HipGrip Pelvic Stabilization Device for Wheelchair Users Phase II Final Report

Prepared by:

Peter W. Axelson, Director of Research & Development
Denise Yamada Axelson, Research Coordinator
Amy M. Hayes, Physical Therapist
Seanna L. Hurley, Research Associate
Jamie H. Noon, Seating Designer
Allen R. Siekman, Seating Designer

Beneficial Designs, Inc.
1617 Water Street, Suite B
Minden, Nevada 89423-4310

775.783.8822 voice
775.783.8823 fax

Prepared for:

National Institutes of Health (NIH)
National Institute of Child Health and Human Development (NICHD)
National Center for Medical Rehabilitation Research (NCMRR)
6100 Executive Blvd. Rm 2A03
Bethesda, MD 20892-7510

SBIR Phase II Grant # 2 R44 HD36156-02A2

301.402.4221 voice
301.402.0832 fax

30 December 2004

HipGrip Pelvic Stabilization Device for Wheelchair Users Phase II Final Report

ABSTRACT **1**

ACKNOWLEDGEMENTS **1**

Specific Aims 2

1. Design of the HipGrip 2
   a. HipGrip Components 2
   b. Design and Performance Criteria 3
   c. Design Review Meetings with Manufacturing Consultants 5
   d. Preliminary Fittings 6
   e. Compatibility Testing 6
2. Safety and Strength Testing 7
   a. Safety Testing 7
   b. Strength Testing 8
   c. Crash Testing 9
3. Clinical Evaluation of the HipGrip 9
   a. Study Participants 9
   b. Test Methods 10
   c. Sitting Head Height 11
   d. Pelvic Obliquity 13
   e. Forward Lean 15
   f. Lateral Lean 18
   g. Downward Lean 20
   h. Performance and Satisfaction 22
   i. Subjective Feedback 26
4. Conclusions 27
5. References 27
6. Publications 28

APPENDICES

Appendix A – HipGrip Repetitive Load Testing Report
Appendix B – Inclusion Enrollment Report

HipGrip Pelvic Stabilization Device for Wheelchair Users Phase II Final Report

ABSTRACT

Many people who rely on specialized wheelchair seating have difficulties attaining and maintaining proper pelvic positioning, a critical component for achieving good sitting posture. Use of commercially available devices often results in misalignment and areas of high pressure. The objectives of this research and development project were to develop an innovative, dynamic pelvic stabilization device, to demonstrate its effectiveness, and evaluate its functional benefits through clinical evaluations. The HipGrip consists of contoured pads that “grip” the pelvis to provide firm support while allowing anterior/posterior tilting of the pelvis without losing position within the wheelchair. The ability of the HipGrip to improve posture and maintain pelvic positioning was demonstrated through a clinical study involving 23 wheelchair users. The effects of the HipGrip on performance of functional tasks, activities of daily living, and participation in school, vocational and/or recreational activities were assessed. It was demonstrated among 23 wheelchair users that the HipGrip: increases forward, downward and lateral lean; improves posture; and increases user performance and satisfaction. The HipGrip links the user with the wheelchair to provide a stable base of support from which to perform functional tasks without risk of falling out of the wheelchair. This will potentially increase user independence.

Project Period: Beginning: 8/7/01 Ending: 9/30/04

Key Personnel:	Peter Axelson	P.I., Design Director	08/07/01 to 09/30/04	488 hr
	Denise Axelson	Research Coordinator	08/07/01 to 05/18/04	597 hr
	Allen Siekman	Seating Designer	08/07/01 to 09/30/04	2533 hr

ACKNOWLEDGEMENTS

This research project was funded by the National Center for Medical Rehabilitation Research in the National Institute of Child Health and Human Development at the National Institutes of Health through Small Business Innovation Research Phase I grant # 1 R43 HD36156-01 and Phase II grant # 2 R44 HD36156-02A2. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the National Center for Medical Rehabilitation Research, the National Institute of Child Health and Human Development, or the National Institutes of Health. Phase II development was also made possible through the collaboration of Bodypoint, Inc. and Beneficial Designs, Inc.

Specific Aims

This project developed and evaluated the HipGrip pelvic stabilization device that is designed to assist wheelchair users with their sitting posture. Since the pelvis is the foundation of good sitting posture, this system is a key component of the user's seating system. The HipGrip incorporates rear, front, and side supports of the pelvis in an adjustable unit which allows the pelvis to pivot forward or rearward about the hip joint within a specified range. The HipGrip reduces undesired pelvic movement and provides variable resistance to bring the pelvis back into its neutral posture after allowing movement.

In Phase I, a prototype was developed and evaluated by 20 wheelchair users during a brief clinical evaluation. The device improved posture, comfort, and upper body function in the majority of the participants.

The objectives of Phase II of the research project were to:

1) Refine the HipGrip based upon Phase I results and the recommendations of a manufacturing consultant;

2) Perform safety and strength testing and refine the design as needed; and

3) Conduct a 3-6 month clinical evaluation with 25 wheelchair users to determine the postural and functional benefits and to obtain feedback to optimize the design for improved pelvic control and enhanced upper body function.

These objectives were successfully met.

1. Design of the HipGrip

a. HipGrip Components

The HipGrip assembly mounts to the wheelchair frame (Figure 1). It consists of four major components (Figure 2): the wheelchair mounting system (A), contoured pads that "grip" around the lateral and posterior portion of the pelvis (B), a padded anterior belt (C), and a pivot mechanism that allows controlled anterior/posterior tilting of the pelvis (D).

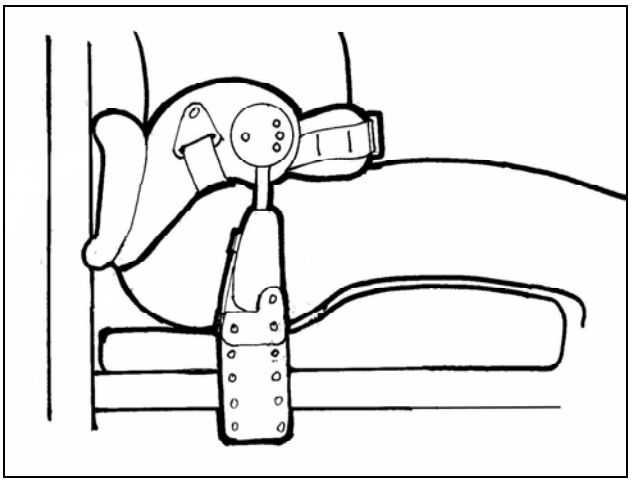

Figure 1. HipGrip Pelvic Stabilization Device (side view).

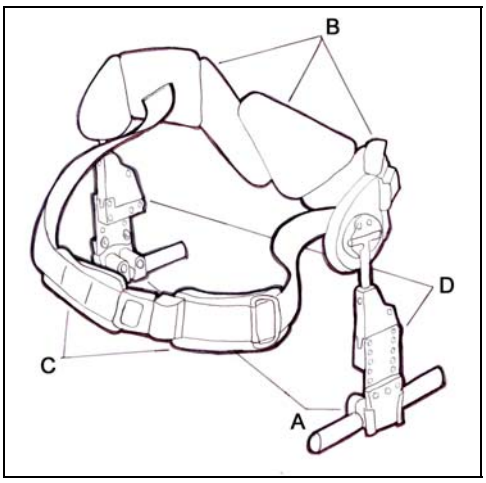

Figure 2. HipGrip Components: A) wheelchair mounting system, B) contoured pads, C) anterior belt, and D) pivot mechanism.

b. Design and Performance Criteria

Traditional methods used to maintain pelvis stability hold the pelvis rearward in the wheelchair. This restricts the normal range of motion of the pelvis. The HipGrip is a dynamic postural control device that allows a wheelchair user's pelvis to tilt both to the anterior and posterior. The HipGrip design provides gentle resistance to the pelvis and facilitates controlled pelvic movement. The design uses elastic tension bands to guide the pelvis back into an upright position after pelvic movement has occurred. The HipGrip gently returns the wheelchair user's pelvis to the desired pre-selected pelvic position.

The following proposed criteria were met:

- Mounts to the existing seating system or wheelchair frame
- Replaces the function of a lower back support, lateral hip pads and positioning lap belt
- Integrates with other seating components
- One person (parent or caregiver) can secure and remove the user from system
- System stays open when a user transfers into the wheelchair
- Front closure mechanism needs only one hand to operate – Front closure uses a standard side release buckle, two-hand operation may be required by some users
- Option for user operation – Most wheelchair users can operate device without assistance
- Accommodates a wide range of body shapes and sizes with two sizes of adjustable pads

- Allows anterior and posterior tilting of the pelvis:
  Specific resistance to anterior or posterior tilt of the pelvis can be set
- The goal was to provide an adjustable limit to anterior and posterior tilting of the pelvis – The device allows for setting of desired pelvic neutral angle and does not restrict anterior tilting of the pelvis; posterior movement of the pelvis is limited by the position of the back support
- Accommodates up to 6.3 cm (2.5 in) of pelvic obliquity
- Maintains pelvic posture during high tone activities
- Promotes active extension of the lumbar spine
- Reduces forward sliding of the pelvis across the seat surface
- Aesthetically pleasing to user and caregiver
- Low profile
- Lightweight
- Easy to use
- Comfortable
- Increases postural stability
- Improves user function

c. Design Review Meetings with Manufacturing Consultants

Numerous meetings were held to conduct design reviews and to gather input on function and application of the HipGrip (Table 1).

Table 1. Series of Design Meetings Regarding the HipGrip

Date	Location	Attendees	Focus
June 20-26, 2001	Minden, NV	Beneficial Designs Staff	Review of Design Concepts
September 7, 2001	Santa Cruz, CA	Beneficial Designs and Bodypoint Staff	Review of Design Concepts
March 6-12, 2002	Vancouver, BC	Therapists and Engineers at International Seating Symposium meeting	Focus Group at the International Seating Symposium; gathering feedback
February 27-March 3, 2003	Orlando, FL	Therapists and Engineers at International Seating Symposium meeting	Presentation at the International Seating Symposium
May 13-14, 2003	Seattle, WA	Allen Siekman, Bodypoint Staff	Manufacturing design review
September 7-10, 2003	San Francisco, Anaheim, San Diego, CA	Durable Medical Equipment Providers and Therapist	Therapist review of working prototype design; review and input on design/function
October 8-11, 2003	Atlanta, GA	Durable Medical Equipment Providers and Therapist	Focus groups; review and input on design/function
November 2-6, 2003	New York, NY	Durable Medical Equipment Providers and Therapist	Focus groups; review and input on design/function
March 9-12, 2004	Seattle, WA Portland, OR	Durable Medical Equipment Providers and Therapist	Develop methods for therapist and provider training; review and input on design/function
March 29-April1, 2004	Nottingham, UK	Designers, Therapists, Engineers	Conference presentation, focus group input
June 8-12, 2004	England, Scotland, UK	Therapists, Rehab Engineers, Providers	Develop methods for therapist and rehab engineer training

The manufacturing consultant, Bodypoint, Inc., agreed to license the HipGrip technology from Beneficial Designs, Inc. Bodypoint, Inc. is currently implementing plans to manufacture and distribute the HipGrip for use worldwide.

d. Preliminary Fittings

Preliminary fittings were completed on non-disabled participants (project staff) throughout the development process in order to ensure that the design changes that were implemented remained within the design criteria and continued to be satisfactory to the user. In addition, the HipGrip was fitted to a 5-year old male weighing 25.4 kg who participated in the preliminary fittings. The HipGrip was installed in a manual wheelchair and fitted to the participants. A range of HipGrip sizes from small to large were used.

The preliminary fittings were used to verify the fit and function of the HipGrip. The range of HipGrip size adjustments and anterior strap location and range of adjustments were evaluated during fittings. The HipGrip was also evaluated for product reliability with safety and fatigue tests conducted in a test laboratory. In addition, the preliminary fittings were used to verify the evaluation methodology and measurement techniques to be used during the 3-6 month evaluation of wheelchair users.

The preliminary fittings successfully demonstrated that the HipGrip was safe, capable of adjusting to fit different body sizes and functioned as designed. No design changes were identified as a result of conducting the preliminary fittings. The 3-month evaluation methodology was finalized.

e. Compatibility Testing

The HipGrip was installed in a variety of wheelchairs to ensure that the device could be attached to a variety of seating systems for both manual and powered wheelchair users.

During the clinical evaluations and focus group activities, the HipGrip was successfully installed into a representative sample of all of the major types of manual and powered wheelchairs. Fitting evaluations were performed with the following wheelchairs: Quickie, Invacare, Permobil, E&J, and TI Sport. A variety of back supports were installed in the wheelchairs including: biangular, contoured, Jay Back, Jay 2, PaxBac with sling upholstery, non-contoured foam/plywood, and standard sling upholstery. Compatibility testing was also completed using adult and pediatric wheelchair models commonly provided by the UK National Health Service.

During the clinical evaluations and focus group activities, compatibility with wheelchair seat cushions was also evaluated. Cushions from a majority of the United States and European Union (i.e., Germany, Netherlands and United Kingdom) manufacturers were successfully used, including anti-thrust, custom built, Jay, Supracor, ROHO, Comfort Mate, and standard flat foam. Compatibility with custom fabricated cushions, seating systems and other pelvic positioning devices were also evaluated.

Clinical evaluations revealed that the original mounting brackets needed modification to allow the HipGrip to be installed on a wide range of wheelchair frames. Problems occurred due to the wide variety of tubing diameters and shapes, as well as frequent interference with brackets for arm supports, wheel locks, clothing guards, and other components.

A variety of mounting components were designed to allow the HipGrip to be installed on most wheelchair frames eliminating the need for custom bracket modifications. These components

included tubing clamps of different diameters and shapes, flat and offset mounting plates, and other specialized brackets to fit specific wheelchairs, such as the small diameter tubing used on many common UK wheelchair designs.

Providing several mounting bracket options to use during HipGrip installation minimized interference problems with other wheelchair components.

2. Safety and Strength Testing

Safety (pinch points, time to exit and intuitive use) and strength (static, impact and fatigue) testing were conducted to confirm that the HipGrip design was reliable and did not expose the user to unnecessary risk.

a. Safety Testing

Prior to clinical evaluations, the HipGrip was assessed for the presence of pinch points, time-to-exit and intuitive use during preliminary fittings by the project seating clinician. The HipGrip continued to be evaluated for the presence of pinch points during the clinical evaluations and during focus group activities. In addition, time-to-exit and intuitive use of the device was also observed during clinical evaluations.

The project physical therapist and seating clinician individually assessed each participant using the HipGrip in their own wheelchair for safety prior to leaving the clinic. Subjective feedback from participants during follow-up phone calls was used to monitor the HipGrip with regard to pinch points, ease of exit and intuitive use.

- Pinch Points – The HipGrip was examined during participant use for pinch points prior to leaving the clinic and participants were prompted to report any problems with the HipGrip during the follow-up phone calls.

  Two of the participants' attendants reported getting their finger pinched by the standard side release plastic belt buckle. No other pinch points were noted or reported during the study.

- Time to Exit – Participants who used the HipGrip were instructed on exit procedures prior to leaving the clinic. Participants who used a sub-ASIS bar in his/her original seating system were asked to compare the time to exit for each device.

  All four participants who used a sub-ASIS bar in his/her original seating system reported that the time to exit using the HipGrip was comparable to the time to exit using the sub-ASIS bar. One participant (118-219) was timed as an assistant removed him from his wheelchair with a sub-ASIS bar and from his wheelchair with the HipGrip installed. Three exit times were collected with each wheelchair configuration. The average time to exit was 6.2 seconds with the sub-ASIS bar and 6.8 seconds with the HipGrip. The assistant reported no difference in difficulty between releasing the sub-ASIS bar and releasing the HipGrip buckle.

- Intuitive Use – Participants who used the HipGrip were instructed on the function of the device. None of the participants reported any use issues during the follow-up phone calls.

It was determined that the original pivot bracket had a potential pinch point, but the risk of injury was insignificant due to the location of the bracket assembly relative to the user. The preproduction design of the final pivot bracket assembly was modified to significantly reduce the risk of pinch point injury.

b. Strength Testing

Prior to clinical evaluations, the HipGrip assembly was strength tested to assure safe and functional operation (Appendix A). Strength testing continued in parallel with the clinical evaluations.

Strength testing of the HipGrip began in May 2002. All HipGrip components were tested for static strength by applying lateral and rearward loads to the pad and bracket assemblies. The pad and bracket assemblies were fit to a repetitive load test fixture to conduct fatigue testing.

- Static Testing – Loads in excess of those expected in actual use were applied to the HipGrip in lateral and rearward directions. A lateral force of 222 N (50 lbs) 13 inches above the pivot point was applied to the HipGrip assembly and a rearward force of 222 N (50 lbs) 13 inches above the pivot point was applied to the center of the posterior HipGrip pad from the front. The application of 222 N (50 lbs) lateral and rearward forces did not result in damage to the HipGrip. The HipGrip was determined to be safe for clinical evaluations.
- Impact Testing – The greatest impact on the HipGrip in the clinical environment was determined to be a rearward force on the HipGrip by the user transferring into the wheelchair. During transfers, the HipGrip contacts the wheelchair back support and there is no further movement of the HipGrip. The wheelchair back support limits the amount of rearward motion of the HipGrip that results from the impact that occurs during a transfer. Impact testing on the HipGrip was therefore not performed since no new information would be gained beyond the impact testing that was already performed on the wheelchair back supports by the wheelchair manufacturers.
- Fatigue Testing – Cyclic testing to 400,000 cycles (80,000 cycles/year X 5 years) was conducted to represent a five-year product life cycle. During the repetitive load testing, the test HipGrip assembly was exposed to an excess of 3 million cycles without a critical component failure. Component failures in the dynamic testing were limited to the replaceable elastic tension bands. The elastic tension bands were tested with a wide range of material types and configurations to determine the best combination of physical characteristics and to optimize durability. The final design for the elastic tension bands provided desired resistance and exceeded the 100,000 cycle design target for durability.

  Changes were made to the design of the pivot bracket to minimize the wear on the spring rods. Several changes were made to the tension bands to improve durability. Early designs used “O” rings for the tension bands. These components were replaced by

a series of die-cut urethane parts of different material formulations. A suitable formulation and shape was obtained that significantly improved tension band life.

c. Crash Testing

Crash testing was not completed. The results of using the HipGrip with a seat belt during crash testing are unknown. Crash testing should be completed prior to recommending use of or using the HipGrip on a transportable wheelchair (one that meets or exceeds the requirements of ANSI/RESNA Wheelchair Standards Section 19).

3. Clinical Evaluation of the HipGrip

Clinical evaluations were conducted in order to assess the postural and functional benefits of the HipGrip. Objective measurements and subjective feedback were collected and used to demonstrate the effect of the HipGrip on pelvis position and upper body function.

a. Study Participants

Twenty-three persons participated in this study: 9 with spinal cord injury (SCI), 13 with cerebral palsy (CP) and one with schizencephaly (grouped with CP for analysis) (Table 2) (Appendix B). All participants used a wheelchair for their primary means of mobility and experienced some difficulty maintaining pelvic positioning.

Table 2. Study Participants (n=23)

Diagnosis			GMFC			M/F		Mean Age (yr) (range)	Mean Height (cm) (range)	Mean Weight (kg) (range)
			III	IV	V	M	F			
CP	athetoid tetraplegic	1 moderate 1 severe	0	2	0	1	1	37.5 (29 to 47)	174.0 (168 to 180)	58.5 (50 to 67)
CP	spastic-athetoid tetraplegic	2 moderate 2 severe	0	2	2	2	2	21.7 (17 to 24)	159.7 (141 to 178)	44.9 (30 to 54)
CP	spastic tetraplegic	5 moderate 3 severe	0	4	4	4	4	17.3 (6 to 34)	137.5 (104 to 155)	35.9 (15 to 57)
SCI	paraplegic	4 complete	3	1	0	3	1	38.0 (21 to 61)	172.1 (168 to 178)	67.1 (50 to 84)
SCI	tetraplegic	3 complete 2 incomplete	2	3	0	4	1	37.0 (13 to 50)	176.3 (152 to 193)	68.4 (52 to 88)
			Total					Mean		
All Study Participants			5	12	6	14	9	27.7 (6 to 61)	159.0 (104 to 193)	51.9 (15 to 88)

The Gross Motor Function Classification (GMFC) scale was developed and validated to classify gross motor function in children with CP (Palisano et al., 1997). The GMFC scale was used in this study to classify the functional levels of all participants regardless of diagnosis or age,

because there was no other appropriate classification system to determine functional levels across different disability groups (Table 3).

Table 3. GMFC Scale

Level	Definition
III	Walks with assistive mobility devices; limitations walking outdoors and in the community.
IV	Self-mobility with limitations; children are transported or use powered mobility outdoors and in the community.
V	Self-mobility is severely limited even with the use of assistive technology.

Two of the persons participated in the study using two different wheelchairs. One person with CP used the HipGrip in a powered wheelchair that was used primarily at school (CP-217) and then used the HipGrip in a manual wheelchair that was used primarily during non-school hours (CP-218). One person with SCI used the HipGrip in a tennis wheelchair (SCI-204) and then used the HipGrip in an everyday wheelchair (SCI-210).

1) Pelvic Positioning Supports

Out of the 25 seating systems tested, four of the participants (16%), all with cerebral palsy, used a rigid sub-ASIS bar in their original seating system (Table 4). Lap belts were used by 15 participants (60%), and one participant (4%) used a thigh belt in addition to a lap belt. Five of the participants (20%), all with a spinal cord injury, did not use any kind of pelvic support device in their original wheelchair.

Table 4. Pelvic supports used by participants in the original seating system

Diagnosis	Sub-ASIS	Lap Belt	Thigh Belt	None
CP – athetoid tetraplegic	0	2	0	0
CP – spastic-athetoid tetraplegic	3	1	0	0
CP – spastic tetraplegic	1	7	1	0
SCI – paraplegic	0	2	0	2
SCI – tetraplegic	0	3	0	3
Total n=25	4	15	1	5

*Twenty-three participants, with two completing the study using two different wheelchairs.

b. Test Methods

This study used a single subject study design to compare each participant's postural and functional changes using the HipGrip compared to their original seating system. Three sets of measurements were used to evaluate each participant in their wheelchair:

1. Postural Measurements;
2. Functional Lean Tests;
3. Canadian Occupational Performance Measure; and
4. Subject Questionnaires.

The study protocol and all consent forms were approved by the Santa Clara Valley Medical Center Research and Human Subjects Review Committee. Each session was approximately four hours. Informed consent was obtained from all participants.

Participants were first evaluated during session 1 with each measure using his/her own wheelchair with their original seating system. Anthropometric measures and a clinical assessment were also performed.

Within one week, the HipGrip was installed in the participant's wheelchair and fitted to the person during session 2. The HipGrip replaced any existing pelvic support devices. All measures were repeated with the participant using his/her own wheelchair with the HipGrip installed.

Seat to buttock interface pressure measurements were taken for each participant using their original seating system and repeated while using the HipGrip. Interface pressure measurements were made using an FSA pressure measurement system (FSA Force Sensitive Applications, Winnipeg, Canada). The project seating clinician evaluated each participant's pressure measurements prior to releasing the participant with the HipGrip.

The participant used the HipGrip in his/her wheelchair for a period of 3-6 months. Follow-up phone calls were made to each participant after approximately three days and after approximately six weeks of use. Follow-up phone calls were used to ensure compliance with use of the HipGrip and to obtain feedback during the first week of use and again after six weeks of use.

Participants were again evaluated during session 3 with each measure using his/her own wheelchair with the HipGrip after a 3-6 month period. The HipGrip was removed from the participant's wheelchair and the original pelvic components were re-installed. The participants were then reevaluated with each measure using his/her own wheelchair with their original seating system.

Upon completion of the study (after session 3), the participant was allowed to sign a release form and have the HipGrip reinstalled into their wheelchair if they preferred the HipGrip to their original seating system.

c. Sitting Head Height

It was hypothesized that the HipGrip would increase the users' sitting head height.

1) Sitting Head Height Instrumentation

Sitting head height was measured in centimeters with a specialized tripod with a measuring tape and a height-adjustable laser attached along the vertical tube. To measure sitting head height, the tripod was attached to the rear wheels of the participant's wheelchair with the vertical tube positioned directly behind the participant's head. The laser beam was aligned to the top of the participant's head and the distance from the floor to the top of the participant's head was recorded (Figure 3).

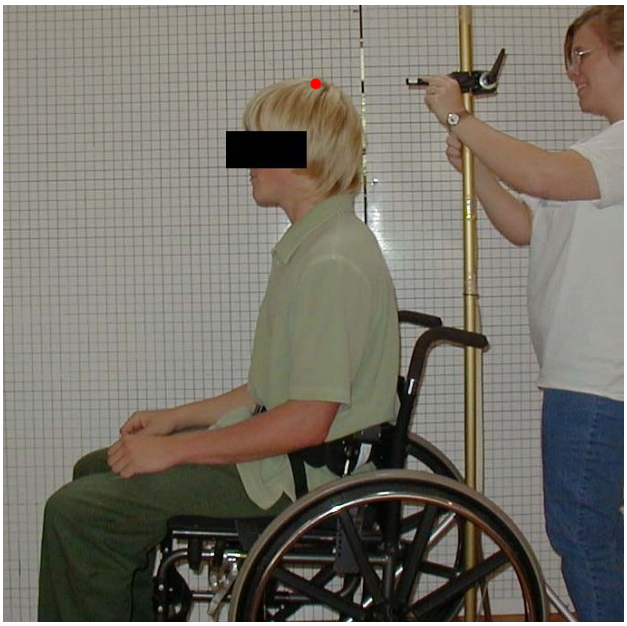

Figure 3. Specialized tripod for head height measurement.

2) Sitting Head Height Measurement Procedure

Participants were asked to assume a typical (neutral) sitting posture in their wheelchair. To simulate typical activities of daily living, participants who had volitional motor activity were asked to reach for a ball held out at designated positions, causing them to reach forward, downward, and to the side. If applicable, muscle spasms were elicited by excitement, touch and/or movement of the wheelchair over a door threshold. Participants were instructed not to reposition themselves.

Upon completion of the movement activities, sitting head height was measured. With the laser aligned with the top of the participant's head, sitting head height was measured from the floor in centimeters. Sitting head height was measured to the nearest tenth of a centimeter and then was rounded to the nearest 0.5 cm for data analysis.

Sitting head height with use of the HipGrip was compared to sitting head height with use of the original seating system (two-tailed, paired t-test, $\alpha=0.05$).

3) Sitting Head Height Results

Participant sitting head height with the use of the HipGrip was significantly more than with their original seating system ($p<0.01$). Sitting head height increased by an average of 1.0 cm with the use of the HipGrip. The average percentage increase in sitting head height was 0.8%.

Fifteen out of 25 (60%) participants (8 CP, 7 SCI) had increased sitting head height with use of the HipGrip compared to their original seating system (Figure 4). Eight out of 25 (32%) participants (5 CP, 3 SCI) had decreased sitting head height with use of the HipGrip compared to their original seating system and two out of 25 (8%) participants (2 CP) had no change in sitting head height.

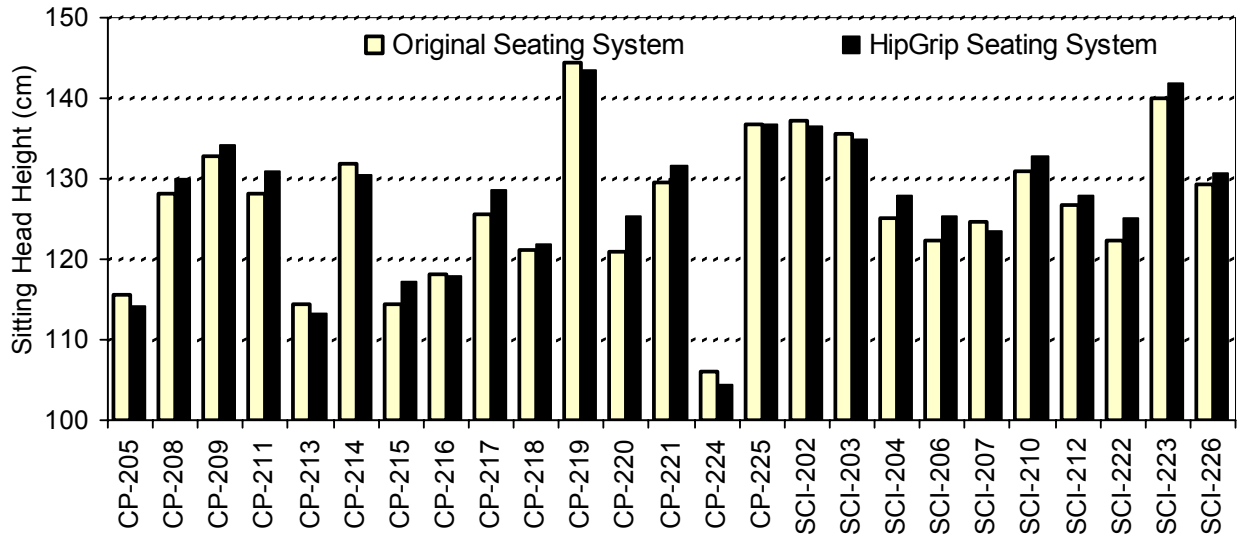

Figure 4. Sitting head height after movement.

The sitting head height results demonstrated that participants sat taller with the use of the HipGrip than with their original seating system. This trend was more prominent in the SCI group with seven out of 10 (70%) SCI participants having increased sitting head height. Increased sitting head height is likely due to improved pelvic posture with use of the HipGrip.

d. Pelvic Obliquity

It was hypothesized that the HipGrip would:

1. Accommodate users with a pelvic obliquity of up to 6.4 cm (2.5 inches);
2. Place the users' pelvis in a more neutral position with less pelvic obliquity; and
3. Stabilize the pelvis and assist the users' pelvis back into a neutral position after the user moves in the wheelchair.

1) Pelvic Obliquity Instrumentation

Pelvic obliquity was measured in degrees with a PALpation Meter (PALM) (Performance Attainment Associates, St. Paul, MN) (Figure 5). To measure pelvic obliquity, the lever arms of the PALM were placed on the left and right anterior superior iliac spines (ASIS). It was necessary to lengthen the lever arms to reach the ASIS of a seated wheelchair user with postural support devices around the pelvis (Figure 6). Lever arm extensions (14.5 cm) were fabricated from 3/8-inch diameter fiberglass rods. The extensions were designed to slip on in the same manner as the accessory tips provided with the PALM unit.

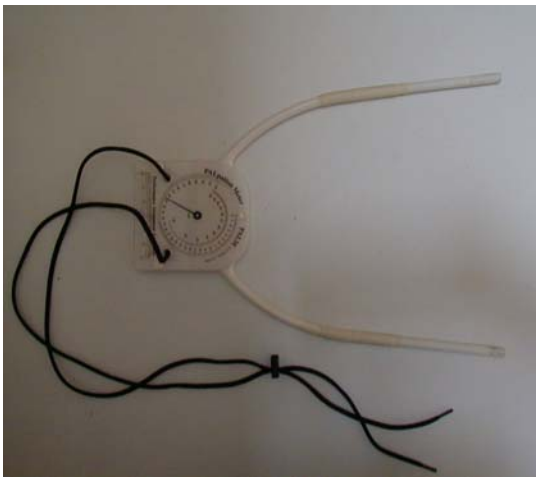

Figure 5. PALpation Meter (PALM) device.

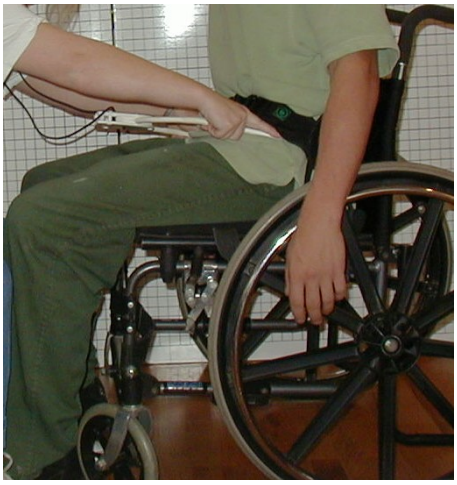

Figure 6. The PALM was used to measure pelvic obliquity.

2) Pelvic Obliquity Measurement Procedure

With the lever arms of the PALM placed on the left and right ASIS, the amount of pelvic obliquity was measured in degrees. The direction of obliquity (i.e., the left or right side lower) was noted.

To assess how well pelvic positioning was maintained during typical activities of daily living, body movement was elicited. Participants who had volitional motor activity were asked to reach for a ball held out at designated positions, causing them to reach forward, downward and to the side. If applicable, muscle spasms were elicited by excitement, touch and/or movement of the wheelchair over a door threshold. Participants were instructed not to reposition themselves. Upon completion of the movement activities, pelvic obliquity was re-measured.

3) Pelvic Obliquity During Sitting

The HipGrip successfully accommodated two participants with pelvic obliquities of 10 and 12 degrees (SCI-202 and CP-216, respectively). Using the distance measured between the ASIS, 29 cm (11.6 in) for SCI-202 and 17 cm (6.8 in) for CP-216, their pelvic obliquities were calculated as 5.0 cm (2.0 in) and 3.6 cm (1.4 in), respectively.

The effectiveness of the HipGrip in positioning the pelvis was assessed by comparing the amount of pelvic obliquity while sitting upright with their original seating system to that of the HipGrip (two-tailed, paired t-test, $\alpha=0.05$). The amount of pelvic obliquity while sitting upright with the HipGrip was significantly less than with their original seating system ($p<0.01$). Pelvic obliquity in an upright sitting position decreased by an average of 1.4 degrees with the use of the HipGrip. The average percentage decrease in pelvic obliquity in an upright sitting position was 44.8%.

4) Pelvic Obliquity Change after Movement

The effectiveness of the HipGrip in maintaining pelvic positioning was evaluated by comparing the amount of pelvic obliquity after movement activities with their original seating system to that

of the HipGrip (two-tailed, paired t-test, α=0.05). The amount of pelvic obliquity after movement activities with the use of the HipGrip was significantly less than with their original seating system ($p<0.01$). Pelvic obliquity after movement activities decreased by an average of 2.9 degrees with the use of the HipGrip. The average percentage decrease in pelvic obliquity after movement was 46.4%.

5) Pelvic Obliquity Averages

To further examine the overall effectiveness of the pelvic support in managing pelvic obliquity, the average pelvic obliquity was determined by calculating the average of the pelvic obliquity measured while sitting upright and after movement activities (Figure 7). The average pelvic obliquity with their original seating system was compared to that of the HipGrip (two-tailed, paired t-test, α=0.05). The average pelvic obliquity with the use of the HipGrip was significantly less than with their original seating system ($p<0.01$). Twenty-two out of 25 (88%) participants had less pelvic obliquity with the use of the HipGrip compared to their original seating system. The average pelvic obliquity decreased by 2.1 degrees with the use of the HipGrip. The average percentage decrease in average pelvic obliquity was 32.4%.

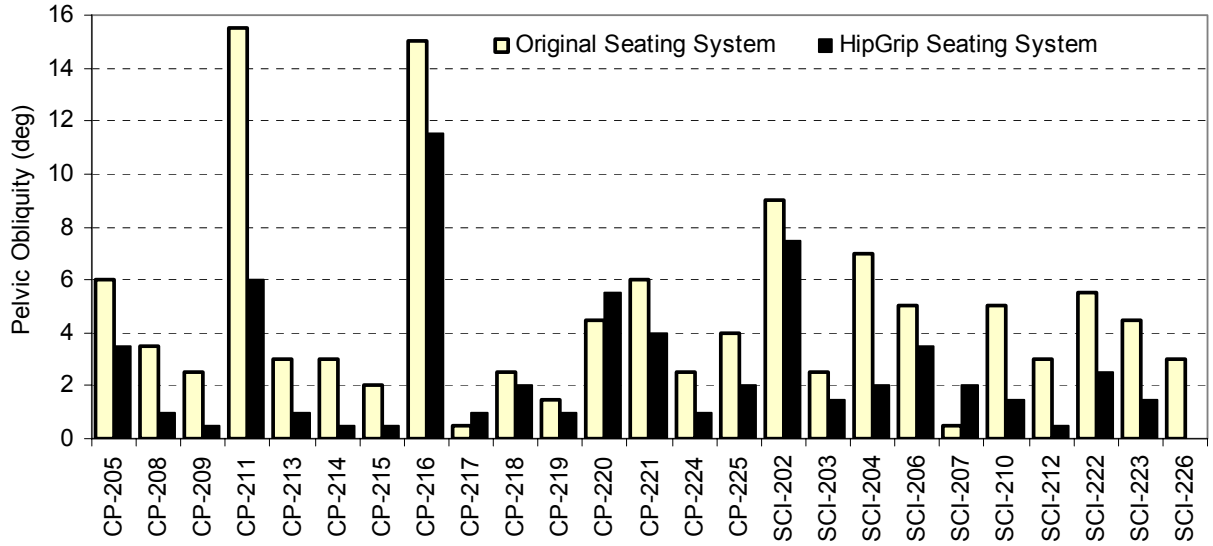

Figure 7. Average pelvic obliquity.

e. Forward Lean

It was hypothesized that the HipGrip would:

1. Increase the users' distal control;
2. Increase the users' forward lean; and
3. Stabilize the pelvis and assist the users' pelvis back into a neutral position after the user moves in the wheelchair.

1) Forward Lean Instrumentation

Forward lean was measured in centimeters with a flexible measuring tape attached to a tripod (Figure 8). The tripod was secured to the rear wheels of the participant's wheelchair so that the vertical tube was positioned directly behind the participant's reaching shoulder. To measure forward lean, the flexible measuring tape attached to the tripod was set at a height level with the acromion process with the participant sitting in an upright position in their wheelchair. The flexible measuring tape was placed on the acromion process to obtain the lean distance measurement.

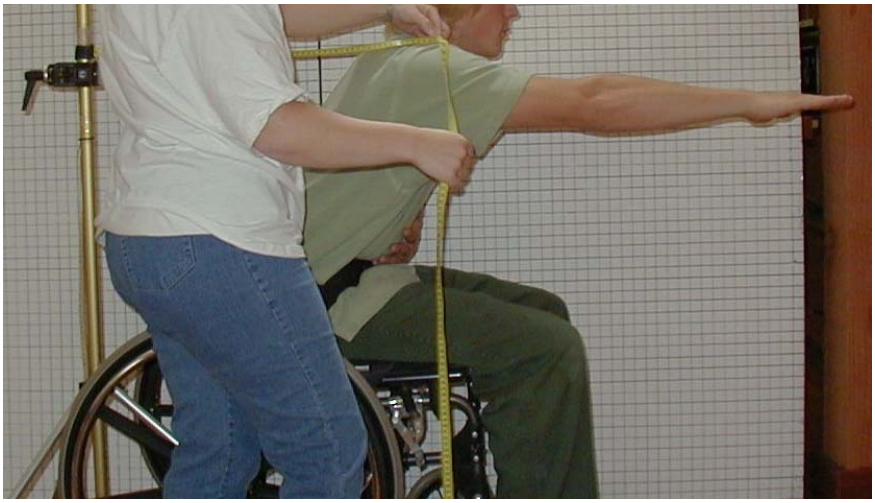

Figure 8. Tripod setup used to measure forward lean.

2) Forward Lean Methodology

A modification of the Modified Functional Reach Test (Lynch, S.M. et al., 1998) was developed to accommodate participants who did not have the upper body control to sit independently and/or the upper extremity control to maintain 90 degrees of shoulder flexion.

Participants were instructed to sit upright in their most neutral position with their back against the back support of the wheelchair. Those who were unable to independently position themselves were assisted by the physical therapist. Participants were instructed to hold their non-reaching arm over their navel, if possible. Otherwise, their non-reaching arm was held in the most free, non-weight bearing position possible.

With the flexible tape measure placed on the acromion process, the baseline position was measured in centimeters. Participants were instructed to lean as far forward as possible to reach for a ball while maintaining the ability to return to an upright sitting position independently without using their upper extremities. A maximum lean measurement of the acromion position was taken with the participants leaning in their most forward position. Each participant performed the test three times on the left and right side.

The forward lean values were calculated for each trial by subtracting the baseline measurement from the furthest forward lean measurement. The maximum forward lean value was determined

for both the participant's original seating system and the HipGrip. The maximum forward lean value obtained with participant's original seating system was compared to the HipGrip.

The effect of the HipGrip on forward lean was assessed by comparing the amount of forward lean obtained with use of the participant's original seating system to that of the HipGrip (two-tailed, paired t-test, α=0.05).

3) Forward Lean Results

The maximum forward lean obtained with the use of the HipGrip was significantly more than with the participant's original seating system ($p<0.01$). Nineteen out of 25 (76%) participants achieved a greater forward lean with the use of the HipGrip compared to their original seating system (Figure 9). Forward lean increased by an average of 6.0 cm and ranged from 1.0 to 22.5 cm. The average percentage increase in forward lean was 40.6%.

Five out of 25 (20%) users showed a decrease in forward lean with the use of the HipGrip: two participants with CP (#215, 221) showed decreases of 2.5 cm and 3.5 cm, two participants with CP (#209, 214) showed a decrease of 1.0 cm, and one participant with CP (#208) was unable to lean forward.

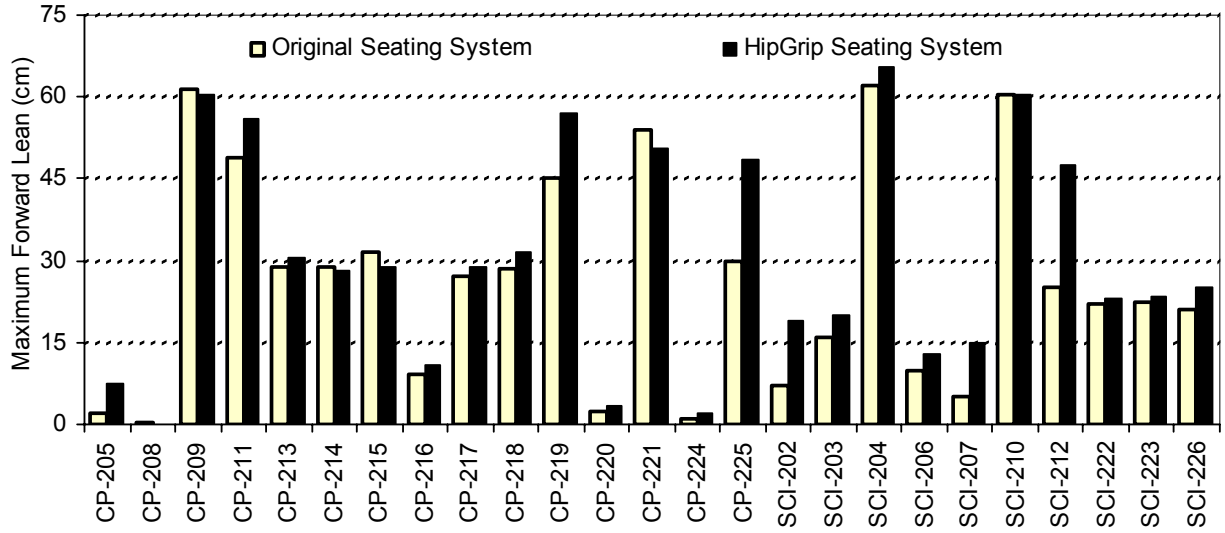

Figure 9. Forward Lean Results.

The HipGrip allowed for more forward lean with the ability to independently sit back up into a neutral posture compared to the original pelvic supports used by the participants.

f. Lateral Lean

It was hypothesized that the HipGrip would:

1. Increase the users' distal control;
2. Increase the users' lateral lean; and
3. Stabilize the pelvis and assist the users' pelvis back into a neutral position after the user moves in the wheelchair.

1) Lateral Lean Instrumentation

Lateral lean was measured in centimeters with a flexible measuring tape attached to a tripod (Figure 10). The tripod was secured to the rear wheels of the participant's wheelchair so that the vertical tube was positioned directly to the side of the participant's non-reaching shoulder. To measure lateral lean, the flexible measuring tape attached to the tripod is set at a height level with the acromion process with the participant sitting in an upright position in their wheelchair. The flexible measuring tape is placed on the acromion process to obtain the lean distance measurement.

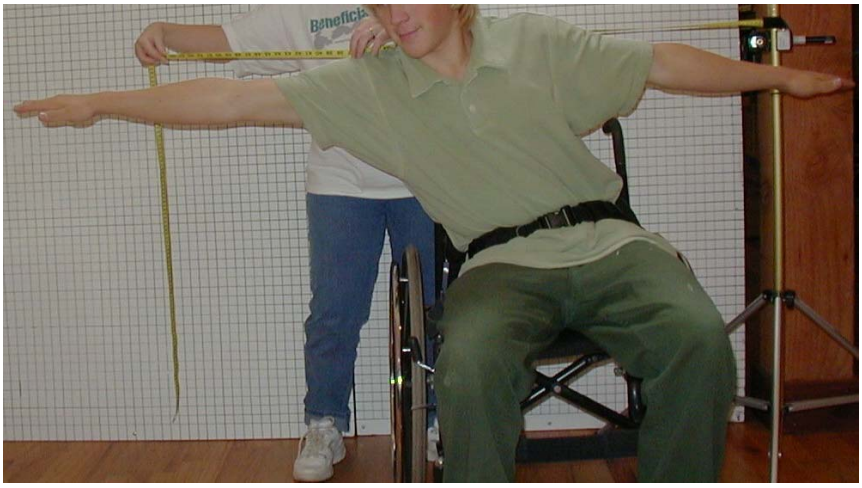

Figure 10. Tripod setup used to measure lateral lean.

2) Lateral Lean Methodology

Participants were instructed to sit upright in their most neutral position with their back against the back support of the wheelchair. Those who were unable to independently position themselves were assisted by the physical therapist. Participants were instructed to hold their non-reaching arm extended laterally in the opposite direction, if possible. Otherwise, their non-reaching arm was held in the most free, non-weight bearing position possible.

With the flexible tape measure placed on the acromion process, the baseline position was measured in centimeters. Participants were instructed to lean to the side as far as possible while maintaining the ability to return to an upright sitting position independently without using their upper extremities. A maximum lean measurement of the acromion position was taken with

the participants leaning in their most lateral position. Each participant performed the test three times on the left and right side.

The lateral lean values were calculated for each trial by subtracting the baseline measurement from the furthest lateral lean measurement. The maximum lateral lean value was determined for both the participant's original seating system and the HipGrip. The maximum lateral lean value obtained with the participant's original seating system was compared to the HipGrip.

The effect of the HipGrip on lateral lean was assessed by comparing the amount of lateral lean obtained using the participant's original seating system to that of the HipGrip (two-tailed, paired t-test, $\alpha=0.05$).

3) Lateral Lean Results

Eighteen out of 25 (72%) participants successfully completed the lateral lean test during session 3. Seven participants were unable to complete the test due to either not being capable of following the directions or physically being unable to perform the task. One participant was withdrawn from the study prior to session 3.

The maximum lateral lean obtained with the use of the HipGrip was significantly more than with the participant's original seating system ($p<0.01$). Twelve out of 18 (67%) participants achieved a greater lateral lean with the use of the HipGrip compared to their original seating system (Figure 11). Lateral lean increased by an average of 6.3 cm and ranged from 0.5 cm to 13.0 cm. The average percentage increase in lateral lean was 32.7%.

Six out of 18 (33%) users showed a decrease in lateral lean with the use of the HipGrip: four participants with CP (#209, 214,221,225) showed a decrease from 0.5 cm to 3.5 cm and two participants with SCI (#210, 222) showed a decrease of 3.0 cm and 1.0 cm.

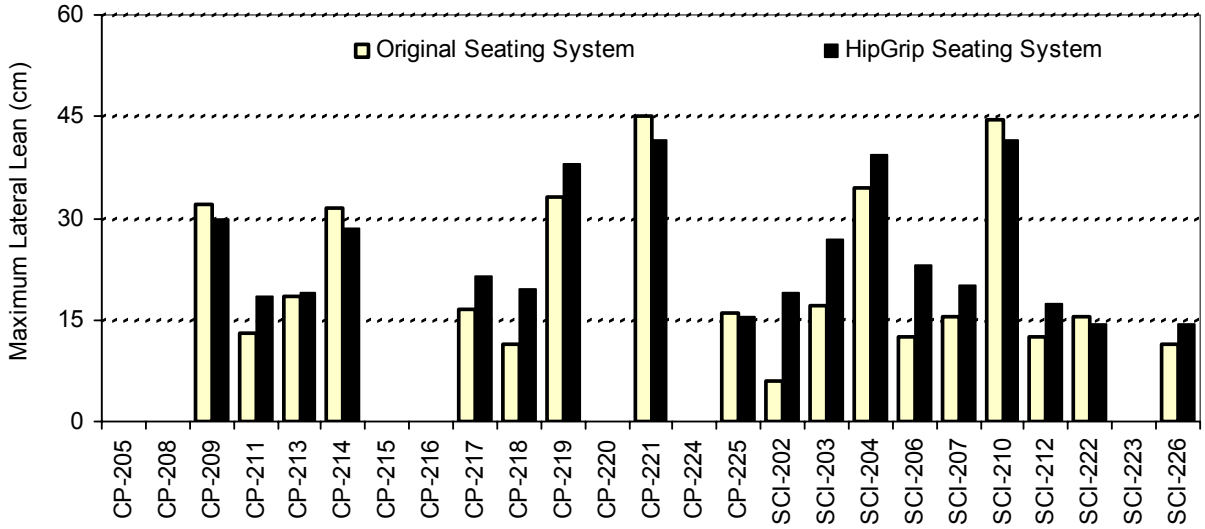

Figure 11. Lateral Lean Results.

The HipGrip allowed for more lateral lean with the ability to independently sit back up into a neutral posture compared to the original pelvic supports used by the participants.

g. Downward Lean

It was hypothesized that the HipGrip would:

1. Increase the users' distal control;
2. Increase the users' downward lean; and
3. Stabilize the pelvis and assist the users' pelvis back into a neutral position after the user moves in the wheelchair.

1) Measurement Instrumentation

Downward lean was measured in centimeters with a steel ruler mounted to aluminum base plate (Figure 12). The steel ruler was positioned adjacent to the trajectory of the participant's downward reach at the side of the participant's wheelchair. To measure downward lean, the steel ruler was set in line with the most distal part of the fingers or elbow with the participant sitting in an upright position in their wheelchair. The steel ruler was used to measure the lean distance.

Figure 12. Steel rod setup used to measure downward lean.

2) Downward Lean Methodology

Participants were instructed to sit upright in their most neutral position with their back against the back support of the wheelchair. Those who were unable to independently position themselves were assisted by the physical therapist.

Participants were instructed to hold their non-reaching arm over but not touching the non-reaching side hand-rim, if possible, in order to prevent complete loss of balance. Otherwise, their non-reaching arm was held in the most free, non-weight bearing position possible. Participants were instructed to extend their reaching arm downward with fingers extended. If the

participant was unable to keep his/her hand in an open position then an alternate point of measurement was recorded. If the participant was able to touch the floor with their fingers, then the distal part of the elbow was used as an alternate point of measurement with the reaching side hand touching a prominent bony structure on the shoulder.

With the steel ruler placed next to the extended reaching arm, the baseline position was measured in centimeters. Participants were instructed to lean downward as far as possible while maintaining the ability to return to an upright sitting position independently without using their upper extremities. A maximum lean measurement of the distal fingertip was taken with the participants leaning in their most downward position. Each participant performed the test three times on the left and right side.

The downward lean values were calculated for each trial by subtracting the baseline measurement from the furthest lateral downward measurement. The maximum downward lean value was determined for both the participant's original seating system and the HipGrip. The maximum downward lean value obtained with the participant's original seating system was compared to the HipGrip.

The effect of the HipGrip on downward lean was assessed by comparing the amount of downward lean obtained using the participant's original seating system to that of the HipGrip (two-tailed, paired t-test, $\alpha=0.05$).

3) Downward Lean Results

Fourteen out of 25 (56%) participants successfully completed the downward lean test during session 3. Eleven participants were unable to complete the test due to either not being capable of following the directions or physically being unable to perform the task. One participant was withdrawn from the study prior to session 3.

The maximum downward lean obtained with the use of the HipGrip was significantly more than with the participant's original seating system ($p<0.01$). Eleven out of 14 (79%) participants achieved a greater downward lean with the use of the HipGrip compared to their original seating system (Figure 13). Downward lean increased by an average of 5.1 cm and ranged from 1.0 cm to 12.0 cm. The average percentage increase in downward lean was 10.9%.

Three out of 14 (21%) users showed a decrease or no change in downward lean with the use of the HipGrip: two participants with CP (#214, 215) showed a decrease of 1.0 cm and 6.5 cm and one participant with CP (#225) showed no change.

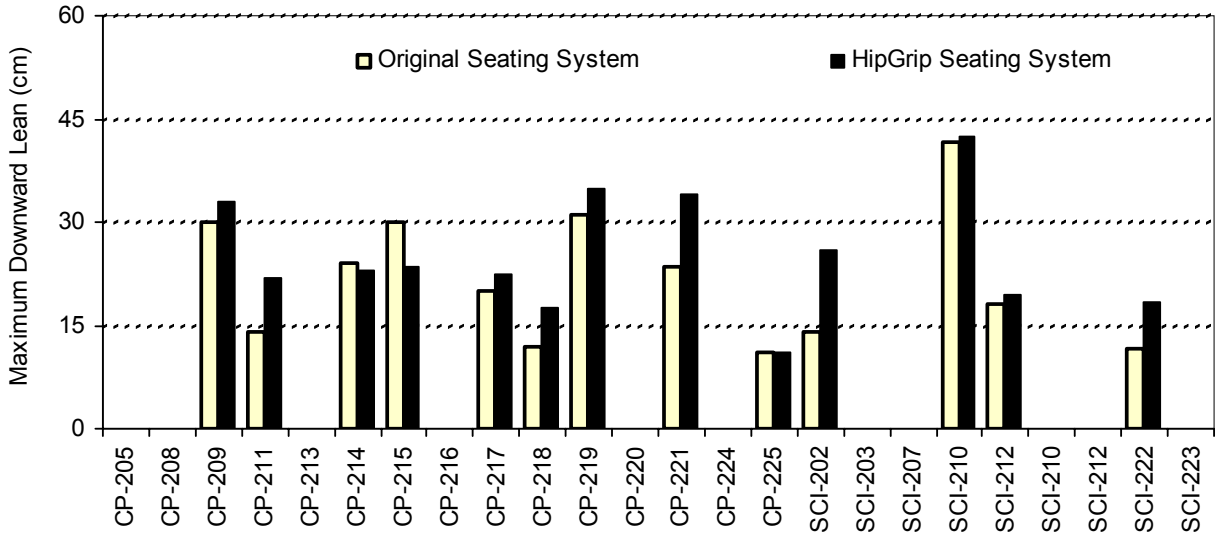

Figure 13. Downward Lean Results.

The HipGrip allowed for more downward lean with the ability to independently sit back up into a neutral posture compared to the original pelvic supports used by the participants.

h. Performance and Satisfaction

It was hypothesized that the HipGrip would:

1. Improve the users' perceived level of performance and
2. Improve the users' perceived level of satisfaction.

1) Canadian Occupational Performance Measure (COPM)

Participant performance and satisfaction were measured using the Canadian Occupational Performance Measure (COPM) (Law et al., 1998). The COPM was developed as an outcome measure to detect change over time in one's perception of their occupational performance. The COPM is an individualized test based on goals identified by the participant, parent and/or therapist. The goals are prioritized according to their importance to the participant and the five most important goals are selected for evaluation.

The COPM was designed to be used for people with varying disabilities (Law et al., 1998) and has been used across many disability groups (Donnelly et al., 2004; Cup et al., 2003; Trombly et al., 2002). The COPM has been demonstrated to be a valid (Cup et al., 2003; McColl et al., 2000; Law et al., 1994) and reliable (Cup et al., 2003; Law et al., 1990) measure.

The initial time to administer the COPM was 30-45 min, which included defining and ranking the goals to be measured. Subsequent COPM measurements consisted only of ranking the previously defined goals which took 10-15 minutes.

2) COPM Methodology

This study used a single subject study design to evaluate each participant's change in performance and satisfaction.

With the assistance of the physical therapist, participants generated a list of goals focusing on everyday activities that may be affected by the HipGrip. The participant then ranked each goal on a scale of 1-10 according to importance, with 10 being very important and one being not important at all. The five most important goals were identified as the set goals for the study. Each of the five set goals were ranked on a scale of 1-10 for performance, with 10 being able to perform the task perfectly and one not being able to perform the task at all. Each of the five set goals were also ranked on a scale of 1-10 for satisfaction, with 10 being very satisfied and one not being satisfied at all. Performance was defined as the self-evaluation of one's current performance of the activity. Satisfaction was defined as the self-evaluation of one's satisfaction with current performance of the activity.

Participants ranked each of the set goals for performance and satisfaction during session 2 referring to their original seating system. Participant performance and satisfaction were measured again after the 3-6 month usage period during session 3 by ranking each of the set goals for performance and satisfaction with the use of the HipGrip.

The effectiveness of the HipGrip in improving participant performance and satisfaction was assessed by comparing the average score of the five set goals using their original seating system with the average score of the five set goals using the HipGrip. A difference of two or more in the satisfaction score was defined as a clinically important increase in satisfaction and a difference of two or more in the performance score was defined as a clinically important increase in performance by the COPM (Law et al., 1998). One participant (CP-208) did not attempt one of the five set goals; therefore, an average was computed based on the four set goals that were attempted.

3) COPM Results

Twenty-four out of 25 (96%) participants successfully completed the COPM study; one participant with tetraplegia (SCI 223) was withdrawn from the study due to an increase in buttocks to seat cushion interface ischial tuberosity pressures from 125 mmHg to more than 200 mmHg with the use of the HipGrip.

All of the participants completed the COPM with the physical therapist and selected five goals for evaluation that were important to them. If the participant was not cognitively able to independently set and rank goals, their caregiver assisted them with this task. Examples of the goals selected by the participants included: reaching tasks; maintaining position; decreasing pain; more effective breathing and swallowing; and increased hand, arm, head, and foot control. Goals also included wheelchair control and playing sports more effectively; including soccer, basketball, tennis, and dance. Participants cited tasks involving reaching (forward, lateral and/or downward) most frequently. Eighteen out of 24 (75%) participants listed at least one task that involved reaching or leaning.

All 24 participants had an increase in performance scores (ranging from 0.8 to 6.8) with the use of the HipGrip (Figure 14). The average increase in the performance scores was 3.5 points. Performance rankings of the set goals with the use of the HipGrip increased more than 2 points for 17 out of 24 (71%) participants when compared to their original seating system (Figure 15).

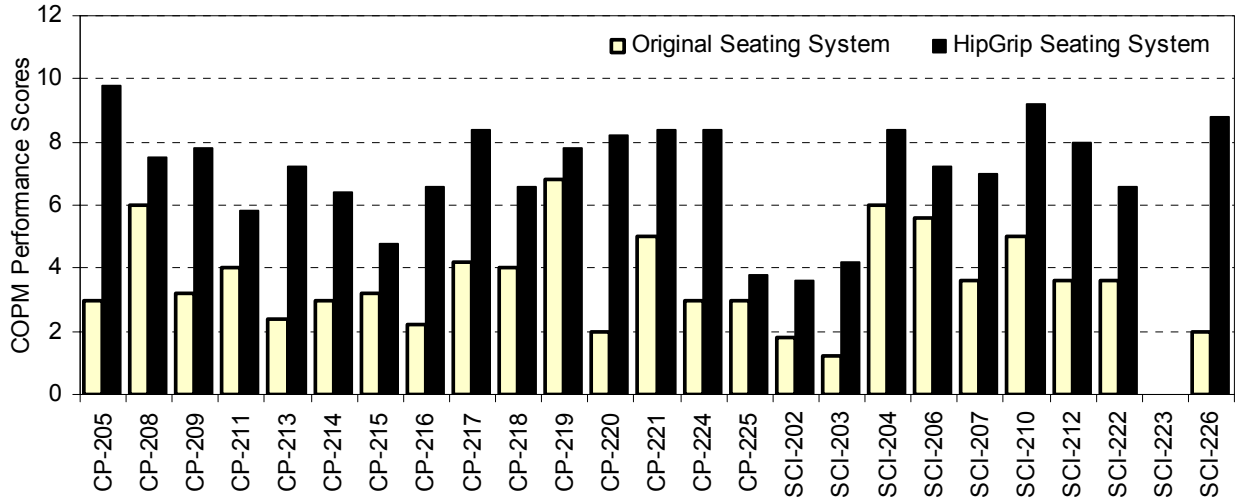

Figure 14. Average COPM Performance Scores.

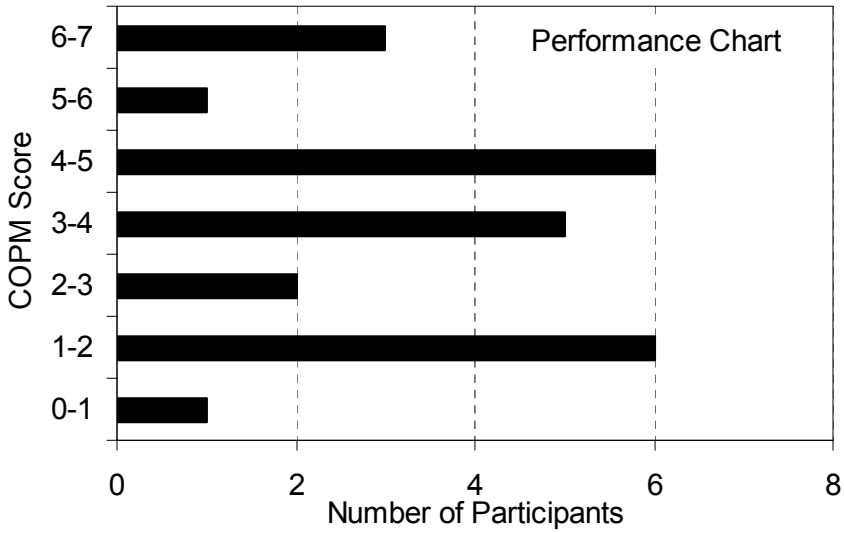

Figure 15. Frequency distribution of the change in COPM Performance scores with use of the HipGrip.

Twenty-three out of 24 (96%) participants had an increase in satisfaction scores (ranging from 0.2 to 7.4) with the use of the HipGrip (Figure 16). The average increase in the satisfaction scores was 3.7 points. One participant, CP-208, had a decrease in satisfaction by 5.5 points with the use of the HipGrip. Satisfaction rankings of the set goals with the use of the HipGrip increased more than 2 points for 19 out of 24 (79%) participants compared to their original seating system (Figure 17).

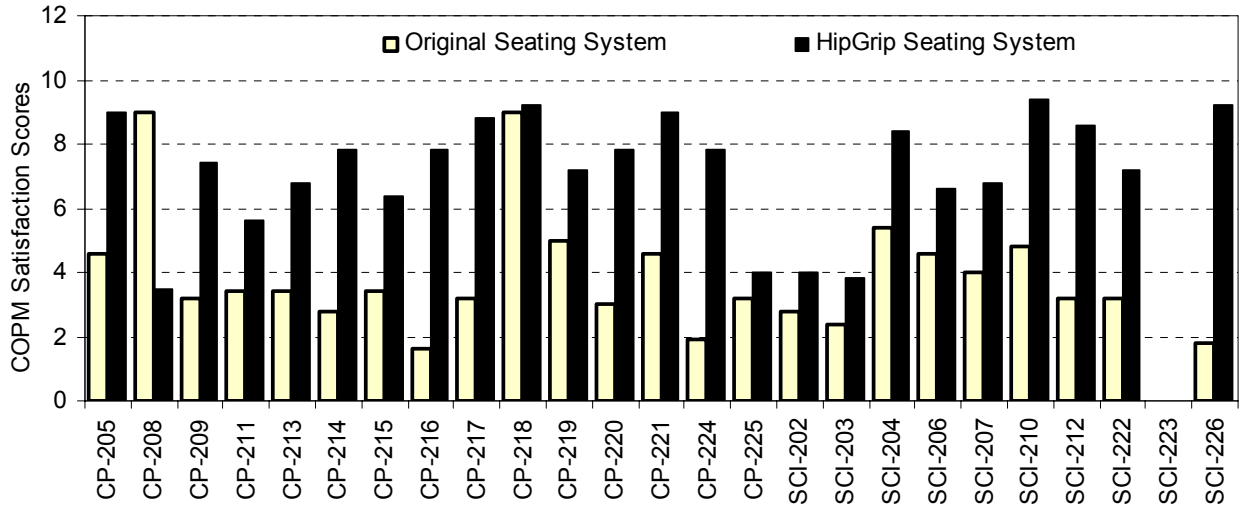

Figure 16. Average COPM Satisfaction Scores.

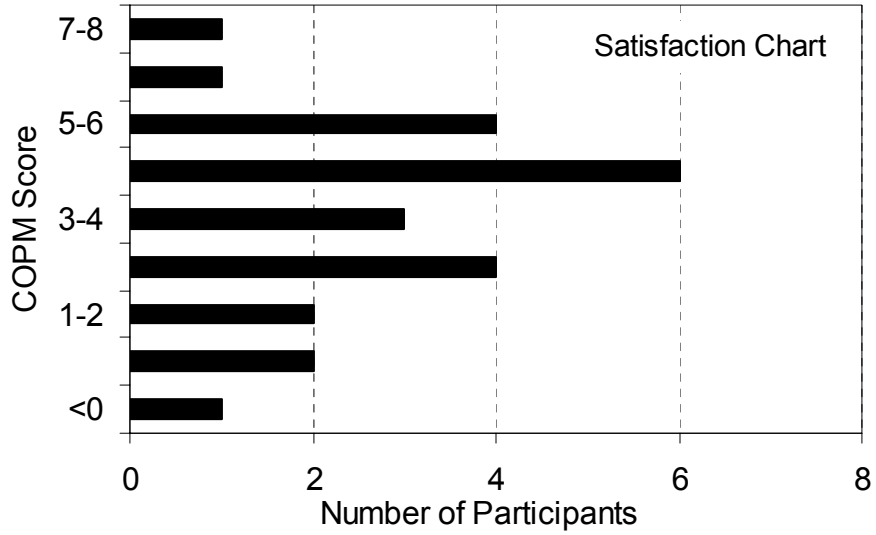

Figure 17. Frequency distribution of the change in COPM Satisfaction scores with use of the HipGrip.

The results of the COPM study demonstrated clinical improvements with the use of the HipGrip for wheelchair users with limited sitting balance. These results suggest that using a HipGrip to stabilize the pelvis for wheelchair users with limited sitting balance improves upper body function.

i. Subjective Feedback

It was hypothesized that the HipGrip would:

1. Improve the users' satisfaction with their functional ability;
2. Improve the users' satisfaction with their posture; and
3. Decrease the users' need to reposition.

1) Subjective Feedback Questionnaire

Participant feedback was gathered during sessions 2 and 3 through questions regarding functional ability, posture and long-term benefit. Participants responded to statements, using a Likert scale (strongly disagree to strongly agree), regarding their functional ability and posture using the HipGrip and using their original seating system. Participants answered yes/no questions regarding their perceived long-term benefit with use of the HipGrip.

Participant feedback was gathered during the follow-up phone calls after approximately six weeks of using the HipGrip. Participants answered yes/no questions regarding a perceived change in the number of times they needed to reposition within their wheelchair and in their ability to perform activities with use of the HipGrip. Participants were asked to compare the HipGrip to their original seating system.

2) Subjective Feedback Results

Twenty-four out of 25 (96%) participants successfully completed the satisfaction questions; one participant with tetraplegia (SCI 223) was withdrawn from the study due to an increase in buttocks to seat cushion interface ischial tuberosity pressures from 125 mmHg to more than 200 mmHg with the use of the HipGrip.

Ten out of 24 (42%) participants reported an increase in satisfaction with their functional ability with use of the HipGrip; 11 participants reported no change, and three participants reported a decrease. Ten out of 24 (42%) participants reported an increase in satisfaction with their posture with use of the HipGrip; 10 participants reported no change, and four participants reported a decrease. The clinical importance of the functional and postural benefits provided by the HipGrip was emphasized when one subject reported that she felt "more secure" using the HipGrip and noticed "increased function."

Eight out of 24 (33%) participants reported that they were able to do some activity using the HipGrip that they previously could not do, citing "freedom of the arms" and increased stability allowing "hand over hand" tasks and increased reach. Two out of 24 (8%) participants reported that they were not able to do some activity using the HipGrip that they previously could do, citing that the HipGrip hindered them from reaching down to the floor. These two subjects reported that they could achieve this activity by releasing the HipGrip buckle.

The need to reposition in the wheelchair using the HipGrip decreased for 16 out of 24 (67%) participants when compared to their original seating system. Four participants reported no change in repositioning and four reported an increase in repositioning. Twenty-three out of 24

(96%) participants reported that they thought the HipGrip would benefit them with long-term use, with one subject reporting that he "will benefit from improved pelvic alignment in chair and not needing to constantly reposition."

During follow-up phone calls, 17 out 24 (71%) participants claimed that they preferred the HipGrip to their original seating system, with most participants claiming that this was due to increased stability, support and/or posture. After session 3, 18 out of 24 (75%) participants opted to continue using the HipGrip in their wheelchair rather than having their original seating system reinstalled upon completion of the study.

4. Conclusions

The results of the clinical evaluation demonstrated that the HipGrip was an effective pelvic stabilization device for many wheelchair users with limited sitting balance. The HipGrip provided better control of pelvic obliquity and improved sitting posture compared to the original seating system used by the participants during quiet sitting and after activity. The HipGrip provided increased pelvic stability, allowing participants more upper body distal control than their original seating system. Using the HipGrip increased the wheelchair user's perception of performance and satisfaction of everyday activities affected by positioning.

5. References

ANSI/RESNA WC/Vol. 1-1998 (2000, Supplement). *American National Standard for Wheelchairs -- Volume 1: Requirements and test methods or wheelchairs (including scooters), Section 19: Wheelchairs used as seats in motor vehicles*. Arlington, VA: RESNA Press.

Cup, E.H., Scholte op Reimer, W.J., Thijssen, M.C., & van Kuyk-Minis, M.A. (2003). Reliability and validity of the Canadian Occupational Performance Measure in stroke patients. *Clinical Rehabilitation*. 17(4):402-9.

Donnelly, C., Eng, J.J., Hall, J., Alford, L., Giachino, R., Norton, K., & Kerr, D.S. (2004). Client-centred assessment and the identification of meaningful treatment goals for individuals with a spinal cord injury. *Spinal Cord*. 42(5):302-7.

Hurley, S.L., Hayes, A.M., Yamada, D.A., Siekman, A.R., Noon, J.H. & Axelson, P.W. (2003). Increased forward lean among wheelchair users with use of a dynamic pelvic stabilization device. *RESNA 26th International Annual Conference*. (CD). Atlanta, GA: RESNA Press.

Law, M., Baptiste, S., McColl, M., Opzoomer, A., Polatajko, H., & Pollock, N. (1990). The Canadian occupational performance measure: an outcome measure for occupational therapy. *Canadian Journal of Occupational Therapy*. 57(2):82-7.

Law, M., Polatajko, H., Pollock, N., McColl, M.A., Carswell, A., & Baptiste, S. (1994). Pilot testing of the Canadian Occupational Performance Measure: clinical and measurement issues. Canadian Journal of Occupational Therapy. Oct;61(4):191-7.

Law, M., Baptiste, S., Carswell, A., McColl, M.A., Polatajko, H., & Pollock, N. (1998). Canadian Occupational Performance Measure (3rd edition). Ottawa Ontario: CAOT publications. (COPM Manual).

Lynch, S.M., Leahy, P., Barker, S.P. (1998). Reliability of measurements obtained with a modified functional reach test in subjects with spinal cord injury. *Physical Therapy*, 78(2): 128-133.

McColl, M.A., Paterson, M., Davies, D., Doubt, L., & Law, M. (2000). Validity and community utility of the Canadian Occupational Performance Measure. *Canadian Journal of Occupational Therapy.* 67(1):22-30.

Noon, J.H., Chesney, D.A. & Axelson, P.W. (1998). Development of a dynamic pelvic stabilization system. *Proceedings of the RESNA 1998 Annual Conference.* (pp. 209-211). Arlington, VA: RESNA Press.

Palisano, R., Rosenbaum, P., Walter, S., Russell, D., Wood, E. & Galuppi, B. (1997). Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Developmental Medicine and Child Neurology.* 39(4):214-23.

Siekman, A.R., Hurley, S.L., Yamada, D.A., Noon, J.H. & Axelson, P.W. (2003). Functional benefits of a dynamic pelvic stabilization system. *Proceedings of the Nineteenth International Seating Symposium.* (pp. 139-140). Pittsburgh, PN: University of Pittsburgh.

Trombly, C.A., Radomski, M.V., Trexel, C., & Burnet-Smith, S.E. (2002). Occupational therapy and achievement of self-identified goals by adults with acquired brain injury: Phase II. *American Journal of Occupational Therapy*. 56(5):489-98.

6. Publications

Hurley, S.L., Hayes, A.M., Yamada, D.A., Siekman, A.R., Noon, J.H. & Axelson, P.W. (2003). Increased forward lean among wheelchair users with use of a dynamic pelvic stabilization device. *RESNA 26th International Annual Conference*. (CD). Atlanta, GA: RESNA Press.

Noon, J.H., Chesney, D.A. & Axelson, P.W. (1998). Development of a dynamic pelvic stabilization system. *Proceedings of the RESNA 1998 Annual Conference.* (pp. 209-211). Arlington, VA: RESNA Press.

Siekman, A.R., Hurley, S.L., Yamada, D.A., Noon, J.H. & Axelson, P.W. (2003). Functional benefits of a dynamic pelvic stabilization system. *Proceedings of the Nineteenth International Seating Symposium.* (pp. 139-140). Pittsburgh, PN: University of Pittsburgh.

Appendix A
HipGrip Repetitive Load Testing

HipGrip Repetitive Load Testing

Prepared by:

Peter W. Axelson, Director of Research & Development
Allen R. Siekman, Seating Clinician

Beneficial Designs, Inc.
1617 Water Street, Suite B
Minden, Nevada 89423-4310

775.783.8822 voice
775.783.8823 fax

Prepared for:

Bodypoint, Inc.
558 First Ave. South, Suite 300
Seattle, WA 98104

206.405.4555 x108 voice
206.405.4556 fax

11 August 2004

Peter W. Axelson

HipGrip Repetitive Load Testing

BACKGROUND **1**
- The HipGrip 1
- Strength Testing 1
- Research Objectives 2

METHOD **2**
- Repetitive Load Test Fixture 2
- Repetitive Load Test Procedure 2

STAGE 1 ..... **3**
- Stage 1 Objective 3
- Stage 1 Results 3
- Stage 1 Discussion 3
- Stage 1 Conclusions 3

STAGE 2 ..... **3**
- Stage 2 Objective 4
- Stage 2 Results 4
- Stage 2 Discussion 4
- Stage 2 Conclusions 4

STAGE 3 ..... **4**
- Stage 3 Objective 4
- Stage 3 Additional Methods 4
- Stage 3 Results 5
- Stage 3 Discussion 5
- Stage 3 Conclusions 5

STAGE 4 ..... **5**
- Stage 4 Objectives 5
- Stage 4 Additional Methods 5
- Stage 4 Results 5
- Stage 4 Discussion 6
- Stage 4 Conclusions 6

STAGE 5 ..... **6**
- Stage 5 Objectives 6
- Stage 5 Additional Methods 6
- Stage 5 Results 7
- Stage 5 Discussion 7
- Stage 5 Conclusions 8

HipGrip Repetitive Load Testing

BACKGROUND

The HipGrip

The HipGrip is a positioning device that provides dynamic pelvic stabilization in wheelchairs. The HipGrip was designed to position and support the pelvis while permitting natural pelvic movement to occur. The HipGrip may increase upper body function, such as forward and lateral reach distance, by providing a stable base of support.

The HipGrip consists of two rear pads, two front pads, two lateral hip pads, a pivot mechanism, and attachment hardware (Figure 1). The rear pads prevent the upper pelvis from moving backward by providing support at the posterior superior iliac spines (PSIS). The two front pads support the front of the pelvis at the anterior superior iliac spines (ASIS). The two lateral hip pads prevent the hip from moving laterally. A pivot mechanism allows the pelvis to tilt forward as needed and facilitates active extension of the lumbar spine. Dynamic resistance straps gently return the pelvis to its neutral position after allowing movement. Attachment hardware allows the device to be mounted to a variety of seat systems and wheelchairs.

Figure 1. HipGrip in Wheelchair without and with user.

Strength Testing

Allen Siekman supervised the strength testing of the complete HipGrip device at the Design Center of Beneficial Designs in Santa Cruz, California beginning in May 2002. The HipGrip was dynamically tested using a repetitive load test fixture and statically tested by applying lateral and frontal loads to the pad and bracket assemblies to determine strength and durability.

The dynamic and static tests were performed prior to enrolling human subjects in a research study to evaluate the clinical effectiveness of the HipGrip. Testing was continued to provide data to assist the refinement of design and engineering as well as to evaluate the HipGrip and components of the HipGrip seating system. Testing was broken up into five separate stages differentiated by parts used and research objectives posed.

Research Objectives

Five stages of testing were conducted to test the performance of the HipGrip pre-fabricated and manufactured parts to assure safety and durability of all components and assembly.

METHOD

Repetitive Load Test Fixture

The repetitive load test fixture was designed and built to simulate standard pelvic movement of a person seated in a wheelchair with the HipGrip engaged (Figure 2). The test fixture consists of a wooden torso dummy free to rotate about a point to simulate the movement of forward reach to and from a neutral/upright seated positioning. The motion is achieved by attaching the torso dummy to a motor that rocks the dummy in a controlled range of movement. The number of rocking cycles is recorded with a counter.

Figure 2. Repetitive Load Test Fixture.

The repetitive load test fixture allows dynamic testing of the entire HipGrip assembly. During the testing, the pad assembly, pivot mechanism, and tension springs were tested.

Repetitive Load Test Procedure

The HipGrip part assemblies were mounted on the repetitive load test fixture for testing. The HipGrip assemblies used for this test used the larger size pelvic pads and were adjusted to fit the torso dummy. The repetitive load fixture cycled the HipGrip through a 5” travel, 3.5” forward and 1.5” to the rear of the neutral resting position. This range of motion is 20 degrees, which is similar to the HipGrip under normal use. The test fixture was adjusted to complete 60-70 cycles per minute.

The following test criteria were used during all four stages of testing:

1) No component shall be fractured or have visible cracks.
2) No nut, bolt, screw, locking pin, adjustable component or similar item shall be detached after being tightened, adjusted or refitted once.
3) All parts that are intended to be removable, folding or adjustable shall operate as described by the manufacturer.
4) Any multi-position or adjustable component shall not be displaced from the preset position.
5) No component or assembly of parts shall exhibit deformation, free play or loss of adjustment that adversely affects the function of the device.

STAGE 1

Stage 1 testing was conducted prior to any human subject testing to ensure that the HipGrip assembly met or exceeded safety requirements.

Stage 1 Objective

Repetitive load testing was conducted to determine if the HipGrip with pre-production parts manufactured in-house is durable for a simulated 5-year use cycle (approximately 400,000 cycles).

Stage 1 Results

The repetitive load test was run for 1,232,446 cycles (Table 1). No component critical to subject safety failed. Newly designed spacers and pivot brackets were added to the HipGrip assembly for testing.

Table 1. Summary of Stage 1 Data

Testing	Date (start – stop)	Cycles (#)
Rep Load Test	5/5/02 – 6/27/02	1,232,446

Incident Type	Incident (#)	Description	Action Taken
O-Ring Assembly	8	Broken, cracked	Replaced
Spring Rod	2	Hairline stress, slipped	Monitored
Flex Rod	3	Loose	Tightened

Stage 1 Discussion

The primary failure noted was with the O-Ring tensioners that provide return force to the HipGrip. The O-Ring components are considered to be consumable items, i.e. like tubes, tires or shock absorbers on a car. In a commercial product, they would be replaced on a normal maintenance schedule.

A thin stress line noted on the left spring rod was observed at 153,295 cycles. The rod did not fracture or splinter and was left in place for the duration of the test. In post-test examination of the components, it was determined that an increased radius on the edge of the spring rod hole in the pivot bracket would minimize the stress to the spring rod at that point. This change was incorporated in the components to be used for subject testing.

Stage 1 Conclusions

The HipGrip passed the repetitive load testing with no major incidents. It was determined that no failures occurred within stage 1 testing that would pose a safety concern during human subject testing.

STAGE 2

Stage 2 testing was conducted with pre-production parts fabricated by an external manufacturer

to ensure that the HipGrip met or exceeded safety requirements for human subject testing.

Stage 2 Objective

To determine if the HipGrip with pre-production parts fabricated by an external manufacturer (Bodypoint, Inc.) were durable for a simulated 5-year use cycle (approximately 400,000 cycles).

Stage 2 Results

The repetitive load test was run for 392,380 cycles (Table 2). No component critical to subject safety failed.

Table 2. Summary of Stage 2 Data

Testing	Date (start – stop)	Cycles (#)
Rep Load Test	6/27/02 – 7/1/02	392,380

Incident Type	Incident (#)	Description	Action Taken
O-Ring Assembly	2	Broken, cracked	Replaced
Pivot Bracket	1	Loosened	Tightened

Stage 2 Discussion

As in Stage 1, the primary incident was with the O-Ring tension bands. They are not critical safety items. A fracture of an O-Ring may affect the functional benefit for the user, but will not create a safety hazard.

Stage 2 Conclusions

The HipGrip passed the repetitive load testing with no major incidents. It was determined that no failures occurred within stage 2 testing that would pose a safety concern during human subject testing. It was decided to proceed with extended testing of pre-production parts.

STAGE 3

Stage 3 was continued testing conducted with pre-production parts fabricated by an external manufacturer.

Stage 3 Objective

To evaluate if the HipGrip and integrated parts (parts tested in Stage 2) were durable over an extended period of use and to test various O-Ring types.

Stage 3 Additional Methods

Testing continued with use of parts from Stage 2 for an extended period with frequent visual inspection to assure testing criteria were being met. Various O-Rings with different material type and sizes, including Buna and Neoprene, were tested to identify an O-Ring with an acceptable balance between longevity and tension characteristics.

Stage 3 Results

The repetitive load test was kept running for a total of 4,217,531 cycles (Table 3). No component critical to subject safety failed.

Table 3. Summary of Stage 3 Data

Testing	Date (start – stop)	Cycles during Stage 3 (#)	Cycles during Stage 2 and 3 (#)
Rep Load Test	7/1/02 – 10/28/02	3,825,151	4,217,531

Incident Type	Incident (#)	Description	Action Taken
O-Ring	21	Broken, cracked	Replaced
Spring Rod	2	Stress cracks, wear	Monitor

Stage 3 Discussion

As in Stage 1 and 2, the primary incident was with the O-Ring tension bands. They are not critical safety items. A fracture of an O-Ring may affect the functional benefit for the user, but will not create a safety hazard.

It was determined that the Neoprene O-Ring #316 provided the greatest longevity with the desired tension for proper function.

Stage 3 Conclusions

The HipGrip components used in stage 3 passed the repetitive load testing with no major incidents. A better O-Ring was identified, but it was still not ideal. It was decided to investigate alternatives to the O-Ring.

STAGE 4

A newly designed resistance strap that would replace the O-Ring was tested to ensure that the HipGrip met or exceeded safety requirements for human subject testing.

Stage 4 Objectives

To evaluate the newly designed dynamic resistance straps (that were considered to be consumable components within the system) and to continue testing the durability of the HipGrip and integrated parts (parts tested in Stage 2 & 3) during an extended period of use.

Stage 4 Additional Methods

Parts from Stage 2 and 3 were used for an extended period to evaluate different configurations of tension bands with frequent visual inspections to assure testing criteria was being met.

Stage 4 Results

The repetitive load test was kept running for a total of 5,009,303 cycles (Table 4). No component

failed during Stage 4 testing.

Table 4. Summary of Stage 4 Data

Testing	Date (start – stop)	Cycles (#) during Stage 4	Cycles (#) during Stage 2, 3, and 4
Rep Load Test	3/9/03 – 5/10/03	758,772	5,009,303

Stage 4 Discussion

The newly designed resistance straps performed without incident, proving to be much more viable than the O-Ring. It was determined that the HipGrip was ready to be transferred to the manufacture for final manufacturing engineering and production changes.

Stage 4 Conclusions

The HipGrip components used in stage 4 passed the repetitive load testing without incident. The newly designed resistance straps exceeded 5 years of normal use (approximately 400,000 cycles) and the HipGrip component assembly more than exceeded the 5 years of normal use at over 5 million total cycles.

STAGE 5

Stage 5 Objectives

To test the performance of a new rubber spring design simulating a useful life of two to three years of use (we estimate 100,000 cycles is adequate). Rubber springs were provided by Bodypoint, Inc. for testing. The rubber springs replace the O-Rings used in Stages 1-4.

Stage 5 Additional Methods

Test Equipment / Resistance Force

A rigid frame is used to mount the redesigned pivot brackets. Action is made through an actuator mounted to be perpendicular when pivot bracket is at 30 degrees. Mounting is made so that when the actuator arm is at full extent, the bracket is pivoted 30 degrees. The supplied mounting arms are too long to achieve the requested 4” offset. The shortest offset obtainable is 4 13/16”. Measurements were made with a 5” offset, for ease of calculations

Test Equipment / Repetitive Load

Use the same equipment and setup as in Stages 1 – 4.

Test Procedure / Resistance Force

Install new pivot brackets on rigid frame to allow resistance force testing of new spring design. Apply load to pivot 30 degrees, note pounds force applied. Repeat five times and record the average.

Test Procedure / Repetitive Load

Install one pivot bracket on each side of the HipGrip test frame with a rubber spring mounted in

the pivot bracket. Run repetitive load test to 50,000 cycles.

Remove the brackets from the HipGrip test frame, and install brackets on the rigid frame to test resistance force as done above. Remount brackets on the HipGrip test frame. Run endurance test for another 50,000 cycles (100,000 total).

Perform resistance force test and record the results as noted above.

Figure 3. Resistance Force test to 30 degrees

Stage 5 Results

Table 5. Stage 5 Resistance Force to Achieve 30 Degrees of Movement

Spring Type	Pre Test	After 50k Cycles	After 100k Cycles
0 Bumps	5.08 lbf	4.44 lbf	4.40 lbf
1 Bumps	9.12 lbf	10.00 lbf	9.84 lbf
2 Bumps	11.24 lbf	11.72 lbf	11.44 lbf
3 Bumps	17.12 lbf	17.92 lbf	17.68 lbf
4 Bumps	8.04 lbf	8.0 lbf	7.96 lbf

Table 6. Stage 5 Additional Results

Spring Type	After 150k Cycles	After 200k Cycles	After 250k Cycles	After 300k Cycles
2 Bumps	11.20 lbf	11.40 lbf	11.40 lbf	Not measured
3 Bumps	18.24 lbf	18.28 lbf	Not tested	Not tested

Additional testing was preformed on the 2-bump band initially to balance the load while testing the 3-bump band. Testing was continued to 300,000 cycles as a matter of endurance.

Stage 5 Discussion

Pre-test measurements were made using a visual reference to 30 degrees. After testing began,

it was decided to setup with the 30-degree mark achieved at full extension of the actuator arm. This could account for the slight increase in force of bands 1, 2 and 3.

It is difficult for one person to change the springs. Pulling the spring with one hand and aligning and starting the screws with the other is a challenge, as the screw tends to push the axel through with out threading. If pressure is released on the spring with the axel inserted, the axel is pulled too far out of alignment to allow the screw to thread.

After 300,000 cycles of testing for the 2-bump band, repetitive testing was postponed. The pivot bracket was left on the repetitive testing device, but not turned on. The brackets were left in the fully upright position with no forward flex. The bands were intact at this time, the evening of April 26th. The bands were checked on April 29th, and were intact. On the morning of April 30th it was noted that the 2-bump band had failed. The break in the band was clean, showing the newly exposed rubber to be glossy (Figure 3).

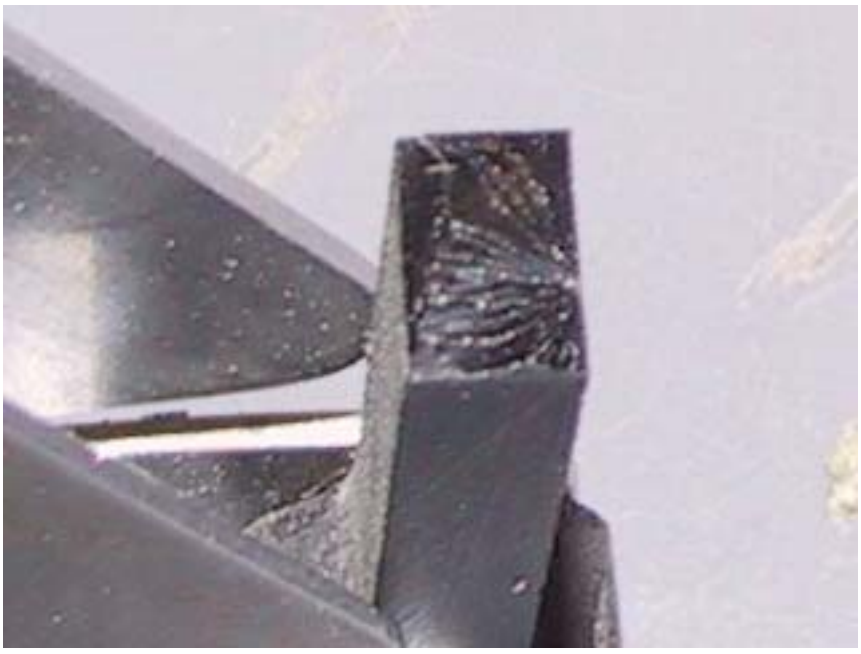

Figure 3. Broken 2-bump band

Stage 5 Conclusions

The HipGrip components used in stage 5 passed the repetitive load testing with no major problems. This test approximated 2 years of normal use.