Orthotic management of talipes equinovarus in newborns using the Newborn Dynamic Torsion KAFO to reproduce the sequential progression of Ponseti casting.

Jerald Cunningham, CPO, Lorna W. McHattie, PhD

Contact information:
Cunningham Prosthetic Care
Jerald@CunninghamCare.com
http://www.CunninghamProstheticCare.com/clubfoot-bracing

INTRODUCTION

THE NEED FOR CHANGE

This paper will present a simple, low cost orthotic device designed to be used in underserved areas of the world that is capable of achieving the sequential correction of clubfoot in the newborn that is currently managed almost universally utilizing Ponseti casting. Despite the widely acknowledged efficacy of the serial casting developed by Dr. Ponseti in the 1950s, there are circumstances where applying the technique is problematic. In many underserved areas, the utility of the technique is compromised by limited access to sophisticated orthopedic care, economics, geography and hygiene issues making it impractical for many infants despite widespread efforts to promulgate the technique.

The orthosis described herein represents a paradigm shift that will be shown to provide an alternative treatment option that addresses these limitations while preserving the underlying concept of sequential progression of the newborn clubfoot. The hope is that this design will engender sufficient interest to prompt further study and development by orthopedists and clinicians with the goal of expanding access to critical care necessary to successfully eradicate one of the most prevalent birth defects.

The orthosis described will demonstrate the following benefits:

1. Decreased dependence on access to skilled clinicians
2. Improved acceptance by parents
3. Decreased risk to the newborn
4. Decreased need for weekly treatment
5. Decreased dependence on access to centralized clinical facilities
6. Decreased treatment costs

EPIDEMIOLOGY

Congenital talipes equinovarus (CTEV), also known as clubfoot, is one of the most common congenital orthopedic conditions affecting 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).

Estimates of the number of babies in middle or low income countries afflicted with this deformity range as high as 80% (Penny 2005, Ponseti 2017). Despite many excellent programs and initiatives to treat clubfoot in third world settings, there remains a significant percentage of the 120,000-160,000 babies located in these areas that remain untreated due to limited access to care, lack of financial resources, social stigma and lack of education or social awareness (Lavy et al, 2007, Mayo et al, 2015).

Clubfoot has been shown in many studies to have significant impact on quality of life both for the child born with clubfoot and for the families of these children (Drew 2016, Mayo 2015, McElroy 2007). For the child, in addition to a lifetime of pain and poor function, access to education and employment is limited and clubfoot results in marginalization by their families and social groups. For the mother of clubfoot infants there is often significant stigma and exclusion. In a study undertaken in Kenya in 2008 for example, 75% of mothers experienced rejection by either their husbands, their families or both (Mayo 2015).

Although the clubfoot deformity has been essentially eradicated in developed countries, extrapolation of the birth rates, incidence rates and information about access to care has led some studies to conclude that over the next 10 years, *2 million adults* will be living with crippling clubfoot deformities throughout the world (Mayo 2015). The need for successful clinical and educational programs cannot be overstated.

THE PHYSIOLOGY OF CLUBFOOT

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. The retracting fibrosis in the medial and posterior tarsal ligaments, the Achilles' tendon and the posterior tibial tendon causes severe equinus, medial displacement of the navicular, calcaneal adduction and inversion, and forefoot adduction (Ponseti 2002, Staheli 2009).

This dysfunction in the posterior and medial aspects of the lower leg, ankle and foot results in decreased muscle size and excess collagen synthesis. The involved 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 constructively tolerate, and eventually retain, stretching is the basis of correction of what is essentially a soft tissue deformity.

KINEMATICS OF CORRECTION OF THE CLUBFOOT

To reduce the clubfoot deformity, correction is initiated at birth or shortly thereafter to take advantage of this innate ability of the tissue to be molded into a more appropriate position. Ponseti is attributed with first describing the need to manage the progression sequentially with rotation of the foot about the talus to allow the bony anatomy to return to a functional position. Historically, attempts to make the foot appear corrected without regard for this sequence, resulted in a foot with poor biomechanics, decreased range of motion and lifelong pain (Salzman 2009, Matos et al 2010).

Specifically, Ponseti demonstrated the importance of the following sequence: As shown in figure 1 below, with Stage 1 referring to the uncorrected clubfoot, in Stage 2 the first ray is elevated to decrease the cavus through supination of the forefoot relative to the hindfoot, during this the hindfoot is allowed to remain inverted and continues plantarflexed. In Stage 3, with the position of the talus stabilized, the mid and forefoot are abducted about the anterior aspect of the talus by laterally rotating the midfoot about the hindfoot. This moves the navicular into correct position in front of the anterior talus and the calcaneus is moved under the talar head. In Stage 4, with the midfoot aligned, the midfoot supination and the hindfoot varus are reduced. At this point, the hindfoot is then correctly aligned within the talocrural mortise. In Stage 5, the hindfoot equinus is reduced. Dorsiflexing the calcaneus requires countering the tight Achilles and is complicated by the weakness of the midfoot structure. Upward pressure is focused 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 and is often completed by performing a release of the Achilles tendon. Throughout this progression, it is necessary to maintain the knee in a flexed position to provide effective resistance to gradually decrease the internal tibial torsion with an external rotational force oriented about the axis of the tibia.

Figure 1, The progression of the clubfoot correction and corresponding casts

CURRENT TREATMENT PROTOCOLS

THE PONSETI METHOD

The Ponseti method is arguably the gold standard of treatment for talipes equinovarus. Developed in the 1950s and currently used extensively throughout the world (Ponseti 1996, Morcuende et al 2004, Radler 2013), the above described progression is achieved through a 6-8 week period of serial casting. Each week the clinician stretches the appropriate part of the foot based on the sequencing to prepare it for casting. The foot and lower leg is then put in cast to the groin level with the knee in flexed at 120 degrees using plaster bandage with the newly stretched foot being held in position through the plaster by the clinician until it is set. The cast is then removed one week later and the process is repeated for the next step in the sequence and so on until a neutral foot is produced. Although it is described as a step by step process, interestingly Ponseti indicates that “all components of the clubfoot deformity except for the ankle equinus, are corrected *simultaneously*” (Ponseti 1996).

This casting requires a highly trained clinician with substantial experience as the amount of pressure placed with the plaster must be carefully directed and modulated to not over or under pressurize the foot. Excess pressure can result in wounds and infection, misplaced pressurization can produce inappropriate movement of the bony anatomy and under pressurization can result in little or no change. Frequently a percutaneous tendoachilles lengthening is performed prior to the final cast application which is then maintained for 3 weeks to allow full healing (Faulkes 2009, Ponseti 1996, Ponseti 2002).

Following successful reduction of the deformity through this process, orthotic management is then undertaken for the next 4-6 years to maintain the correction and decrease the risk of relapse of the deformity. Typically, the brace is a bar with footgear that holds the feet shoulder width apart with the affected foot (or feet) in an externally rotated and slightly dorsiflexed position. There have been many variations of this developed over the years but they all share the basic characteristics of this “boots and bar” approach.

EFFICACY OF PONSETI CASTING

Multiple studies have confirmed the efficacy of the sequential casting developed by Dr. Ponseti (Salzman 2009, Faulkes 2009, Gray 2014). Studies consistently demonstrate 90-95% efficacy when undertaken by appropriately trained clinicians. At this time, the technique has been exported all over the world and is routinely used in clinics from South America to India to Africa (Global Clubfoot Initiative 2017). Minimal materials or facilities are required as the basic tools are plaster bandage for casting and the ability to remove the cast which can be done with water if a cast cutting saw is not available.

Despite this wide-spread acceptance, there are several critical weaknesses in the Ponseti protocol:

1. The need for a skilled clinician. As described above, it is clear to see that correct execution requires a subtle understanding of each clubfoot presentation and then a very careful application of force. The subjective nature of this can make is somewhat problematic as poorly executed casting can produce an under-corrected or poorly corrected foot. In areas without access to sophisticated orthopedic care, the availability of physicians is limited and they frequently are engaged in more pressing work (Ramirez 2011)
2. The need for multiple weekly visits. In under-served areas families may have to travel significant distances to clinics weekly for treatment. Multiple visits with the clinician and the necessary travel can impose a financial burden on families that is often insurmountable; even where care is subsidized by charitable or government organizations, the few dollars required can be out of reach. Anecdotally for example, a clinic in Ghana, often requires a family to travel to the clinic and stay nearby for the duration of the 6-8 week treatment displacing them from their home and support network. At the Kijabe hospital in Kenya, parents will routinely have to travel several hours each way for treatment and even then, there are many outlying communities that are sufficiently far away that the orthotists will travel for a day or more to provide care but only on a monthly basis making Ponseti casting impossible.
3. Issues with cast maintenance. Conditions in these areas are often far from hygienic and because it is impossible to visualize the limb within the cast for a week or more during each stage, skin integrity can be compromised by bacterial or fungal rashes, a simple scratch or a pressure ulcer with potentially life threatening results due to infection and sepsis. Growth or sub-optimal casting can also result in compression of the limb that can negatively impact circulation with potentially disastrous results.

THE FRENCH FUNCTIONAL METHOD: DYNAMIC STRETCH vs. STATIC POSITIOING

The French Functional Method is an alternate approach that has been developed that relies on extensive, long term dynamic stretching of the foot rather than the brief stretch followed by fixation with plaster used in the Ponseti method to achieve correction of the foot. During periods when the foot is not being actively manipulated, dynamic taping is used to maintian the correction achieved. This technique is effective and rapidly achieves correct positioning and increased range of motion (Richards et al 2005).

Despite the demonstrated efficacy, this approach also has limitations in real-world settings such as underserved areas due to the need for trained clinicians skilled in manipulation techniques, extensive follow up and significant amounts of time committed to stretching the foot on the part of both the clinician and the parents.

Figure 2, French functional taping

SEQUENTIAL PROGRESSION OF THE NEWBORN FOOT UTILIZING AN ORTHOSIS WITH DYNAMIC STRETCH: THE *NEWBORN DYNAMIC TORSION KAFO*

OVERVIEW

The Newborn Dynamic Torsion KAFO applies the principle of dynamic stretch to duplicating the sequential repositioning of the clubfoot as described by Ponseti. Ponseti casting employs a brief period of manipulation before each cast is applied, the cast then fixes the foot in the position achieved by this stretching until the next session 1 week later. The Newborn Dynamic Torsion KAFO is designed to provide gentle, *ongoing*, dynamic stretch throughout the entire course of correction without periods of static positioning (casting). This approach allows for improved comfort and compliance with decreased treatment times while preserving the efficacy of the Ponseti progression. The ability to promote movement of the limb is also beneficial for decreasing muscle atrophy commonly experienced with casting.

Figure 3, the Newborn DTKAFO worn by an infant treated at Kijabe Hospital, Kenya

The underlying principle of Ponseti casting is the need to progress the lower limb through a specific *sequence* to produce a functional foot. Rotation of the navicular about the talus cannot take place while the forefoot is pronated, eversion of the hindfoot cannot take place while the midfoot is adducted, dorsiflexion cannot be created while the calcaneus is in varus, and so on. In Ponseti casting, the clinician carefully applies only the selected force appropriate for that step; correction proceeds only as each previous position is achieved. Yet as mentioned earlier, Ponseti describes his sequence as a continuum where all of the components are corrected simultaneously.

To recreate this sequential progression with a single orthosis it is therefore necessary to provide a means of progressively applying forces to the foot such that each force only acts when the foot is positioned to correctly and constructively experience it. The key concept behind the Newborn Dynamic Torsion KAFO is that this progression can be achieved by structuring the forces being applied so that they range from an “irresistible” force to a very weak force that is barely felt. Because a stronger force acts sooner to effect change, a *hierarchy* of forces will result in a *sequential* progression of changes.

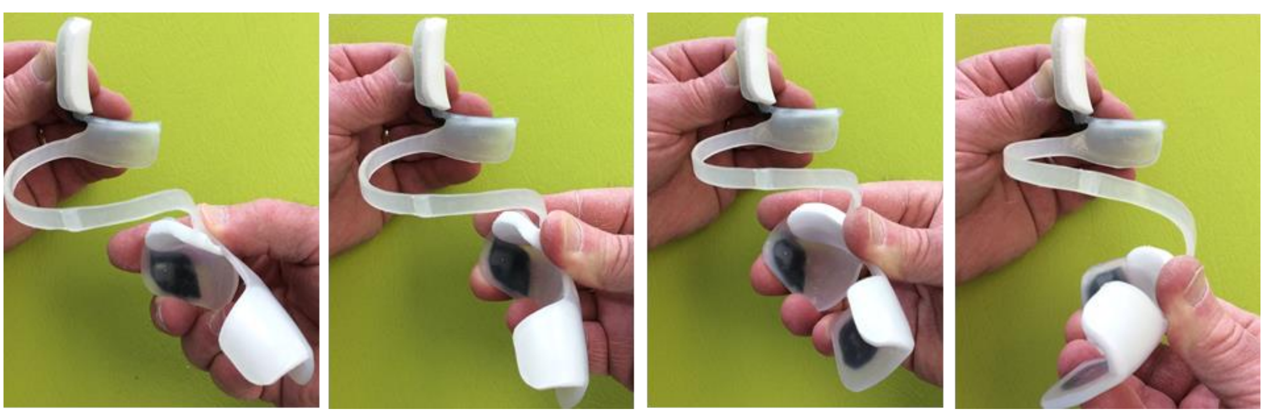
MECHANICS OF THE NEWBORN DTKAFO FUNCTION

Lateral view *Anterior view* *Medial view*

Figure 4, The Newborn Dynamic Torsion KAFO;

The Newborn Dynamic Torsion KAFO incorporates a thin, 5mm wide by 2mm thick, spiral of plastic that connects a thigh cuff to a foot shell. The foot shell is articulated at the midfoot and the limb is held in place with gentle stretchable Velcro straps, at the midfoot and thigh. The configuration developed with this shape results in the desired hierarchy of forces being applied to the limb: Initially, the strongest force acts upon the foot more or less immediately with weaker forces gently challenging, but not altering, the position of the other structures of the foot. A gentle, persistent, dynamic stretch is created though and as the components are *able* to be moved into position, they do. The result is that each successively weaker force acts to reposition the foot in a sequence that duplicates Ponseti casting.

Figure 5, the brace being positioned to demonstrate the stages corresponding to Ponseti casting shown in Figure 1.



Stage 2 *Stage 3* *Stage 4* *Stage 5*

Upon initial donning, the foot encounters the strongest force (~13.8N) which is an elevation of the first ray that supinates the forefoot relative to the hindfoot - the clubfoot remains internally rotated, the mid and forefoot adducted and the hindfoot plantar flexed (Stage 2 above).

As time goes by the next strongest force applied by the orthosis (~8.2N) begins to abduct the mid and forefoot, rotating the navicular into correct position with the talus while leaving the hindfoot plantar flexed and in varus; the talus is stabilized through placement of a small foam pad affixed to the midfoot strap not shown (Stage 3 above).

Following this change in position, the persistent stretch then exerts a force (~3.7N) on the medial hindfoot to reduce the varus although it is allowed to remain plantar flexed (Stage 4 above).

Plantar flexion is then reduced through application of a dorsiflexion force (~2.0N). Throughout this process, a weak external rotation force (~1N) is being employed that encourages the de-rotation of the tibia and externally rotates the foot to 10-20 degrees with the foot in supination (Stage 5 above).

Following this process, the foot is correctly aligned with functional hind and midfoot joints and is ready to be managed further with a second orthosis to prevent regression of the deformity as the soft tissue reconfiguring is consolidated and stabilized.

ACCOMMODATION FOR GROWTH DURING TREATMENT

Preliminary results suggest that treatment times are reduced by 50-60%. As this is closer to a few weeks than 6-8 weeks, growth during the period is somewhat less of an issue. Further, unlike casting where growth produces increased volume of the limb within the cast resulting in compression of the limb impacting circulation and comfort, the Newborn Dynamic Torsion KAFO does not come in contact with the baby except at the thigh cuff and foot shell. Both of these components of the brace are “open” in the sense that they engage the limb on only the medial and plantar sides (or medial and posterior as regards the thigh cuff). This not only easily accommodates growth, it also allows for a wide range of limb sizes to be fit with a single brace size.

Tibial length can also change over time with growth and varies somewhat from child to child. Similar to the Maintenance Dynamic Torsion KAFO described elsewhere, the distance between foot and thigh is deliberately slightly shorter than the limb being treated, this results in an upward force on the bottom of the foot that acts to maintain the foot shell in contact with the foot without the need for rigid strapping. This feature means that a range of limbs lengths can be accommodated with a single brace size as well.

INTERNATIONAL APPLICATIONS

the Newborn DTKAFO has been developed to address critical requirements of babies and children in developing countries where economics, expertise or accessibility may be limiting factors to treatment:

1. Ability to fit the orthosis by simply trained personnel – the brace is easily applied by placing the foot into the foot shell, attaching the midfoot strap to a pre-marked location and then rotating the thigh component into place and securing it with the thigh strap.
2. Accessibility for parents – a simple initialization process is used to gently accustom the foot to the presence of dynamic stretch over the first few days and the foot and leg are easily visualized within the brace easing concerns about what is happening. Throughout the treatment, the brace is removed twice daily for inspection of the skin and for hygiene.

3. Need for follow up reduced from weekly to monthly – following fit and initialization the brace is simply worn full time (with two 30 minute breaks) for 3-4 weeks without the need for adjustment or specific follow up. Although weekly follow up at this age is always preferred, it is not absolutely necessary and can be extended as dictated by circumstances.
4. Fit and follow up completed outside of traditional centralized clinical facilities – in the model where clinicians travel to outlying areas infrequently rather than having the infant brought to a central clinic weekly or where weekly travel is not possible, the brace can be fit in the field and left with the parents to monitor until a subsequent visit is possible. If the foot is corrected sooner than scheduled follow up, the brace can continue to be used without injury until the next opportunity for follow up as the foot will be "parked" in a corrected position without discomfort.
5. Ease of manufacturing with basic orthotic equipment – at this time the brace is fabricated by simply vacuum forming 1/8" poly propylene over a mold; the rough shape is then cut off and ground and polished to final shape. Other than adding pads and straps, there is no assembly as it is a one-piece brace. All of these steps are easily completed with basic orthotic equipment available in most fabrication facilities.
6. Scalability – as the technology progresses, the brace may be fabricated on a point-of-use basis using 3D printing only requiring the addition of pads and straps. Mass production is also possible with traditional injection molding if quantities are sufficiently high to offset start-up costs.
7. Low cost – materials needed for hand fabrication are limited to a small piece of plastic, a small amount of plastizote foam for pads and two straps; the cost of these materials is about $5USD. Approximately 2 hours of labor is required for fabrication.
8. Reusability – due to the modular nature of the brace, following use, the brace can be readied for the next baby by cleaning and replacing the pads and straps at a minimal cost.

SELF-REPORTED EFFECTIVENESS

To date, the Newborn Dynamic Torsion KAFO has been only been used once at Kijabe Hospital in Kenya while working with Dr. Joseph Theuri, director of the CURE Clubfoot Kenya program, and Dr. Paul Mangoli, the chief pediatric orthopedist at Kijabe Hospital in Kenya. Results were good with rapid, comfortable progression of the foot. Since then there have been several iterations of the design based on continuing international study.

CONCLUSION: THE NEED FOR FURTHER STUDY

The Newborn DTKAFO presented here represents a radically different approach to creating the sequential correction described by Ponseti. While acknowledging that the Ponseti treatment dramatically improved outcomes as compared to previously used surgical intervention, we now have the opportunity to further improve treatment in terms of accessibility, affordability and safety. Additional study is critical to evaluate and document the effectiveness of this approach with the ultimate goal of increasing its availability where it is required to help with the goal of eradicating clubfoot as an adult deformity.

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

Drew, S, Lavy, C, Gooberman-Hill, R,. *What factors affect patient access and engagement with clubfoot treatment in low- and middle-income countries? Meta-synthesis of existing qualitative studies using a social ecological model.* Tropical Medicine and Health, 10 March 2016

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 2017. *What is Clubfoot?* Accessed on-line http://globalclubfoot.com/clubfoot. Last accessed 21 January 2017

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

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

Lavy CB, Mannion SJ, Mkandawire NC, Tindall A, Steinlechner C, Chimangeni S, Chipofya E., *Club foot treatment in Malawi - a public health approach.* Disabil Rehabil. 2007 Jun 15-30;29(11-12):857-62.

Matos MA, de Oliveira LA. *Comparison between Ponseti's and Kite's clubfoot treatment methods: a meta-analysis.* J Foot Ankle Surg. 2010 Jul-Aug;49(4):395-7. doi: 10.1053/j.jfas.2010.04.020.

Mayo E. A, Cuthel, A, Macharia, J. T., Lavy,C. B., Mead, T.C., *Creating a countrywide program model for implementation of a Ponseti method clubfoot treatment program in developing countries*. Essential Surgery: Disease Control Priorities, Third Edition (Volume 1), 2015

McElroy T, Konde-Lule J, Neema S, Gitta S 2007 *Understanding the barriers to clubfoot treatment adherence in Uganda: a rapid ethnographic study.* Disability and Rehabilitation 29 (11-12) 845-855

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

Penny, J. N. 2005. *The Neglected Clubfoot*. Techniques in Orthopaedics, 20(2), 153-166.

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

Ponseti International Association website, accessed at: www.ponseti.info last accessed 02/12/17

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

Radler, C, Mindler, GT, Riedl, K et al, 2013. *Midterm results of the Ponseti method in the treatment of congenital clubfoot International* Orthopaedics (SICOT) (2013) 37: 1827. doi:10.1007/s00264-013-2029-8

Ramírez N, Flynn JM, Fernández S, Seda W, Macchiavelli RE. *Orthosis noncompliance after the Ponseti method for the treatment of idiopathic clubfeet: a relevant problem that needs reevaluation.* J Pediatr Orthop. 2011 Sep;31(6):710-5. doi: 10.1097/BPO.0b013e318221eaa1.

Richards, B. Stephens MD; Johnston, Charles E. MD; Wilson, Holly PT, *Nonoperative Clubfoot Treatment Using the French Physical Therapy Method.* Journal of Pediatric Orthopaedics: January/February 2005 - Volume 25 - Issue 1 - pp 98-102

Salzman H 2009, International initiative to eradicate clubfeet using the Ponseti method. Foot and Ankle International 30 (5): 468-471

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