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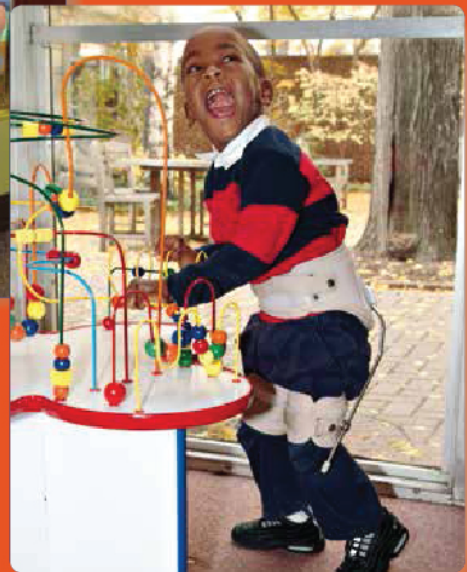
S.W.A.S.H.[®]



SITTING



WALKING



AND STANDING

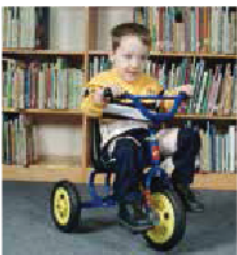


PRIMO ORTHOCARE SDN BHD (1014391-A)

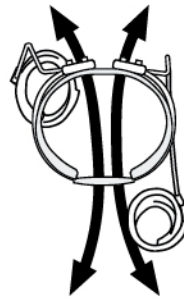
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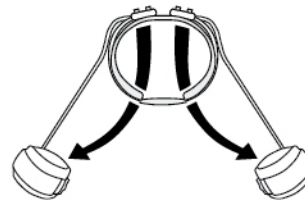
Increase Levels Of Function



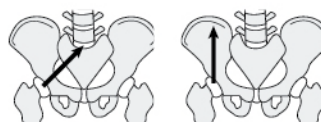
What makes SWASH unique to other hip orthoses is that it offers controlled variable abduction. It is engineered with a complex series of angles to maintain good hip alignment as the uprights follow the pathways of motion of the femurs.



While standing or walking, SWASH provides just enough abduction to prevent scissoring and medial femoral rotation.



As the hips are flexed to assume the sitting position, it automatically further abducts the hips to create a tripod base for enhanced sitting stability and more upright posture.



With

Without

The most visible benefits of the SWASH are readily apparent by improvements in sitting and standing posture and stability, and for the ambulatory user, improvement in gait. However, perhaps the most important benefit the SWASH offers is guidance for hip alignment.

S.W.A.S.H.[®]

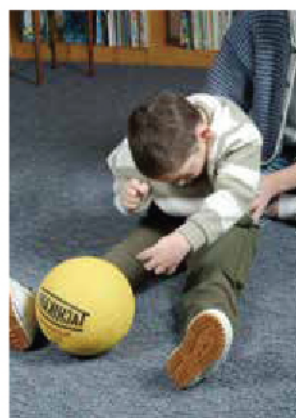
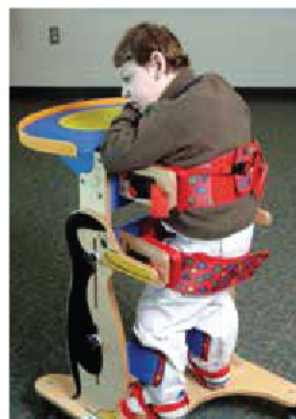
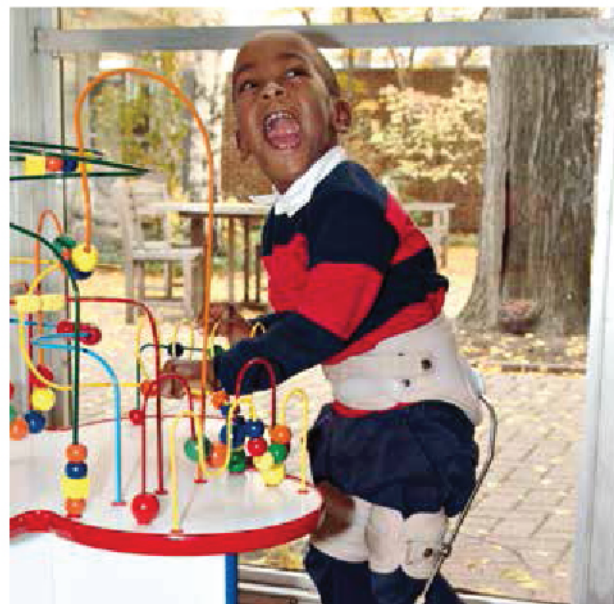
- is a hip stabilization and sitting orthosis
- can offer significant benefits for both non-ambulatory and ambulatory children
- can work for neuromuscular disorders other than just Cerebral Palsy
- can work for children with severe involvement as well as mild
- is available in sizes that fit infants to small adults
- does not interfere with children's ability to play
- does not interfere with most walkers, wheelchairs, or even standing frames

Developmental Medicine & Child Neurology, AACPDM, Abstracts 2003, No. C:2, page 10. Roslyn Boyd MSC PT, H Kerr Graham MD, Gary Nattrass MD, Dinah Reddihough MD, Pam Thomason PT, Fiona Dobson PT, Jenny Parrott PT, Kevin Lowe MD, Ann Lancaster PT, Alfild Larsen MD, Jenine Oates PT, Jane Valentine MD, Sarah Love PT, John Carlin PHD, and Members of the Multicentre Hip Study Team, Mac Keith Press, London UK.

A 3-year, randomized multicenter trial with concealed allocation to either BTX-A and bracing or observation. Ninety children with bilateral spastic cerebral palsy with hips at risk (migration percentage MP> 15<40% at entry) were entered.

CONCLUSION:

"Injections of BTX-A combined with SWASH bracing reduces hip displacement and delays or prevents the need for orthopaedic surgery."



Two Styles Of Orthoses To Meet Different Patient Needs



Original

- Plastic pelvic section extends from L2/L3 to the coccyx, providing maximum torso support for candidates with flaccidity or very limited trunk control
- Single strap fixed front closure to secure torso support
- Increased posterior and side support
- "Childproof" thigh cuff closure
- Proven results in several different independent studies
- Available with 115° or 123° uprights



Low Profile II

- Anatomically shaped metal pelvic section rests over the pelvis and is secured in position by attaching to a small plastic reinforced abdominal pad
- Double strap front closure allows symmetrical application
- 8 mm diameter uprights in all sizes - extra strong for extra high tone
- Interchangeable thigh cuff sizes
- Overlap design thigh cuff closure for easy application and removal
- Contoured posterior joints reduce interference with posterior walkers and other standing/walking/sitting aids
- Available with 115° or 123° uprights

Two Options For Upright Selection

More abduction in sitting

Increased abduction offers maximum opportunity for muscle lengthening in the sitting position and is also recommended when there is need to influence the trunk toward more spinal extension.



Less abduction in sitting

Reduced abduction better accommodates wheelchairs with narrow seat structures and is better tolerated by children with tight adductor muscles.



SWASH® SIZING CHART

Dimensions in mm.		Pelvic Section Circumference	Thigh Cuffs Circumference	Leg Bar Length Diameter	
SWASH® CLASSIC	SIZE 1	400 - 465	210 - 250	310	6
	SIZE 1A		210 - 250		7
	SIZE 2	460 - 550	250 - 290	375	7
	SIZE 3	540 - 630	290 - 330	440	7
	SIZE 4	620 - 720	330 - 380	480	7
SWASH® LOW PROFILE II	SIZE 1	400 - 465	210 - 250	310	8
	SIZE 2	460 - 550	250 - 290	375	8
	SIZE 3	540 - 630	290 - 330	440	8
	SIZE 4	620 - 720	330 - 380	480	8
	SIZE 5	710 - 810	380 - 440	540	8
	SIZE 6	800 - 900	440 - 500	600	8

SWASH is jointly owned by CAMP Scandinavia AB in Sweden and Prim S.A in Spain. For a more detailed technical information see www.ortoprim.com or www.campscandinavia.se under SWASH. SWASH is a patented product.

More information about the product and the fitting procedure can be found in the SWASH Fitting & Customization Manual and in the SWASH Clinical Manual.



S.W.A.S.H.[®]

Sitting Walking And Standing Hip orthosis



MANUAL

Clinical

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Acknowledgements

To Dr. Paul Meyer of Cambridge, England who took the time and the effort to design a way to help his daughter, Rebecca, and children everywhere with cerebral palsy.

To Bertil Allard, Past President and CEO of Camp Scandinavia AB, whose vision, commitment and perseverance have made the SWASH® available around the world.

To Jan Smits, CPO, of The Netherlands, along with Prim SA of Spain, whose combined engineering and manufacturing skills have made the complex simple, and the simple simply work.

And especially to the children with physical disabilities, whose love, enthusiasm and enduring spirit are an inspiration to all of us.

HISTORY OF DEVELOPMENT

In 1984, a four-year old girl with dystonic cerebral palsy developed subluxation of her left hip. She had been able to sit, stand and walk with support (albeit with scissoring). A fixed abduction brace was recommended to stabilize her hip, but her father was concerned about the negative side effects such a device could impart on "normal" function.

He researched medical literature published on use of hip orthotic devices, and concluded the "ideal" brace for his daughter must permit:

- Independent hip flexion
- Maximum abduction during hip flexion
- Minimum abduction - just enough to prevent scissoring during hip extension and weight-bearing
- Normal anatomical movement as the orthosis moves from minimum abduction with hip extension to maximum abduction with hip flexion

Based on the findings in available literature, the father concluded a device was required that:

- Would allow the child to pursue a more normal range of activities with reduced risk of hip dislocation
- Would further enhance acetabular modeling and development of the hip joint complex.

With this in mind, he set about to design his daughter a brace that uses the rotation of leg bars about an inclined pivot to achieve abduction which was continuously variable according to the degree of hip flexion. The result of this effort is the SWASH® (Sitting, Walking And Standing Hip) Orthosis.

The first commercial use of the SWASH® began in 1992. Since then, thousands of children and some adults worldwide with varying degrees of disabilities have been able to realize the functional and psychological benefits offered by the assistance of this innovative orthotic intervention.

Primary development goals of the SWASH®

1. Increase abduction and stretch hip adductors to improve hip alignment
2. Prevent excessive adduction during sitting, standing and walking
3. Optimize sitting and standing posture
4. Achieve the above goals with an automatic transition from neutral (walking, standing) to abduction (sitting)

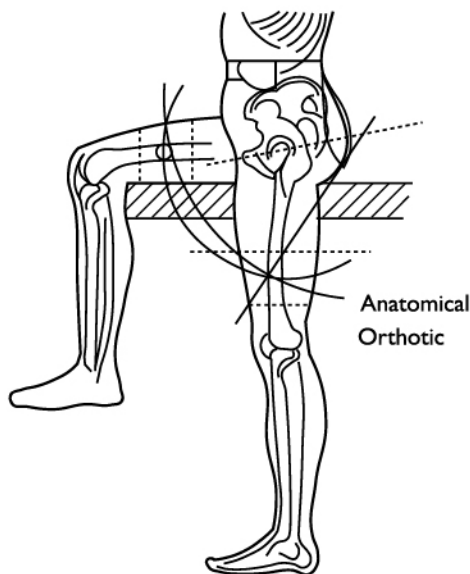
BIOMECHANICS OF SWASH®

A Major Biomechanical Engineering Accomplishment

The SWASH® appears to be a relatively simple device, but looks can be deceiving. From the distal tip of one upright to the distal tip of the other, there are a combination of twenty-one (21) joints and angles in the SWASH®. Changing one angle affects the function of the other twenty.

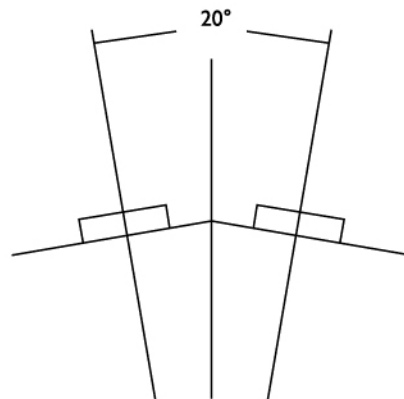
Anatomic vs. Orthotic Pathways of Motion

At first glance, it appears that the orthosis should cause significant "pistoning" of the thigh cuffs on the thighs, as the wearer moves from standing to sitting. The orthotic hip joints do not approximate the location of the anatomical hip joints. The orthotic joints are actually positioned closer to the sacroiliac joints than they are to the hip joints.



But in fact, the pathways of motion of the SWASH® thigh cuffs do mimic the pathways of motion of the femurs. This is designed into the orthosis through a combination of the angle of the pelvic band in the sagittal plane, and the angle of the hip joint assemblies in the transverse plane. Also contributing are the angles of the uprights through the hip joints, and the planes on which the angles on the uprights themselves are shaped.

The result of this tri-plane engineering is that "pistoning" of the cuff on the thigh is minimized.



Center of Gravity

Upon seeing the SWASH® orthosis, one would expect that the center of gravity would be posterior to the trunk. The joints are posterior, leading to the expectation that the center of gravity would also be posterior.

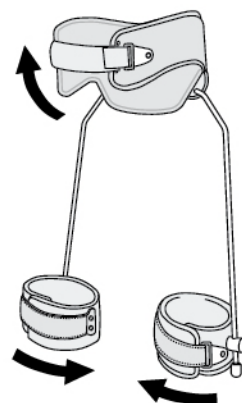
In fact, however, the tri-plane engineering again utilizes all the angles described previously to bring the center of gravity just anterior to L2, through the center of the trunk. Of most significance is the 20° angle in the transverse plane designed into the posterior section of the pelvic band. This angle moves the center of gravity from posterior to mid-trunk alignment.

Proximal Transfer of Adductor Tone

High adductor tone affects posture of the entire body. It drives the feet into pronation, internally rotates the lower limbs, and has a flexion influence on both the knees and the hips. This lower extremity reaction to adductor tone influences the trunk into a slouched posture.

It is theorized that as SWASH® overcomes adductor tone, two things happen. First, the biomechanical effect of the tone is reversed.

It exerts an external rotary influence on the lower limbs (without twister cables), the knees and hips are influenced more towards extension, and the trunk stands more erect. Second, as the SWASH® reaches its limit for adduction, it transfers adductor force proximally, assisting anterior rotation of the pelvis to help achieve a more erect postural position.



NOTE: Preliminary results of a 10- patient study reports there is no increase in adductor tone associated with the use of a SWASH®.

HIP STABILIZATION

The most visible benefits of the SWASH® are improvements in sitting and standing posture and stability, and for the ambulatory user, improvement in gait. The benefits can be immediate and are often dramatic. Continued improvements may be seen after the wearer has become acclimatized to the orthosis.

Given the visible benefits, perhaps the most important benefit the SWASH® offers is its influence on hip stability. The very nature of high adductor tone places dislocating forces on the hips. The internal rotation and adduction forces leave hips at risk. Data shows that ambulatory children with CP have a 30% incidence, and non-ambulatory children have a 60% incidence of hip subluxation requiring medical intervention.

Excessive adduction with internal rotation causes a posterior dislocating force, which is opposed by the SWASH® variable abduction brace. Although this may be expected to reduce the risk of hip dislocation, ongoing studies to document this benefit have not yet been completed.



ADduction
Internal Rotation
Unstable Alignment



ABduction
External Rotation
Better Alignment

This case example offers some insight into the effects of SWASH® to help prevent hip displacement over an extended period of time.



In this before fitting x-ray, pelvic obliquity and (R) hip subluxation are readily evident. The acetabulum is shallow and does not cover the femoral head.



At year two post fitting shows further improvement of the femoral head within the acetabulum.



One year post fitting shows improvement in pelvic angle and hip subluxation. Approximately 80% of the femoral head is now covered.



Three years post fitting shows normal pelvic angles and closer to normal hip development.

FUNCTIONAL INFLUENCE



Sitting Posture & Stability

Many individuals with neuromuscular disorders are very unstable during sitting due to spastic adduction leading to a narrow base of support. This is demonstrated by a typical slouched posture during sitting, along with the need for external assistance or the use of hands for "touch balance". While it is common to refer to one's "envelope of function", this type of sitting instability might be described as limiting one to a "cocoon of function", as hands are functionally tied down to the sitting surface.

When in the sitting position, SWASH® abducts the hips to create a wider tripod base for sitting stability. This wider base of support, combined with the spinal and pelvic support of the pelvic band, often provides sufficient postural assistance to open a whole new world for the user who otherwise is unable to sit without external assistance. Harnesses, wedges, and bolsters may often be considerably reduced if not eliminated.

The less involved child, who may be able to sit without external assist but requires use of the upper extremities for touch balance, may be able to sit independently when wearing the SWASH® - freeing the hands for eating, interacting with others, for more active participation in therapy programs, and for playing.

From the mild to the severely involved, the stable base for sitting will result in a more upright sitting posture - certainly

a significant benefit for hip and spine alignment. The opportunity for enhanced upper extremity function may also improve trunk strength and control.

Standing Posture & Stability

With a successful fitting, SWASH® may offer significant improvements in standing posture. Non-ambulatory wearers will often be better able to stand more upright in their standing frames with reduced external assistance. For the ambulatory wearer, there will often be improvements in trunk posture, reduced scissoring and a wider base of support for standing.

As a result of overcoming adductor tone and its biomechanical consequences, standing frames or walkers will generally need to be adjusted higher to accommodate the more erect posture.

Proprioceptive Implications

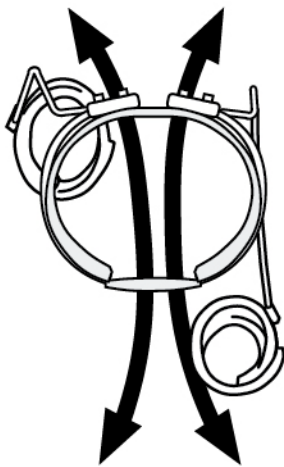
While the biomechanical aspects of the SWASH® may be relatively well understood, it is more difficult to understand the proprioceptive implications. In almost every instance, fitting the SWASH® will result in a decrease in spasticity and improved reach targeting of the upper extremities. The mechanism for this common outcome is not entirely understood.

FUNCTIONAL INFLUENCE

Gait Dynamics

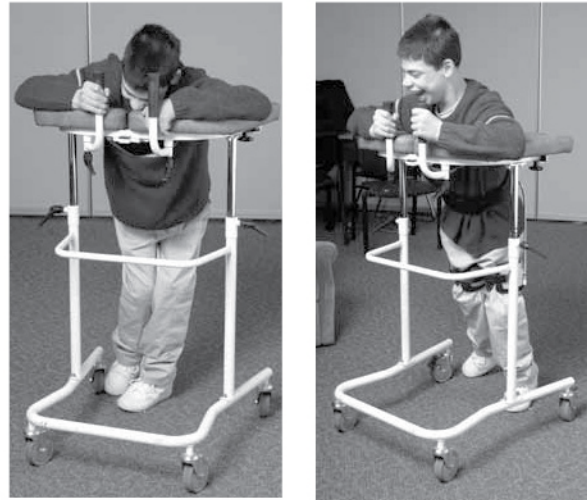
SWASH® is the only hip orthosis that is designed to offer variable hip abduction - requiring no "unlocking" or other adjustments by the wearer or the caregiver.

For the ambulatory patient, this can offer significant functional benefits. With a successful fitting SWASH® can provide enough abduction to prevent scissoring during standing and gait. As the hips are flexed to the sitting position, the SWASH® uprights guide the femurs to further abduct the hips to create a tripod base for sitting stability and to stretch the hip adductors.



Control of scissoring gait, more upright posture, and ability to shift from standing to sitting and sitting to standing with minimal, if any, external assistance can offer numerous benefits for ambulatory candidate:

- They may ambulate with greater independence. Many children who have never taken more than a few steps without someone having to untangle their feet can now walk to the limits of their endurance without scissoring.
- SWASH® may help conserve energy. Without the energy consumed in attempting to stabilize the trunk and untangle scissoring feet, the child is often able to walk more fluidly for greater distances.
- With the ability to walk better and more independently, they will want to walk more, and their distance/walking may improve. Walking now becomes a means of getting from here to there instead of an exercise to be endured during supervised therapy sessions. With better gait biomechanics and greater gait capacity, they will be better able to participate in physical therapy protocols to increase muscle length and reduce tone in the hamstrings and calf group.



Respiratory and Speech Functions

The improved posture reduces the compromising of breathing capacity which can be a side effect of slouched posture. Many therapists have reported this improved posture can also have a positive impact on speech as a result of the improved breathing control and since the user can now bring the head and neck (less constriction of the vocal cords) into a more upright position.

INDICATIONS & CONTRAINDICATIONS

Indications

- Spastic Hemiplegia
- Spastic Diplegia
- Spastic Quadriplegia
- Risk of hip displacement (both ambulatory and non-ambulatory)
- Low trunk tone (may require customized combination with spinal jacket).
- Post-Botulinum Toxin A (Focal spasticity management) A three year, randomized multi-centre trial with concealed allocation to either BTX-A and bracing and/or observation concluded: "Injections of BTX-A combined with SWASH® bracing reduces the rate of hip displacement and delays the need for orthopaedic surgery".
- Post-operative - For stabilization when abduction in both flexion and extension is required.
- Night Splint - This application can be especially useful if the child spends the first two or three hours of the day overcoming muscle shortening that occurred during sleep. It is recommended to first allow the child to become accustomed to wearing the brace during the day.

Contraindications

- Dislocated hips
- Fixed hip flexion contracture greater than 20°. There are no finite guidelines for use with non-fixed flexion contracture - this generally is dependent on wearer tolerance.
- Adductors so strong they overpower the SWASH® uprights (SWASH® Low Profile has larger diameter and therefore stronger uprights.)
- Adductor length so short it causes discomfort with SWASH® use in the sitting position
- If ambulatory, excessive tibial torsion or foot involvement, without physician assessment of impact SWASH® impacts on these conditions.

Precautions

- In patients with shortening of hamstrings, psoas, adductors, or Achilles Tendon, great care should be taken when planning the orthotic and therapy program.
- SWASH® is not a treatment for hamstring tightness. If current therapy protocols include exercises to relieve hamstring tightness, it is important these exercises be continued as hamstrings will not be stretched in the SWASH®. Hamstring tightness should be monitored on a regular basis. Any signs of increased tightness should be specifically addressed.
- SWASH® does not eliminate the need for AFOs. Particularly for the ambulatory wearer, it is important to re-evaluate the AFO design as the needs may change as a result of the new stance and gait patterns that will result from wearing the SWASH®.
- SWASH® does not replace rehabilitation or the therapist. It does help overcome some of the major consequences of high adductor tone and therefore allows more specific and functional rehabilitation.
- Patients with spinal asymmetry or deformity may be unable to wear the SWASH®, or may require that the orthosis be incorporated into a custom body jacket.
- With time, for some wearers, spasticity of the adductors may reduce either due to wearing the orthosis or Botulinum Toxin A (BTX-A) injections. It is important on a regular basis to review the amount of abduction correction needed to maximize hip alignment and functional goals.

Limitations

- The SWASH® is not a cure-all for all postural problems. New movement and postural motor control patterns will have to be learned and gained. The SWASH® is seen as a device to facilitate these gains.
- If patients cannot walk at all without the SWASH®, it is highly unlikely they will be able to walk with the SWASH®.
- Even with the SWASH® in use, there may be residual internal rotation of the lower extremities. Very often, unless there are internal tibial torsion or metatarsus adductus issues, the medial hamstrings have been seen to exert this internal rotary influence. An aggressive stretching program of the medial hamstrings has been seen to minimize this residual internal rotation.

CANDIDATE SELECTION

Since its introduction, physicians have prescribed thousands of SWASH® for patients from infants to adults, ambulatory and non-ambulatory, from mild to severe involvement - to protect hip alignment, improve the ability to sit independently or at least with reduced external assistance, improve sitting and standing posture, and for improvement of stepping for patients with scissoring postures.

The following are guidelines presented by subject area.

Age

The following age discussions are intended as a guide only, based on fitting experiences. However, it is important to remember every candidate and level of development varies at different ages, so there will definitely be exceptions in each age category:

Early Intervention (9 months - 2 years):

Both SWASH® and SWASH® Low profile will fit an infant as young as 9-10 months. SWASH® has been widely prescribed for infants at risk for spastic hip displacement. When properly fitted, SWASH® will not interfere with crawling. For the child that may be able to learn to walk, SWASH® can often help them to better stabilize as they pull themselves up on furniture. For the child who may only be able to sit, the wide abduction base may help them achieve a more stable position.

2 - 6 years

This age group will generally adapt to the SWASH® very quickly. They tend to accept quite readily the correction it offers and, with guidance from the physical therapist and caregiver, develop new skills. They usually accept the sitting stability it offers and quite freely start using their upper extremities for function instead of for sitting balance.

6 - 12 years

Around this age the child can be slower to adapt. By the time a child reaches 9 or 10, there may also be muscle length issues (contracture), muscle strength issues, and long-standing neuromotor patterns that can be very difficult to overcome. For the child in this age group with strong adductor tone, the SWASH® Low Profile is generally recommended as the uprights in this model are stronger.

13 - Adult

The pelvic band of the Classic SWASH® will fit a waist circumference up to 72 cm (28 1/4 inches). SWASH® has been successfully fitted on small adults who fit within this range. Again, due to the increased strength of the uprights, the SWASH® Low Profile may be required to control the adductor tone. A larger size SWASH® Low Profile with longer uprights and larger cuffs is now available.

Acclimatization Time

Age, cooperation, and the degree of functional involvement all affect the length of time for the wearer to become accustomed to the orthosis. As a general rule, the younger the candidate, the quicker they accommodate to the orthosis. Even those that acclimate quickly, will continue to improve in function as they continue to wear the orthosis. If immediate results are not seen, it is encouraged to allow the candidate to continue to wear the orthosis at least an additional 30 minutes to one hour as it has been observed that given time to relax in the orthosis - they start to realize how they can use its support to sit, stand, or walk better. If no improvement is seen after one hour, it is unlikely SWASH® will be of benefit.

Sometimes improved posture is evident immediately upon application, but then he or she tends to return to the original slouched posture. This is usually indicative that the orthosis will work, but physical therapy and re-training may be required to establish new movement patterns.

Especially children who have always had to use their hands for balance, are scared to "let go" for fear they will topple over. A little "diversion therapy", such as trying to get them to clap their hands or reach for a ball will help them overcome the fear.

PRODUCT SELECTION



Classic

SWASH® Classic

The original design of SWASH® uses a plastic anterior overlap pelvic band to secure the orthosis around the waist and maintain its position, resting over the ASIS, just below the navel. In the back, the pelvic section extends from L2/L3 to the distal margin of the sacrum, providing maximum pelvic support. Children with low trunk tone and/or very limited trunk control strength may benefit from the increased posterior and lateral support this design offers. The thigh cuff closure is a double-lock strapping system to reduce the chances of unwanted removal by children. Pelvic band and thigh cuff padding are removable for laundering.

The uprights are 6mm (size I) and 7mm (sizes 2-4) diameter. The smaller diameter uprights on the size I allow more "spring", permitting less restriction of movement. This is often desirable for the developing infant.



Low Profile

SWASH® Low Profile

SWASH® LP uses a padded iliac extension that can be positioned in one of two places: it can be fit immediately above the iliac crest between the crest and the inferior angle of the costal flail, or it can be fit between the ASIS and the greater trochanter. The latter is used to minimize any influence towards lumbar flexion when sitting. The double strap front closure allows for symmetrical application. In the back, the padded metal posterior frame extends from approximately L2/L3 to S1/S2. The metal offers positive non-slip contact for the abduction control joints, and includes clear markings to monitor abduction settings. The joints are tapered downward to accommodate most walker styles. The thigh cuff closure is a simple double Velcro fold-back closure for easy donning and doffing. The pelvic band cover and thigh cuff padding are removable for laundering. The uprights for all sizes are 8mm diameter. This increase in diameter offers added strength to manage very high tone, plus it allows cuffs to be completely interchangeable between all sizes.

Guidelines for Product Selection

The following are offered as general guidelines only. When possible, it is recommended to try each style on the patient to best assess which offers optimum function.

SWASH® Classic

- When maximum trunk control is required, i.e., for the candidate who lacks muscle strength or upper body control to sit upright.
- When patient is primarily non-ambulatory (GMFCS IV-V).
- When a smaller diameter (6mm) uprights on the size I are desired to permit less restriction of movement.
- When the greater pelvic coverage area triggers more desirable neuro-sensory motor response.

SWASH® Low Profile

- When the primary goal is to control scissoring gait and the posterior joints on the SWASH® Classic interfere with posterior walker, and a new walker is not an option.
- When wearer has limited space between the iliac crest and the rib cage.
- When maximum upright strength is required to manage adductor tone.
- When candidate and/or caregiver acceptance of "bracing" is an issue, the Low profile is more cosmetically acceptable to some.

PRODUCT SELECTION

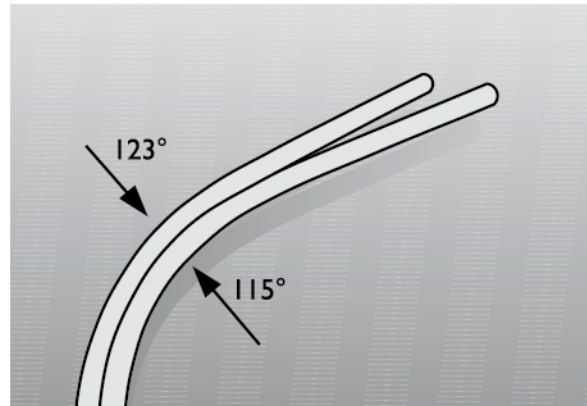
115 or 123 Degree Uprights?

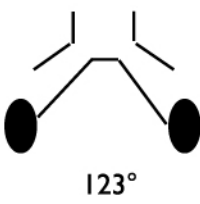
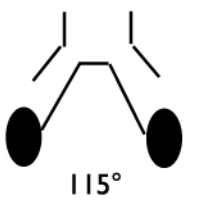
SWASH® is available with either 115° or 123° uprights. This refers only to the fixed angle of the most proximal visible curve in the uprights – it does NOT refer to the exact degree of abduction obtained while wearing the orthosis.

Standing and walking functions of both uprights are very similar. Generally the differences between the two are related to sitting function, with the 123° uprights creating greater amounts of abduction and the 115° uprights creating relatively smaller amounts of abduction.

NOTE: In sitting, the 123° uprights will have a greater influence towards posterior pelvic rotation, thereby increasing the flexion influence on the trunk.

The selection of the 115 or 123-degree uprights does have an effect on the postural outcome of the fitting. The following are offered as guidelines:



123 Degree - Wide Sitting Base	115 Degree - Narrow Sitting Base
 <ul style="list-style-type: none"> • When the greatest amount of adductor muscle lengthening in the sitting position is desired. • When more trunk lumbar flexion influence is desired during sitting. • When more lumbar extension is desired during gait. 	 <ul style="list-style-type: none"> • The wearer is primarily chair mobile and the 123° uprights would be too wide in the sitting position for the child to fit in the chair or car seat. • Adductors are too tight and the amount of abduction when sitting in the 123° uprights would be impossible or painful. • When less trunk flexion influence is desired during sitting.

PRE AND POST-FITTING FUNCTIONAL EVALUATIONS

Pre-Fitting Functional Evaluations

A pre-fitting assessment should be done and documented with a team consisting of at least a physical therapist and the orthotist. It is also desirable to have the primary caregiver present during this assessment. Each person brings to the evaluation their own areas of expertise and observational skills. Don't be surprised if the primary caregiver sees more than the rest of the medical team! Their observations and comments can be surprisingly insightful.

The assessments should be oriented toward assessing the hip stability/displacement and overall function as opposed to individual components of function. Carefully observe function or limitations of the adductors, hamstring, and hip flexors. Be aware of and document symmetries found during the evaluation. Some facilities are using videotape as one of the ways to document the before and after effects of the SWASH®. Clinically proven assessment methods such as Gross Motor Function Measure (GMFM), or the Peabody Developmental Motor Scales (PDMS), among other tests will add validity and proven repeatability to the assessment process.

Below is a guide of areas to assess posture and function PRIOR to SWASH® fitting:

SITTING (90/90 position)

- Overall sitting height from sitting surface
- Time no touch sitting
- Reaching distance capacity
- Ball catch capacity
- Sit to stand functional performance
- General stability and posture
- Hip adduction
- Pelvic tilt posture due to hamstring tightness

STANDING

- Overall stance height
- Foot position and alignment
- Reaching capacity with extrinsic support
- Reaching capacity without extrinsic support
- Stand to squat functional performance
- General posture
- Femoral alignment

WALKING

(with normal ambulatory aid and with normal AFOs if used)

- Incidence of scissoring and scissoring posture
- Transverse plane alignment both sides (one limb rotated more than the other?)
- Stride length
- Stride base width
- Heel to toe utilization during gait
- Speed
- Distance capacity

Primary & Secondary Goals

Based on above assessment, establish primary and secondary goals for the orthotic intervention. For example: Hip alignment? Stretch adductors? Increase walking capacity? Improve sitting posture? Appropriate product selection (Classic or Low Profile, 115° or 123° uprights) and proper fit are highly dependent on knowing these goals.

Post-Fitting Functional Evaluations

During this process, simply repeat the evaluations accomplished in the pre-fitting evaluation. Note any changes in functional capacity that are measured or observed.

Please consider the following:

Age

The younger wearer typically adapts to the orthosis and shows more immediate improvements than the older wearer.

Acclimatization Time

While some differences are usually apparent immediately after fitting, many more changes will become apparent after days, weeks, or months in the SWASH®. It may take some time for the wearer to acclimatize to and to trust the orthosis. Many children will demonstrate a more erect and stable standing posture. It may take some time to become acclimatized to this new posture and elevation. Cervical hyperextension and spinal rotation should diminish as pelvic stability increases. Improvements in standing balance and stability may be demonstrated after a few hours or days.

Walker, Standing Frame, Crutch Adjustment

Be certain that the height of any standing or walking assistance device is evaluated with the child wearing the SWASH®. It will often need to be raised to accommodate to the new stance height of the child.

Abduction Adjustment

In initially setting up the orthosis, it is difficult to judge the amount of abduction required to provide optimum hip stability and achieve established goals. If ambulatory and scissoring is still hindering gait, abduction angles will need to be re-adjusted by the fitter.

PROTOCOLS AND PROPER FIT GUIDELINES

Protocols

Wearing time

The number of hours the orthosis is to be worn should be determined by the physician. This time will vary depending on the degree of involvement of the pathology, the goals of the rehabilitation program, and the tolerance of the wearer. While up to 24 hour use may be indicated, the recommended wearing time is at least six hours per day, usually during periods of highest activity (sitting, standing, and stepping). The SWASH® may also be prescribed to be worn at night to control night time scissoring.

Fitting over / under clothing

The orthosis should ideally be fitted under clothing to optimize the control it has over hip alignment. This also facilitates the child who is managing their own toilet.

Liner care instructions

The liner in the SWASH® Classic and the cover of the SWASH® Low Profile are removable. Both may be removed, hand washed in cool water with mild detergent, and dried flat. Replacement liners and covers are available through your orthotist.

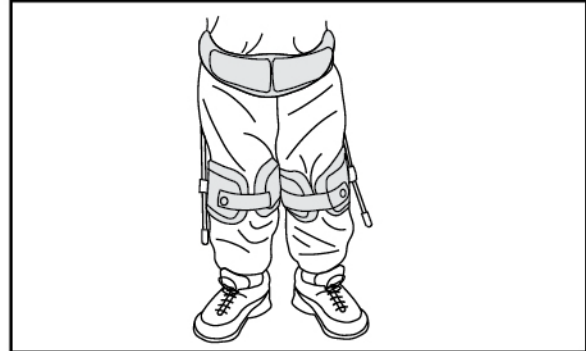
Skin care

Red marks that appear as a result of wearing the orthosis should disappear within 30 minutes of removing the orthosis. The most persistent red marks are usually on the inside part of the thigh under the thigh cuff. Consult your orthotist if the red marks do not disappear within 30 minutes after removing the orthosis.

Orthotist Follow-Up

A one-to-two week post-fitting check-up is recommended to assure the integrity of the orthosis and caregiver fitting technique. The primary purpose of this follow-up is to check for the need to adjust hip abduction to assure proper hip alignment.

Proper Fit Guidelines



Pelvic Band

Location:

SWASH® Classic - Immediately over the ASIS.

SWASH® L.P. - The waist band should rest comfortably on the ASIS. It should be contoured to the shape of the waistline and extend no more than 2 inches / 5 cm toward anterior midline.

Symmetry

For both orthoses, make certain the orthosis is applied as symmetrically as possible. The orthosis should NOT be rotated on the wearer as this can result in loss of control of hip alignment.

Tightness

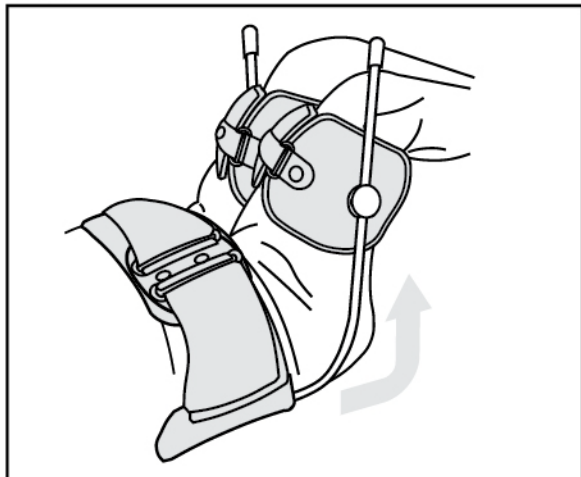
You should be able to insert the fingers of one hand between the padding and the abdomen.

Amount of abduction

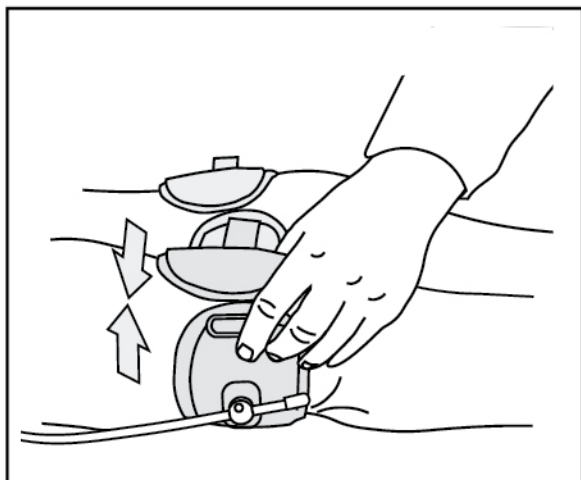
The abduction setting varies considerably from patient to patient, depending on primary and secondary goals for the orthosis. For both non-ambulatory and ambulatory wearers, the "ideal" is to adjust abduction to provide appropriate hip containment and knee clearance.

PROTOCOLS AND PROPER FIT GUIDELINES

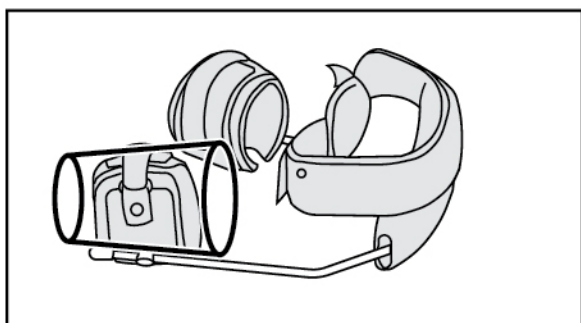
Cuffs



Location - Usually as distal as possible without interfering with popliteus, but may be located up to distal 2/3 of femur if flexion influence is present.

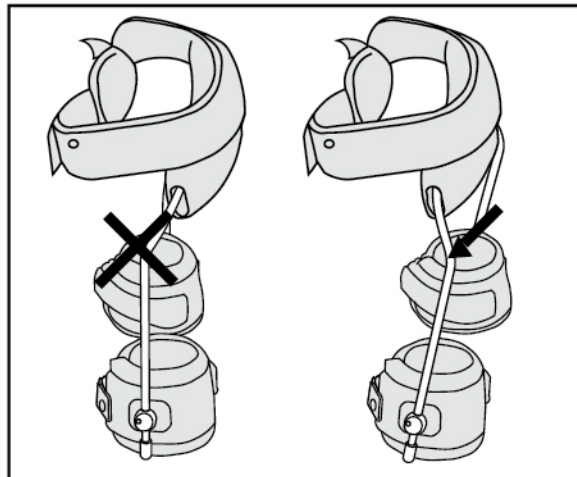


Closure Gap - There should be no more than 2 inches / 5 cm gap between the medial and lateral sides of the plastic. The cuffs should fit comfortably snug, never so tight as to cause red marks or compromise circulation.

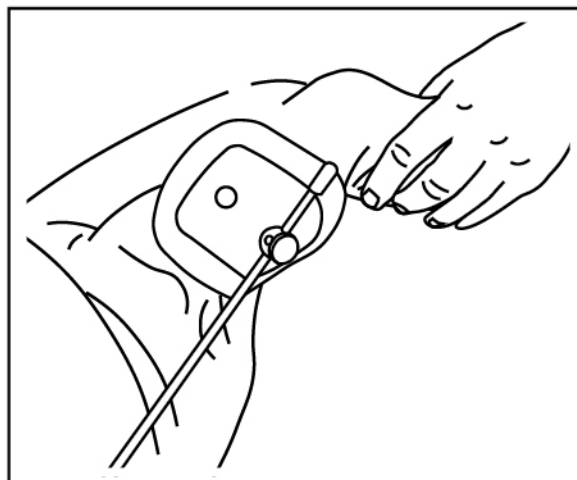


The cuffs are conical shape. They should be fitted so the greater circumference is proximal.

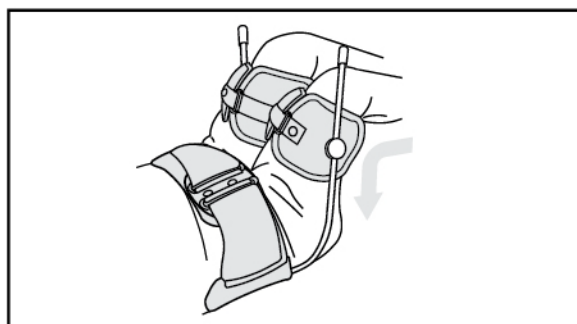
Uprights



Left and Right - There is a left and right for the uprights. When standing, the 1st curve from the distal end should angle to the posterior. If it doesn't, it is on the wrong side.



Length - The distal end of the upright should be in line with the distal end of the cuff padding.



Hip Clearance - The uprights should be as close as possible to the greater trochanters without impinging on them when the hips are flexed.

BENEFITS AND OUTCOMES

Benefits

- Limits or controls adduction when sitting, standing and walking to prevent scissoring
- Provides additional abduction for muscle lengthening and sitting stability
- Provides support throughout the day
- Limits adduction during the night
- May reduce hip displacement caused by strong adductors
- Improves hip alignment
- Can prolong effects of other treatment modalities
- Maintains muscle length
- May delay the progression to surgery

Outcomes

- Improved ambulation when wearing the orthosis. "Gait scores showed improved pelvic symmetry, better knee clearance, and progression in functional walking scales in most cases"
- Longer walking distances using less energy is reported by some parents
- Vertical positions and dynamic walking are associated with improved respiratory, bladder and kidney functions
- Improved trunk control facilitates upper body function for enhanced stretching and other exercises to improve muscle control and coordination skills
- Improved sitting balance means the possibility of using both hands to perform tasks such as eating, playing, manipulating objects, and interacting with others instead of holding the sitting surface for touch balance
- Neutralizing the dislocating forces secondary to high adductor tone may arrest or reduce hip displacement
- Clinically observable impact on the function of the proprioceptive response. This can generally be seen in the
 - a) Reduced tone of the adductors
 - b) Improved posture of the trunk and
 - c) Enhanced coordination of the upper extremities resulting in better reach targeting
- Often helps the wearer overcome pathological movement patterns
- Early mobilization may also reduce subluxation and dislocation of the hips
- Improved respiratory function as a result of the more upright posture

FREQUENTLY ASKED QUESTIONS ABOUT SWASH®

Is the SWASH® usually worn over or under clothing?

The SWASH® is generally fitted under clothing to optimize the control the device has in enhancing hip alignment.

What about toileting?

Generally SWASH® must be removed for toileting because the orthosis interferes with easy donning and doffing of underwear and diapers.

Will using SWASH® strengthen adductors?

The opposite is true because the SWASH® serves to stretch the adductors and cause them to clinically present with lower tone.

When will patients progress to not needing the SWASH®?

The SWASH® helps manage the consequences of high adductor tone. While there may be some carryover in lessened adductor tone after use of the SWASH, it is not known if it will return if SWASH® use is totally discontinued.

Will AFOs still be necessary?

The SWASH® does not alter the need for AFOs. It may, however, change the design criteria for some patients. Because the SWASH® has a significant influence over transverse plane rotation of the lower extremities, AFOs will generally need to be set up in relatively neutral position relative to rotation.

How long should the patient wear the SWASH® each day?

The SWASH® is generally worn at least six hours each day. It can also be very appropriate for use as a night splint.

Are there any side effects to using the SWASH®?

Pressure marks may be evident on inside thigh where the SWASH® overcomes the forces of abnormal adductor tone. These marks should disappear within 30 minutes of removing the SWASH®.

The patient still seems to sit in too much spinal flexion. Can anything be done about that?

115° uprights tend to minimize this problem. Adding a sitting wedge (thicker part under seat, narrow part under legs) can also help to minimize the negative postural effects of tight hamstrings. If the problem persists, return to the orthotist for further adjustments.

How long before a child will "outgrow" his or her SWASH®?

SWASH® will usually fit a child for 2-3 years. Components are sold separately, so it is possible for the orthotist to adjust up to a larger cuff or longer uprights should that be necessary.

INITIAL FITTING ASSESSMENT

Patient ID# _____ Date _____

Physical Therapist _____ Orthotist _____

Physician _____

	WITHOUT SWASH	WEARING SWASH
SITTING (90/90 position)		
Hip adduction		
Pelvic tilt posture due to tight hamstrings		
Sitting height from sitting surface		
Time no touch sitting		
Reaching distance capacity		
Ball catch capacity		
Sit to stand functional performance		
General stability and posture		
STANDING		
Femoral alignment		
Overall stance height		
Foot position and alignment		
Reaching capacity w/extrinsic support		
Reaching capacity w/o extrinsic support		
Stand to squat functional performance		
General Posture		
WALKING		
Incidence of scissoring		
Transverse plane alignment both sides (one limb rotated more than the other?)		
Stride Length		
Stride Base Width		
Heel to toe utilization during gait		
Speed		
Neuromuscular control (jerky? fluid? balance issues?)		
Distance capacity		

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► HYDROTHERAPY

Time for

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By K

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was conceptualized in 1980 at the Madigan Army Medical Center in Tacoma, Washington.⁹ It is a modality of pediatric physical therapy treatment that integrates therapeutic exercises, neuromuscular reeducation, and functional training.

At Danbury Hospital in Danbury, Connecticut, neonatal hydrotherapy is provided to promote neonatal movement for those infants who demonstrate a paucity of spontaneous generalized movements and who also demonstrate poor primary movement repertoires, such as reciprocal leg kicking and hand to mouth. These findings have been correlated with abnormal development.

It has also been found that this treatment often promotes improved state control and state regulation, especially for infants diagnosed with neonatal abstinence syndrome.¹² Neonatal abstinence syndrome consists of a wide variety of central nervous system signs of irritability, (jitteriness, increased tone), gastrointestinal problems (hyperphagia, diarrhea), respiratory symptoms (tachypnea) and autonomic dysfunction.¹²

Sweeney has reported that there is improved feeding proficiency in preterm neonates following hydrotherapy in the NICU setting.¹⁰ Feeding proficiency was measured by duration of feeding which was decreased and (continued on page 8)

"The following article is an excerpt from the March/April 2007 issue of NDTA NETWORK. To learn more about NDTA, visit www.ndta.org."

Pediatric Orthopedics Part IIIa:

PLANE ISSUES AND ACHIEVEMENTS

k, PT, MS, COF/BOC

In Part 1 of this series [Network March/April 2006], we reviewed the influences of normal, strain-inducing, mechanical loads on developing bone geometry and joints. In Part II [Network July/August 2006], we examined the connective and muscle tissues in similar contexts, with a discussion of the relationship between the history of muscle recruitment and clinical evidence of muscle imbalances and soft tissue transformation. Suffice to say that our understanding of the transformation process is still evolving.

In the final three installments, I'll discuss musculoskeletal changes in the spine and lower extremities as they emerge in each cardinal plane, beginning in the sagittal plane in this piece, and progressing into the frontal and transverse planes.¹

Self-organized movement skills develop in the

presence of a system of body segments that are normally linked by soft tissue constraints (Table 1). The intrauterine, flexed-limb position is the most common prenatal position. Full-term healthy neonates, therefore, typically exhibit "physiologic flexion," a remarkably strong, active-and-passive resistance to passive limb joint extension.¹ The shortened state of the muscles, connective tissues, blood vessels, nerves, and skin—all located on the concave side of the flexed joints—follows the final two months of marked body-size increase in utero. By limiting the degrees of freedom in developing movements, the neonatal soft-tissue constraints mechanically guide the course of musculoskeletal as well as neuromotor development.^{2,3} (continued on page 10)

TABLE 1

TORSO	HIP JOINTS	KNEE JOINTS	ANKLE JOINTS
<p>Muscles:</p> <ul style="list-style-type: none"> Pectorals Rectus Abdominus Oblique Abdominals Transverse Abdominus 	<p>Muscles:</p> <ul style="list-style-type: none"> Iliopsoas Proximal Rectus Femoris Piriformis Superior & inferior gemellae 	<p>Muscles:</p> <ul style="list-style-type: none"> All distal hamstrings Distal Gracilis Distal Sartorius Popliteus 	<p>Muscles:</p> <ul style="list-style-type: none"> Tibialis Anterior Extensor Digitorum Longus
<p>Ligaments:</p> <ul style="list-style-type: none"> Anterior intervertebrals Anterior aponeurosis Inguinal 	<p>Ligaments:</p> <ul style="list-style-type: none"> Iliofemoral Anterior capsule 	<p>Ligaments:</p> <ul style="list-style-type: none"> Posterior/medial capsule Anterior cruciate Posterior medial collateral 	<p>Ligaments:</p> <ul style="list-style-type: none"> Anterior joint capsule Anterior talofibular Anterior deltoid fibers
<p>Associated nerves, blood vessels, and skin</p>	<p>Associated nerves, blood vessels, and skin</p>	<p>Associated nerves, blood vessels, and skin</p>	<p>Associated nerves, blood vessels, and skin</p>

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- 7 Patient Perspective: Find a Therapist | 19 Therapy Talk: Orthotics

Protecting Hips at Risk

THE ROLE OF A VARIABLE HIP ABDUCTION ORTHOSIS TO IMPROVE POSTURE AND FUNCTION

BY JAN F.A. SMITS, C.P.O.

In the U.S., there are over a half million adults and children with symptoms of cerebral palsy. The overall prevalence of cerebral palsy was 3.6 per 1,000 in 1996 and 3.1 per 1,000 in 2000 (Bhasin et al). Cerebral palsy is a challenging condition in which patients have to fight “high muscle tone” most of the time and in which coordinated movement is difficult to achieve. This large group of patients is in constant need for our devoted attention.

It is common sense to bring these children to an upright position as early as possible, not only to improve kidney and bladder function, but also to prevent damage at the hip joints. Most commonly, posterior dislocation results from inadequate opposition of adduction and internal rotation of the femur. Spasticity, abnormal muscle coordination, and abnormal synergies compounded by delayed or absent weight bearing result in abnormal development of the acetabulum and the femoral head, and stretching of the joint ligaments. Approximately 60% of children who were not walking by five years of age were likely to develop subluxation of the hip, with the greatest risk in those with severe neurological involvement (Gordon, Simkiss 2006). This statistic strongly supports starting treatment as young as possible; sometimes even before the child can stand or walk.

Traditional hip bracing may cause negative effects, such as a lack of movement and weight bearing; motor functions may be lost in that process. A more appropriate brace would enable the child to have a normal range of motion while maintaining the hip in good alignment to help prevent subluxation or dislocation. If a brace can accomplish these tasks successfully, it may be possible to delay or even prevent surgical intervention.

Such a brace must be able to create a “new balance,” even when performing independent flexion or extension. During flexion or sitting, a maximal abduction is required,

while during walking a minimal adduction is needed—just enough to prevent scissoring. An “ideal” brace would self-adjust to permit this change from one extreme into the other without having to make manual adjustments.

This “ideal” brace could also be beneficial post-surgically. Post-surgical complications, such as deterioration of the non-operated hip, avascular necrosis of the femoral head, osteoporotic hip fractures, and nerve palsies have been reported following adductor tenotomy. It is proposed these results could be improved with post-operative bracing

Orthoses like the Atlanta or Newington brace were designed to achieve a 90° abduction angulation of the femur and are used primarily for treatment of Perthes disease. The Scottish Rite orthosis allows free flexion and extension, a functional advantage for management of Perthes, but the abduction degree is fixed during both hip flexion and hip extension. This fixed angle is beneficial for Perthes, but restricts normal anatomical movement of the hip, a risk for the patients with cerebral palsy not inclusive of Perthes disease. Perthes is normally treated at the age of six or seven,

Fig. 1

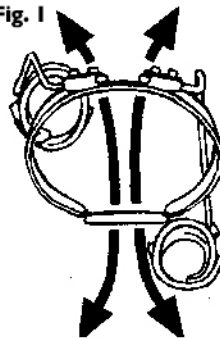


Fig. 2



Fig. 3



that would appropriately position the femoral head in the acetabular socket while still allowing function.

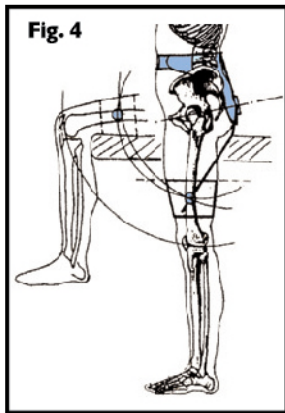
Such a device is available. Called SWASH, an acronym for “Sitting, Walking and Standing Hip Orthosis,” it is generically referred to as a Variable Abduction Hip Orthosis (VAHO). SWASH offers independent hip flexion, maximal abduction during hip flexion, minimum abduction during hip extension and weight-bearing, and continuous variation of abduction between these extremes. As simple as it looks, the SWASH hip orthosis has comprehensive biomechanical functions. It prevents adduction while standing and walking, and only gets into abduction during sitting mode, thus reducing contractures and creating a stable sitting base.

while patients with CP benefit most when we can help them manage the adductor tone, ideally from a very early stage and on.

The indications for a VAHO are subluxation, scissoring gait, and unstable sitting. Scissoring can often be observed during the resting period. In that case the brace is also indicated during the night. The users can be children with spastic diplegic or spastic quadriplegic, even children with spina bifida with their hips at risk may benefit from this VAHO. Optimum results are best realized when the child can be fitted at the youngest age possible, ideally one to four years of age. In these children, this VAHO may help to manage dystonia, hip migration, scissoring gait interfering with ambulation, and hip adduction, which limits independent sitting.

Dislocated hips and hip flexion contractures of more than (continued on page 22)

(Protecting Hips at Risk continued from page 21)



20° are contraindications for the use of a VAHO. Excessive tibial torsion might cause problems for “normal” walking. Tibial torsion cannot be solved by this brace. Internal rotation of the leg can normally be influenced in a positive way.

Although the hip joints of the orthosis are placed dorsally to the natural joints, the mechanics of the joints are designed to compensate for this mal-placement. Moving the hip joint from extension into flexion will not cause any migration or chafing of the thigh cuffs or the pelvic band.

The axes of the hip joints are oblique angled and although they describe a circle in space, the projection of this circle on the floor shows an oval, which results in the typical movement of the thigh cuffs, hardly any abduction when standing and walking, and a maximum abduction when going into flexion. If we look from cranial, the joint housings are under a 20° angulation, which places the neutral balance within reach of the gravity line.

For normal walking and standing, a virtual straight path is used, while the cuffs reach their neutral point at the gravity line of the body. Adductor tone and movement fixes the pelvic band in an extended position, thus stabilizing the trunk. When moving from standing into sitting the cuffs reach the narrow end of the oval, resulting in maximum abduction, thus creating a wide base for stable sitting and prevention of contractures. (Fig. 1 & Fig. 2)

The hip joint assemblies will allow for two different adjustments: the degree of abduction

and the width of the uprights. For these adjustments, the axis finds its bearing in a nylon housing, which is fixed on the pelvic band. The nylon housing can be rotated to influence the amount of abduction. The appropriate width over the greater trochanters can be adjusted by sliding the axis in or out. (Fig. 3)

The thigh cuffs will guide the legs throughout the whole range of motion. The pathways of motion of the thigh cuffs mimic the pathways of motion of the femurs. (Fig. 4) The pressure on the inside of the leg can be high, so a long leverage will decrease the amount of pressure. The control and the effect are best when the cuffs are close to the condyles as long as they don't prohibit normal sitting, kneeling or squatting.

The thigh cuffs can also be rotated around the upright for achieving the proper location of the retaining rings, which should be free from the sitting surface. This adjustment may be done when wearing the brace.

Every adjustment must be verified for symmetry, which is of the utmost importance for proper function and appropriate result. The forces are passing 21 joints and angulations when we follow the route from the right inside leg to the left inside leg. Some of the angulations can be critical for the right balance created by this brace. Differences in leverage or angulation will also create imbalance in muscle function, because the brace is the counter force for all muscle activity around the hips and legs. For this reason, it is important that the orthotist continually check to assure symmetry with all adjustments.

CASE STUDY #1

In Fig. 5 we see a seven-year-old boy with severe scissoring. He is very persistent in his attempts to walk, but after only three or four steps his feet tangle up and he has to start all over again. Notice the improvement (Fig. 6) in his posture and the position of the feet when fitted with the VAHO. A little fine-tuning by the orthotist accommodated for the varus position and the inner rotation of especially the left leg. Normally the cuffs are kept just free from each other. In this particular case a little more abduction was needed, because of the varus position of the legs, to make sure that the feet can pass.

The weaning time for the SWASH brace can be four or five days, depending on the child. A wearing time of approximately six hours during daytime is normally enough to keep contractures under control. If scissoring occurs during the night, it is advisable to use the brace also during the night.

CASE STUDY #2

Fig. 7 shows a child who demonstrates the sitting instability frequently seen in children with C.P. They always keep one or even two hands on the chair to protect themselves from falling down. Fig. 8 shows the wide base created by the SWASH offers a solid base for sitting. When the child experiences this, he will lift his arms higher and higher. The child will gradually discover his hands are no longer needed at the chair for safety reasons and he will be freer to use his hands for other tasks—to sit at table to play, for example. Having a (continued on page 23)

(Protecting Hips at Risk continued from page 22)



SWASH user confident enough in the brace to perform more advanced task means also that you added quality of life.

CASE STUDY #3

The eight-year old in Fig. 9 has spastic diplegia and has already had dislocated hip surgery. She demonstrates the hard task of walking with just her walker. Her face shows the effort she must make for each step. After being fitted with SWASH (Fig. 10), she was able to walk more relaxed, could coordinate her feet very well and could walk longer distances.

CASE STUDY #4

Fig. 11 shows a young lady who readily demonstrates how adductor tone can put the hips at risk for subluxation or dislocation. In Fig. 12, with the orthosis fitted, you can readily see the improved posture and reduced stress on the hips.

CASE STUDY #5

High adductor tone is one of the most common and obvious symptoms of spastic cerebral palsy. This tone affects posture of the entire body. It drives the feet into pronation, internally rotates the lower limbs, and has a flexion influence on both the knees and hips. This lower extremity posture influences the trunk into a slouched posture as demonstrated in this 14 year old in Fig. 13. The VAHO shown in Fig. 14 exerts an external rotary influence on the lower limbs (without twister cables), the knees and hips are influ-



enced more towards extension, and the trunk stands more erect. The biomechanical effect of the tone is thereby reversed. It exerts an external rotary influence on the lower limbs (without twister cables), the knees and hips are influenced more towards extension, and the trunk stands more erect.

CASE STUDY #6

Fig. 15 shows a 2 1/2-year old with neuronomigrational defect and tethered spinal cord release. With any attempt at sitting, she would fling herself backwards. With SWASH, shown in Fig. 16, she was able to find a good position of balance so she was able to sit for long periods of time.

In the "ideal" world, the therapist and orthotist jointly review the biomechanical function. The following is an assessment form that we encourage therapists to complete before and after fitting. Unfortunately, I don't think it is often used. Most prescriptions from physicians are written based on recommendation from the ther-

apist. However, there certainly are incidences where a physician will write a prescription and the patient goes directly to the orthotist. The latter is very unfortunate because the therapist is key to helping the wearer achieve maximum benefits from the orthosis. ■

Jan F.A. Smits, C.P.O. is director of research and product development at Camp Scandinavia in Helsingborg, Sweden. He can be reached at jan.smits@campscandinavia.se

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(continued on page 24)

(Protecting Hips at Risk continued from page 23)

SWASH® Initial Fitting Assessment

Patient ID# _____

Dx _____ Age: _____

WITHOUT SWASH**WEARING SWASH****SITTING**

Hip adduction		
Sitting height from sitting surface		
Time no touch sitting		
General stability and posture		
Sit to stand functional performance		

STANDING

Femoral alignment		
Foot position and alignment		
Distance between feet		
Overall stance height		
General Posture		

WALKING

Neuromuscular control (jerky? fluid? balance issues?)		
Incidence of scissoring		
Transverse plane alignment both sides (one limb rotated more than the other?)		
Stride Length		
Heel to toe utilization during gait		
Speed		

Primary Goal: _____

Secondary Goal: _____

Waist: _____ Waist to Knee _____ Thigh _____ Walking Aid? _____

FITTED WITH: ☐ CLASSIC ☐ LP SIZE: Pelvic _____ Cuffs _____ Uprights _____

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A randomised trial of Botulinum Toxin A (BTX-A) combined with hip bracing in children with marked spastic cerebral palsy: Impact on functional outcomes

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Objectives: Following presentation of the delay of progression to surgery outcomes the present study aims to determine whether BTX-A combined with a variable hip abduction orthosis improves gross motor function in children with marked spasticity and hip displacement.

Design: A 3 year prospective randomised multicentre trial with concealed allocation to either BTX-A and bracing and/ or observation.

Methods: Ninety children with bilateral spastic cerebral palsy with hips at risk (MP > 15 < 40%) were entered. After randomisation children were allocated to receive either intramuscular BTX-A every six months of 16U kg/bodyweight (Botox, Allergan) to both adductors and hamstrings with the addition of 8 hours use per day of the variable hip abduction orthosis (SWASH, CAMP Ltd) and /or observation. In the observation group no concomitant hip bracing was undertaken, though physiotherapy and specialised seating were monitored. When MP > 40 % and /or the AI > 27° they exceeded study criteria and were presented for independent (blinded) analysis by a surgeon to determine progression to surgery. Changes in function were measured using the Gross Motor Function Measure (GMFM 88) measure at baseline and 12 monthly intervals until study completion or progression to surgery. Data for functional outcomes was analysed blinded to group allocation (BTX-A and control) using generalised estimating equations (GEE). Secondary analysis analysed annual GMFM change by Gross Motor Function Classification System (GMFCS) level.

Results: *Post hoc* analysis demonstrated no differences between the groups at baseline (Est. mean diff. 1.6; 95%CI -1.7, 4.9; $p=0.4$). Over the 3 yr f/u there was a significant annual improvement in GMFM of 4.6 % per year for the BTX-A group (95%CI 3.5.7; $p=0.001$). Between group differences demonstrated an annual improvement for the control group that was 1.2% less per annum than the BTX-A group (95%CI -2.8, 0.4; $p=0.13$) however these group differences were not significant. Adjusting for GMFCS level at baseline for Level II& III subjects the control group had a 2.6% greater annual change in GMFM ($p=0.02$) but more of these children progressed to surgery; in Level IV the BTX-A group had a 1.9% greater annual change ($p=0.3$, NS) and Level V there were a 1.5 % annual change in GMFM for both groups ($p=0.003$). Using the log rank test for comparing progression to surgery between the groups there was a statistically significant treatment effect ($p=0.004$) for the BTX-A and brace group.

Conclusion(s): There was a positive delay in the progression to surgery for BTX-A and hip bracing in the conservative management of hip displacement compared to standard conservative management. Both groups improved in gross motor function over time, however there was a greater annual improvement for the BTX-A treated group. There were no significant differences between the groups according to level of severity.

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C:2

Botulinum toxin A (BTX-A) combined with hip bracing delays the need for surgery in children with bilateral cerebral palsy: a randomized clinical trial and survivorship analysis

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Objectives: To determine whether intra-muscular injections of BTX-A combined with a variable hip abduction orthosis, delay or reduce spastic hip displacement and progression to soft tissue surgery for children with spastic hip displacement.

Design: A 3-year, randomized multicentre trial with concealed allocation to either BTX-A and bracing or observation. **Method:** Ninety children with bilateral spastic cerebral palsy with hips at risk (migration percentage MP > 15 < 40% at entry) were entered. After randomization children were allocated to receive either intramuscular BTX-A every six months of 16U/kg/bodyweight (Botox, Allergan) to both adductors and both hamstrings with the addition of 6 to 8 hours use per day of the variable hip abduction orthosis (SWASH, CAMP Ltd) or observation. BTX-A was given under mask anaesthesia. In the observation group no concomitant hip bracing was undertaken, though physiotherapy and specialized seating were monitored. Children were followed up six monthly for 3 years and when their MP > 40% and/or the Acetabular index (AI) exceeded 27° they were presented by the research physiotherapist for independent analysis by a surgeon who was blinded to group allocation to determine progression to surgery (censored). Data from all sites for admission to the study and progression to surgery was reviewed in the lead center. Data for progression to surgery was analysed independently using Kaplan Meier survivorship analysis.

Results: Using the log rank test for comparing progression to surgery between the groups there was a statistically significant

treatment effect ($p=0.02$) for the BTX-A and brace treated group. At 3-year follow up 73% of the BTX-A treated group had not progressed to surgery (95% CI 0.55, 0.84) while in the comparison group only 53% had not progressed to surgery (95% CI 0.37, 0.67).

Conclusion(s): Injections of BTX-A combined with SWASH bracing reduces hip displacement and delays or prevents the need for orthopaedic surgery.

Acknowledgements: National Health and Medical Research Council grant, (580753) Australia, Murdoch Children's Research Institute salary support grant. Educational grant from Allergan PLC, provision of SWASH braces by CAMP Ltd Sweden.

C:3

A single blind randomized trial of Botulinum toxin A (BTX-A) and upper limb training in congenital hemiplegia – activity, participation, and health-related quality of life

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Objectives: To determine whether training with or without intramuscular BTX-A enhances function, participation, and health-related quality of life.

Design: A single-blind matched randomized trial of upper limb training with or without BTX-A.

Setting: A tertiary referral center

Participants: Thirty children with congenital hemiplegia matched for age (5–15 years), sex, and side of hemiplegia.

Method: Baseline assessments were made in the following domains of the International classifications of Functioning, Disability and Health (ICF): Impairment – Resonant Frequency (RF); Activity – Melbourne Upper limb assessment; Participation – Paediatric Motor Activity log (PMAL); Canadian Occupational Performance Measure (COPM) and societal change – Goal Attainment scale (GAS); Child Health

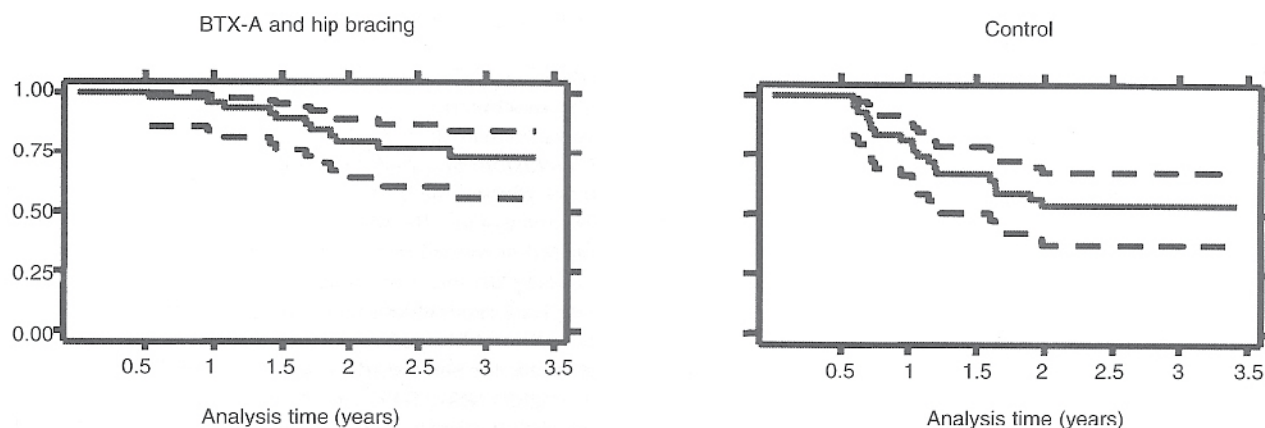


Figure C:2

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