

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

Custom design to optimize alignment, control, compression, total contact and relief



Ease of donning and doffing for patient and caregiver



Soft inner surface for sensitive soft tissues and bony prominences



Improved comfort and compliance to increase wearing time and optimize outcomes



Easy cleaning and care to enhance hygiene processes



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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

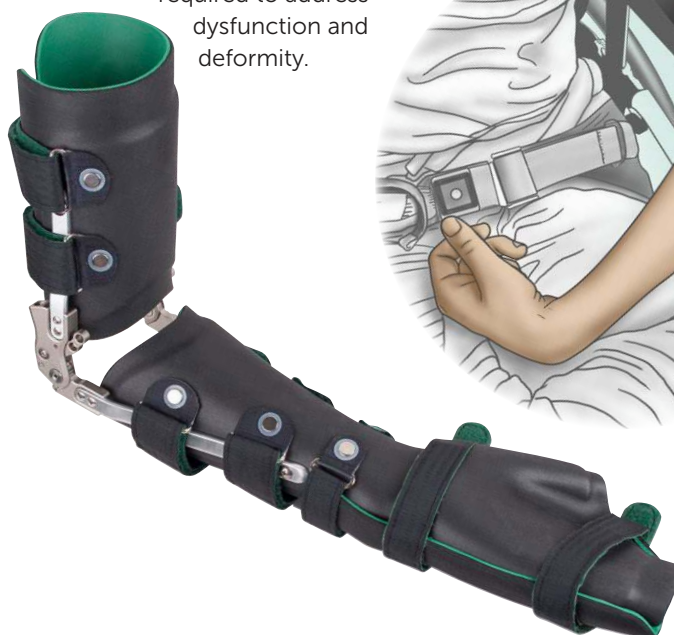
Spontaneous pain	painful sensations are felt without any apparent or evident stimulus
Allodynia	pain due to stimulations that do not normally cause pain
Hyperalgesia	increased pain response to a painful stimulus
Dysesthesia	an unpleasant sensation, may be spontaneous or provoked
Paresthesia	an abnormal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

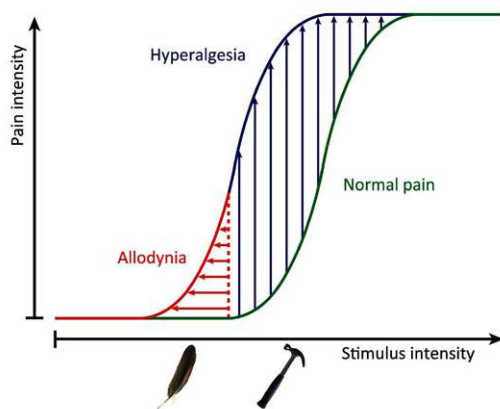
ambulatory situations. Whether secondary to spasticity, impaired motor control or disuse, soft tissue shortening develops on joint concavities and soft tissue lengthening occurs on joint convexities. In the pediatric patient, joint congruencies become permanently altered and lead to the development of 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

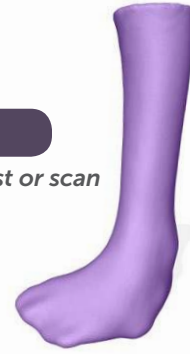
- ✓ Circumferential compression
- ✓ Varying degrees of flexibility and stability
- ✓ Greater control and comfort
- ✓ Improved compliance
- ✓ Ease of modifications
- ✓ Manage volume changes
- ✓ Counterbalance the negative influences of sensory integration dysfunctions
- ✓ Decrease abnormal loading
- ✓ 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.



REFERENCES

- Chen, J-C & Shaw, F-Z (2014). *Progress in sensorimotor rehabilitative physical therapy programs for stroke patients. World J Clin Cases, 2(8):316-326.*
- Jensen, TF & Finnerup, NB (2014). *Allodynia and hyperalgesia in neuropathic pain: clinical manifestations and mechanisms. The Lancet, 13(9):924-935.*
- Lolignier, S, Eijkelkamp, N * Wood, JN (2015). *Mechanical allodynia. Pflugers Arch - Eur J Physiol, 467:133-139.*
- MacKenzie, C & McIlwain, S (2015). *Evidence-based management of postural control in a child with cerebral palsy. Physiotherapy Canada, 67(3):245-247*
- Michael, JW (Ed.), Hsu, JD (Ed.), & Fisk, JR (Ed.) (2008). *AAOS Atlas of Orthoses and Assistive Devices, Fourth Edition. Philadelphia: Mosby Elsevier.*
- Skalsky, AJ & McDonald, CM (2012). *Prevention and management of limb contractures in neuromuscular diseases. Phys Med Rehabil Clin N Am, 23(3):675-687.*
- Thompson AJ, Jarrett L, Lockley L, et al (2005). *Clinical management of spasticity. Journal of Neurology, Neurosurgery & Psychiatry, 76:459-463.*


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