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The Effects of Supramalleolar Orthoses on the Biomechanics of the Knee, Foot, and Ankle during Gait: A Single-Subject Design

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THE EFFECTS OF SUPRAMALLEOLAR ORTHOSES ON THE BIOMECHANICS
OF THE KNEE, FOOT, AND ANKLE DURING GAIT:
A SINGLE-SUBJECT DESIGN

by

Jennifer Ruth Stauffer
Bachelor of Science in Physical Therapy
University of North Dakota, 1994

An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical Therapy
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Master of Physical Therapy



Grand Forks, North Dakota
May
1995

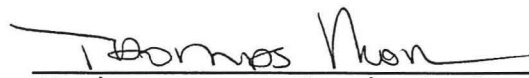
This independent study submitted by Jennifer Stauffer, in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.



Faculty Preceptor



Graduate School Advisor



Chairperson, Physical Therapy

PERMISSION

Title The Effects of Supramalleolar Orthoses on the
 Biomechanics of the Knee, Foot, and Ankle
 During Gait: A Single-Subject Design

Department Physical Therapy

Degree Master of Physical Therapy

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ABSTRACT

Gait deviations are a common problem associated with disorders of movement and posture such as cerebral palsy (CP). Inhibitive casts and ankle-foot orthoses have been used to treat gait deviations in children with CP, but they have not satisfied the needs of children who are able to achieve active dorsiflexion and plantarflexion but lack stability at the subtalar joint. Supramalleolar orthoses (SMOs) were developed to address that need. SMOs, along with physical therapy, have been used to treat children with CP, but little research has been conducted to determine the actual effects of the SMO on lower extremity biomechanics during gait. The purpose of this study was to describe the biomechanical changes that occur at the knee, foot, and ankle as a single-subject walked barefoot, with shoes, and with shoes and SMOs. It was hoped that while walking with shoes and SMOs, the subject's gait pattern could be documented as more similar to normal ambulation patterns.

The subject walked on a treadmill while he was videotaped, and measurements of joint range of motion and bony alignment were taken from video photographs. From this data, it was determined that although utilization of SMOs did not produce a normal gait pattern, they did effectively

control medial and lateral movement at the subtalar joint
while normalizing tone.

CHAPTER 1
INTRODUCTION

Cerebral palsy (CP) is a nonprogressive disorder of movement and posture due to a defect or injury on the immature brain.¹⁻³ It is caused by a lack of oxygen and/or blood flow to the brain during pregnancy, delivery, or postnatally. Over 12000 children born in the United States are affected with a neurological disability like CP in a given year.⁴ CP is characterized by muscle weakness and abnormal muscle tone along with problems of coordination and voluntary movement. These problems can ultimately lead to gait deviations in the children who are ambulatory.

Abnormal bony alignment, joint range of motion, contracture, and motor weakness may contribute to the abnormal posture as well as gait deviations present at the knee, foot, and ankle of individuals with CP.¹ A flexed posture is one commonly assumed by the child with CP while standing. This often consists of hip and knee flexion with a pronated foot. The child may also stand on his/her toes to create more stability at the foot and ankle.⁵

Through gait analysis, Gage¹ has described some of the common abnormalities found in a cerebral palsy gait pattern. Common deviations at initial contact and loading response

include excessive knee flexion and plantarflexion of the foot. This means the individual begins the gait cycle with toe contact, positioning the knee in 30° to 40° of flexion resulting in knee extension and ankle dorsiflexion in the loading response. At midstance, overactivity of the soleus may lead to knee hyperextension, whereas, underactivity causes excessive knee flexion. Pes planus is also frequently apparent at this phase of gait. Common abnormalities that occur at terminal stance and pre-swing are due to inadequate plantarflexion strength, abnormal foot position, and flexion contractures at the knee which may result in diminished heel rise and decreased knee extension. Finally, foot clearance problems are common throughout the swing phase of gait in individuals with CP.

Because of the deviations present in the gait patterns of children with CP, lower leg orthoses are used in conjunction with physical therapy to improve their walking.^{1,6-9} The goals of utilizing the orthotics during gait are to prevent deformity, support normal joint alignment and mechanics, provide variable range of motion when appropriate, and facilitate function.^{4,5} Lower leg orthoses are designed to restore proper structural and biomechanical alignment by firmly grasping the calcaneus to prevent medial and lateral motion of the subtalar joint, stabilizing the forefoot, and supporting the arches to

prevent pronation and protect the medial and lateral plantar ligaments.

In the past, inhibitive plaster casts and steel or aluminum braces with adjustable ankle joints were used along with physical therapy to treat children with CP.^{4,5} Although inhibitive casts and early ankle-foot orthoses (AFOs) did improve bony alignment and reduce tone, the materials that were used to create the devices were not ideal. For instance, plaster casts could not get wet and were quite heavy. Some individuals required frequent cast changes; therefore, making the casts became a time consuming task for the clinician, especially one who paid careful attention to detail.⁵

The early AFO consisted of a shoe attached to a metal, double rod leg brace. This was recognized as an unsatisfactory approach to securing the spastic foot and ankle in a plantigrade position because the leather straps holding the brace in place tended to deform under stress of hypertonic deviations, taking the shape of the deforming foot and ankle.⁵ The heel also did not remain fixed within the shoe, and the shoe itself was not made as a sturdy foundation for the metal brace.

By the early 1980s, fixed polypropylene AFOs were being molded with features designed to hold the subtalar joint in neutral, prevent pronation, and inhibit spasticity.⁴ Brodke and coworkers¹⁰ found that the new light-weight plastic AFOs

increased the walking speed and cadence of their subjects when compared to their walking with metal AFOs. The fixed AFO was designed to provide assistance with deficient dorsiflexion while blocking excessive, unwanted plantarflexion. The orthosis was reported to act as a stabilizing force on the tibia, prohibiting the tibia's normal 10° to 15° of motion over the foot after midstance and at pre-swing.⁵

Although the use of AFOs is mentioned frequently in literature regarding the treatment of individuals with neurological disorders,⁴ limited investigative research has been done with children with CP. The studies that have been done regarding the use of AFOs in the treatment of children with CP are diverse with very little repeated research on any given topic area. Mossberg and coworkers³ focused on energy expenditure during ambulation. The results of the study revealed energy expenditure was reduced when subjects ambulated with AFOs compared to ambulation without the orthoses.

AFOs have also been found to affect lower limb deformities and foot posture.^{9,12,13} Sankey et al¹² found that the need for surgical correction of deformities was reduced in a group of children who wore AFOs with a dorsiflexed foot-piece and straps placed below the knee and at the ankle. A single-subject wearing AFOs in a study by Taylor and Harris⁹ demonstrated improved foot posture and a more

symmetrical stance posture during standing activities. Ricks and Eilert,¹³ however, found no significant change between radiographic measurements of bony alignment at the foot and ankle during weight-bearing barefoot and with AFOs in place. The authors then concluded that the effectiveness of the orthoses must occur dynamically with immobilization of the foot itself as the mechanism by which the AFOs are effective.

Using a single-subject design, Harris and Riffle⁷ found standing balance could be improved by the utilization of AFOs. The subject of their study consistently demonstrated a longer duration of independent standing while wearing orthoses. Rosenthal¹⁴ felt that the use of AFOs had the greatest value in improving standing balance by inhibiting extensor tone.

The limitations of active ankle motion imposed by the solid AFO compete with the advantages of the child who is able to manage a greater degree of motion at the ankle. This has led to the development of the supramalleolar orthosis (SMO) which is designed to allow active dorsiflexion and plantarflexion while stabilizing the subtalar and midtarsal joints in the frontal plane. SMOs are inhibitive ankle-height orthoses made of light-weight polypropylene plastic which have proximal trimlines extending 30 to 50 mm above the malleoli for the purpose of controlling medial and lateral movement at the subtalar

joint. The orthoses are trimmed anteriorly and posteriorly to allow plantarflexion and dorsiflexion.^{4,5}

Only one study has investigated the effects of SMOs on gait in a child with CP. Embry et al⁶ revealed knee flexion could be reduced in a 2-year-8-month-old subject with diplegia by using SMOs in conjunction with Neuro-Developmental Treatment (NDT) principles. The authors did not discriminate between the effects of NDT or the SMOs.

Due to limited information regarding SMOs, research that adds to the understanding of these orthoses should be conducted. The purpose of this study is to describe the biomechanical changes at the knee, foot, and ankle of a single subject during ambulation barefoot, with shoes, and with shoes and SMOs. It is hoped that while walking with shoes and SMOs the subject's gait pattern can be documented as more similar to normal ambulation patterns. The study may also serve as a research design for further study of SMOs and their effects on lower leg biomechanics.

CHAPTER 2

LITERATURE REVIEW

The information available concerning orthotics is quite extensive; however, research on orthotic devices used specifically for treating children with CP is limited. A study by Knutson and Clark⁴ reviewed the literature on orthoses commonly used for ambulation in children with CP. Although they found numerous references to and discussions of orthotic devices, very few of these reports were of an investigative nature. In all, eight articles were found on orthotic research for children with CP from 1986 to 1990. Of those eight articles, only one article focused on the SMO and its effects on knee kinematics during gait. Knutson and Clark⁴ concluded that as progress is being made in the understanding of how orthoses affect gait variables, further research will be needed as advances are made in material properties and designs.

At the present time, investigative research on the use of the AFO in a cerebral palsy population is diverse with very little repeated research regarding the effects of AFOs on different variables. Specifically, these studies have investigated walking velocity and energy expenditure, lower

limb deformities and bony alignment, standing balance, and kinematics during gait.^{6,7,9,11-13}

Mossberg and colleagues¹¹ conducted a study that compared the energy costs of ambulation in a spastic diplegic population using bilateral AFOs. Eighteen children with CP walked a marked distance with or without AFOs while their heart rates were monitored with a telemetry device. Energy expenditure measured in beats per meter was reduced when the subjects ambulated with AFOs compared to ambulation without the orthoses. The investigators concluded that the results did support the use of AFOs for reducing the energy demands of gait in children with spastic diplegia. Most of the subjects also improved in their gait efficiency with the orthoses.

The use of AFOs to help correct lower limb deformities and improve foot posture can enhance the physical therapy treatment of children with CP.^{1,6-9,12-15} Cusick and Sussman¹⁵ have found that a stable base at the foot and ankle allows physical therapists to direct more effective techniques proximally at the trunk and pelvis. Orthoses have also contributed to the reduction of the need for surgical correction of alignment and deformities. Sankey et al¹² found that the need for surgical correction of deformities was markedly reduced in the group of children treated with AFOs.

Ricks and Eilert¹³ have compared the bony alignment of the ankle and foot of children with spasticity in and out of inhibitory casts, static ankle-foot orthoses, and articulated ankle-foot orthoses during weight-bearing. The subjects were divided into groups based on which orthotic device they utilized. After wearing the prescribed device for 1 to 3 weeks, the subject's right foot and ankle was x-rayed barefoot and while wearing the orthosis in a weight-bearing position. Five different angles that described the posture of the foot and ankle were measured on each x-ray. The investigators found no significant change between measurements of bony alignment during weight-bearing while barefoot and with the orthoses in place. The authors concluded that the effectiveness of the orthoses must occur dynamically with immobilization of the foot itself being the key mechanism by which inhibitive devices are effective.

In a single-study by Taylor and Harris,⁹ a subject with spastic diplegia demonstrated improved foot position during standing activities while wearing AFOs. While standing barefoot, the subject stood completely up on his toes in an equinus position on the left, and his right heel did not come in contact with the floor. With the orthoses in place, the subject was able to bear weight on the ball of his left foot while his right heel was flat on the ground in a plantigrade position when standing. The subject also appeared to have a more symmetrical stance posture.

Harris and Riffle⁷ examined the effects of AFOs on the standing balance of a 4-year-6-month-old male with moderate spastic quadriplegia. Trials of independent standing were timed to determine how long the subject was able to maintain his balance while standing barefoot and while wearing his AFOs. Results of the study showed the subject consistently demonstrated a longer duration of independent standing when wearing the orthoses. The child's posture, which was asymmetrical with weight bearing primarily on the right while barefoot, was more symmetrical with equal weight bearing when the orthoses were in place. The ease with which the subject could regain his balance had also improved while wearing the AFOs. When the subject appeared to start to lose his balance, he was able to regain balance on his own without falling. Rosenthal¹⁴ also found that children wearing AFOs demonstrated improved standing balance. He felt the AFOs helped improve standing balance by holding the ankle in neutral to inhibit extensor tone. Rosenthal¹⁴ thought an improvement in standing balance would also show an improvement in balance during the stance phase of gait.

Embry et al⁶ has researched SMOs in the treatment of children with CP. The authors evaluated the effectiveness of inhibitive SMOs used in combination with Neuro-Developmental Treatment (NDT). A 2-year-8-month old female with diplegia who ambulated independently with increased hip, knee, and ankle flexion during all phases of gait,

participated in the study. Videographic data were collected regarding knee flexion during gait. The results showed a decrease in excessive knee flexion at initial contact, midstance, and pre-swing when NDT was used in conjunction with the SMOs. The investigators noted that the combined intervention provided more immediate changes in the amount of knee flexion than the use of NDT in isolation. It was also reported that after the NDT/SMO treatment, the subject fell only once or twice per day compared to 6 to 10 times per day prior to treatment.

The current research on orthoses in the treatment of children with CP has focused mainly on the AFO and its effects on several different gait variables. Very little research has been conducted to determine the effectiveness of SMOs, even though the use of the orthotic is quite common in ambulatory children with CP. This single-subject study will add to the understanding of SMOs by describing biomechanical changes at the knee, foot, and ankle during ambulation by a subject with CP under three different conditions. The single-subject design is appropriate for studying individuals with CP since there is great individual variability in deficits among children, making it difficult to match subjects to form equivalent groups for a group design.¹⁶ This design shows the effects of treatment for individual clients, and is a simple and straightforward approach to evaluation.¹⁶

It is hoped that when walking with the SMOs in place, the subject's gait pattern will more closely resemble normal ambulation. The study may also serve as a research design for further study on the effectiveness of SMOs.

CHAPTER 3

METHODS

Subject

The subject of this study was a 9-year-old male with athetoid CP who had been informed of the study procedure and participated with the informed consent of his parents. He had been walking moderate distances while wearing supramalleolar orthoses (SMOs) since the age of 5. At the time of the study the subject had periodically used a treadmill at a comfortable speed with supervision for approximately 1 year.

Equipment

The following equipment was utilized in this study: A Medtrack R60 treadmill (Quinton Fitness Equipment, Seattle, WA), a Sony 8 mm high-speed video camera with a Sony 8 mm videotape (Sony Corp, Park Ridge, NJ), a stopwatch, a 4 in. plastic goniometer, a 3 in plastic protractor, a marking pen for marking bony landmarks on the skin, and athletic tape to mark the subject's shoes and SMOs for measurements.

Procedure

The subject, accompanied by his mother, entered the Sports Acceleration Program of the Medical Center Rehabilitation Hospital, Grand Forks, ND, where the testing

occurred. At this time the procedure was explained to both the subject and his mother, and the subject's parent was asked to read and sign a consent form. The subject was then asked to undergo a bilateral lower extremity musculoskeletal examination. This exam consisted of measuring joint range of motion and bony alignment at the knee, foot, and ankle statically, for the purpose of comparing these measurements with measurements that were recorded in the dynamic second portion of the study. Any changes could then be noted between the two sets of measurements. No invasive procedures were utilized in this exam.

Range of motion at the knee was measured passively by aligning the lateral malleolus, the knee joint space, and the greater trochanter with the arms of a plastic goniometer. The subject was positioned in prone to measure knee flexion and in sitting to measure knee extension. Generally, goniometric measurements have been found to have an intratester reliability of 2° to 3° .¹⁷

Tibial torsion was measured as the subject sat with his legs over the edge of the examination table. The amount of torsion was determined by the angle created when one arm of a goniometer was aligned with the medial and lateral malleoli and the other arm was aligned perpendicular to the shaft of the tibia.¹⁸

Gastrocnemius flexibility was determined by measuring the amount of dorsiflexion (DF). DF was measured while the

subject sat in a long-sitting position with a towel roll under his lower leg. The arms of the goniometer were aligned with the fifth metatarsal, lateral malleolus, and fibula as the subject actively dorsiflexed his ankle. Picciano et al¹⁹ and Elveru et al²⁰ have found intratester reliability to be high (ICC=.90) for ankle dorsiflexion.

Maximal calcaneal eversion was measured with the subject lying in prone with his legs in a figure-four position. Two lines bisecting the distal one-third of the subject's posterior leg and calcaneus were drawn with a marking pen. The stationary arm of the goniometer was placed along the bisection of the distal lower leg and the moveable arm was aligned with the calcaneal bisection. Passive range of motion (PROM) was measured to the nearest degree by everting the calcaneus to a firm endfeel. This procedure for measuring subtalar range of motion has been shown to have fair (ICC=.75) intratester reliability.²⁰

Tibio-fibular varum was measured as the subject stood barefoot on an elevated platform in an equal weight-bearing stance position. The bisection of the lower one-third of the leg was used to align the moveable arm of the goniometer and the stationary arm was positioned parallel to the horizontal of the platform. Intratester reliability was found to be high (ICC=.96) for this method of measuring tibio-fibular varum.²¹

To measure navicular drop, the subject stood with his foot positioned in subtalar joint neutral. This was achieved by asking the subject to invert and evert his foot until equal palpation of the talus was felt by the examiner. The examiner then placed an upright index card next to the medial portion of the subject's foot and made a mark on the card where the tuberosity of the navicular was located. The subject was then asked to stand with both feet in an equal weight-bearing position. The index card was again aligned with the medial part of the subject's foot and another mark corresponding with the position of the navicular tuberosity was made on the card. The distance between the two marks was measured on the card and recorded as navicular drop. The navicular drop test described by Elveru¹⁹ has been found to have poor to fair (ICC=.61-.79) intratester reliability. Results of the musculoskeletal examination are found in Table 3.1.

Table 3.1.—Results of Lower Extremity Musculoskeletal Examination		
Position	R	L
Knee flexion	145°	147°
Dorsiflexion (active = passive)	9°	15°
Tibial torsion	35°	35°
Navicular drop	8.5 mm	9.5 mm
Calcaneal eversion	20°	10°
Tibial varum	1°	7°

In the second portion of the study, the subject walked on the treadmill once barefoot, with his shoes, and finally with his shoes and SMOs. The reason for the three different walks was to show if the biomechanics of the knee, foot, and ankle would progressively become more like the biomechanics of a normal gait pattern. First, a gait belt was fastened around the subject's waist. One investigator assisted the subject onto the treadmill. When the subject was standing with one leg on either side of the treadmill track one investigator held the back of the subject's gait belt as another investigator started the treadmill at .08 mph. The subject then stepped barefoot onto the treadmill track and began walking. At this time, a stopwatch was started by another investigator. The subject walked a total of three minutes. This procedure was repeated when the subject's shoes and shoes and SMOs were in place. Time was taken in between walks to put on the subject's shoes and braces and mark them with the tape and marking pen. The markings corresponded with the head of the fibula, the lateral malleolus, the shaft of the fifth metatarsal, the bisection of the calcaneus, and the bisection of the lower one-third of the leg.

As the subject walked, he was filmed with an 8 mm high-speed video camera at a shutter speed of 1000 frames per second by an investigator kneeling 4 feet from the treadmill for each side view and 2 feet for the posterior view.

Starting at the right side viewpoint, this investigator moved to the posterior viewpoint at 50 seconds and the left side viewpoint at 1 minute 50 seconds during the subject's walk. These movement times were indicated verbally by the investigator responsible for timing. The investigator repeated this procedure for each of the walks. To protect the confidentiality of the subject, he was not identified on any video or written results of the study.

The videotape was played in a Sony Super 8 player and viewed on a Sony Trinitron video monitor. Through frame-by-frame advancement, the principal investigator selected beginning midstance, end midstance, and beginning pre-swing at each side view, and maximal calcaneal eversion during the stance phase of gait at each rear view. Beginning midstance was defined as the initial point of single-leg stance. End midstance was defined as the point at which the hip was in direct alignment with the ankle. Beginning pre-swing occurred as the swing leg made initial contact with the ground and the stance leg began to push off into swing phase. A Sony digital video adapter XV-D30 stopped the action, and the picture was reproduced through a Sony videographic printer UP-850. Examples of video photographs are shown in Figure 3.1 and Figure 3.2. The angle formed by a line drawn from the head of the fibula to the lateral malleolus, intersecting with a line parallel to the fifth metatarsal, was measured on each side view print with a

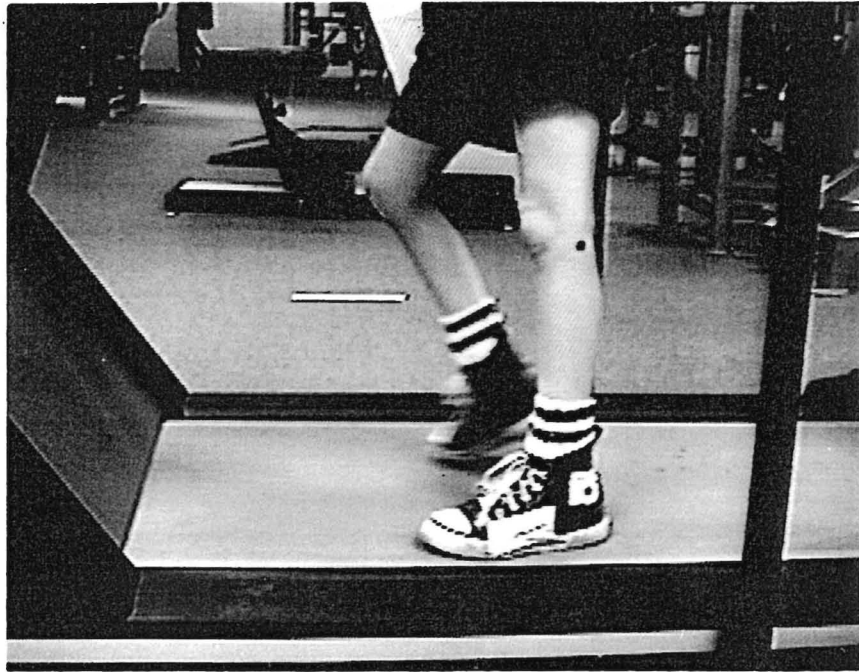


Fig 3.1.—Left sideview video showing plantar flexion during end midstance.

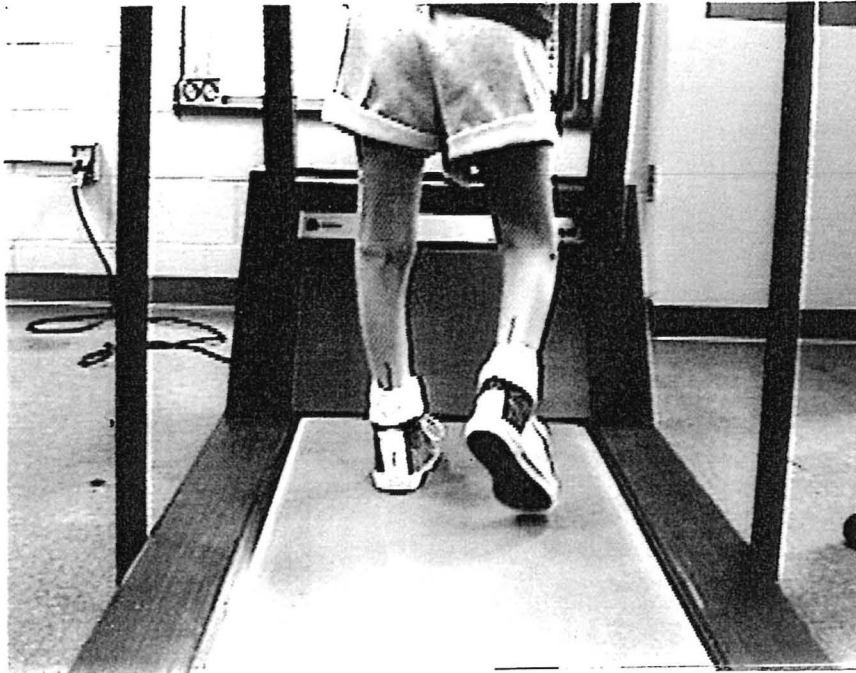


Fig 3.2.—Left maximal calcaneal eversion shown in a rearview video photograph.

plastic protractor and recorded as dorsiflexion or plantarflexion. The angle formed between the bisection of the distal lower leg and the bisection of the calcaneus was measured on each rear view print with a plastic protractor and recorded as maximal calcaneal eversion.

DATA ANALYSIS

An analysis of variance (ANOVA) was performed with degrees of plantarflexion and maximal calcaneal eversion as the dependent variables, and gait phase and device (barefoot, shoes, or shoes and SMOs) as the independent variables with a significance level of .05. Results of the ANOVA are listed in Tables 4.1 through 4.3.

An observational gait analysis was also performed to note any changes in the subject's overall gait pattern between the three gait conditions.

CHAPTER 4

RESULTS

The two-way ANOVA revealed a significant interaction between the devices and the amount of plantarflexion and maximal calcaneal eversion. The least amount of control of calcaneal eversion occurred when the subject was barefoot, while the most control occurred with the SMOs in place. Results are shown in Table 4.1 and Table 4.2.

Table 4.1.—Results of Statistical Analysis					
Source of Variation	SS	DF	MS	F	Sig of F
Main effects					
Devices (BF, shoes, SMO)	9613.5	2	4806.7	73.6	.000
Phases (PF only)	1366.4	2	683.2	10.5	.000
2-Way interactions					
Devices position	1840.9	2	920.5	13.6	.000
Devices phase	887.7	4	221.9	19.8	.000

Table 4.2.—Mean Degrees of Eversion and Plantar Flexion with Each Device		
Devices	Position	
	Ever.	PF
BF	6.05	32.98
Shoes	3.10	8.85
SMO	-0.28	17.44

Although dorsiflexion should be evident in midstance and pre-swing in a normal gait pattern, the subject was unable to achieve dorsiflexion consistently in these phases of gait. Plantarflexion was instead measured in the beginning and end of midstance and the beginning of pre-swing. The amount of plantarflexion was controlled the least when the subject was barefoot, and the most while the subject wore shoes. The least amount of plantarflexion occurred at pre-swing, while the most occurred at the beginning of midstance. Results are shown in Table 4.1 and Table 4.3.

Table 4.3.—Mean Degrees of Plantar Flexion with Each Device During Each Phase of Single-Leg Stance			
Devices	Phase		
	Beg MS	End MS	Beg PS
BF	33.80	33.33	31.80
Shoes	17.18	10.45	-1.09
SMO	20.31	18.54	13.46

Observational Gait Analysis

Observational gait analysis revealed the subject ambulated with a varying base of support throughout the three gait conditions. When barefoot and wearing SMOs, the subject walked with a wide base of support. The greatest variation in base of support occurred as the subject walked with shoes. Under this condition, the subject began to ambulate with a wide base of support which would gradually

narrow until the subject would strike the stance leg with the swing leg. The base of support would then quickly widen.

At the knee, the subject exhibited excessive genu recurvatum bilaterally in midstance while walking under all three gait conditions. The lower extremities were in a position of excessive external rotation during swing phase, and the subject appeared to circumduct at the hip to advance the swing leg.

Bilaterally, initial contact occurred on the medial border of the foot in the barefoot and shoe conditions. When ambulating with the SMOs, however, initial contact occurred on the lateral border of the calcaneus, bilaterally. It was also noted that excessive external rotation at the hip along with excessive tibial torsion contributed to excessive toe out at initial contact. Toe out did decrease while the subject ambulated with SMOs when compared to the barefoot and shoe conditions. Excessive calcaneal eversion was also apparent bilaterally in stance during the barefoot and shoe gait conditions.

It is important to note the subject used his arms to maintain his balance and an upright posture during ambulation. The subject also exhibited a large step length and jerky gait movements throughout the gait pattern when ambulating with SMOs.

CHAPTER 5

DISCUSSION

This study evaluated the biomechanical changes at the knee, foot, and ankle of a single-subject during ambulation barefoot, with shoes, and with shoes and SMOs. Ultimately, it was hoped the study would determine the effectiveness of SMOs in eliciting a normal gait pattern.

Results of this study revealed genu recurvatum was present bilaterally in all three gait conditions. Excessive calcaneal eversion was found to be effectively controlled with the use of the SMO. Even though the subject was capable of achieving sufficient dorsiflexion, plantarflexion was present during midstance and beginning pre-swing where the foot and ankle should normally be in 10° of dorsiflexion and in a neutral position, respectively. The amount of plantarflexion, however, was controlled the most when the shoes were in place. The subject's gait pattern was also smoother with a more consistent base of support while ambulating with the SMOs.

The plantarflexion occurring in midstance and pre-swing instead of dorsiflexion was due to the subject's posture when walking on the treadmill. The subject maintained his balance by holding on to the handrails of the treadmill.

This caused the subject to flex his trunk forward which resulted in hip flexion, genu recurvatum, and plantarflexion.

The subject may have used more energy to walk with shoes. This could contribute to the most effective control of plantarflexion occurring with the utilization of shoes since walking with shoes may have resulted in loss of balance due to weakness or fatigue. Loss of balance would cause the subject to walk with an increased period of double-limb stance because the original stance leg would have to remain off the ground longer to regain balance. As a result, the foot and ankle would move into decreased plantarflexion (increasing dorsiflexion) as the treadmill continued to move.

Altered proprioception may have resulted in the inconsistent base of support present when the subject walked with shoes. The contact of the SMOs would increase proprioception, leading to a more consistent base of support. Total contact is also a feature of the SMO which helps to normalize tone.⁴ This may have led to the subject's smoother gait pattern when wearing the SMOs.

One limitation of this study may have involved the use of the treadmill. The subject walked while holding on to the handrails which led to a flexed posture when walking. The subject also had to walk at a consistent rate. This may have led to fatigue or the possibility of the subject having

to alter his gait to keep up with the treadmill. More precise data could have been obtained by a computer-assisted, three-dimensional motion analysis lab where all aspects of the subject's gait could be monitored without external influence.

CHAPTER 6

CONCLUSION

This study evaluated the effectiveness of SMOs in eliciting a normal gait pattern by describing the biomechanics of the knee, foot, and ankle of a single-subject during ambulation. Observational gait analysis and freeze-frame videography were used to evaluate lower extremity biomechanics during gait.

SMOs are designed to control the amount of medial and lateral movement at the subtalar joint while allowing active dorsiflexion and plantarflexion. In this study, SMOs were found to effectively control medial and lateral subtalar joint movement, evident in the reduction of the subject's calcaneal eversion during gait. Observational gait analysis revealed that the contact of SMO served to increase proprioception and normalize the subject's fluctuating tone. This was evident in the subject's more consistent base of support and smoother gait pattern with the SMOs in place.

Use of the SMO did not control the amount of dorsiflexion and plantarflexion during the subject's gait. This, however, is not the purpose of the SMO. The SMO should allow for active dorsiflexion and plantarflexion, but not necessarily control movement. Other factors such as

posture, weakness, or fatigue could have contributed to abnormal dorsiflexion and plantarflexion during ambulation.

Since the function of the SMO is to provide support at the subtalar joint to prevent excessive medial and lateral movement while inhibiting tone, this study can conclude that although utilization of SMOs did not lead to a normal gait pattern, the SMO did perform the function for which it was designed.

APPENDIX

UNIVERSITY OF NORTH DAKOTA'S
INSTITUTIONAL REVIEW BOARD

DATE: September 7, 1994

NAME: Jennifer Stauffer DEPARTMENT/COLLEGE Physical Therapy

PROJECT TITLE: The Effects of Supramalleolar Orthoses on the Biomechanics of the
Knee, Foot, and Ankle During Gait: A Single-Subject Design

The above referenced project was reviewed by the University's Institutional Review Board on September 2, 1994 and the following action was taken:

Project approved. Next scheduled review is on September 1995.
If no date is given then review will be required in 12 months. (See REMARKS SECTION for any special condition.)

Project approval deferred. (See REMARKS SECTION for further information.)

Project denied. (See REMARKS SECTION for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairman or ORPD.

cc: P. Mohr, Adviser
Dean, Medical School

9-7-94

Signature of Chairperson or designated IRB Member Date
UND's Institutional Review Board

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 596 Form may be required. Contact ORPD to obtain the required documents. (9/87)

- J. The Board reviewed the proposal from Jennifer Stauffer (Physical Therapy) entitled "The Effects of Supramalleolar Orthoses on the Biomechanics of the Knee, Foot, and Ankle During Gait: A Single-Subject Design." J. Stauffer answered questions from Board members. R. Sopher reported that there were no questions from the Subcommittee.

After a brief discussion, R. Lee moved that the proposal be approved; R. Wilsnack seconded, and the motion passed unanimously.

_____ EXPEDITED REVIEW REQUESTED UNDER ITEM _____ (NUMBER(S)) OF HHS REGULATIONS
 _____ EXEMPT REVIEW REQUESTED UNDER ITEM _____ (NUMBER(S)) OF HHS REGULATIONS

UNIVERSITY OF NORTH DAKOTA
 HUMAN SUBJECTS REVIEW FORM
 FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED
 PROJECTS INVOLVING HUMAN SUBJECTS

PRINCIPAL INVESTIGATOR: Jennifer Stauffer TELEPHONE: 777-2831 DATE: 9/2/94
 ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: P.O. Box 9037, Grand Forks, ND 58202-9037
 SCHOOL/COLLEGE: Medicine DEPARTMENT: Physical Therapy PROPOSED PROJECT DATES: Fall Semester 1994
 PROJECT TITLE: The Effects of Supramalleolar Orthoses on the Biomechanics of the Knee, Foot, and Ankle During Gait:
A Single-Subject Design

FUNDING AGENCIES (IF APPLICABLE): _____
 TYPE OF PROJECT: NEW PROJECT _____ CONTINUATION _____ RENEWAL _____ DISSERTATION OR THESIS RESEARCH STUDENT RESEARCH PROJECT
 _____ CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISER, OR STUDENT ADVISER: Peggy Mohr, Ph.D., P.T.

PROPOSED PROJECT: _____ INVOLVES NEW DRUGS (IND) _____ INVOLVES NON-APPROVED USE OF DRUG INVOLVES A COOPERATING INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATIONS, PLEASE INDICATE THE CLASSIFICATION(S):

MINORS (<18 YEARS) _____ PREGNANT WOMEN _____ MENTALLY DISABLED _____ FETUSES _____ MENTALLY RETARDED
 _____ PRISONERS _____ ABORTUSES _____ UND STUDENTS (>18 YEARS)

IF YOUR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL MATERIAL, OR PLACENTAL MATERIALS, CHECK HERE _____

1. ABSTRACT: (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.)

Gait deviations are a common problem associated with children with disorders of movement and posture such as cerebral palsy (CP). In the past, inhibitive casts and steel or aluminum ankle-foot orthoses (AFOs) were used to treat children with CP, but these proved to be over-restrictive and heavy. More recently, light-weight, polypropylene plastic supramalleolar orthoses (SMOs) have been developed out of the need to provide stability at the ankle the AFO was found not to provide. SMOs along with physical therapy have been used to treat gait deviations in children, but little research has been conducted on the actual effects of the SMOs on lower extremity biomechanics. The purpose of this study is to describe the biomechanical changes that occur at the knee, foot, and ankle as a single-subject walks barefoot, with his shoes, and with his shoes and SMOs. It is hoped that while walking with the shoes and SMOs, the subject's gait pattern will become progressively more like that of a normal child. The subject of this study will walk on a treadmill each time while his legs are filmed with a high-speed video camera. The videotape will be viewed frame by frame. Certain phases of gait will be freeze-framed and photographed so that measurements of joint range of motion and bony alignment can be taken.

PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. **PROTOCOL:** (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

SUBJECT:

The subject is a nine year old male with athetoid cerebral palsy (CP) who has been informed of the study procedure and is participating with the informed consent of his parents. He has been walking moderate distances while wearing supramalleolar orthoses (SMOs) since the age of five. The subject has been walking on a treadmill at a comfortable speed for approximately one year with supervision. To protect the confidentiality of the subject, he will not be identified on any video or written results of this study.

EQUIPMENT:

The following equipment will be used in this study: A treadmill with speed and grade controls (available in the Sports Acceleration Program of the Medical Center Rehabilitation Hospital (MCRH), Grand Forks, ND), an 8mm high-speed video camera with an 8mm videotape, a stopwatch, a plastic goniometer and protractor, a marking pen for marking bony landmarks on the skin, and athletic tape to mark the subject's shoes and SMOs for measurements.

PROCEDURE:

The subject, accompanied by a parent, will enter the Sports Acceleration Program at MCRH, Grand Forks, ND, where the testing will occur. At this time the procedure will be explained to both the subject and parent, and the subject's parent will be asked to read and sign a consent form. The subject will then be asked to undergo a lower extremity musculoskeletal examination. This exam consists of measuring joint range of motion and bony alignment at the knee, foot, and ankle statically, for the purpose of comparing these measurements with measurements that will be recorded in the dynamic second portion of the study. Any changes can then be noted between the two sets of measurements. No invasive procedures will be utilized in this exam.

Passive and active range of motion at the knee will be measured by aligning the lateral malleolus, the knee joint space, and the greater trochanter with the arms of a plastic goniometer. The subject will lie prone (on his stomach) to measure knee flexion and sit to measure knee extension. Tibial torsion will be measured as the subject stands barefoot and while wearing his SMOs. The examiner aligns one arm of a goniometer with the medial and lateral malleoli and the other arm perpendicular to the tibia to measure the amount of torsion.

Active and passive dorsiflexion (DF) and plantarflexion (PF) will be measured at the ankle. DF and PF will be measured while the subject is long sitting with a towel roll under his ankle. The arms of a plastic goniometer will be aligned with the fifth metatarsal, lateral malleolus, and fibula as the ankle dorsiflexes and plantarflexes.

Rearfoot position can be measured in the non-weight-bearing or weight-bearing positions. The non-weight-bearing position can be measured with the subject lying in prone with his legs in a figure-four position. Two lines will be drawn with a marking pen that bisect

the calf and the calcaneus. Subtalar joint neutral (STJN) will then be found as the examiner palpates the talus with one hand and alternately pronates and supinates the subject's foot with the other hand until even palpation of the talus medially and laterally is achieved. Once STJN is found, the examiner dorsiflexes the subject's foot and then measures the angle formed by the calf and calcaneal bisection lines with a goniometer. The forefoot position can also be measured in this position by measuring the angle formed between the metatarsal heads and the horizontal. Rearfoot position in weight-bearing is measured the same as in the non-weight-bearing but the subject will be standing.

To measure navicular drop the subject will stand in STJN. The examiner will place an upright index card next to the medial portion of the subject's foot and make a mark on the card where the tuberosity of the navicular is located. The subject will then be asked to stand normally. Another mark corresponding with the position of the navicular tuberosity will be made on the index card. The distance between the two marks will be measured on the card and recorded as navicular drop.

In the second portion of the study the subject will walk on a treadmill once barefoot, with his shoes and finally with his shoes and SMOs. The reason for the three different walks is to show if the biomechanics of the knee, foot, and ankle progressively become more like the biomechanics of a normal gait pattern. First, a gait belt will be fastened around the subject's waist. One investigator will assist the subject onto the treadmill. The subject will be instructed to begin walking as the treadmill starts. When the subject is ready, one investigator will hold the back of the subject's gait belt as another investigator starts the treadmill. The speed will gradually be increased to a comfortable speed as determined by the subject. The subject will walk for three minutes each walk, with an opportunity to rest up to eight minutes in between walks. Time will be kept by an investigator with a stopwatch. The walking may be stopped in the subject experiences and discomfort.

As the subject walks, his legs will be filmed by an 8mm high-speed video camera. This videotape will eventually be viewed frame by frame. Certain phases of the gait pattern will be freeze-framed and printed as photographs so that measurements of the knee, foot, and ankle can be taken. The subject's name will not appear of any written or video material from this study. Videotape will be destroyed upon completion of the study.

3. **BENEFITS:** (Describe the benefits to the individual or society.)

At this time, very little published research is available on SMOs. A benefit of this study could be to add to the limited information on the effects of SMOs on lower extremity biomechanics. This study may also provide a research design for further study on SMOs.

4. **RISKS?** (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

One possible risk of this study is fatigue. This should be limited by giving the subject an ample rest period between walks. Another risk may involve getting on the treadmill or stumbling while on the treadmill. This risk is reduced by the subject's previous experience on a treadmill and by having the subject wear a gait belt. An investigator will assist the subject onto the treadmill and hold the gait belt while the subject is walking.

- 5. **CONSENT FORM:** A copy of the **CONSENT FORM** to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no **CONSENT FORM** is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

Describe where signed consent forms will be kept and for what period of time.

The signed consent form will be kept by the principal investigator throughout the proposed project dates.

- 6. For **FULL IRB REVIEW** forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development
 University of North Dakota
 Box 8138, University Station
 Grand Forks, North Dakota 58202

On campus, mail to: Office of Research & Program Development, Box 134, or drop it off at Room 101 Twamley Hall.

For **EXEMPT** or **EXPEDITED REVIEW** forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SIGNATURES:

Principal Investigator

DATE: _____

Project Director or Student Adviser

DATE: _____

Training or Center Grant Director

DATE: _____

(Revised 8/1992)

CONSENT FORM

Principal Investigator: Jennifer Stauffer, S.P.T.
UND Department of Physical Therapy

_____ has been asked to take part in a single subject study on the effects of supramalleolar orthoses (SMOs) on the gait pattern. The purpose of this study is to describe the biomechanical changes that occur at the knee, foot, and ankle as _____ walks barefoot, with shoes, and with shoes and his SMOs.

Very little published research is available on SMOs. This study will add to the limited information on SMOs and may provide a framework for further study in this area.

The study will take place at the Sports Acceleration Program at the Medical Center Rehabilitation Hospital in Grand Forks. _____ will first be asked to undergo a lower extremity musculoskeletal examination. This exam consists of measuring joint range of motion and bony alignment at the knee, foot, and ankle for the purpose of comparison with information gathered in the second portion of the study.

Next, _____ will be asked to walk on a treadmill barefoot, with his shoes, and finally with his shoes and SMOs to show the biomechanical changes that occur. Each time, he will walk for three minutes at a comfortable speed determined by _____. He will be given the opportunity to rest up to eight minutes between each walk. For safety, _____ will wear a gait belt and an investigator will hold the belt as _____ walks. During each walk, _____'s legs will be filmed by an 8mm high-speed video camera. Eventually this videotape will be viewed frame by frame. Certain phases of the gait pattern will be freeze-framed and printed as photographs so that measurements of the knee, foot, and ankle can be taken.

Participation is entirely voluntary and _____ or his parents have the right to withdraw consent and discontinue participation in this study at any time without prejudice to present or future care or association with MCRH or UND. There is no cost for any part of the study. No discomfort is anticipated. Fatigue and safety on the treadmill will be controlled by allowing adequate rest periods and by having an investigator hold the gait belt, respectively. Information from this study will be anonymously coded to ensure confidentiality and _____ will not be personally identified in any publication containing the results of this study. The videotape from the study will be viewed solely by members of the investigation team from the UND Department of Physical Therapy and will be destroyed upon completion of data analysis. The parents may view and videotape of _____ which is filmed for the study. Jennifer Stauffer, S.P.T. at UND (777-2831 or 777-8123) will be available to answer any questions you may have concerning the study, procedures, and any risks or benefits that may arise.

As the parent of the above-named child, I give permission for him to participate in the research study described. A copy of this consent form has been given to me.

Parent

Date

Principle Investigator

Date

Witness

Date

REFERENCE LIST

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