

SBIR PHASE I FINAL REPORT: DYNAMIC TORSIONAL KAFO FOR LOWER EXTREMITY DEFORMITIES

National Science Foundation Proposal # 0418277

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PHASE I OBJECTIVES

1. Develop a Dynamic Torsional Knee Ankle Foot Orthosis (DTKAFO) to treat children afflicted with Talipes Equinovarus (TEV or “clubfoot”) and the associated deformities of Metatarsus Adductus (MA) and Internal Tibial Torsion (ITT) that offers an effective treatment addressing problems inherent in current protocols to improve compliance and effectiveness.
2. Evaluate this orthosis in terms of the corrective forces applied to the lower extremity, suitable materials and fabrication methods.
3. Perform a clinical trial with a subject group of approximately 30 patients to evaluate the efficacy of treatment with this orthosis including patient (and parental) acceptance and to evaluate it’s effectiveness when compared with other currently utilized treatment modalities.
4. Evaluate use of the DTKAFO not only as a treatment to stabilize correction achieved with serial casting (or surgeries) but as a replacement for serial casting.

RESEARCH SUMMARY

In brief, our research addressed the above-mentioned objectives as follows:

1. The incidence of TEV in the United States is approximately 1:1000 live births¹. A need has been identified among parents of these children and healthcare providers alike to create a better solution to the available treatment protocols. Internationally, more research is required to identify the potential for offering this new treatment in currently underserved areas.
2. Following an in depth review of the current treatment protocols for TEV, we developed an initial orthosis that provided dynamic control of the lower extremity for patients who had undergone initial correction through serial casting. Our DTKAFO provided forces designed to correct the mal-alignments associated with TEV such as calcaneal inversion, plantar flexion, MA and ITT. This orthosis is uniquely dynamic in nature, allowing motion of the limb while in the orthosis yet providing ongoing stretching of the involved soft tissues allowing us to constantly exert significant and proportional forces to correct the lower extremity with improved acceptance by the child. Through feedback from our team and the parents of the patients, this orthosis was refined through 16 prototypes to maximize and enhance control of the lower extremity, improve simplicity of donning, improve acceptance and increase the ability to accommodate the rapid growth associated with infants and children. As our experience provided further understanding, fit of the orthosis was further standardized to suggest that an off-the-shelf orthosis in a range of sizes would accommodate most patients with obvious implications for simplifying production.
3. A range of thermoplastics and composite resins was evaluated for suitability with an eye toward durability, fabrication costs (both custom fabricated and mass produced), and performance at the required force levels. Several materials were selected for testing and orthoses were fabricated in a range of material thicknesses. The corrective force delivered by each orthosis was measured and documented. Polypropylene was selected as the material of choice for use in this trial because of its consistent performance, high resistance to fatigue and suitability for injection molding (appropriate for mass production).
4. For the clinical study patients were selected from our area on referral from project orthopedic surgeons typically following a course of serial casting. Although selection criteria required a diagnosis of TEV there was a wide range in severity of associated MA and ITT. 35 cases were studied utilizing the DTKAFO. Advancements in the DTKAFO were provided to each successive patient as they became available so the effectiveness of the treatment changed over the course of the trial. An extensive series of measurements were taken during treatment to monitor and document changes in the affected limb. Quality of life questionnaires were provided to parents of the patients to provide feedback regarding success and acceptance. Anecdotally, parental acceptance was very high particularly with parents who had experienced other treatment modalities. Duration of treatment ranged from six weeks for patients entering into the study late to 6 months for those starting at the outset. Currently these subjects are continuing their clinical care at AtlanticProCare and their progress is being documented.
5. Ponseti has developed an accepted serial casting technique that sequentially moves the newborn early clubfoot through a series of corrections until a well-aligned and functional foot is achieved.² In parallel with the development of the DTKAFO discussed above used for maintaining position, a prototype orthosis was developed for treatment of the newborn clubfoot prior to (and in lieu of) serial casting. This orthosis utilizes the dynamic principles of the original "maintenance" DTKAFO with modifications to provide a sequential correction to the newborn clubfoot. Following development, this "positioning" DTKAFO was presented to the project orthopedic physicians late in the study and although interest in evaluating its efficacy is high, at the conclusion of this Phase I study no suitable patients have been identified for treatment.

RESEARCH FINDINGS AND PROJECT ACTIVITIES

1. PROTOTYPE DEVELOPMENT (Post serial casting or “Maintenance” DTKAFO)

Currently non-surgical treatments for TEV rely on rigidly fixing the lower extremity in a corrected position for approximately 2 years following serial casting to correct the deformity and to minimize the risk of recurrence¹¹. The Denis Browne (DB) bar (and its variants) achieves this by affixing bilateral reverse last footwear to a rigid bar. The Wheaton Brace^{TM3} is a thermoplastic shell that wraps the posterior/medial aspect of the foot and uses Velcro strapping to hold the limb in place. The ClubaxTM manufactured by Camp⁴ is a hybrid of these two approaches with a shoe attached to a flexed knee thigh component. The DB bar rigidly fixes external rotation and foot position but does not address plantar flexion. Further, the DB bar limits independent lower extremity motion in unilateral clubfoot cases as it constrains the contralateral limb unnecessarily and also limits normal development such as turning over, crawling and standing. The Wheaton Brace is designed to statically hold correction and addresses MTA and ITT⁵ but provides no hindfoot control. The ClubaxTM attempts to address all of these factors but again provides only static positioning and hind and midfoot control is only as effective as the fit of the shoe. None of these orthoses provide the dynamic forces required to provide correction to TEV such as the DTKAFO. Both designs constrain the child to a fixed position. This type of control can be poorly accepted by the child causing them to “fight” the orthosis and struggle to remove it, often with irritation to the skin at the points of fixation.

The DTKAFO prototype was envisioned as an improvement on these approaches. Recognizing that active stretching of the involved soft tissue improves positioning of the foot and understanding the need to eliminate the rigid nature of the orthosis we developed a dynamic orthosis that constantly stretches the foot relative to the flexed knee while allowing independent motion of the leg.

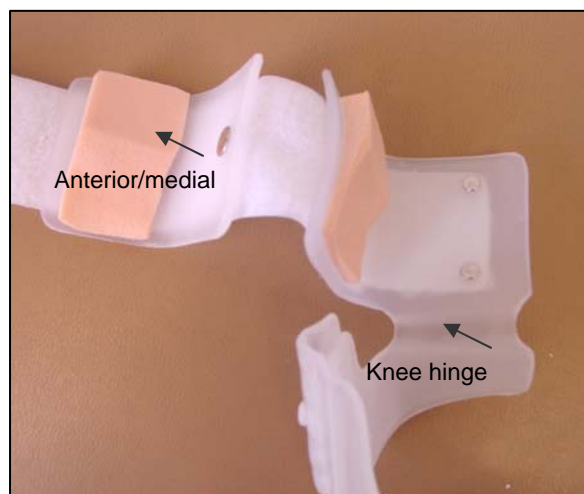


Initially the orthosis was comprised of a foot shell and a thigh cuff connected with the knee in a flexed position by a spiraling band of thermoplastic lined with soft foam. The spiral served to transfer the external rotation force from the thigh to the foot on an axis concentric to the tibia while allowing rotational motion. The forefoot was held in an abducted position relative to the hindfoot (see fig 1). Although the forces were effectively directed, donning involved “unwrapping” the spiral orthosis and rewrapping it around the infant’s leg. This process proved problematic for approximately 30% of the parents/caregivers who utilized this design early on.

Improving on existing orthoses which use tensioned straps to anchor the brace, the DTKAFO tibial region allows approximately 1/8” clearance to the soft tissue with the ‘spiral’ portion used only to connect the points of fixation at the foot and thigh. The resultant opposing forces eliminate the need for foot or tibial strapping.

Fig 1. Initial design using a simple, continuous, “spiral” of polypropylene around the limb.

After various designs of thigh fixation were trialed to improve donning and control, the final design consists of a cuff that has a lateral and posterior shell with a separate piece comprised of a medial and anterior shell. The two shells are joined by a simple Velcro strap (see fig 2). This design allows the orthosis to be easily positioned without wrapping the spiral component around the leg. The foot is drawn into the foot shell with a simple cotton tubular stockinette donning aid that also serves as an interface. As the thigh cuff swings into



position, the foot is rotated externally. The thigh cuff also incorporates a knee flexion angle of 45° that allows motion through a simple hinge created by a thinned area of polypropylene bent to this knee angle. This bent position ensures the rotational force is directed through and concentric to the tibia.

Finally, two supracondylar pads (medially and laterally) were added that provide soft tissue compression proximal to the femoral condyles and serve to effectively and comfortably anchor the thigh cuff.

Fig 2. The final design for the thigh cuff.

The other significant refinement to the thigh component was the incorporation of a connection system between the thigh cuff and the spiral/foot assembly that allows for up to 2" of longitudinal bone growth with a simple adjustment. A radiolucent Delrin™ screw is used to attach the spiral/foot assembly to a series of nuts that allow adjustment in ½" height increments (see fig. 3). The open sided design mentioned above and this connection system also allowed standardization to 2 sizes of thigh cuff ("small" for 3-6 month olds and "large" for 6 month to toddler) that can be matched with the appropriate spiral/foot options, simplifying fabrication and standardized treatment options.

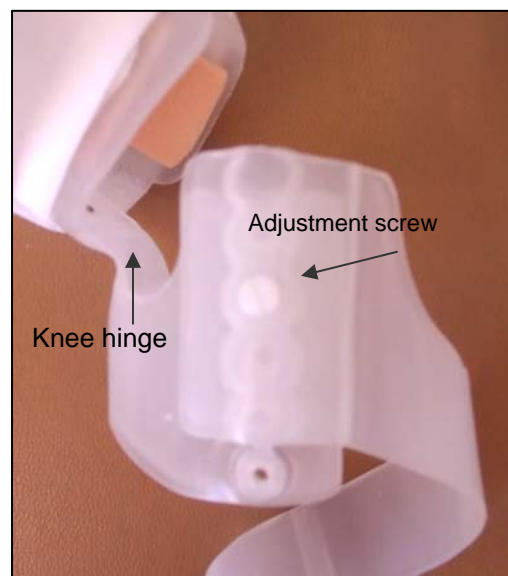
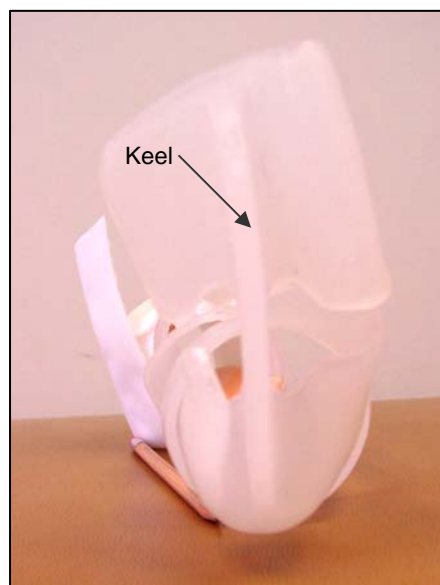


Fig 3. Detail of the attachment of thigh.



The foot shell was also developed from its original form to focus a dynamic abduction force on the forefoot by stabilizing the hind and mid-foot just proximal to the lateral aspect of the base of the 5th metatarsal. This constrains the hind foot, stabilizes the talus position and uses the cuboid as the fulcrum for abduction of the forefoot. A 1/8" pelite pad is utilized at this pressure point and also along the medial aspect of the forefoot where the abduction force is generated (see fig 4). In keeping with the dynamic nature of the orthosis the forefoot was also articulated from the hind foot with a plantar keel that allows some adduction motion but consistently works to stretch the medial musculature back into the abducted position (in patients with a foot length of greater than 3cm). This active stretching allows forces of 2-3N to be generated along the medial forefoot. For two older patients this keel was further modified with a platform along the lateral border of the keel to allow ambulation.

Fig 4. Detail of the plantar keel and articulated forefoot of a right DTKAFO.

Experience showed us that to maintain control of the lower extremity in the orthosis it was critical to control two aspects of the fit: The first is the thigh cuff as discussed above. The second is the anterior-posterior dimension of the ankle-heel structure. An exact fit in this dimension with a mild Achilles pressurization accurately fixes the A-P dimension while maintaining the foot securely without any strapping. Equally importantly, it allows the spiral component to be generously sized for circumferential growth because it does not need to contact the skin to maintain control (see figs. 5 and 6). This increased circumferential clearance and the tibial growth adjustment mentioned previously allow a single orthosis to accommodate a 37% increase in tibial growth and a 20% increase in circumference allowing, typically, 3-5 months of utilization for each orthosis.



Fig. 5. DTKAFO showing generous circumferential dimensions on a subject's right lower extremity.



Fig. 6. Final design of the DTKAFO shown above.

2. FORCES AND MATERIALS ASSESSMENT

Forces involved. The nature of TEV requires a complex, multi-axial, control of the entire lower limb that must include all of the following:

- a. Abduction of the forefoot with counter forces at the lateral cuboid and medial posterior calcaneus.
- b. Eversion of the calcaneus with control of the talus.
- c. Correction of the cavus longitudinal arch.
- d. Dorsiflexion of the talo-crural joint with an associated Achilles stretch.
- e. External rotation of the foot relative to the knee.

As can be seen in the following diagrams (figs. 7, 8 and 9), the DTKAFO provides these forces with carefully positioned surfaces.

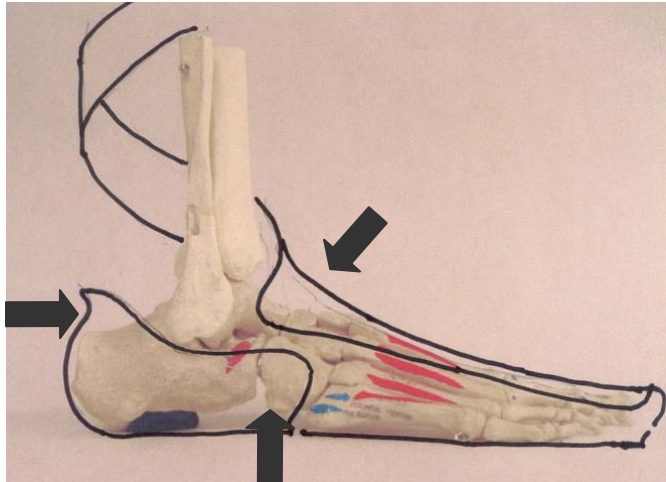


Fig 7. Lateral view of the foot with an outline of the DTKAFO

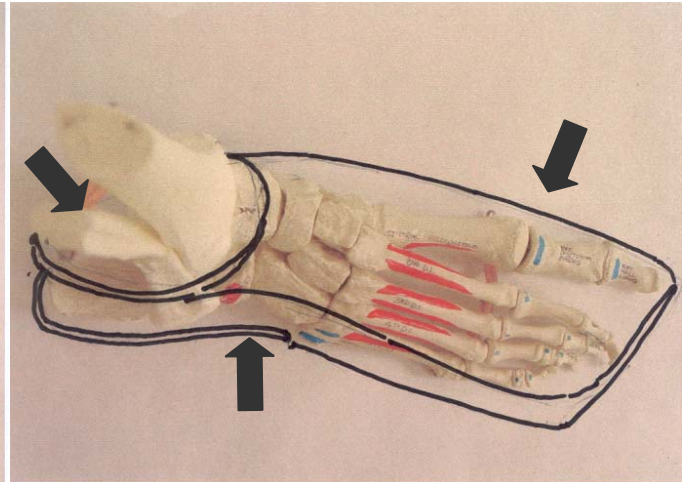


Fig 8. Dorsal view of the foot with DTKAFO outline

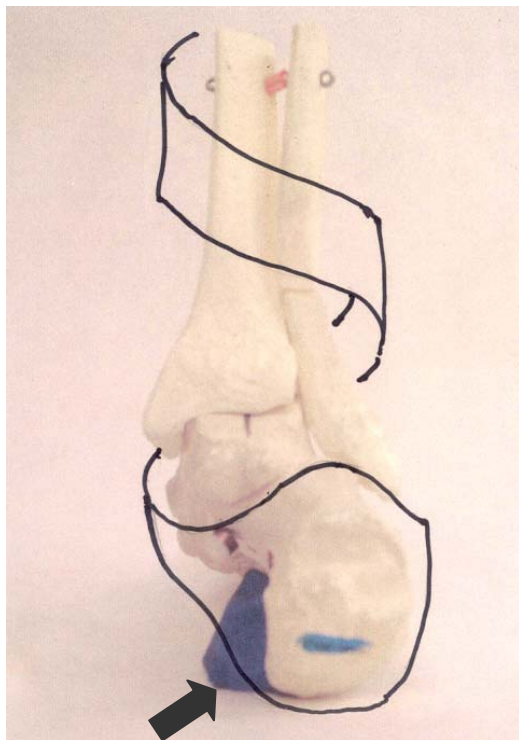


Fig 9. Posterior view of the foot with DTKAFO outline

Materials. A range of readily available thermoplastics such as polypropylene, copolymer, and polyethylene and composites such as acrylic and carbon fiber braid were evaluated for suitability with an eye toward durability, performance at the required force levels and workability both on a custom fabrication basis and for mass production. We developed orthoses in copolymer and acrylic for testing but found that at the thicknesses desired for minimizing bulk they failed to deliver corrective forces in the ranges required. Figure 10 shows materials tested.

Fig. 10. Materials tested for use

ID #	MATERIAL	THICKNESS
1	Carbon Fiber	0.085
2	Copolymer	0.17
3	Polypropylene	0.15
4	Polypropylene	0.155
5	Polypropylene	0.16
6	Polypropylene	0.165
7	Polypropylene	0.17
8	Polypropylene	0.17
9	Polypropylene	0.18
10	Polypropylene	0.19

Polypropylene was determined to be the material of choice. It is readily thermoformed and injection molded, it performs linearly throughout the range of motion and it has demonstrated minimal fatigue over the working life of the orthosis. After fabrication, a representative selection of 10 DTKAFO's was bench tested to determine the rotational force (torque) delivered by the spiral component of the orthosis. The graph in figure 11 shows force response characteristics of the materials tested.

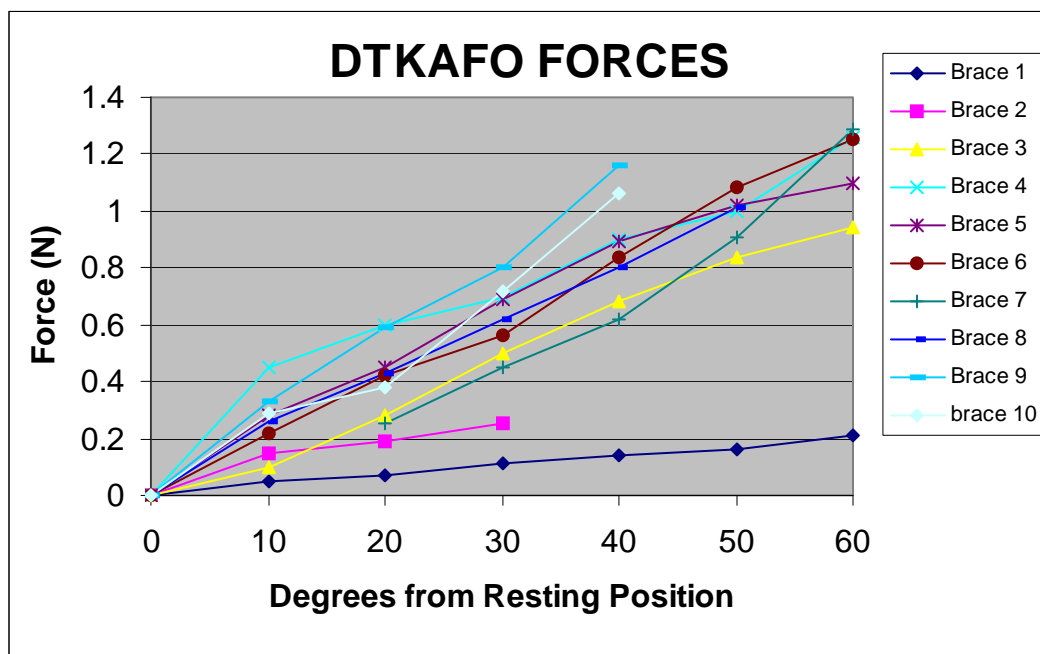


Figure 11. Force required to change rotation position of the forefoot relative to the knee.

This chart demonstrates the linear nature of the corrective response provided by the materials tested. The acrylic and polyethylene DTKAFO's show maximum corrective forces less than .5N even at maximum deflection making them unsuitable at these thicknesses. As will be shown, the force provided by the polypropylene is appropriately scaled to the actual force typically required to correct the ITT in our patients.

Production. All of the DTKAFO's utilized in the clinical trial are custom fabricated from CAD tracings of the affected limb. The digitized image is rectified and carved utilizing a PDI Pro Series 110-60 CAD-CAM NEXFORM digital carving lathe. The orthosis is then vacuum formed by hand draping a sheet of thermoplastic and trimming as required.

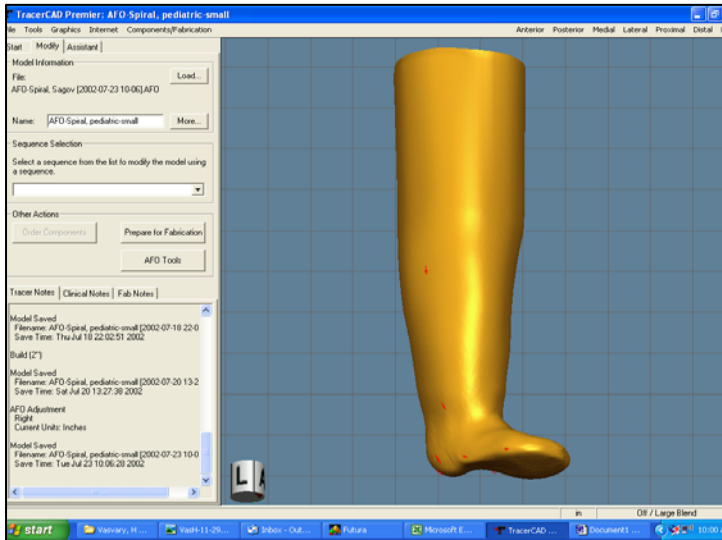


Fig 12. Screen shot of CAD model

As discussed above, we found that only certain key dimensions were critical for an appropriate fit: Identifying the A-P dimension at the ankle heel to generate a secure hold on the foot and securing the femur with supracondylar pads comfortably anchors the orthosis. Interestingly, we determined that there is relatively little change in the ankle A-P over the working life of the orthosis (i.e., 2" increase in tibial growth, 30% increase in tibial circumference) so that this dimension can be fixed at the outset. Further this A-P dimension appears to be consistently proportional to the length of the tibia. Given this, we determined that 4 sizes of the lower component (small, small/stout, medium and large) would accommodate the majority of patients appropriately. Padding is also included at the anterior ankle to accommodate slight differences from patient to patient and over the period of use. Growth in the thigh circumference or length is accommodated by the Velcro positioning strap.

This suggests that mass production is possible for a “custom-fit” orthosis for the majority of patients (as opposed to custom fabricated) utilizing the two sizes of thigh components discussed previously and these four lower leg components. Custom fabrication may be required for those patients falling outside these parameters. Further study and a larger sample would be appropriate to refine our understanding of the parameters critical for creating a standardized fit.

Injection molding would appear to be the most economical solution for mass production. Three plastics manufacturers who specialize in injection molding were contacted to discuss production techniques and costs. The DTKAFO, as designed, could be fabricated from a single cavity mold (6 parts per cavity) utilizing polypropylene for a cost of approximately \$8 per orthosis initially with a decrease to \$1.67 per orthosis after tooling costs are defrayed. Assembly, padding and strapping would result in an additional cost per orthosis.

3. PROTOTYPE DEVELOPMENT (Newborn or “Positioning” DTKAFO)

Developing an orthosis for a newborn with clubfoot is a problem requiring a series of forces to act over a period of weeks with one orthosis. Ponseti outlines a progression of corrections through the course of serial casting necessary to move the foot towards a corrected, functional foot². The models we developed, shown in figures 13, show the desired progression of the foot during serial casting. Ponseti suggests that non-sequential changes, while improving the appearance of the clubfoot, can reduce normal biomechanical function as the foot develops². To paraphrase, Ponseti suggests the following sequence during serial casting:

- Stage 1. The cavus foot is reduced with elevation of the first ray.
- Stage 2. The talus is depressed to preserve its location within the ankle mortise while the calcaneus is everted.
- Stage 3. The forefoot is abducted relative to the hind foot.
- Stage 4. Dorsi-flexion of the ankle and external rotation of the tibia are encouraged.



Fig 13. Models showing the progression of the foot during treatment.

After extensive development we have created a single orthosis that will provide the appropriate forces sequentially. This was achieved by creating a “hierarchy” of force magnitudes that would work on the deformed limb progressively over time. The Positioning DTKAFO is similar in concept to the original DTKAFO utilizing a spiral band of polypropylene to transfer force from the flexed knee to the foot but the forces exerted are *graduated*. Bench testing our prototype as with the Maintenance DTKAFO we have developed an orthosis with a corrective force to elevate the first ray of approximately 3.5N, a calcaneal eversion force of 0.75N and a forefoot abduction force of 0.25N. Plantar flexion of the ankle and internal tibial torsion is allowed in this orthosis. The proportionally greater force exerted on the first ray will make this the dominant force—it acts immediately. As soft tissues are stretched and calcaneal eversion is possible, this change will begin to happen. Finally, the relatively “weak” force associated with external rotation of the foot will be the last force to affect the foot’s position. The combination of the force vectors typically associated with serial casting and the benefits of active, dynamic, stretching provide a compelling, corrective progression. The accommodations for growth developed for the Maintenance DTKAFO allow for growth over the period of use for this orthosis also. We anticipate that a single orthosis will be all that is required to prepare the foot for the Maintenance DTKAFO, and in fact may act more rapidly than the typical 6-8 weeks required for serial casting.



Fig 14. Positioning DTKAFO own in its three progressive positions (from left to right).

Development of this prototype progressed throughout the course of our 6 month study concurrently with the clinical trials and was presented to the project orthopedic surgeons once finalized. The surgeons indicated positive interest in evaluating the Positioning DTKAFO with the next available patient but as of this writing, no suitable candidates have been selected. We are eagerly anticipating the opportunity to continue with development of this orthosis.

4. CLINICAL TRIALS

Patient population. Patients were selected for the study based on referral from the project orthopedists. 35 cases were studied; 80% had undergone a 6-8 week course of serial casting, 28% had received a surgical tenotomy, 14% had undergone more extensive surgery typically involving a calcaneal osteotomy with additional casting, 6% had received no previous treatment. Patient age ranged from 8 weeks to 3 years old. All of the patients had a diagnosis of TEV (clubfoot) and there was typically associated MA and ITT ranging from severe to mild.

Each subject was evaluated by the project orthotist. The treatment process was provided and discussed with the subject's parents at length. A custom orthosis was developed and each subject was fit with the DTKAFO to begin observed treatment.

Following a course of serial casting initiated at birth, the affected foot is typically well positioned and reasonably supple. The goal of treatment in these cases was to *maintain* or improve the positioning and flexibility. For those presenting with deformity and/or rigidity we were attempting to restore correct position and function.

As expected, a high percentage of parents reported a family history of TEV. Three patients were foster children (or became foster children during the study) and compliance and follow up was compromised due to disruption in the patient's care.

As with any orthotic management, compliance is critical to success and parent education was stressed throughout the process.⁶

Following typical orthopedic protocol for management of TEV, full time wear was recommended for the first 3-4 months following casting with nighttime-only wear after that. Treatment protocol may be modified at the orthopedist's discretion.

Patient data. Data was gathered for each patient including:

1. Family and medical history.
2. Bleck's positional deformity.
3. Bleck's rigidity.
4. Internal tibial torsion (at weight bearing).
5. Force measurements for correcting forefoot abduction, dorsi-flexion, and internal tibial torsion.
6. Quality of life questionnaire.
7. Alberta developmental scale.

Bleck's positional deformity⁷. Bleck's criteria for deformity evaluates and rates the degree of forefoot abduction and or pes cavus by imagining a heel bisector and measuring its position relative to the toes. A scale of 0-4 then rates severity with 4 being the worst. We utilized a photographic process to document the plantar surface during weight bearing and from this developed the Bleck's rating. Figure 15 shows a typical sample.



Fig 15. Photographic image of the plantar surface at weight bearing with heel bisector shown.

Bleck's rigidity⁸. Bleck's criteria for rigidity evaluates and rates the degree of rigidity of the clubfoot from a supple foot that can be passively over corrected to a rigid foot that cannot be corrected. The scale ranges from 0-2 with 2 being the most rigid. This rating was determined clinically during examination and was also quantified with the force measurements to be discussed below.

Internal Tibial Torsion. At weight bearing the clubfoot is often (but not necessarily) characterized by internal rotation of the tibia resulting in a measurable in-toeing of the *entire* foot (as distinct from MA). This information was gathered from the same photographic mapping of the plantar surface of the foot, as used above in figure 15, and confirmed during dynamic evaluation.

Compliance. A rating was assigned at each follow up visit to evaluate compliance over the period since the preceding exam. The scale ranges from 0-3 with 3 indicating appropriate wear as directed, 2 indicating decreased wear, 1 indicating intermittent wear and 0 indicating withdrawal from the study.

5. RESULTS

Patient data is provided below showing net changes in ITT, Bleck's deformity and Bleck's rigidity over the course of treatment. Improvement is indicated by a negative value for ITT (a reduction in Internal Tibial Torsion) and for Bleck's criteria (decreased rigidity or deformity). The compliance rating is averaged over the course of treatment. Also summarized is information regarding patient age, history and compliance.

SUBJECT NUMBER	STARTING AGE	TREATMENT PRIOR TO ENTERING STUDY	ITT Δ (DEGREES)	BLECK'S DEFORMITY Δ	BLECK'S RIGIDITY Δ	COMPLIANCE (AVERAGED)
1	7 mos	Cast x 2wks, DB bar, d/c'ed at 5 mos	-5	-1	-2	3
2	2 mos	Cast x 8wks, Tenotomy at 6 wks	10	2	1	3
3	7 mos	Cast x 2wks, DB bar	-5	-1	-1	3
4	9 mos	Tenotomy, cast @ wk1 x 3 mos	5	1	1	2
5	3 mos	Cast x 7wks	0	0	0	0
6	3 mos	Cast x 8wks, rev last shoes x 6wks	-20	-3	-1	3
7	2 + 6 mos	Cast, wheaton, full surgery	0	0	0	0
8	6 mos	Cast x 8 wks, rev last shoes, manipulation	-20	-1	-1	1.5
9	5 mos	Cast x 3 mos, DB bar, B tenotomy	0	0	0	1.5

10	6 mos	None	-20	-2	-1	1
11	5 mos	Cast x 3 mos, DB bar, B tenotomy	0	0	0	1
12	1 1/2 mos	Cast x 6wks	-20	-2	-1	3
13	4 months	Cast x 10 wks	-25	-1	0	3
14	4 months	Cast x 10 wks	-15	-1	0	3
15	1 + 9 mos	None	-10	0	0	2
16	3 mos	Cast off and on over 12 wks	0	0	0	N/A
17	3 mos	Cast x 9 wks	0	-1	0	2.67
18	10 mos	Cast x 2 mos, full surgery	-20	-1	-1	3
19	2 yrs	Cast x 6 mos, DB bar x 2 mos, tenotomy	-20	-1	0	2
20	7 mos	Cast off and on over 5 mos	-20	-1	0	3
21	10 mos	Cast x 2 mos, full surgery	-10	-1	0	2
22	11 mos	Cast, Wheaton x 3 mos	10	1	0	1
23	11 mos	Cast, surgery, DB bar, rev last shoes	0	0	0	N/A
24	2 mos	Cast x 2 mos	-10	-1	0	2.67
25	3 mos	Cast x 3 mos, tenotomy	-10	0	0	3
26	2 + 6 mps	Cast x 2 mos, 2 surgeries	-25	-1	0	2
27	8 mos	Cast x 2 mos, DB bar, tenotomy	0	0	0	3
28	5 mos	Cast x 3 mos,	0	0	0	3
29	2 mos	Cast x 4 weeks	-10	0	-1	N/A
30	2 mos	Cast x 7 weeks	0	1	1	N/A
31	3 mos	Cast x 3 mos, tenotomy	0	1	0	2.75
32	8 mos	Cast x 2 mos, DB bar, tenotomy	-20	0	0	1.4
33	5 mos	Cast x 3 mos,	0	0	0	1.4
34	3 mos	Cast x 3 mos, tenotomy	0	1	0	N/A
35	2 mos	Cast x 4 weeks	-20	0	-1	N/A

As discussed, the range of starting conditions in our patient population suggests that the most representative information isn't the actual criteria values but the net *change* over the course of treatment. The table below (fig. 16) averages before and after values, summarizes the net changes and shows their statistical significance.

PARAMETER	INITIAL	AFTER	P VALUE	SIGNIFICANT?
Bleck's position	1.23	0.76	.0439	Yes
Bleck's rigidity	0.67	0.39	.0397	Yes
Internal tibial torsion (deg)	5.4	-4.4	.0107	Yes

Fig. 16 Change in average position and rigidity during treatment with independent significance.

Force measurements. Specific values for the force necessary to overcorrect forefoot abduction, dorsiflexion and ITT were measured using an Ametek Accuforce Cadet 0-9kg force gauge, with a customized forefoot "sling" to control the foot during tibial rotation and a custom flexible pressure pad for improved comfort for the patient when measuring forefoot abduction and dorsi-flexion forces. A series of 3 values for each parameter was recorded and then was averaged for each visit. Force measurements show a decreasing force required to correct the foot and lower limb over time corresponding to the results for the decreasing Bleck's rigidity values shown above.

Evaluating forces over the course of treatment graphically (see fig. 17 for a representative patient display) shows a steady decrease over time in the force required to over correct the foot. It is worth noting that the forces correlate appropriately with the values measured in the orthosis when fabricated with polypropylene: Initially the force required to correct exceeds the force delivered by the orthosis (the limb is not fully corrected) but over time the orthosis is "stronger" than the foot requires and the amount of positional correction increases to maximum. This creates a situation where the amount of stretch is increasing automatically over time as the patient is able to tolerate it mimicking the benefits of passive stretching therapies.

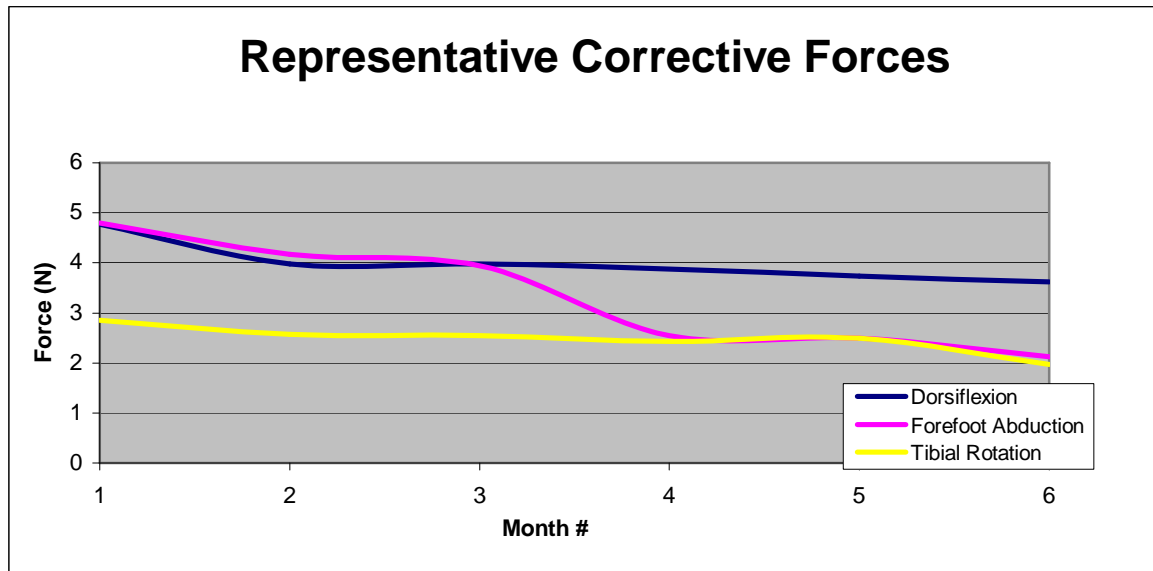


Fig. 17. Corrective forces measured over time for a representative patient.

Questionnaire results. Two standardized questionnaires and a supplemental questionnaire specific to this project were utilized to track developmental and quality of life changes.

Alberta Infant Motor Scale (AIMS)⁹ Results: This standardized scale was used to track developmental changes in the infants during treatment. Because of its design it was not appropriate for children over 15 months. The Alberta Infant Motor Scales provides a performance-based, norm-referenced measure of infant motor maturation from birth to 18 months. A percentage score is assigned ranging from 0-100%. Increasing values suggest appropriate motor development. None of our patients fell into the abnormal or at-risk categories.

TNO AZL Children's Quality of Life (TACQOL)¹⁰: The motor functioning portion of this questionnaire was used to assess changes in quality of life over the course of treatment. Items on the standard TACQOL were scored on a scale from 0-4. These scores were combined for a total score ranging from 0-32. A higher aggregate score suggests an improvement in the quality of the patient's life.

To further refine our information regarding our treatment of TEV, 9 additional questions were provided that target issues specific to lower limb deformity. The following questions were added with item scores ranging from 0-100. A scaled, aggregate score was created with possible values from 0-100. An increase in aggregate score also suggests an improvement in quality of life as it specifically relates to a lower limb deformity.

1. How do you feel about the appearance of your child's lower extremity? (0=very bad, 100=very good)
2. Do you feel that your child's lower extremities are symmetric? (0=Not symmetric, 100=Very Symmetric)
3. Do you feel that your child's mobility is limited? (0=Limited, 100=Not Limited)
4. How easy was it for your child to do what they wanted (i.e. Playing, tasks) (0=Very Hard, 100=Very Easy)
5. How do you feel about your child's standing and/or sitting posture? (0=Very bad, 100=Very Good)
6. How easy is it for your child to ambulate? (walking and/or crawling) (0=Very Hard, 100=Very Easy)
7. How easy is it for your child to perform simple daily exercises? (i.e. playing, ambulating) (0=Very Hard, 100=Very Easy)
8. How much emotional concern do you have for your child's lower extremities? (0=A lot, 100=None)
9. How much do your child's lower extremities affect you and your well-being? (0=A lot, 100=None)

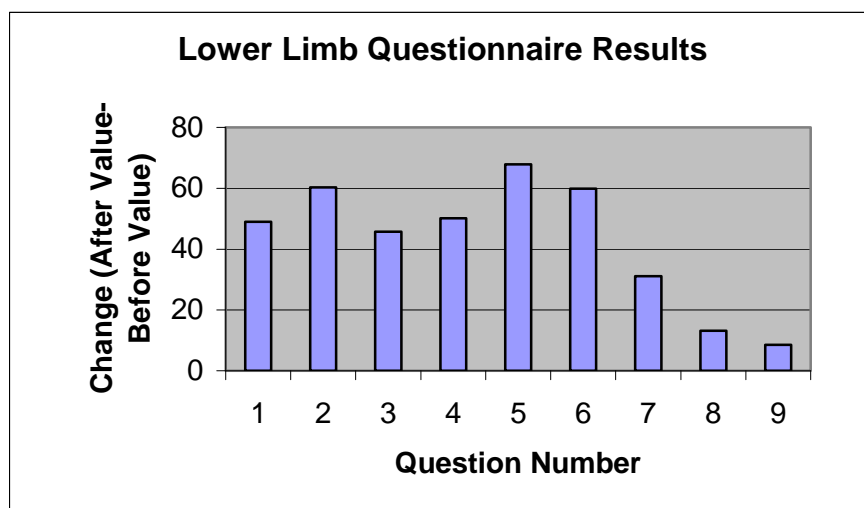


Fig. 18. Results from lower limb questionnaire shown graphically

A summary of the net changes as measured by the Questionnaires is presented in the following table:

TEST	INITIAL	FINAL	NET Δ	IMPROVED	SIGNIFICANT
Alberta Infant Motor	63.3%	75.8%	12.5%	Yes	No
Standard TACQOL	30.4	31.1	0.7	Yes	No
Lower limb questionnaire	50	83.6	33.6	Yes	Yes

The P-value for the AIM was 0.263 a non-significant result due to the limited impact of TEV on early motor development. For the TACQOL, the P-value of the result was 0.1743, which is also considered not significant probably due in large part to the general nature of the questions. The P-value result for the lower limb questions was .0001 suggesting significant improvement when the issues involved are addressed directly.

DISCUSSION

Our Phase I study identified and met several key objectives: A need was identified in the area of treatment of children with Talipes Equinovarus (TEV). A prototype was evaluated and further developed. Materials testing and design refinement was carried out. A clinical trial was executed to evaluate the efficacy of this treatment relative to other treatments and a complimentary design was presented along with its associated treatment protocol.

As discussed previously, there are several other treatment modalities in use at this time but with all, compliance is a key to success. Dr. Ponseti reports a 90% success rate combining casting with use of the Denis Browne bar¹¹. Follow up studies of this approach show a 78% success rate¹². Treatments using the labor intensive physiotherapy without immobilization have demonstrated success rates from 15-50%.^{13,14}. The limiting factors inherent to these modalities have been addressed previously.

The data that we have collected and analyzed shows clear and statistically significant trends towards improvement in the patient's clinical status. Due to the fact that typical treatment durations last 2-4 years and that our clinical trials were limited to a brief six-month period (or some part thereof), we acknowledge that further study is indicated in order to validate the efficacy of this promising treatment of TEV. The iterative nature of prototype development in a clinical setting is a rich environment for observation and improvement. Feedback was immediate and readily communicated to the team. Advancements in the sophistication of the prototype were rapid. Initially the technique required for donning discouraged good compliance with four of the parents using the initial design but this was resolved quickly with a series of improvements as discussed above. We saw improving results as the study continued. Documentation of quantitative improvement is somewhat problematic however because one is studying a "moving target" over a relatively short period of

time. Nonetheless, our experience showed that improved ease of use for the parent and acceptance by the child promoted improved outcomes.

Reviewing our cases as per the criteria reported our overall success rate was 59%. Considering those parents who used the orthosis as instructed, the success rate increases to 95% (only 1 child in 20 did *not* improve with appropriate duration of wear). Comparing patients in the first half of the study to the later half to roughly differentiate early prototypes from more recently improved designs, compliance went from 42% to 86%. These numbers suggest that future study of the finalized design over longer periods will yield improved success rates over what we have seen to date.

In treating TEV, we know that actively stretching the soft tissue immediately begins to create improvement even after a matter of minutes, that stretching therapies have produced good results and that casting as practiced by Ponseti is remarkably effective. Intuitively an orthosis that combines the principles of casting and *dynamic* stretching is a powerful combination. The newborn or "Positioning" orthosis may be particularly valuable because of its ability to provide correction in settings where access to intensive orthopedic care is limited. Many underserved populations where care is currently limited might benefit from this type of treatment ultimately decreasing the number of complications seen in the adult population.

Additional study is warranted to confirm our preliminary results of the "Maintenance" DTKAFO using a larger group and following them over an extended period. It is well understood that TEV management typically must continue until at least age 2 to minimize relapse and we anticipate that this will also be true with our design.

We are encouraged to take this project to the next phase with the goal of executing a successful commercialization plan.

AtlanticProCare would like to acknowledge the contributions of James Kasser, MD for his input on this project.

¹ Ponseti I et al. Forward: Clubfoot Ponseti Management. Global-help.org 2003

² <http://www.vh.org/pediatric/provider/orthopaedics/Clubfoot/Clubfoot.html>

³ <http://www.wheatonbrace.com/>

⁴ Camp International, PO box 89, Jackson, MI 42904

⁵ Jay RM. *Pediatric Foot & Ankle Surgery*. 1999. W.B.Saunders Company Philadelphia

⁶ Dobbs, MB Rudzki JR, Prucell DB, Walton T. Factors Predictive of Outcome After use of the Ponseti Method for the Treatment of Idiopathic Clubfeet. *Journal of Bone and Joint Surgery* 2004; 86A(1):22-27

⁷ Bleck EE. *Metatarsus Adductus: classifications and relationship to outcomes of treatment*. *J Ped Orthoped*, 1983; 3 (1) 2-9

⁸ Smith JT, Bleck EE, Gamble JG, Rinsky LA, Pena T. *Simple Method of documenting Metatarsus Adductus*. *Journal of Pediatric Orthopaedics*. 1991. 7 (3) 305-310.

⁹ Darrah J and Piper MC, Assessment of gross motor skills of at-risk infants: predictive validity of the Alberta Infant Motor Scales, *Developmental Medicine and Child Neurology*, 1998; 40: pp. 485-491

¹⁰ TNO AZL Children's Quality of Life [TACQOL] Child Form [Dutch] (1996). Vogels T; Verrips GH. IN: Salek S. (1998). *Compendium of Quality of Life Instruments*. (5 vols.). Chichester, West Sussex: Wiley. V.5, 3B:7, Pg.1 (datasheet), V.5, 3B:7a, Pg.1-7 (instrument).

¹¹ Ponseti et al. Clubfoot: Ponseti Management. Global Help Publication

¹² Cooper DM, Dietz FR. Treatment of idiopathic clubfoot. A thirty-year follow up note. *J Bone Joint Surg Am*. 1995; 77:1477-89

¹³ Crawford AH, Gupta AK. Clubfoot Controversies: Complications and Causes for Failure. *Instr Course Lect* 1996; 45:339-46

¹⁴ Yamamoto H, Muneta T, Morita S. Nonsurgical treatment of congenital clubfoot with manipulation, cast and modified Denis Browne splint. *J Pediatr orthop*. 1998;18:538-42