Evidence Notes

Management of hypotonic children with Meerkat SMOs.

Background/Problem Statement

Poor muscle tone and hypermobile joints can compromise normal biomechanics, impair stability and postural control and can additionally lead to abnormal bone remodeling over time. Hanger Clinic's department of Clinical and Scientific Affairs (CSA) has identified three evidence-based clinical recommendations to focus on when treating lower limb orthoses in children with hypotonia.

These three areas for lower limb orthotic treatment include: 1) improving foot alignment 2) improving gross motor function and 3) promoting independent ambulation. This paper summarizes the findings of managing hypotonic patients treated with Meerkat supramalleolar orthoses (SMO). The Meerkat SMO design incorporates several features unique to this category of braces and include; a medial intrinsic heel modification, an external heel post wedged to 4° of varus, and a sustentaculum tali modification comprised of a medial longitudinal cast mold arch reduction, with an apex under the sustentaculum tali (ST) which gently tapers in a shallow arch along the medial aspect of the calcaneus (Fig. 1). These modifications, described by **Coleson et.al.**[1], are designed to control the unstable subtalar joint typically seen in individuals with hypotonia, and provide improved rear-foot alignment and control (Fig. 2). In standing this improved distal alignment is translated up the kinetic chain and may positively impact the child's ability to stabilize over their base, and move and reach more effectively. Also, the appearance and packaging are done in a way that encourages adherence to wear and use guidelines.

Figure 1[1]

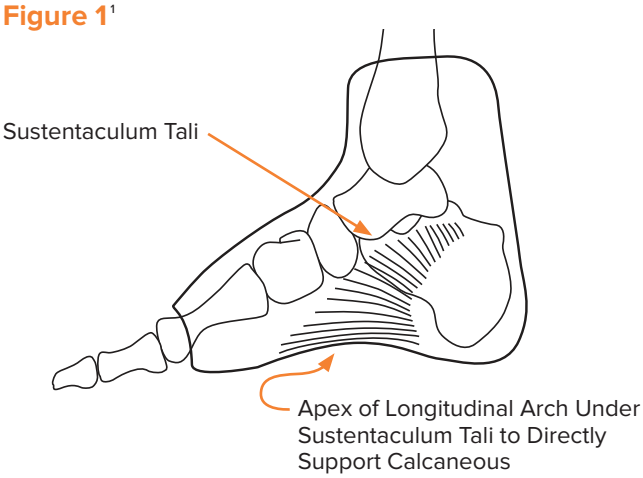
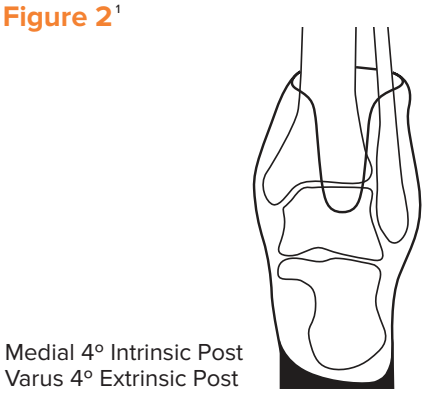


Figure 2[1]



Method

Clinicians were asked to observe each patient *standing* without and with Meerkat SMO and *walking* without and with Meerkat SMO during the initial device delivery. Clinicians noted their findings in a digital platform to enhance central tracking. Differences between conditions were tested for significance using a standard Chi-Square test (α=0.05).

Results & Discussion

A total of 45 clinicians participated, providing data from 171 from patients. Meerkat had a statistically significant impact on controlling ankle valgus, mid-foot pronation, forefoot abduction, forefoot neutrality and coronal plane stability. In combination, these biomechanical controls promote favorable foot alignment and normal bone growth. There were no statistical differences found with reciprocal gait or knee hyperextension with Meerkat. These findings align with design characteristics and clinical expectations.

STANDING WITH VS WITHOUT MEERKAT SMO	p-value (significant at p<0.05)
is the ankle in valgus?	<0.001
is the ankle stable in coronal plane?	<0.001
is the midfoot pronated?	<0.001
is the forefoot abducted?	<0.001
is the forefoot in neutral?	<0.001
WALKING WITH VS WITHOUT MEERKAT SMO	
is the child clearing his/her foot in swing?	0.007
does the knee move normally (i.e. no hyperextension or buckling motion)?	0.942
is the child's gait reciprocal?	0.062

[1]Coleson, Martin J; Berglund, Gene; An Effective Orthotic Design for Controlling the Unstable Subtalar Joint. Orthotics and Prosthetics. 1979; 33:1, 39-49

Appendix: Hanger Clinic Clinical Practice Guidelines

As defined by the Institute of Medicine, clinical guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances". Over the past decade, clinical guidelines have increasingly become a familiar part of clinical practice. Every day, clinical decisions, rules of operation at hospitals and clinics, and health spending by governments and insurers are being influenced by guidelines.

Clinical Practice Guidelines (CPG) should be viewed as an adjunct to clinical decision making, they are guides and may not apply to all patients and all clinical situations, thus the CPG is not intended to replace the clinical judgement of the orthotist or prosthetist or other members of the surgical and rehabilitation team. Our goal at Hanger Clinic is to provide our clinicians with recommendations based on the best available evidence; to inform clinicians of when there is no evidence; and finally, and most importantly, to help our clinicians deliver the best orthotic and prosthetic care possible.

The overall process and guiding principles we employ for CPGs at Hanger Clinic are being modeled after the established American College of Physicians (ACP)'s CPG program structure. Our CPG statements follow a multistep development process and are based upon the best available evidence related to a specific pathology or episode of care.

CPG Summary: Indications, Benefits and Potential Shortcomings of Lower Limb Orthoses in the Management of Children with Hypotonia[1]

Recommendation #1: Among children with hypotonia, lower limb orthoses are indicated to improve foot alignment.

Paleg et al reported the strength of their findings using the AACPDM[2] evidence levels, and cited level II evidence (proven effective recommendation) in support of the statement that lower limb orthoses are indicated to promote better stability, foot structure and alignment in children with hypotonia who are ambulating independently.[3] Weber and Martin similarly reported more stable foot alignments leading to improved body alignment.[4]

Recommendation #2: Among children with hypotonia, lower limb orthoses may improve gross motor function.

With regard to activity and function, Weber and Martin identified six studies inclusive of 62 children with hypotonia using FOs and five studies inclusive of 31 children with hypotonia using SMOs.[4] Of the 10 studies that examined the impact of lower limb orthoses on activity and function, seven concluded that orthoses may be beneficial for the gross motor development of children with hypotonia.[4] The remaining three studies also acknowledged the value of orthoses, but questioned the timing of their introduction relative to the acquisition of the independent walking.[4] However, Weber and Martin reported that after independent ambulation has been achieved, all authors agree that orthoses have a beneficial effect on gross motor skill.[4] This sentiment was subsequently echoed by Paleg et al's assertion that orthoses improve gross motor function in this population, based on levels of evidence that suggest positive results, while advocating the measurement of outcomes to ensure benefit at the level of the individual child.[3] The Peabody Developmental Motor Scales (PDMS) were the most commonly used assessment measures, reported in three of the clinical trials, with an increase in raw scores as children progressed towards, or in some instances, met age-equivalent norms.[4]

Recommendation #3: The impact of full time use of lower limb orthoses by children with hypotonia prior to independent ambulation is not fully understood and requires additional research.

While available evidence suggests that orthoses provide children with hypotonia a more stable foot position, some authors have suggested that children may benefit from time spent barefoot to experience the sensations associated with unassisted weight bearing and weight shifting and explore movement patterns.[3,4] Specifically, authors have indicated that children who are pulling to stand and demonstrating an interest in exploring their environment be allowed to do so without the restriction of full-time orthotic use.[3,4] However, some children may lack the foot and ankle stability necessary to explore their surroundings in a standing posture, compromising their ability to maximize their cognitive, motor and social development by restricting their immediate environment.[3] For these children, lower limb orthoses permit an enhanced opportunity to practice and develop gross motor skills.[4] Ultimately, Paleg et al suggest a wearing schedule of 50% waking hours when children are pulling to stand or cruising.[4]

Limitations and Inconclusive Areas of Evidence

Consistent with much of the evidence related to orthotic rehabilitation, reviewers reported that the overall quality of evidence related to the orthotic management of hypotonia was compromised by small sample sizes, lack of randomization or control group, a lack of blinded assessors and a lack of power analyses.[4] The comparative efficacy observed between FOs and SMOs has thus far been confined to a single pilot study and fails to provide adequate insight to influence clinical decision making.[4]

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We would like to extend our appreciation to the many additional clinicians who participated in this effort.

[1]Stevens P, DiBello S. Established Indications, Benefits and Shortcomings of Lower Limb Orthoses in the Management of Children with Cerebral Palsy: Clinical Practice Guidelines. Dev Med Child Neurol. 2019;61(S3):205

[2]Stevens P, DiBello T. Indications, Benefits and Potential Shortcomings of Lower Limb Orthoses in the Management of Children with Hypotonia: Clinical Practice Guidelines. Dev, Med Child Neurol. 2019;61(S3):10.

[3]Paleg, Ginny & Romness, Mark & Livingstone, Roslyn. (2018). Interventions to improve sensory and motor outcomes for young children with central hypotonia: A systematic review. Journal of pediatric rehabilitation medicine. 11. 57-70.

[4]Weber, A., & Martin, K. (2014). Efficacy of orthoses for children with hypotonia: a systematic review. Pediatric physical therapy, 26(1), 38–47.