

Fuzion™

CLINICAL WHITE PAPER

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Understanding the Treatment Options of the Fuzion Orthotic System for Complex Patient Profiles

"Fusion" is the process of joining two or more things together to form a single entity. Orthomerica's *Fuzion* system combines clinical expertise with technical excellence to produce a line of orthotic devices for the most challenging patient profiles. Patients with heightened sensitivities, pain, hypertonicity, severe deformities, impaired motor function and contractures present with many unique needs. Enhancing the comfort of orthotic control is key to increasing compliance and ultimately to increasing the overall benefits of an orthotic care program.

KEY FEATURES

Current concepts in optimal patient care have identified five key areas for success. The purpose of the Fuzion system is to provide advanced treatment options to better address complex situations such as:

- Heightened sensitivities to touch, pressure, movement and temperature
- Excessive loading of ligaments, muscles, tendons and joints
- Unstable joints and segments needing total contact to optimize alignments
- Variable tone secondary to upper motor neuron disruptions, postures, medications, pain and stress
- Unresolved pressures
- Volume changes

1. Custom
2. Comfort
3. Control
4. Compression
5. COMPLIANCE

The multidurometer foundation and individual design of each Fuzion device provides strategic compression, relief, total contact, control and improved comfort. Material improvements optimize wearing opportunities for pediatric and adult patients who have experienced limited acceptance of more traditional plastic designs. The ease of donning, doffing and cleaning also enhances the wearing program for both patients and caregivers. Ultimately, the result is an improved quality of life for everyone involved in daily patient care tasks.

Key features of the Fuzion



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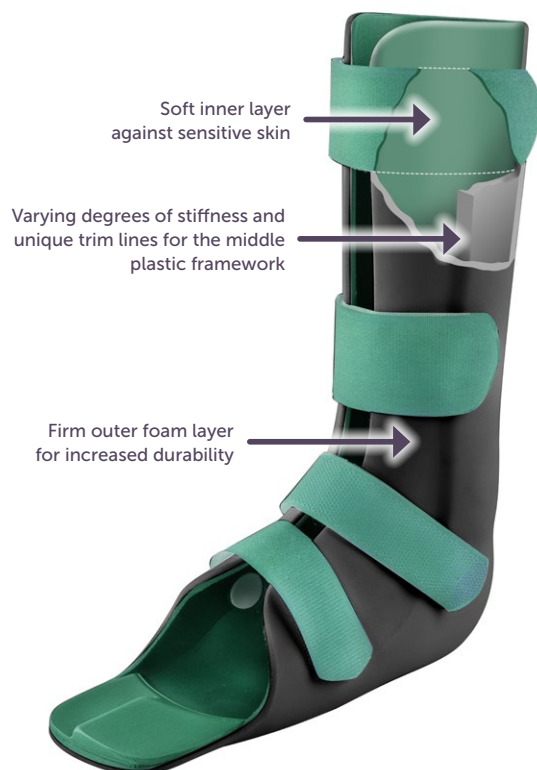
REHABILITATION PROGRAMS

Custom orthoses provide an efficacious alternative or adjunct to both pharmacological and surgical treatment programs. Rehabilitation programs rely on orthoses to sustain, promote, enhance and reinforce therapeutic efforts. Many Fuzion design variations exist to best meet the needs identified by the interdisciplinary treatment team. In many instances, further clinical and technical consultations serve to optimize orthotic design details based upon the experience and expertise available at Orthomerica. Founded in 1989, Orthomerica continues to be the partner of choice in the design and fabrication of custom orthoses.

ABSTRACT

Some of the most challenging patient profiles require the refinement of traditional orthotic approaches. Patients often experience heightened sensitivities to touch, pressure, movement and temperature. Such sensory integration dysfunctions can result in negative experiences and reactions to corrective pressures in hard plastic orthoses. Ongoing struggles with pain, discomfort, excessive pressures, stability and control can significantly impact motivation and potentially detract from an orthotic treatment program. The Fuzion system addresses the need for a different approach with new material properties and design features.

Strategic layering of multidurometer materials



The Fuzion line of multidurometer orthoses offers alternative design considerations for complex patient profiles. The internal lining is soft and forgiving to increase comfort over sensitive areas. Customizing the middle framework with a variety of plastic options allows control of alignment, determines the overall rigidity or flexibility of the system, prevents the progression of deformities, and accommodates bony prominences as needed for each individual. The final outer layer completes the Fuzion system by securing the soft inner liner and frame, as well as to enhance donning and increase durability.

Chronic medical conditions and disabilities



Pain and discomfort
Severe deformities
Abnormal loading of tissues
Dysfunctional postures
Allodynia



Heightened sensitivities
Impaired motor function
Unstable joints
Unresolved pressures
Hyperalgesia



Hypertonicity
Contractures
Dysfunctional alignments
Volume changes
Sensory integration dysfunctions

INTRODUCTION

The purpose of an orthotic care program may include any or all of the following: support and alignment of body segments and joints; control of ineffective or disruptive movements; prevent pain and discomfort; provide or enhance stability; and limit or enhance motion. The foundational concept of the Fuzion orthoses is to address as many of these goals as possible, especially in medically complex patients who have struggled with more traditional orthotic designs.

Patients with chronic medical conditions require improved management of sensorimotor and proprioceptive inputs. By focusing on the influence and impact of the somatosensory system, the Fuzion system provides patient-friendly support to

Negative sensations experienced by patients

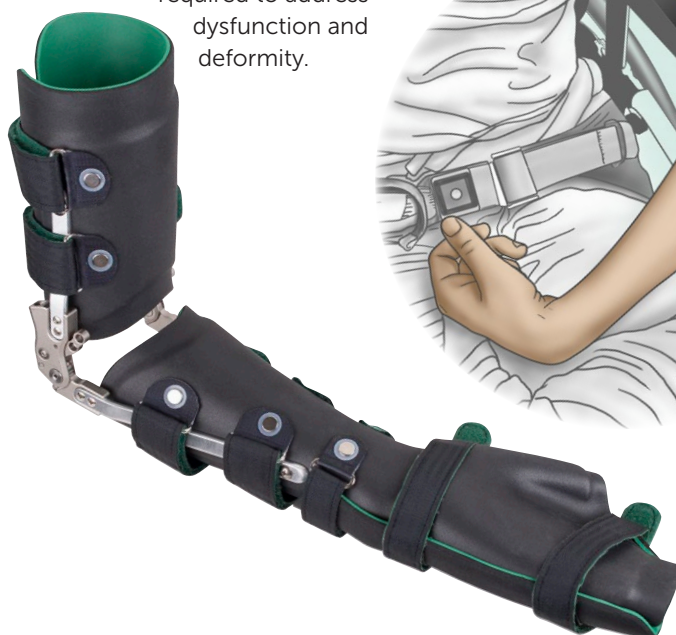
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|------------------|--|
| Spontaneous pain | painful sensations are felt without any apparent or evident stimulus |
| Allodynia | pain due to stimulations that do not normally cause pain |
| Hyperalgesia | increased pain response to a painful stimulus |
| Dysesthesia | an unpleasant sensation, may be spontaneous or provoked |
| Paresthesia | an abnormal sensation, may be spontaneous or provoked |
| Summated pain | a combination of any/all of the above |



kinesthesia, neural control, neuromuscular function and balance. As a result, improvements in comfort and compliance serve to supplement therapeutic programs and improve the quality of life for patients and their families.

There are many types of painful sensory symptoms that disrupt therapeutic and orthotic treatment programs. These clinical symptoms are found in many different patient populations including but not limited to: cerebral palsy, spina bifida, diabetes, peripheral neuropathies, Guillain-Barre, Charcot-Marie-Tooth, Ehlers-Danlos syndrome, complex regional pain syndrome, fibromyalgia, peripheral neuropathies, and spinal cord injury. The Fuzion system has been reported to successfully address many of these challenging presentations by providing soft stability and comforting compression. Orthotic clinicians are also able to provide Fuzion designs as a preemptive solution for at-risk patients by preventing sensitization of the nervous system to the forces and control

required to address dysfunction and deformity.



CLINICAL CHALLENGES

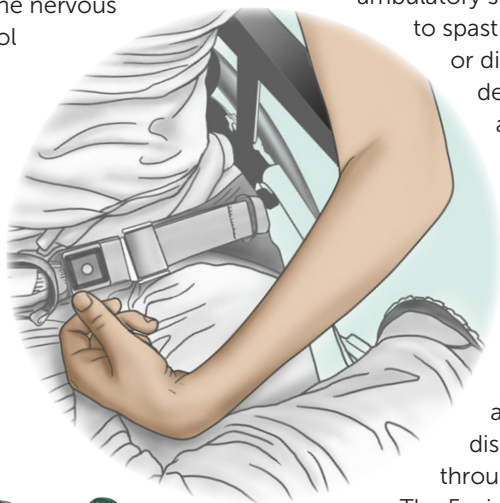
The Fuzion system provides clinical differentiation of treatment approaches in many areas; only a few of the common challenges are covered here.

Hypertonicity — Patients with upper motor dysfunction often present with spasticity, clonus, muscle weakness, loss of dexterity and fatigue. Sustained contractions result in altered postures and alignments, with continuous stress and strain of the physiologic systems. Autogenic inhibition is commonly seen in low-force, prolonged stretches and results in relaxation of the affected muscle(s). The Fuzion system applies gentle and sustained pressures to promote relaxation.

Contractures and severe deformities — Patients with chronic medical conditions are susceptible to contracture formation in both ambulatory and non-

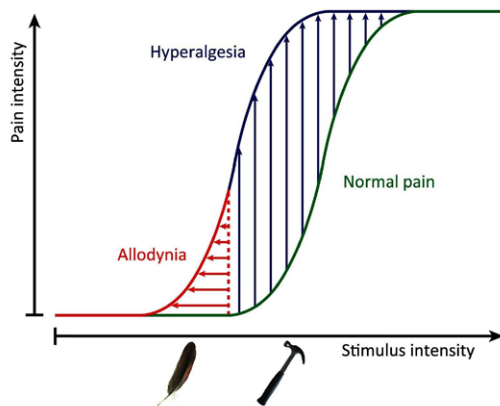
ambulatory situations. Whether secondary to spasticity, impaired motor control or disuse, soft tissue shortening develops on joint concavities and soft tissue lengthening occurs on joint convexities. In the pediatric patient, joint congruencies become permanently altered and lead to the development of severe deformities. Adult patients often experience pain and discomfort as the contractures alter the magnitude and distribution of forces transferred through mature joint configurations.

The Fuzion system offers a softer solution when accommodation is needed as well as improved comfort when progressive realignments are planned.



Sensory integration dysfunctions — Different kinds of painful sensations are noted on the top of the previous page and are especially difficult to address in patients with medically complex conditions and cognitive limitations. In particular, allodynia and hyperalgesia are often underreported yet can significantly impact the patient's acceptance of or ability to acclimate to an orthosis. Patients with allodynia may be especially sensitive to static touch or pressure, dynamic contact, changes in temperature and normal joint function. Hyperalgesia can be localized or general as a result of pain on the injured and/or surrounding tissues. The soft inner lining of Fuzion designs decreases pain and discomfort, and minimizes negative reactions to corrective pressures.

Allodynia vs. Hyperalgesia



Lolignier, S., Eijkelkamp, N. & Wood, J.N. *Pflügers Arch - Eur J Physiol* (2015) 467: 133. doi:10.1007/s00424-014-1532-0

Unresolved pressures — Many orthotic patients have bony prominences, progressive deformities and/or dystonic movement patterns that result in discomfort and possibly skin breakdown within an orthosis. Early signs of pressure or friction produce a reddened area or callus, and may also be accompanied by blisters and skin breakdown. These concerns are effectively addressed by the Fuzion designs with the soft inner layer and strategic design of the middle plastic framework. The plastic will be selected based upon the desired degree of rigidity or flexibility, and custom trim lines and cut-outs avoid pressure-sensitive areas.

The designs and features of the Fuzion systems can be a successful alternative to traditional orthotic management of complex patients. Clinical experience has shown that the total contact, circumferential plastic and foam materials of the Fuzion system are well tolerated by most patients. Feedback from patients, orthotists, therapists and family members has been extremely positive. Protecting joint integrity, positioning for optimal function, and preventing continued progression are

foundational components of improving the quality of life for Fuzion patients.

CLINICAL SOLUTIONS

Many years of clinical experience with these most challenging patients led to the development of the Fuzion system. The multidurometer material blends softer materials for increased comfort within a rigid framework to maintain control and alignment. Circumferential designs add hydrostatic forces over soft tissue and body segments. This is very similar to applications used in the sports arena to enhance muscle recovery, lower perceived pain and fatigue, decrease muscle soreness, and prevent damage to contractile muscle fibers. Compression is now commonly advocated for athletes to enhance muscle recovery, lower perceived pain and fatigue, decrease delayed-onset muscle soreness (DOMS), and prevent excess damage to contractile muscle fibers.

These same benefits of compression have been used in different therapies with soft splinting for patients with hypermobility disorders, chromosomal disorders, muscular dystrophy, sensory processing disorders, Rett syndrome, cerebral palsy, autism, Angelman syndrome, etc. It is evident that patients with complex medical conditions benefit from orthotic compression to suppress spastic responses, decrease tone, decrease pain, improve posture, increase range of motion, maintain skin integrity, improve limb awareness, decrease edema, and increase comfort. Fuzion is the only orthotic system to maximize the benefits of compression with its unique line of custom designs.

Hydrostatic compression over soft tissues is a series of three-point pressure systems—essentially a “clinical hug”. The advantages experienced by rehabilitation populations are similar to those obtained in the sports and therapeutic environments:

- Improved joint and segment stability
- Muscle support
- Altered blood flow
- Increased oxygenation
- Decreased edema
- Increased security
- Perception of decreased weight
- Improved alignment and control of affected joints
- Improved function and movement patterns
- Improved posture and balance

The Fuzion system is appropriate for many different types of orthotic treatment programs. Dosing of orthotic wearing times impacts full- and part-time use, therapy applications, nocturnal stretching programs, non-ambulatory and positioning strategies, activity-specific designs for ADLs and IADLs, and desensitization opportunities. Clinical and technical collaborations individualize the orthotic treatment program and optimize success for each patient.

Clinically differentiating features of the Fuzion system

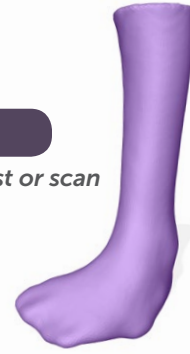
- ✓ Circumferential compression
- ✓ Varying degrees of flexibility and stability
- ✓ Greater control and comfort
- ✓ Improved compliance
- ✓ Ease of modifications
- ✓ Manage volume changes
- ✓ Counterbalance the negative influences of sensory integration dysfunctions
- ✓ Decrease abnormal loading
- ✓ Promote transitional (or dosed) programs
- ✓ Provide joint and segment stability
- ✓ Suppress spastic responses
- ✓ Manage sensorimotor and proprioceptive input
- ✓ Decrease progression of deformities
- ✓ Prevent further complications
- ✓ Increase mobility
- ✓ Address unresolved pressures
- ✓ Improve quality of life

PRODUCT DETAILS

The designs and features of the Fuzion system can be a successful alternative to traditional orthotic management of challenging patients. The total contact soft inner liner, strategic framework of the middle plastic layer, and the circumferential outer surface fuse together to create a unique orthotic system. The Fuzion system's five C's of success are shown here.

CUSTOM

from a cast or scan



COMPRESSION

of segments and soft tissues



COMFORT

with a variety of multi-durometer material combinations



CONTROL

of unwanted motions and alignments

COMPLIANCE

and improved quality of life!



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CONCLUSION

Fuzion designs offer triplanar support and alignment with maximum control and comfort. The circumferential design provides total contact compression to align joints and relax muscles. Fuzion braces are fabricated utilizing Orthomerica's unique heat adjustable plastic inner shell for ease of clinical modifications. The plastic inner shell can also be designed to provide perimeter support with only the soft inner and outer layers covering sensitive areas and bony prominences. The Fuzion's design and materials promote greater patient compliance for a variety of challenging clinical conditions, and was specifically designed for patients who have not received optimal benefit from traditional plastic designs.



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Fuzion™

CLINICAL WHITE PAPER #2

The Fuzion Orthotic System for Patients with Cerebral Palsy and Lower Extremity Pain

KEY CONCEPTS

Cerebral palsy (CP) affects two to three children of every 1,000 live births, and represents approximately 764,000 children and adults living with this condition in the United States. Over 500,000 of these people are under the age of 18 years. It is estimated that 25%–70% of individuals with cerebral palsy experience pain resulting from orthopedic, gastrointestinal, surgical and rehabilitative procedures and/or conditions. As a result, severe consequences to a child's overall health, happiness and quality of life may occur if the pain is not managed effectively. Unidentified or addressed, children and their families may experience fear, frustration, anxiety, depression, social withdrawal and inability to cope in a situation when medical support is so important.

It is estimated that 75% of children and up to 84% of adults with cerebral palsy experience pain, with at least half reporting persistent pain on a daily basis at multiple locations. Mild, moderate and severe levels of pain were described by approximately 60%, 25% and 15%, respectively. More than 25% of children endure chronic pain that disrupts their development and independence. Activities of daily living (ADLs) are also impacted across the lifespan as many patients resort to a reduction in function to manage and minimize their pain.

BIG PICTURE

An important aspect in the medical management of patients with cerebral palsy is transitioning the mindset from a pediatric pathology to a lifespan

disability. While CP is a lifelong condition, many early intervention programs exist and have focused on the childhood years while fewer programs focus on the adolescent and adult years. Walking difficulties are increased with the advancement of contractures, pain and fatigue. Joint subluxations and dislocations negatively impact ambulatory abilities and potentials. Arthritis and joint deterioration also occur as the result of years of altered joint alignments. This is evidenced with more than 25% of adults with cerebral palsy reporting declines in mobility compared to early activity levels and abilities.

Although the neurological injury is non-progressive, adults with CP develop associated musculoskeletal and neurological symptoms as they age. It is important to ensure that lifelong care programs support and expand upon early intervention efforts. The success of the transition from pediatric to adult status relies on effective communication between and collaboration of the entire medical team, patients and the families. Patients will not continue to flourish with a simple "hand-off" to adult care providers. Instead, an anticipatory clinical "handshake" with the next level of care ensures the continuation of developmentally appropriate environments and treatments.

Ultimately, patients with cerebral palsy have a strong desire to continue their mobility, independence and activity levels. Early intervention, continuous care and advanced orthotic management programs are key to maintaining the structural integrity of affected limbs. New materials and design concepts like the Fuzion orthotic system

have been shown to address much of the pain, discomfort and heightened sensitivities experienced by challenging patient profiles. Operating in a true team environment optimizes outcomes and abilities at many levels for patients affected by disorders of posture and movement.

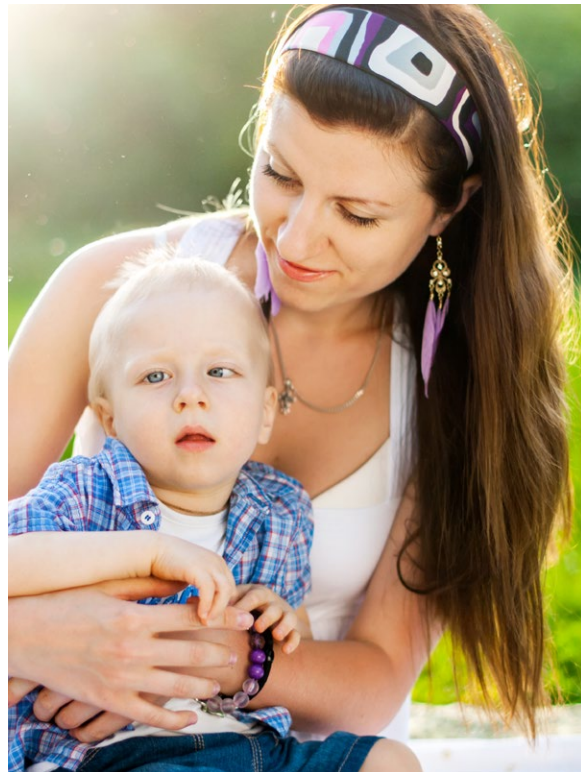
ABSTRACT / SUMMARY

Cerebral palsy encompasses a variety of clinical presentations secondary to non-progressive injury and malformation of the developing brain. Spasticity is a common form of CP, creating contractures and joint deviations that require therapeutic and orthotic care, and may also require surgical interventions. Many different orthopedic conditions may contribute to pain, and effective medical team management is necessary for patients to meet their own physical, psychological and functional goals. Effective orthotic design concepts help to prevent the loss of function and deterioration of quality of life associated with pain and declining mobility. This is especially important during the adolescent years to maintain adherence to treatment programs, and to maintain structural competence of the lower extremities during a period of time when increasing body weight presents increasing challenges to the musculoskeletal system. Educational strategies for both the patients and families should focus on promoting independence and improved outcomes for adolescents, while also developing responsible health care attitudes for their adult years.

INTRODUCTION

Permanent and non-progressive brain damage and the associated effects on the musculoskeletal and motor control systems affect individuals diagnosed with CP in different manners. Cerebral palsy presents with spastic, dyskinetic, ataxic and mixed forms; with spasticity affecting 70%-80% of individuals. It is important for health care providers to understand that while the damage to the brain may be static, the impact on function and abilities changes over time. Different orthotic challenges exist for the pediatric, adolescent and adult age groups relative to functional skills, walking, ADLs and instrumental activities of daily living (IADLs), and lifespan skills required to maintain independence.

Many exercise, health, and rehabilitation efforts focus on a "use it or lose it" approach. In contrast, adolescents and young adults with cerebral palsy may be faced with a "conserve it and preserve it" approach as they deal with pain, progressive musculoskeletal impairments and changing functional deficits. Young adults may report barriers



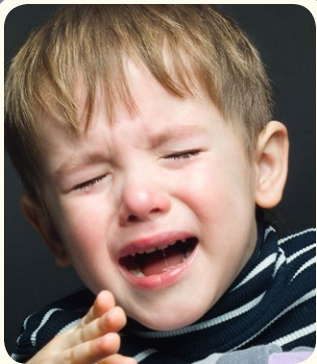
to continued health care, and as many as 75% of people with cerebral palsy who were previously ambulatory have stopped walking by the age of 25 years. Another significant drop in walking abilities occurs around 45 years of age as fatigue, pain in weight-bearing joints, poor balance, and inefficiency of movement culminate after years of unintended functional abuse. This decreased function significantly impacts a person's ability to maintain health and physical function, as well as negatively influences behavior and social relationships.

While pain is a recognized issue and secondary impairment, the long-term changes in somatosensory and pain processing systems are not well understood. Pain begins in childhood, persists throughout adolescence, and is often exacerbated in adulthood. In contrast to unaffected people, many young adults find it difficult to adhere to a regular exercise program for a variety of reasons beyond the physical limitations. These include but are not limited to inadequate facilities, lack of knowledge by staff and trainers, cost of membership at fitness facilities, discontinuity from regular and specialty health care visits, and low perceived value. Poor exercise habits begun in adolescence carry over into the young adult and adult years.

There are many factors to be considered regarding the medical care needs for adolescents and young adults, such as: severity of involvement, type of cerebral palsy, daily assistance needed, living environment (i.e. home with parents, independent, group home, etc.), overall level of independence, and other associated conditions involving cognitive, physical, visual or auditory impairments. Many young adults with cerebral palsy remain reliant on their parents or health care providers to make important decisions and choices. Parents should be encouraged to support their adolescent children to become more proactive in their own health care programs. Early engagement in health care choices will allow young adults with cerebral palsy to take on the responsibilities and challenges in directing and participating in ongoing medical care that addresses their personal needs and optimizes their individual experiences.

BACKGROUND / PROBLEMS

Rehabilitation programs for children with cerebral palsy often focus on the motor disabilities, as standing and walking are important goals for most families. It is important to note that numerous associated conditions must also be addressed across the lifespan. These conditions may involve any combination of the following: seizures, sensory and perceptual alterations, growth disorders, intellectual impairments, visual disruptions, communication disorders, auditory impairments, cognitive deficits, learning disabilities, and a variety of orthopedic conditions. Brief descriptions of common orthopedic conditions are listed in the table below, and some will be discussed in more detail.



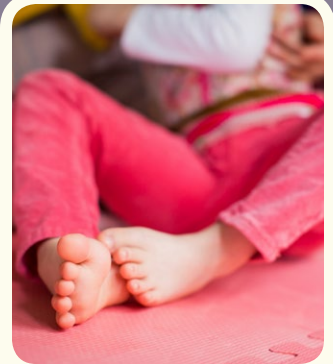
Pain—Often a result of contractures, abnormal postures, dystonia, skin breakdown, subluxations, dislocations, overuse and scoliosis; may also be related to a variety of rehabilitation measures (e.g. stretching, strengthening, surgery)



Fatigue—People with CP require more energy to walk compared to unaffected people; common in all age ranges; may negatively impact school and job performance



Spasticity—Spastic CP accounts for about 70%-80% of cases; more likely to have a higher number of areas of pain and worse pain; may result in subluxations, dislocations, or degenerative joint disease



Musculoskeletal deformities—High risk for patients with cerebral palsy as multiple body systems involved during developmental years; includes dislocations, subluxations, contractures and abnormal alignments



Contractures—A loss of joint motion due to structural changes in the muscles, ligaments and tendons surrounding the affected joint(s)



Scoliosis—A triplanar deformity of the spine involving curvatures in the lumbar, thoracic and/or cervical regions; may be accompanied by increased or decreased kyphosis and lordosis



Dystonia—A movement disorder characterized by involuntary and uncontrollable muscle contractions; causes twisting and writhing motions, repetitive movements and abnormal postures; may be a significant cause of pain



Sensory processing —Disturbances in the processing of sensory information limits children's abilities to effectively interact with their environments; includes both heightened and dampened reactions

Spasms
Scoliosis
Respiratory problems
Joint dysfunction
Limited ROM
Immobility
Motor dysfunction
Arthritis
Rehabilitation efforts
Fatigue

Osteoarthritis
Esophagitis
Spine conditions
Gastrointestinal
Overuse
Abnormal postures
Constipation
Surgical
Related to falls
Orthopedic
Nerve injuries

Urinary tract infections
Dystonia
Abnormal gait
Subluxations
Weakness
Dislocations
Contractures
Weight-bearing joints
Spasticity

1 Pain

Pain is defined as an unpleasant experience with both sensory and emotional concerns, and is also associated with actual or potential tissue damage. It is very subjective, often multifaceted, and is both distracting and disabling for the person experiencing its effects. As noted, pain is common in childhood and may increase over time. It may be acute or chronic and is attributed to musculoskeletal deformities, arthritis, and overuse syndromes. Weight-bearing joints are the most common locations for pain and occurs in the ankle/foot, knee, hip and spine. Common causes and locations of pain in pediatric, adolescent and adult patients with cerebral palsy are listed above.

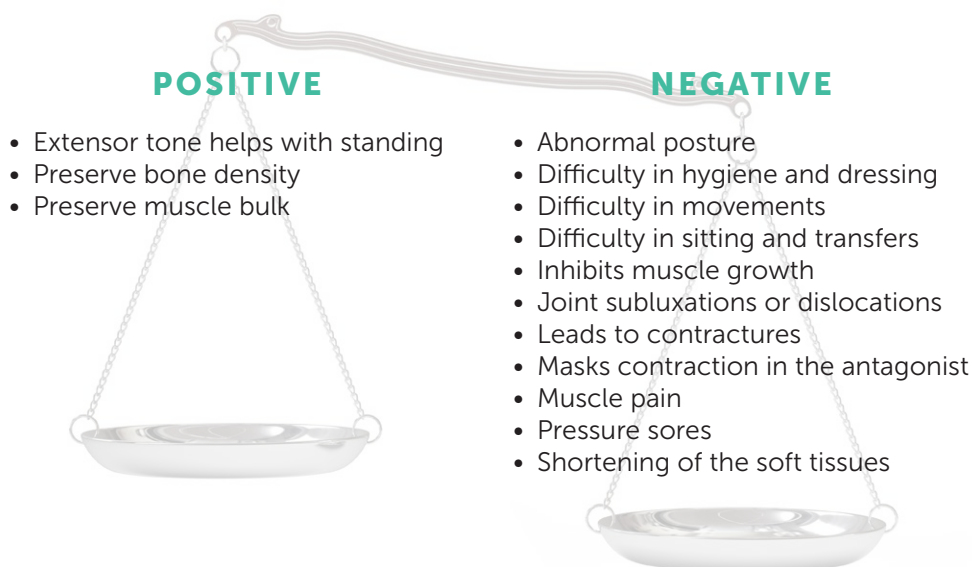
As there are many causes of pain, each person should be individually evaluated starting in childhood. Determining the source(s) of pain allows health care professionals to develop appropriate physical, therapeutic or psychological treatment plans. Both short- and long-term functional goals and physical abilities are considered, along with personal goals and motivations. In particular, the lower extremities are especially susceptible to damage secondary to excessive joint compressions from muscle imbalances, abnormal timing of muscle activations, abnormal loading of joint surfaces, developmental deformities, articular cartilage degeneration and other contributors to acute and chronic pain. Neuropathic (or nerve) pain may also be a source of dysfunction for people with cerebral palsy.

2 Fatigue

Pain and fatigue go hand in hand, and both are frequently present in school-aged children with cerebral palsy. Studies have shown that school functioning can be negatively impacted as children with more severe diagnoses experience greater amounts of both pain and fatigue on a daily basis. Opportunities to modify dimensions of pain and fatigue will likely enhance children's academic performance, overall -related quality of life, and interactions with their families.



Effects of Spasticity



3 Spasticity

Spasticity is a frequent problem for patients with cerebral palsy and can lead to a multitude of problems including contractures, deformities and functional impairments. Associated with upper motor neuron involvement, patients can present with increased tone, hyperreflexia, clonus and/or resistance to stretching. Negative and positive effects of spasticity are noted below.

Spasticity creates numerous functional problems and can lead to contractures and cartilage deterioration. ADLs such as walking, feeding, washing, toileting and dressing are at risk. Further problems associated with spasms and pain includes disrupted sleep, difficulty with transfers, altered seating positions, impaired standing and walking, joint and bone deformities, subluxations and dislocations.

4 Musculoskeletal and Secondary Conditions

A **secondary condition** occurs as a result of the primary pathology, and presents as an injury, impairment, functional limitation or disability. Continued loss of function and deterioration of quality of life occur with the onset of secondary conditions. As noted previously, while the damage to the brain is non-progressive, **musculoskeletal conditions** can develop or progress over time as a consequence of the primary motor dysfunctions. Individuals with cerebral palsy are at an especially high risk for secondary conditions because of the multiple physical systems initially affected from birth or early childhood.

Scoliosis is identified by abnormal curvatures of the spine and often presents with pelvic obliquity and hip dislocations. This triplanar deformity may create abnormal weight bearing on the ischial tuberosities, sacrum and ribs in the non-ambulatory patient, and may produce asymmetrical weight bearing in the lower extremities for ambulatory patients. Severe presentations will impact mobility, feeding, hygiene, ADLs and overall levels of independence. While the primary progression of idiopathic curves occurs in childhood and adolescence, the spinal involvement for neuromuscular conditions associated with cerebral palsy should be monitored across the lifespan.

Osteoarthritis arises from atypical joint compressions, muscle activations and disrupted timing of muscle contractions during various movements. Degeneration of articular cartilage and bony deformities develop and are often determined to be significant sources of pain for the affected person, especially during adolescence and the adult years. Pain may be acute or chronic and directly related to musculoskeletal deformities, arthritis or overuse syndromes.

Involuntary motions associated with athetoid presentations create abnormal compressive and shearing forces. Repetitive motions and limited movement patterns often lead to **overuse syndromes**. Fatigue, pain, nerve entrapments, overexertion and other factors are also associated with reduced function and pain.

Other **orthopedic deformities** associated with cerebral palsy include patellar displacement,

equinovarus, pes planus and pes cavus, scoliosis (as well as kyphosis and lordosis), pelvic obliquities and contractures on a variety of joint concavities. These deformities lead to chronic pain and instability of the foot, ankle, knee, hip, back and upper limbs. Contractures lead to the development of abnormal positioning, skin breakdown, impaired mobility and fixed deformities. Hip, knee and foot pain are some of the most common complaints and are negatively influenced by congenital dislocations, abnormal joint stresses, hypertonic muscles and overuse damage. The lower extremities are especially susceptible to non-traumatic fractures due to the combination of osteoporosis, long lever arms and contractures. The table below summarizes some of the most common musculoskeletal and secondary conditions associated with cerebral palsy.

5 Sensory System Disruptions

Sensory system disruptions produce significant constraints on a person's motor and functional abilities. Patients with cerebral palsy exhibit heightened sensitivities with proprioception, touch and pain thresholds, as well as increased sensitivities to non-painful stimuli. These disturbances in sensory processing interfere with a person's ability to gain useful information from the environment. Disrupted sensory modulation and discrimination can exacerbate motor dysfunctions, as noted in the table below.

DISRUPTED SENSORY MODULATION AND DISCRIMINATION

- Sitting/standing discomfort
- Struggles with food
- Inappropriate physical responses
- Low self-esteem
- Restlessness
- Reclusiveness
- Speech delays
- Strong reactions to textures, sounds and light
- Postural control deficits
- Altered cortical reorganization
- Poor balance
- Sensitive to temperature
- Altered levels of physical activity
- Uncoordinated
- Over- or under-sensitivity to touch
- Behavioral issues
- Little reaction to external events
- Overwhelmed
- Fight or flight
- Limited ADLs
- Somatosensory processing deficits
- Visual deficits

PATHOLOGIES

- Fractures
- Osteoarthritis
- Osteoporosis
- Scoliosis

FUNCTIONAL LIMITATIONS

- Inability to perform hygiene needs
- Dependency on others for ADLs
- Limitations in mobility, function and activities

IMPAIRMENTS

- Abnormal tone
- Atypical postures
- Behavioral issues
- Cardiovascular disorders
- Constipation
- Contractures
- Degenerative joint disease
- Dental problems
- Depression
- Dislocations
- Emaciation
- Fatigue

- Gastrointestinal problems
- Incontinence (bowel/bladder)
- Low self-esteem
- Nerve entrapments
- Obesity
- Overuse syndrome
- Pain
- Problems with balance
- Seizures
- Sensory system disruptions
- Spinal cord compression
- Ulcers
- Visual disruptions

DISABILITIES

- Difficulties living independently
- Limited recreational opportunities
- Problems with social relationships and intimacy
- Social isolation
- Difficulty with role as a patient when medical professionals fail to make accommodations for treatment
- Underemployment

Adapted from Shamsoddini, A, Amirsalari, S et al. (2014)



6 Caregiver and Family Issues

With parents reporting up to 59% of their children experiencing pain, what is the effect on the patient's and family's quality of life? Children, adolescents and adults with cerebral palsy may experience behavioral problems, emotional problems, anxiety, restricted movement, restricted activities, impaired ADLs, disrupted sleep, detriments to school or work functioning, inability to focus, decreased quality of life, and increased family concerns. It should be noted that children experience and respond to

pain in a different manner than adults, and require a different approach from their medical team. Adolescents suffer from higher levels of pain than their unaffected peers, and pain severity is greater for all patients with spastic quadriplegia than either hemiplegia or diplegia.

Pain may also be related to rehabilitative procedures, like surgery or therapy, or secondary to the neurologic condition. Still, many patients with pain are under-treated or not treated at all due to the lack of recognition, inadequate assessments, and limited communication abilities of the patient. Physicians, therapists and orthotists should collaborate to create unique orthotic programs that minimize functional limitations and disabilities, and promote the overall health-related quality of life for patients with cerebral palsy and their families.

Interventions may be needed to reduce the stress experienced by caregivers, especially for parents of children experiencing pain. Pain negatively impacts not only the child but also the parents and family, reducing the overall quality of life for all. For parents, pain management becomes a daily challenge treated by a variety of therapies and medications. Often, it is the very therapies that are designed to maintain and improve function and independence, such as stretching or donning orthoses, that may create painful situations. Independence and function are sometimes at odds with the reduction of pain and quality of life, placing parents in a precarious position to make decisions about their child's welfare. Weighing the benefits of short- and long-term gains is often taxing to parents involved in these daily care activities, and eliminating or minimizing their child's pain remains a primary focus.

UNDERSTANDING A CHILD'S PAIN

Many children with cerebral palsy also present with communication challenges such that efforts by inexperienced clinicians to accurately identify and address the source(s) of their pain may be limited. It is important to understand and recognize specific pain behaviors as well as communicate effectively with parents and caregivers. Such behaviors in non-verbal children include feeding difficulty, facial grimaces, crying with movement and sleep disruptions. Children with communication difficulties rely on their care team to accurately assess and manage their pain as they often require frequent hospitalization and care by unfamiliar clinicians, have medical conditions that cause pain, undergo procedures that cause pain, and are unable to express their discomfort and pain.

Many factors contribute to a child's pain and ability to self-report that pain. Cognitive impairments, clinical condition, learned behaviors, ability to vocalize, developmental level and mobility may all influence a child's interaction with his/her family and medical team. Children exhibit pain in a very individual manner, with a wide variety of physical and expressive abilities. In a study on adolescents with cerebral palsy, Doralp and Bartlett (2010) used the Gross Motor and Function Classification System (GMFCS) to determine that GMFCS level II males and GMFCS level IV females had the highest self-reported pain prevalence. The table below outlines the GMFCS and the most common sites of pain reported by adolescents.

**ABBREVIATED GMFCS AND COMMON SITES OF PAIN
REPORTED BY ADOLESCENTS WITH CEREBRAL PALSY**

| LEVEL I | LEVEL II | LEVEL III | LEVEL IV | LEVEL V |
|--|--|---|--|--|
| Children walk at home, school, outdoors and in the community. | Children walk in most settings and climb stairs holding onto a rail. | Children walk using a hand-held mobility device in most indoor settings. | Children use methods of mobility that require physical assistance or powered mobility in most settings. | Children are transported in a manual wheelchair in all settings. |
| PAIN SITES AND PREVALENCE | | | | |
| <ul style="list-style-type: none"> • Ankle/foot • Knee • Calf • Lower back | <ul style="list-style-type: none"> • Ankle/foot • Knee • Lower back | <ul style="list-style-type: none"> • Ankle/foot • Knee • Lower back • Hip • Neck | <ul style="list-style-type: none"> • Ankle/foot • Thigh • Hip • Knee • Shoulder • Lower back | <ul style="list-style-type: none"> • Ankle/foot • Knee • Upper back • Lower back |

Adapted from Palisano, et al. (1997)

TESTS AND MEASURES

Assessment tools need to be not only reliable and valid but also clinically feasible. Clinical feasibility requirements include a test that is simple, quick and inexpensive. There are numerous tests and measures available that are appropriate for use with patients with cerebral palsy. It is important for the medical treatment team to collaborate on the most useful instruments, obtain appropriate training for the administration of these tests, and ensure consistency of communication between the different care environments (e.g. school, outpatient, orthotic care center, pediatrician, specialists, therapists, etc.). Non-verbal children require additional efforts by the medical team to assess pain indicators through parents or caregivers. The figure below identifies some tests that may be relevant to the medical management of children with cerebral palsy.

Although self-reporting is considered the gold standard for pain assessment, it is not always possible for all people with cerebral palsy. Further, the subjective and individual nature of pain experiences make accurate assessment and management especially challenging. Characteristics of an effective measurement tool include:

- Ability to reflect individual differences
- Requires a minimal amount of time to perform
- Easily scored and interpreted
- Minimal training to learn
- Performed consistently by a variety of medical team members
- Psychometrically sound for the pathology, age and other factors

TREATING PAIN

Effectively managing pain allows a child to participate in therapies and programs to enhance health and well-being, and also to better enjoy the opportunity of just being a child. As discussed, pain can negatively impact the physical, psychological, functional and social components of a child's life. Medications may be used to treat pain, along with injections, physical treatments (e.g. stretching) and/or positioning. At times, surgery may be required for secondary conditions such as skin issues, variable muscle tone, dislocations, and deformities that may also cause pain during the rehabilitation period. It should also be noted that the most common form of pain from daily living has been identified as assisted stretching. Other therapeutic and medical procedures that are reported to commonly cause pain are range of motion exercises and injections.

In general, pain intensity of 3 on a 0 to 10 scale is considered clinically significant and detrimental to a person's well-being. Appropriate assessments should identify the primary source of pain, and interventions should be implemented before the pain reaches or exceeds this level. Without appropriate pain management programs, children will often experience social withdrawal, fear, anxiety, depression and frustration. Unfortunately, many health care professionals receive inadequate education and training in regards to pain assessments and interventions.





ORTHOTIC MANAGEMENT

It has been reported that orthotic management may be a specific source of pain for some patients, although the benefits of improved alignment, function and range of motion are well documented. This is a primary reason for the development of the Fuzion system. Patients with pain and heightened sensitivities, and those who have not acclimated well to more traditional orthotic materials and designs require a unique orthotic management program. Fuzion is based on foam-enhanced designs that integrate five key concepts: custom, compression, control, comfort and compliance. (This unique orthotic management system will be discussed in more detail in the Clinical Partnerships, Fuzion Visuals and Conclusion sections of this paper.)

Orthoses are intended to address many functional and orthopedic conditions that limit a person's ability to optimally engage in his/her environment, participate in family activities and perform self-care tasks. Children should learn to don and doff the orthoses as independently as possible, and also to inspect the mechanical devices for normal wear and tear. Understanding the function, purpose and benefits of the orthoses will also help to promote independence, self-advocacy, and adherence in later years. As adolescents and young adults, it is important for the patient to adopt self-reliant wearing schedules and pursue appropriate consultations for orthotic design updates as advances in materials and components are made. Many physical and functional changes will occur over time from childhood to adolescence and into adulthood. Consultation and ongoing follow-up with an age-appropriate medical team will ensure that the person's changing needs across the lifespan are being addressed.

Orthoses and other forms of adaptive equipment can have a significant and often critical influence on the overall quality of life for a person with

cerebral palsy. As children with cerebral palsy age into adolescence and adulthood, the orthotic and adaptive equipment needs may change dramatically as they take on new roles and responsibilities. Unfortunately, the beneficial devices used by children may not be covered for adults by private and governmental medical plans. Much of the equipment owned by adults with cerebral palsy becomes outgrown and outdated. Many people who were able to walk and be independent in ADLs are no longer able to do so. Patients benefit from a proactive medical team that anticipates transitional needs as patients move from adolescence to young adult status.

THERAPEUTIC INTERVENTIONS

There are many aspects to therapeutic interventions that may include but are not limited to: orthotic management, home exercise programs, stretching, strengthening, mobility training, focus on ADLs, serial casting, range of motion activities, training with adaptive equipment, standing frames, and electrical stimulation. Collaborating with an orthotic clinician ensures that patients have the opportunity to be evaluated for the most current orthotic designs, materials and components. Children are assessed and an individual program is developed to improve their functional and physical status. Minimizing pain and discomfort during and after these sessions is always a key concern.



EVIDENCE-BASED INTERVENTIONS

- Specific treatments
- Applications with significant scientific support
- Applications that should be monitored by tests and measures to document efficacy
- Applications without scientific support; found to be ineffective for people with cerebral palsy

Serial casting

Improve passive range of motion (ROM) of lower extremity (LE)

Augment effects of Botox

Improve passive ROM of upper extremity (UE)

Improve function

Reduce muscle spasticity



Electrical stimulation

?

Improve gait parameters

Improve muscle strength

Augment effects of Botox



Orthotics

?

Improve stride length and ROM via ankle-foot orthoses (AFOs)

Improve LE function

Improve UE function

Prevent contractures



Prevent hip dislocation via hip orthoses and Botox

Stretching

?

Contracture prevention via manual stretching

Contracture prevention via splinting or positioning



Therasuits

?

Improve gross motor function

SOLUTION

Pediatric orthotic programs require unique designs and features as children are not merely smaller adults. Effective pediatric care involves the understanding of the plasticity of the growing anatomical structures, delays or disruptions associated with a variety of diagnoses, and a comprehensive plan of coordination and communication by the entire medical team. Ongoing communication and collaboration by physicians, therapists, orthotists and others ensure the best outcomes of each child. Orthomerica continues to partner with these clinical teams to develop effective pediatric orthotic devices and then promote an interdisciplinary approach by offering clinical education and training programs, clinical support, technical support, and collaboration with subject matter experts.

FUZION VISUALS

As discussed, alternative orthotic designs are often needed for children with special medical concerns such as pain and heightened sensitivities. The Fuzion line of custom orthoses was specifically developed to address the needs and challenges of these patient populations. The unique multidurometer material characteristics and circumferential compression provide secure joint alignment and stability of the lower limb. Patient and parent acceptance has been positive with anecdotal reports of increased wear time. Managing a child's pain or discomfort in an effective manner will lead to improved acceptance and wearing time of AFOs. Maintaining the structural integrity of the lower limbs during the early developmental years empowers both the individuals and their families to experience a higher quality of life with greater comfort while still achieving the goals of the orthotic treatment program. A variety of Fuzion custom designs are shown below.



CONCLUSION

Children with cerebral palsy have a lifelong disability that requires early intervention and ongoing treatment throughout adulthood. Chronic pain is common, especially in children with spasticity, and often becomes more intense over the lifespan due to inconsistent muscle tone, impaired movement, dislocations and subluxations, degenerative joint disease and other associated medical conditions that drastically impact the overall quality of life for the patient and family. Unaddressed, limited movement and spasticity often lead to contractures and the need for surgical interventions throughout childhood. Orthotic care with the Fuzion system can limit or minimize the impact of these deformities on the growing child.

Adolescents and adults with cerebral palsy benefit from continued use to address such concerns as contracture management, improving or maintaining range of motion, aligning joints, improving mobility and independence, etc. Clinical experiences with the Fuzion designs have been extremely positive. The purpose of this new treatment option for children with multiple challenges is to enhance their current care program, maintain their musculoskeletal structures for future mobility and/or ambulation abilities, improve the quality time spent with family and caregivers, and enhance their overall health-related quality of life.

CLINICAL PARTNERSHIPS

Since 1989, Orthomerica Products has been a manufacturer of prefabricated orthoses and has evolved into a worldwide leader in the design, development and fabrication of custom orthotic solutions. Orthomerica's manufacturing capabilities span the complete breadth of the orthotic industry with a mission to continue providing innovative products of exceptional quality and unparalleled customer service to the healthcare marketplace. Orthomerica provides comprehensive clinical programs for the Fuzion product line – with a focus on pediatric applications. Fuzion orthotic systems are made from proprietary materials that use foam-based materials adhered over a plastic frame to increase comfort while still providing structural integrity to the orthotic design.

Orthomerica's manufacturing facility is located in Orlando, FL, and the clinical reach of the products and services expands across the United States and around the world. These interdisciplinary and international relationships serve to enhance the dissemination of scientific research, clinical information and experience, and subject matter expertise that result in enhanced care programs for patients in need of orthotic treatment.

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