternative protocol for post-Ponseti casting. This innovative orthotic management of Talipes equinovarus is being utilized on a small scale and is resulting in effective maintenance following Ponseti-casting of clubfeet. We are now looking to collaborate with researchers to further study this intervention's effectiveness.

Congenital talipes equinovarus (CTEV), also known as clubfoot, is one of the most common congenital orthopaedic conditions affecting between 1-5: 1,000 (Herring 2002). Between 150,000 and 200,000 babies are born with clubfoot worldwide each year (Global Clubfoot Initiative 2016). The condition is characterized by one or both feet being turned in and positioned in severe equinovarus. In a small percentage of cases CTEV can be associated with a range of co-morbidities such as cerebral palsy, spina bifida or developmental dysphasia of the hip (DDH) (Boston Children's Hospital 2016).

Talipes equinovarus is a combination of several deformities that develop in utero during the second trimester (Herring 2002). Ligaments of the posterior and medial aspect of the ankle and tarsal joints are very thick and taut with shortening of the Achilles musculature that results in the hindfoot being positioned in equinus and the navicular and calcaneus in adduction and inversion with the foot rotated internally about the axis of the tibia (Staheli 2009).

This dysfunction in the posterior and medial aspects of the lower leg, ankle and foot causes a decreased muscle size and excess collagen synthesis. The retracting fibrosis in the medial and posterior tarsal ligaments, the Achilles' tendon and posterior tibial tendon causes severe equinus, medial displacement of the navicular, heel varus and forefoot adduction (Ponseti 2002).

Muscles and tendons, particularly the Achilles, show increased connective tissue rich in collagen that presents as “crimping”. Stretching of these structures results in elongation of the tissue without damage but the crimping returns over a period of time. This ability to constructive tolerate, and eventually retain, stretching is the basis of correction of what is essentially a soft tissue deformity.

PHYSIOLOGY/KINEMATICS OF TREATMENT GOALS

In correcting the clubfoot deformity, initially the first ray is elevated to decrease the cavus through supination of the forefoot relative to the hindfoot; the hindfoot is allowed to remain inverted and continues plantarflexed. The next step is to abduct the mid and forefoot about the talus. With the forefoot supinated, the foot can then be laterally rotated about the talus with the navicular moving into correct position in front of the anterior talus and the calcaneus moving under the talar head. Once the foot is rotated about the talus into corrected position, the midfoot can be correctly pronated. At this point the hindfoot is also correctly aligned within the talocrural mortise and the equinus can be reduced. Dorsiflexing the calcaneus requires countering the tight Achilles and is complicated by the weakness of the midfoot structure. Pressure on the mid and forefoot can appear to produce dorsiflexion on gross exam, but in actuality, the calcaneus may maintain a plantar flexed position and the midfoot can deform into what is referred to as a midfoot “break”. If maintained, this will produce a permanent “rocker bottom” deformity (Staheli 2009). Dorsiflexing the heel correctly requires upward pressure on the anterior aspect of the calcaneus just distal to the axis of the talocrural joint with minimal pressurization of the foot distal to that point. The typical stretches used to mobilize the hindfoot reflect this as there is a downward “pull” on the posterior heel coupled with an upward directed pressure on the *proximal* longitudinal arch allowing the mid and forefoot to remain free. Once anatomical neutral is achieved, correction of the internal tibial torsion is accomplished by rotating the foot externally about the longitudinal axis of the tibia. It is necessary to maintain the knee in a flexed position to decrease pressure on the hip joint that results when the lower limb is rotated externally with the knee is in extension.

CURRENT TREATMENT METHODS

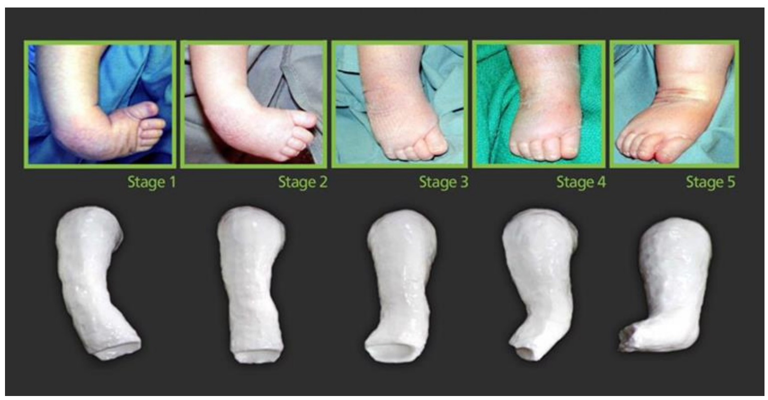


Figure 1 showing progression of the foot through Ponseti serial casting

The current gold standard of treatment for talipes equinovarus, developed in the 1950s and currently used extensively throughout the world, is the Ponseti method (Ponseti 1996, Morcuende et al 2004, Radler 2013). A 6-8 week period of serial casting, when the foot is transitioned to a neutral anatomical position, is followed by orthotic management for 4-6 years, initially full time and then nocturnally, to maintain the correction achieved through casting (Lehman et al 2003). The foot abduction brace has been used in many variations but is referred to generically as the boots and bar. These braces statically position both feet in boots that are then attached to a bar that separates the feet in an externally rotated position; both feet are attached to the bar even with unilateral clubfoot (Ponseti 1996). Frequently a percutaneous tendoachilles lengthening is performed prior to the final cast application (Faulkes 2009).

Figure 2, One of the modern variations on the original Denis Browne bar originally described in 1934

ISSUES WITH THE PONSETI TREATMENT PROTOCOL

Having their movement restricted by the bar often provokes struggling in the infant that can result in pain, soft tissue injury and occasionally even damage to the bar (Radler 2013). Gray et al (2014) report that most trials do not report the prevalence of adverse events such as relapse rates, but describe issues such as plaster sores, skin irritation, infection and skin grafting. Laaveg and Ponseti (1980) reported in a longitudinal study that "satisfactory" results were achieved in 88% of cases, but that "in the majority of the patients, foot and ankle motion was limited and talocalcaneal angles were not fully corrected”.

A study completed by the Texas Scottish Rite Children’s Hospital reported a 37% relapse rate in children treated by the Ponseti method and 29% for the French Functional method (a system of strapping and physiotherapy) (Faulkes 2009, Richards et al 2008). In some practices, concerns about relapse rates have prompted increased treatment times to upwards of 6 years.

Due to the accessibility of social media in the last 5-10 years, communication between parents has improved significantly. As a result, there has been increased patient/parent-driven reporting of concerns including both quality of life issues and relapse. Parents are reporting skin irritation, swelling, discomfort, sleeplessness, hip and knee problems and difficulty with normal motor skills development for infants using the foot abduction brace (Pietrucian-Materek et al, 2011). A range of issues were reported in a study in Madagascar including financial hardship, emotional distress and social ostracism that resulted in a failure of 46% of the study group to complete treatment (Ramahenina, H. et al, 2016).

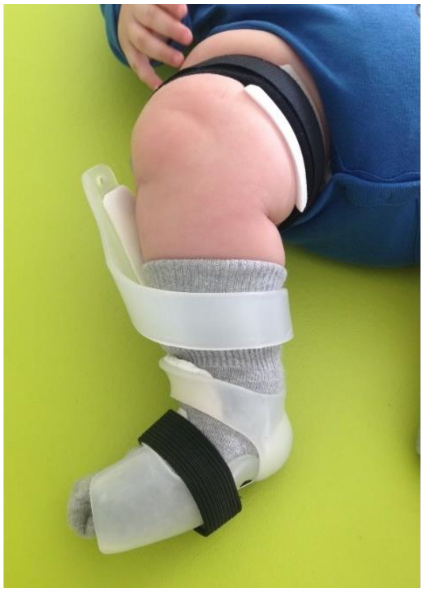
Financial implications of treatment include the cost of multiple shoes and bars which are required over the multi-year treatment. In third world settings, the problem is compounded by access to materials and sophisticated orthopedic care. There are programs to assist with treatment using the Ponseti method, but efforts are often hampered by lack of access to hospitals and the travel distances involved (Grimes 2016).

In conclusion, although the Ponseti method has been shown to improve outcomes compared to surgical intervention, issues with treatment efficacy and advances in biomechanics and technology, suggest that it is time to find more effective, cheaper and more acceptable treatments for affected children and their parents.

AN ALTERNATIVE DESIGN UTILIZING DYNAMIC STRETCH: THE DYNAMIC TORSION KAFO

OVERVIEW

The Dynamic Torsion Knee Ankle Foot Orthosis (DTKAFO) has been developed to produce optimal soft tissue stretching while allowing a virtually full range of motion of the limb. The brace is fitted to the infant following successful Ponseti casting and is worn full time until the child is ready to begin walking although it is possible to stand and ambulate while in the brace. It is then used nocturnally until approximately age 2 when treatment is complete. Typically, two braces are required over this time span and it is only required to be applied to the affected limb so it can be used either unilaterally or bilaterally as appropriate.

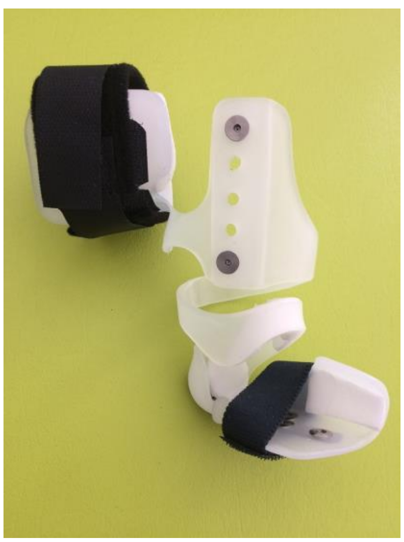


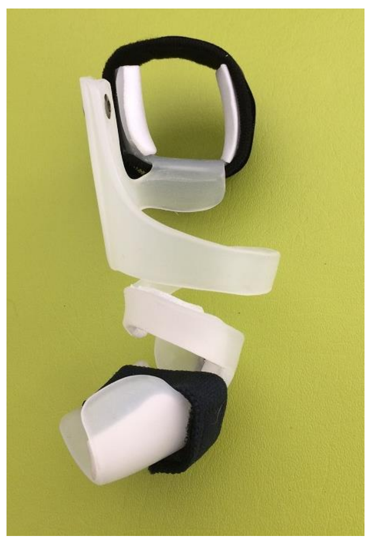
The DTKAFO design approaches clubfoot treatment in an innovative way allowing the infant a full range of motion including rolling over, crawling, standing and ambulating while gently stretching the limb in all 3 planes whenever the child is not actively moving. Adjustability for growth is built into the brace allowing each brace to be used from 5 – 12 months. The result of this freedom of movement is improved motor development and much higher acceptance and therefore compliance; children do not appear to be aware of the brace and parents report very few issues with skin irritation, discomfort or difficulty sleeping. Early results also show a significant decrease in the incidence of smaller foot and calf size typical of the clubfoot due to the ability to move freely and against gentle resistance following casting. Treatment times have been reduced to around 24 months of age when the second brace is outgrown.

Figure 3 shows the DTKAFO in place on an 8 month old child.

A short presentation of the DTKAFO is available on YouTube at the Cunningham Prosthetic Care channel: https://www.youtube.com/channel/UC6OPkXjsOJlNnypPPgodSfg

THE DTKAFO DETAIL DESIGN FEATURES





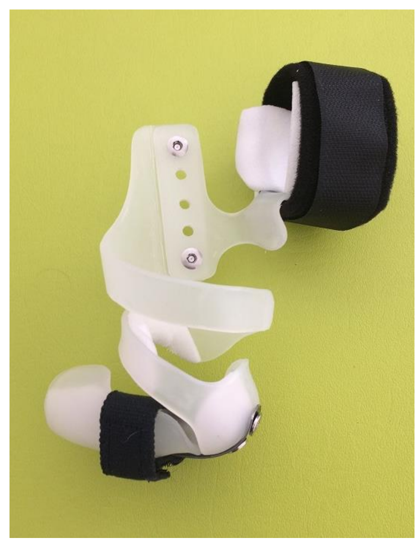


Figure 4.1-4.3, The DTKAFO;
Lateral view *Anterior view* *Medial view*

A thigh cuff with posterior and lateral flanges is positioned just proximal to the femoral condyles. A strap goes around the thigh with medial and lateral padding that is anatomically configured to “lock” the thigh cuff above the condyle without compromising circumference. The thigh piece has a 90 degree bend in the popliteal area but the plastic is configured to allow knee extension.

The thigh cuff is attached to a foot shell that has a plantar surface with medial wall that is configured into forefoot abduction using a spiral of plastic that travels around the tibia circumferentially. The footshell is articulated between the hind and midfoot using a spring-steel "keel" that allows for plantar flexion of the mid and forefoot. A flexible midfoot strap travels from the plantar/lateral midfoot to the medial midfoot and pressurizes the lateral midfoot and creates hindfoot valgus and forefoot abduction. The plantar surface of the midfoot is contoured to create pressurization of the medial and lateral proximal arch just anterior to the fulcrum of the talocrural joint. Padding is supplied in areas of increased pressurization at the medial forefoot and hind foot and is removed as the foot grows.

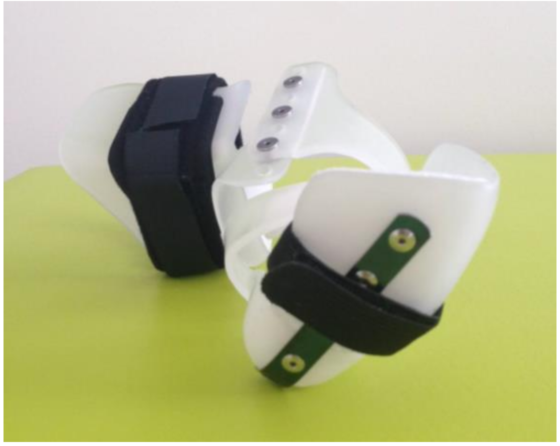


Figure 5, Plantar view showing flexible keel

FORCES GENERATED THROUGH COMPRESSION AND DISTRACTION OF THE SPRING MECHANISM

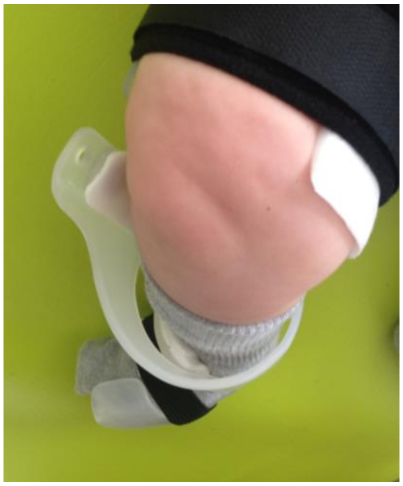


Figure 6 shows the oversized spiral connecting the foot to the thigh with no soft tissue contact, note the external rotation of the foot relative to the axis of the femur

The spiral is used to transfer force from the foot to the thigh. In its resting position, the foot shell is externally rotated at 40 degrees from the longitudinal axis of the femur and can be internally rotated by the child up to 30 degrees. This allows complete freedom of movement in the transverse plane but when the baby is not actively moving, the foot is returned to the stretched, externally rotated position. The flexed position of the knee insures that the force is exclusively focused on the correcting the tibial torsion without over-pressurization of the hip.

The other essential force provided by the spiral is a longitudinal force directed upward along the axis of the tibia that is created by extension of the spring on donning. This creates an upward force along the plantar surface of the foot. The shape of the proximal arch support contoured into the plastic then insures an upward force on the distal calcaneus that acts to actively dorsiflex the heel without over-pressurization of the mid and forefoot.

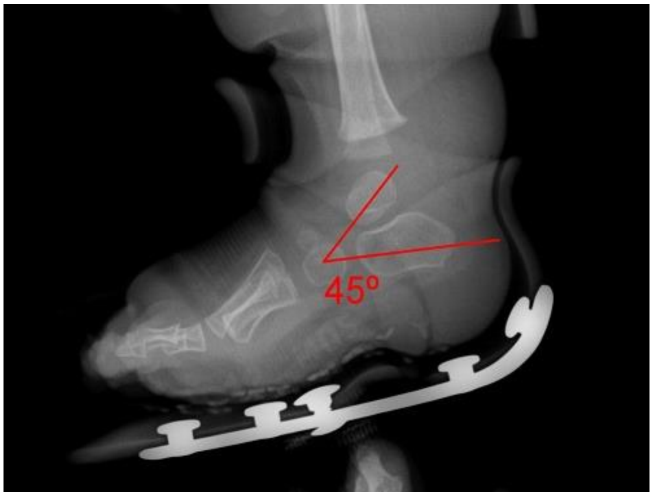


Figure 7 shows in-brace, radiographic imaging demonstrating dorsiflexion of the heel with correct mid and forefoot alignment

The presence of an upward directed force holding the foot shell against the foot means that the plastic moves with the child and eliminates the need for any rigid fixation of the foot in the brace. A single .75” flexible Velcro strap crossing the midfoot is sufficient.

The midfoot strap is also used to pressurize the midfoot and create a medial/plantar force the maintains the midfoot in adduction and the forefoot in abduction. Padding is provided along the medial hind and forefoot to accommodate this pressure and can be removed to decrease the abduction force when appropriate.

ACCOMMODATIONS FOR GROWTH DURING TREATMENT

Growth is accommodated in several ways allowing for an intimate fit throughout the treatment. The spiral is connected to the thigh using a simple adjustable connection that can be extended in 0.5” increments to allow for longitudinal, skeletal growth of the tibia. The spiral is deliberately oversized relative to the child’s lower limb to allow for future circumferential growth. Padding is also added at the anterior ankle that is removed sequentially as the AP dimension of the ankle increases. These features allow for easy adjustment as the child grows and typically the first brace accommodates growth for boys from 4-5 months and for girls from 6-8 months. A second brace is then provided that is typically outgrown by about 24 months of age when treatment is concluded.

ADVANTAGES OF DYNAMIC vs. STATIC STRETCH

Although it is possible to alter the arrangement of the bony anatomy of the foot through statically forcing the foot into a corrected position as with a reverse last sandal with multiple pads and straps, dynamic therapies allow manipulation of the foot to stretch the soft tissues. An example of this is the French functional method where extensive stretching and taping is used to repeatedly stretch the foot in the appropriate ways.

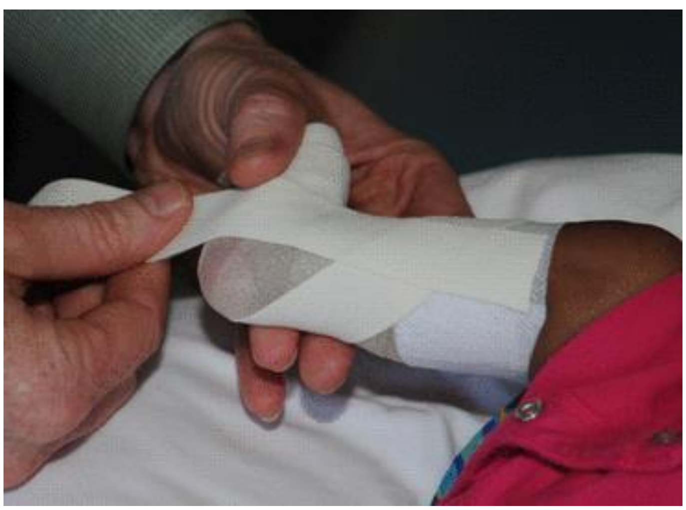


Figure 8 shows dynamic taping following manipulation used in the French Functional Method

This has shown appropriate and rapid increase in range of motion but is hampered by the need for skilled manipulation and significant amounts of time committed to stretching the foot. Similar to the Ponseti technique, relapse rates for the French Functional Method are reported at 29% (Faulkes 2009).

While statically positioning the foot in a boot affixed to a bar allows/promotes some dorsiflexion of the ankle there is relatively little active forefoot abduction our calcaneal eversion. Forces exerted by the structure of the boot maintain range but there is minimal active stretching of the foot to encourage significant *increases* in range. Most therapeutic treatments for increasing range of soft tissue rely on active manipulation of any given joint; it is well understood that fixing the position of a joint for any significant period of time actually works to "freeze" the joint as soft tissues require active stretching to maintain and improve range (Hyung 2009, Lattanza 1988, Magee 1997, Yoon 2013, Terada 2013).

A MODULAR DESIGN: FLEXIBLE LIFE LONG TREATMENT FOR UNDERSERVED COUNTRIES

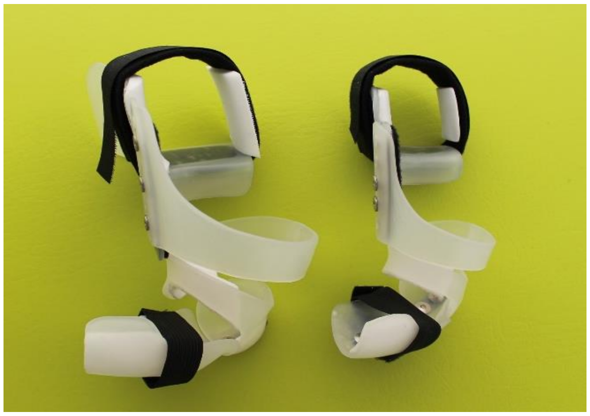


Figure 9 shows the two modular sizes required for treatment

A modular version of the DTKAFO brace has been developed that uses two sizes suitable for virtually any presentation from post-casting to end of treatment at 24 months old. The brace can be fabricated with a minimum of equipment and materials and can be reconditioned and reused in third world settings.

This approach is uniquely suited for developing countries where higher incidence and birth rates are accompanied by lack of access to sophisticated orthopedic care. In India, for example, the incidence rate is estimated at 5:1,000 and 50,000 clubfoot babies are born *per year*. Despite their best efforts, organizations such as CURE International are currently only able to treat 10% of those children. Untreated, clubfoot results in a lifelong, crippling deformity with profound physical, social and economic impact.

In an effort to help with this global problem, partner organizations are currently being taught how to fabricate and fit the orthosis and monitor progress. We are also partnering with Messiah College in Pennsylvania in a multi-year program to develop improved point-of-use fabrication with 3D printing which may ultimately be the best means of low cost dissemination to the areas where it is most needed.

Cunningham Prosthetic Care has initiated a program to encourage parents of children treated in Maine to donate their used braces at the end of treatment. They are then re-conditioned and donated to CURE for use in the Kijabe Hospital Study currently underway in Kenya.

SELF-REPORTED EFFECTIVENESS

The orthotist who designed the DTKAFO brace reports that in treating approximately 300 feet over the past 12 years most have experienced good to excellent outcomes with a relapse rate of around 10%, compared to 29-37% for French Functional or Ponseti and that there has been no report of need for later tendon transfer surgeries.

THE NEED FOR FURTHER STUDY

At this time, there has been minimal independent study of the efficacy of the DTKAFO brace. The methodological quality of published evidence of all clubfoot treatments is considered to be low to very low (Gray et al 2014) indicating a need for improved methodological designs in future studies, such as randomized controlled trials and long term follow up.

A National Science Foundation grant funded a 1 year study of 40 infants using an earlier form of the DTKAFO brace reported good results but there was no long term follow up to document relapse rates.

Following a pilot study of 6 infants (Cunningham 2017), CURE International has initiated a study of about 60 infants and plans to follow them over a 5 year period that will study outcomes including relapse rates.

CONCLUSION

Despite its demonstrated efficacy and almost universal acceptance, upon closer examination the Ponseti method, particularly as regards orthotic management post casting, has reported deficits that limit its effectiveness. The most significant factor appears to be issues with comfort and soft tissue management when utilizing the “boots and bar” approach that concerns parents and degrades compliance. Significant concerns have also arisen about potential deleterious impact on hip and knee function and the impact of statically positioning the sound side limb in cases of unilateral clubfoot.

The DTKAFO presented here represents an alternative approach that preserves tri-planar control of the multiple aspects of clubfoot but does so in a way that allows effectively uninhibited motion of the affected limb and requires no bracing for unaffected limbs. This has resulted in increased patient comfort with significantly improved parental compliance. A modular system has been developed with particular attention to low cost fabrication materials and methods that make this an attractive solution in settings where access to sophisticated orthopedic care is limited by economics and/or geography.

The increasing interest in this protocol, largely driven by parents seeking an alternative to the boots and bar, has demonstrated the need for further study to document the efficacy of the DTKAFO as anecdotal feedback suggests that it is significantly more acceptable to the infants and families who require orthotic management following Ponseti casting.

REFERENCES

Boston Children's Hospital 2016. *Clubfoot symptoms and causes*. Accessed on-line http://childrenshosptial.org/conditions-and-treatments/conditions/clubfoot/symptoms-and- causes. Last accessed 21 January 2017

Faulkes, S, 2009. *Clubfoot Treatment: Ponseti and French Functional Methods are Equally Effective.* Clin. Orthop. Relat. Res. May, 467 (5) pp1278-1282

Global Clubfoot Initiative 2016. *What is Clubfoot?* Accessed on-line http://globalclubfoot.com/clubfoot. Last accessed 21 January 2016

Gray, K et al, 2014. *Interventions for congenital talipes equinovarus (clubfoot).* Cochrane Database of Systematic Reviews. DOI 10.1002/14651858.CD008602.pub3

Grimes, CE et al, 2016. *Cost-effectiveness of clubfoot treatment in low-income and middle-income countries by the Ponseti method.* BMJ Global Health. May 2016
DOI 10.1136/bmjgh.2015-000023

Herring, JA, 2002. Ed. In *Congenital talipes equinovarus (clubfoot).* Tachdjian's Paediatric Orthopaedics. WB Saunders. Vol 2 3rd ed. pp922-959

Hyung, IH et al, 2009. *The effect of muscle activities and dynamic balance ability with mobilization and active exercise on pronation foot.* Korean Soc Sport Leis Stud. 37 pp1023 - 1032

Laaveg, SJ and Ponseti, IV, 1980. *Long-term results of treatment of congenital club foot.* J. Bone Joint Surg Am. Jan 62 (1) pp23-31

Lattanza, L etc, 1988. *Closed versus open kinematic chain measurements of subtalar joint eversion: implications for clinical practice.* J. Orthop Sports Phys Ther 9 pp 310-314

Lehman, WB et al, 2003. *A method for the early evaluation of the Ponseti (Iowa) technique for the treatment of idiopathic clubfoot.* J Ped. Orthop. 12, pp 133-140.
DOI 10.1097/00009957-200303000-00011

Magee, DJ, 1997. *Orthopedic physical therapy.* WB Saunders. Philadelphia

Morcuende, JA et al, 2004. *Radical reduction in the rates of extensive corrective surgery for clubfoot using the Ponseti method.* Paediatrics Feb, 113 (2) pp 376-8Radler, C, 2013. *The Ponseti method for the treatment of congenital clubfoot: review of the current literature and treatment recommendations.* Int. Orthop.Sep. 37 (9) pp1747-1753

Pietrucian-Materek, M et al, 2011. *Parenting a child with clubfoot: a qualitative study.* International Journal of Orthopaedic Trauma Nursing. Nov. Vol 15 (4) pp176-184.
DOI 10.1016/j.ijotn.2011.02.004

Ponseti, IV, 2002. *Relapsing Clubfoot: Causes, Prevention and Treatment.* Iowa Orthopaedic Journal vol. 22, pp55-56

Ponseti, IV, 1996. *Congenital Clubfoot: Fundamentals of Treatment. Oxford University Press. Oxford.*

Ramahenina, H, O'Connor, R and Chamberlain, MA, 2016. *Problems encountered by parents of infants with clubfoot treated by the Ponseti Method in Madagascar: A study to inform better practice*. Journal of Rehabilitation Medicine, 48 (5). pp. 481-483. ISSN 1650-1977

Richards, BS et al 2016. *A comparison of two non-operative methods of idiopathic clubfoot correction: the Ponseti method and the French Functional (physiotherapy) method.* J. Bone Joint Surg. Am. Nov vol 90, (11) pp2313-2321
DOI 10.2106/JBJS.G.01621

Staheli, L, Ponseti, IV et al, 2009. *Clubfoot: Ponseti Mangement, Third edition*. Accessed on-line http://global-help.org/publications/books/help_cfponseti.pdf. Last accessed 27 January 2017

Terada, M et al, 2013. *Interventions for Increasing Ankle Dorsiflexion After Ankle Sprain: A Systematic Review. J.Athl.Train Sep-Oct 48 (5) pp696 -709*

Yoon, Ki-S and Park, S-D, 2013. *The effects of mobilization and active stretching on the difference of weight-bearing distribution, low back pain and flexibility in pro aged-foots subjects. j.Exerc.Rehabil. Apr. 9)0(2) pp 292 - 297*