

Novel Mechanical Testing Methodology for Clubfoot Orthoses and Introduction of the Crawford Smart Brace.

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INTRODUCTION: Clubfoot is a complex congenital deformity of the foot that affects from 1/1000 live births up to 1/125 in Polynesians. If left untreated it results in a lifetime of disability and pain. To engineers, the Ponseti serial casting method fixes the ankle/foot combination in a corrective aligned configuration analogous to joint reconstruction and obtains correction in over 90% of treated feet but the technique requires children to wear abduction orthoses until five years of age to maintain deformity correction by preventing regress to misalignment. Despite differences in severity, the post correction abduction bracing protocol is not made different across patients based on their condition; feet are placed approximately at shoulder-width abduction using a rigid metal bar, and the affected feet are externally rotated 60°-70° while unaffected feet are maintained at 15°-30° external rotation. Due to the multi-segmental, multiaxial, and biologically variable nature of the deformity, it is very difficult to estimate the forces/moments internal to the foot to optimally select the brace configuration, rigidity and resistance to them. Therefore, we have instrumented a Ponseti brace to determine all-six degrees of freedom forces/moments from under each foot loaded by the patient, onto the brace. The aim of this study was (1) Design a testing methodology to mechanically test Ponseti orthoses, (2) to verify the accuracy and performance of this new instrumented brace for optimizing outcomes of the Ponseti correction method.

METHODS: A 4-axis MTS 858 Bionix universal hydraulic testing machine was used such that each orthotic shoe could be fastened to an actuator through a polymer block simulating a foot/ankle and a bent threaded steel rod simulating a leg (Fig 1). Multiple configurations were necessary to actuate one or more anatomical axes of translation or rotation while keeping the test machine and orthosis measurements in line. Our lab computationally modeled, designed, and manufactured a custom modified Ponseti Brace (MD Orthopedics) outfitted with two Mini40 Force/Torque Transducers (ATI Industrial Automation) each measuring in 6-degrees of freedom (3 forces and 3 moments). The instrumented brace was then tested in in each configuration, with waveforms run for 60 seconds with either a 0.15 Hz linear displacement or a 15° angular displacement sinusoid while other actuators were allowed either to be free to move (force or torque controlled to be zero) or static to keep stability/not break the brace in a minority of configurations. Waveform amplitudes and motion extremes were selected to stretch the system throughout its safe elastic deformation range. Direct or indirect (calculated) orthosis measurements from onboard the brace were compared to the corresponding (MTS) test machine measurements. Correlation coefficients were calculated, and comprehensive plots showed how well the two sets of measurements compared. After these in vitro validation measurements, to verify the range of forces and moments used in our in vitro study, the brace was applied to two patients (1 and 5 years old) at 0°, 30°, and 60° external rotation and data collected as part of an ongoing clinical study.

RESULTS: Measurements from the 4-axis MTS test machine were graphed alongside corresponding measurements from onboard the orthosis and their corresponding correlation plots (Fig 2). For accurate visual comparison and to keep a sense of scale as to which forces/moments were dominant, the ranges of the force and moment correlation plots were kept consistent. Correlation statistics are presented in Table 1. All the results agreed to a very high degree (all showed $p < 0.005$), and so p values were omitted. The slope, intercept, and R^2 values from linear regression are reported instead. Due to the variable compliance of the brace and fixtures in different directions, much larger Medial/Lateral forces were achieved than Posterior/Anterior or Superior/Inferior forces. Some slipping of the foot in the shoes were also expected, and that was most pronounced in the Internal External moments shown in Figure 2, where the waveform was not sinusoidal. Responses in all channels to activity, with signals ranging from ~0-10 N and 0-5 Nm were found in the clinical testing.

DISCUSSION: This study demonstrates a novel testing methodology that can mechanically characterize not only our novel instrumented smart brace, but can quantitatively describe the mechanical differences between commercially available braces. Our in vitro data demonstrates high reliability of the device to accurately measure the forces exerted by the feet in the brace. Our clinical testing demonstrates the feasibility of the system to collect clinical data and measure differences between patients. Expanding the clinical testing and further refinement of the clinical protocol is underway.

SIGNIFICANCE: The mechanical testing methodology developed in this study can provide clinicians and families objective information about the numerous commercial orthoses on the market today. This is the first onboard instrumented Ponseti orthosis demonstrating mechanical accuracy and clinical viability, being capable of recognizing child dissatisfaction/early recurrence (severe forces/moments) or brace redundancy or ineffectiveness (nominal forces/moments). This capability promises to improve clubfoot management by transitioning brace wear from an empiric angular and age based regimen to personalized biomechanical based brace wear protocols.

REFERENCES: [1] Beals, 1978; [2] Dobbs+, 2006; [3] Desai+, 2010;[4] Zions+, 2010.

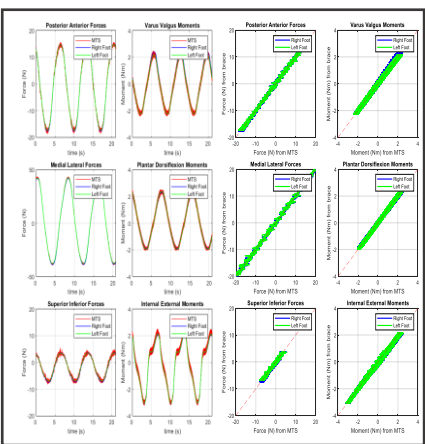
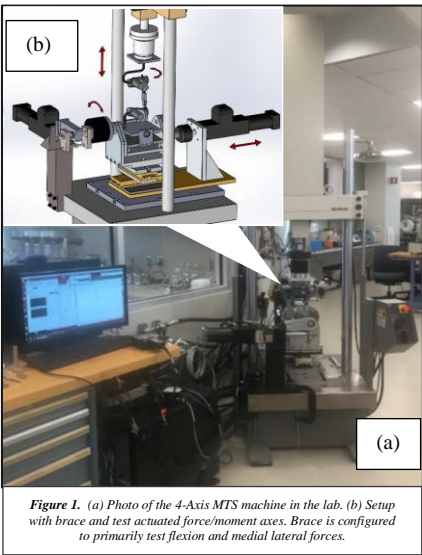


Figure 2. Measurements from the MTS plotted with direct and indirect measurements from the instrumented orthosis (Left) and correlation plots of measurements from instrumented orthosis plotted against measurements from the MTS. (Right).

Forces	Left Foot					Right Foot				
	Correlation Coefficient	Linear Regression			R ²	Correlation Coefficient	Linear Regression			R ²
		Slope	Intercept				Slope	Intercept		
Posterior Anterior	0.9984	1.0116	-0.0518	0.9968	0.9998	0.9988	0.0196	0.9992		
Medial Lateral	0.9998	0.9969	-0.4945	0.9995	0.9997	0.9940	0.0008	0.9985		
Superior Inferior	0.9905	1.0172	-0.1695	0.9810	0.9908	0.9676	-0.0931	0.9816		
R ²										
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Moments	Left Foot					Right Foot				
	Correlation Coefficient	Linear Regression			R ²	Correlation Coefficient	Linear Regression			R ²
		Slope	Intercept				Slope	Intercept		
Varus Valgus	0.9912	1.0333	0.0363	0.9824	0.9914	-0.0279	0.9986	0.9826		
Plantar Dorsiflexion	0.9940	0.9828	-0.0090	0.9881	0.9940	1.0065	-0.0123	0.9881		
Internal External	0.9935	0.9645	-0.0925	0.9871	0.9936	0.9727	-0.0711	0.9872		
R ²										

Figure 3. Correlation coefficients and linear regression values for plots in Figure 2.



Figure 4. Patient 1: 1yr 6mo both feet set to 30 degrees external rotation.