

# The Effect of Gel Padding on Pressure Distribution in Ankle Foot Orthoses

Patricia Lawrence, MD, Linda Fieback, MA,PT, Andrew  
Cinque,CPO, Xiofang Wei, MD, Angela D' Alessandro, MD,,  
Steven Lichtman, EdD, Heather Onorato, ATC, SPT,  
John Rossi, PTA, SPT, Andrew Michalski, SPT,  
Doris Nieves, SPT

Blythedale Children's Hospital  
Valhalla, New York

# Background and Significance

- Neuromuscular Disorders  
Spasticity
- Orthoses (AFO' s)  
Clinical Uses  
Types

# Background and Significance

- Focus of Current Research
  - To analyze padding materials within an orthosis
  - Area that is lacking in current literature
- Project Significance
  - Determine if one material is better than another
  - If differences seen could enhance:
    - tolerance to orthosis
    - acclimation period
    - realignment of the foot

# Literature Review

- **‘Gait assessment of fixed ankle-foot orthosis in children with spastic diplegia’ -Abel, et al, 1998**
  - Evaluated the effectiveness of an ankle-foot orthosis vs. barefoot gait in 35 patients with mean age of 8.7 years.
  - Patients were prescribed orthoses to control equinus (n=18) or pes planovalgus (n=17).
  - Variables studied were spatio-temporal distance factors (velocity, stride length, cadence and stance times), and joint excursion at the pelvis, hip, knee and ankle.
  - Used a vision system to evaluate the spatiotemporal parameters, and force plates to quantify forces coincident with joint positions.

# Literature Review

- **Abel, et al, 1998 (cont' d)**
  - Found use of AFO' s during gait produced an increase in velocity, stride length, and single support time, a decrease in double support time and no change in cadence.
  - Attributed temporal changes to decreased ankle excursion and increased pelvic, hip and knee excursion.
  - Good study with good design that shows AFO' s can improve gait function in diplegic patients.
  - Gives validity to our investigation to enhance the effectiveness and comfort of orthoses to the patient.

# Literature Review

- **‘Design enhancement of a solid ankle-foot orthosis: real-time contact pressures evaluation’ -Nowak, et al, 2000**
  - Evaluated pressures at the interface between the ankle/foot and a custom molded orthosis in subjects during ADL’ s.
  - Studied orthosis that is used clinically to reduce plantar contact pressures in adult neuropathic diabetic patients.
  - Used 4 non-impaired adult male controls with right side orthosis.
  - Conducted real time pressure recording at surface interaction utilizing a pressure sensing system.
  - Found consistent patterns of high pressure within the orthosis in all subjects.

# Literature Review

- **Nowak, et al, 2000 (cont' d)**
  - From results, made recommendations for modifications of orthosis to improve comfort and to decrease weight.
  - Authors stated results of study could be useful to orthotists in improving basic designs, and to researchers who do finite element analysis of orthoses.
  - First study to look at total interface pressures in an orthoses other than just the plantar surface.
  - Served as a model for our research in technique used.

# Hypotheses

- **Purpose**

To compare the pressure absorbing effects of gel padding versus conventional foam padding at the interface surface inside an AFO.

- **General Hypothesis**

Gel will show greater ability at absorbing pressures than conventional foam.



- **Specific Hypotheses**

- When gel pressures within orthoses are compared from Day1 to Day 14 in sitting, standing and walking, there will be less pressure in Day 14.
- When foam pressures within orthoses are compared from Day1 to Day 14 in sitting, standing and walking, there will be less pressure at Day 14.
- When gel and foam pressures within orthoses are compared in sitting, standing and walking, the gel padding will display lower mean pressures than foam padding at Day 1 and at Day 14.

# Methods

## Subject Selection

- **Sampling method**

Subjects will be selected on a volunteer basis based on a sampling of convenience from patients receiving inpatient or outpatient care at Blythedale Children's Hospital in Valhalla, New York.

- **Subjects**

Seven participants:

- ❖ 2 ambulatory
- ❖ 5 non ambulatory

## **Inclusion criteria:**

- ❖ Diagnosis of a neuromuscular disorder
- ❖ Greater than 6 years of age
- ❖ Flexible or fixed ankle/foot deformity

## **Exclusion criteria:**

- ❖ Open wounds to the foot or ankle
- ❖ Progressive neuromuscular disorder
- ❖ Edema of the foot and/or ankle
- ❖ Refusal to participate in the study

# Methods

## General design

### General Research Design

- Prospective
- Experimental
- Randomized
- Single factor
- Double-blinded
- Repeated measures

# Methods

## Definition of Variables

- Independent variables:  
Gel and foam padding
- Dependent variable:  
Pressure measurements

# Methods

## General Protocol

- Each subject had 2 pairs of orthoses fabricated for them
- One pair used gel and the other used conventional foam to pad specific boney prominences
- Pressure differences were compared between and within both types of padding in sitting, standing and ambulating

# Subject Characteristics

Subject #	Sex	Age	Diagnosis	Height (cm)	Weight (kilos)	AFO Subject Prefers To Wear
1	M	14	Hypoxic Brain Injury	154.9	74	Gel lined
2	F	25	CP-Spastic Diparesis	147.3	73.6	Gel lined
3	M	14	CP-Spastic Diplegia	154.9	44.5	Foam lined
4	F	11	CP- Spastic Quad	119.4	20	Gel lined 2 <sup>o</sup> to fit
5	F	13	CP-Spastic Quad	124.5	21.3	Gel lined
6	M	7	Spastic Quad 2 <sup>o</sup> Shaken Baby Syndrome	125.1	27.6	Gel lined
7	M	14	CP- Spastic Quad	134.0	28.7	Gel lined Tolerance built more easily

# Methods

## Specific Procedures

- Subjects wore each pair of orthoses for a period of approximately 14 days (range of 13-15 days).
- The pair worn was randomly selected.
- Pressure measurements were taken at Day 1 and then again at Day 14 utilizing FSA's octopod system. This system shown valid and reliable by Pearsall, et al in 2004.
- 2<sup>nd</sup> pair of AFO's were then donned with the same procedure repeated.



# FSA Octopod Sensors



# Methods

## Specific Procedures

- For sitting and standing, pressure measurements were taken for 30 seconds with mean pressure used.
- For walking, subjects ambulated a total distance of 20 feet. Pressure measurements were taken for 30 seconds with mean pressure used.
- Pressure measurements were taken at the 1<sup>st</sup> and 5<sup>th</sup> metatarsal heads, the navicular, and the medial and lateral malleoli.

# Methods

## Statistical Methods

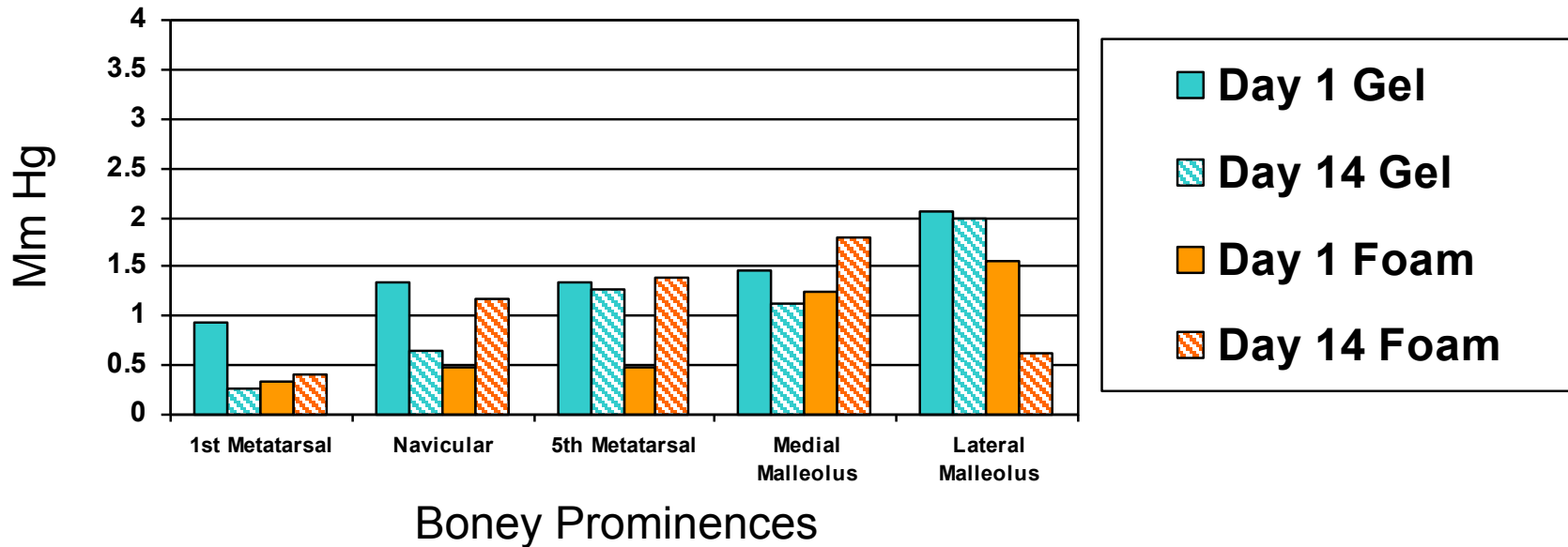
- Sitting Total Pressures  
(paired t-tests) Alpha level was set at 0.01
  - To date 7 participants: Each foot considered an individual subject totaling 14 subjects.
  - All 14 subjects were compared at Day 1: Gel to Foam
  - All 14 subjects were compared at Day 14: Gel to Foam
  - All 14 subjects compared Day 1 to Day 14: Gel to Gel
  - All 14 subjects compared Day 1 to Day 14: Foam to Foam

# Methods

## Statistical Methods

- Standing & Walking Total Pressures  
(paired t-tests) Alpha level was set at 0.01
  - 2 ambulatory participants: Each foot considered an individual subject totaling 4 subjects
  - All 4 subjects were compared at Day 1: Gel to Foam
  - All 4 subjects were compared at Day 14: Gel to Foam
  - All 4 subjects compared Day 1 to Day 14: Gel to Gel
  - All 4 subjects compared Day 1 to Day 14: Foam to Foam

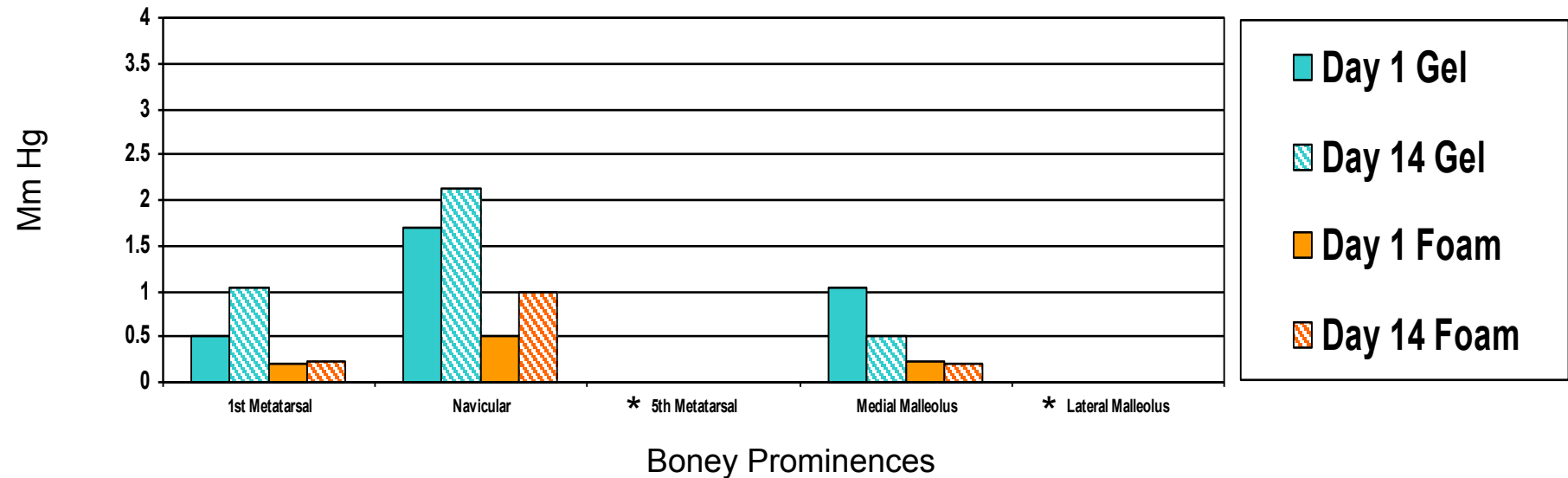
# Mean Pressures in Sitting



	Gel vs. Foam Day 1					Gel vs. Foam Day 14					Gel Day 1 vs. Day 14					Foam Day 1 vs. Day 14					
	1st Met	Nav	5 <sup>th</sup> Met	Med Mall	Lat Mall	1st Met	Nav	5 <sup>th</sup> Met	Med Mall	Lat Mall	1st Met	Nav	5 <sup>th</sup> Met	Med Mall	Lat Mall	1st Met	Nav	5 <sup>th</sup> Met	Med Mall	Lat Mall	
Gel (mean ± SD)	.94 ± 1.10	1.35 ± 1.37	1.35 ± 1.42	1.45 ± .87	2.06 ± 2.70	.26 ± .19	.64 ± .39	1.28 ± 1.20	1.12 ± 1.14	2.00 ± 2.59	.94 ± 1.10	1.35 ± 1.37	1.35 ± 1.42	1.45 ± .87	2.06 ± 2.70	.33 ± .32	.49 ± .48	.48 ± .43	.48 ± .43	1.24 ± 1.42	1.55 ± 2.15
Foam (mean ± SD)	.33 ± .32	.49 ± .48	.48 ± .43	1.24 ± 1.42	1.55 ± 2.15	.41 ± .28	1.17 ± 1.63	1.38 ± 1.61	1.79 ± 1.75	.63 ± 1.19	.26 ± .19	.64 ± .39	1.28 ± 1.20	1.12 ± 1.14	2.00 ± 2.59	.40 ± .28	1.17 ± 1.63	1.38 ± 1.61	1.79 ± 1.75	.63 ± 1.19	
P value	.184	.058	.200	.653	.560	.235	.355	.883	.120	.244	.096	.140	.650	.280	.873	.649	.224	.330	.182	.433	
# Subj	8	10	4	10	6	8	10	4	10	6	8	10	4	10	6	8	10	4	10	6	



# Mean Pressures in Walking (Lofstrand)



	Gel vs. Foam Day 1					Gel vs. Foam Day 14					Gel Day 1 vs. Day 14					Foam Day 1 vs. Day 14				
	1st Met	Nav	5 <sup>th</sup> Met	Med Mall	Lat Mall	1st Met	Nav	5 <sup>th</sup> Met	Med Mall	Lat Mall	1st Met	Nav	5 <sup>th</sup> Met	Med Mall	Lat Mall	1st Met	Nav	5 <sup>th</sup> Met	Med Mall	Lat Mall
Gel (mean ± SD)	.50 ± .55	1.70 ± 2.81	NA	1.05 ± .72	NA	1.04 ± 1.98	2.12 ± 3.99	NA	.50 ± .87	NA	.50 ± .55	1.70 ± 2.81	NA	1.05 ± .72	NA	.20 ± .34	.50 ± .87	NA	.24 ± .24	NA
Foam (mean ± SD)	.200 ± .34	.50 ± .87	NA	.24 ± .24	NA	.22 ± .32	.98 ± 1.62	NA	.20 ± .22	NA	1.04 ± 1.98	2.12 ± 3.99	NA	.50 ± .87	NA	.22 ± .32	.98 ± 1.62	NA	.20 ± .22	NA
P value	.476	.304	NA	.139	NA	.495	.404	NA	.535	NA	.646	.537	NA	.497	NA	.391	.297	NA	.391	NA
# Subj	4	4	NA	4	NA	4	4	NA	4	NA	4	4	NA	4	NA	4	4	NA	4	NA

# Conclusions

At this point, for all conditions, we must accept the null hypothesis indicating that there was no significant differences in pressure absorption between the orthoses with gel and the orthoses with conventional foam padding.



# Study Limitations

## Small sample size

- May mask significant results
- On-going study has a goal of 15 participants totaling 30 subjects

## Orthosis fabrication

- Both AFOs are made from the same mold
- Compare custom orthoses to off-the-shelf orthoses

## Limited number of trials

- Additional trials would increase statistical power
- Standing and walking ability criteria for inclusion in study

# Conclusions

- Significance to physical therapy
  - Clinically important information to decrease incidence of pressure ulcers and improve comfort
  - Examination of individual pressure measurements increases ability to customize orthoses
- Future areas of study
  - Extend the follow-up intervals of pressure measurement to one and three in preferred orthosis to establish trend of decreasing pressure with gel and increasing pressure with foam
  - Comparison of custom orthoses and off-the-shelf orthoses
  - Comparison of baseline and long-term pressure measurements