Clinical White Paper #1

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Part I: Defining the Problems

INTRODUCTION

The exact pathogenesis of peripheral neuropathies, Charcot foot degeneration and wound development is often difficult to establish. The potential interactions and progressive nature of the different yet related pathologies remains alarming. The purpose of this two-part clinical white paper is to (I) define the problems and (II) refine the solutions. Topics will include the physiological processes of these three major lower limb involvements, interaction of one physiological process upon the next, key concepts of orthotic treatment, effective orthotic design solutions, and lifespan care programs for the effective long-term management of patients presenting with these conditions.

Peripheral neuropathy

The primary task of the peripheral nervous system is to transmit information from the brain and spinal cord to all parts of the body. It is estimated that more than 20 million Americans suffer from some form of peripheral neuropathy (PN) resulting in dysfunction and disability. Compression, loss of myelin sheaths, disconnection and degeneration are contributing factors to the more than 100 different types of peripheral neuropathy. Each form of neuropathy has its own cause, symptoms, progression and prognosis. The symptoms associated with PN and can range from a mild tingling or numbness to excruciating burning pain or even paralysis. The causes of PN are as varied as the symptoms and are listed in Figure 1.

Figure 1. Causes of peripheral neuropathies.

- Alcohol excess
- Medication
- Infections
- Nutritional imbalances
- Hormonal imbalances
- Diabetes
- Autoimmune diseases
- Systemic diseases
- Vitamin deficiencies
- Heredity
- Injury
- Chemotherapy
- Exposure to toxic substances
- Dietary deficiencies
- Vascular disorders
- Kidney disorders
- Tumors

Neuropathies may be sensory, motor or autonomic in nature. ***Sensory neuropathies*** are accompanied by strange sensations including but not limited to pain, inability to feel pain, tactile disruptions, sensitivity to temperature, lack of coordination, loss of reflexes, numbness, tingling or burning sensations. ***Motor neuropathies*** produce muscle weakness and loss of muscle control along with decreased balance, incoordination, muscle spasms or cramping, and difficulty moving the affected limbs. ***Autonomic neuropathies*** can affect the function of organs and glands, breathing, sweating and blood pressure among others. In the most challenging situations, patients may present with a combination of neuropathies that involve disruptions to sensory, motor and autonomic systems.

Diabetes accounts for up to 60% of all peripheral neuropathies while the remaining are idiopathic and secondary to a variety of other causes. In longstanding diabetes and secondary to the loss of protective sensation, joints fail to recognize the abnormal and high forces transferred through them or the altered joint alignments. Continued load bearing during normal daily activities produces repetitive microtrauma to the affected joints and leads to further bone trauma, progression of joint deformities and eventually tissue breakdown. Nerve conduction testing, electromyography, nerve and skin biopsies are used to confirm the diagnosis, while physical therapy, medication, orthoses and lifestyle modifications are recommended to improve overall function. It is important to note that not all peripheral neuropathies result in the development of Charcot joints, however the single most prevalent cause found in Charcot joints is peripheral neuropathy. Clinical management of peripheral neuropathy is outlined in Figure 2.

Figure 2. Clinical management will be discussed in Part II: Refining the Solution

Considerations for orthotic treatment programs include pathogenesis (diabetic, non-diabetic, etc.), degree of dysfunction, deformity, contractures, ligamentous laxity, potential for progression, acute vs. chronic, and prognosis.

Key concepts for orthotic design include controlling and decelerating initial loading, strategic progression of the center of pressure across the plantar surface of the foot during weight bearing, terminal stance strategy, swing phase dorsiflexion assist, and improving balance. **Prevention of progression of functional deficits, joint deformity and repetitive microtrauma is critical.**

Charcot joints

In many cases, peripheral neuropathy is the predisposing factor for the development of a Charcot joint. It is important to note that any pathology accompanied by a loss of sensation may be identified as a causative factor in the pathogenesis. The terminology relating to Charcot joints lacks professional consensus and more than 40 different names have been proposed in the literature. For the purpose of this paper, the combination of signs and symptoms will be referred to as Charcot foot syndrome (CFS). The exact cause of CFS remains disputed, however, a combination of repetitive microtrauma and changes in the circulation may trigger the resorption of bone and susceptibility to fractures and dislocations. Although CFS was first noted in non-diabetic patients, diabetic patients currently account for the majority of people diagnosed with CFS. The "rocker bottom" foot is a common result of the insidious process of marked deterioration and acquired deformity. (Figure 3)

Charcot foot syndrome is exacerbated by a combination of mechanical, vascular and other physiological factors. CFS involves a non-infectious and destructive process to weight bearing bones and articulations in patients with insensate limbs affected by peripheral neuropathies. The unilaterality of the condition is emphasized in most studies, however bilateral cases are reported in 10% to 30% of patients. Unilateral presentation can also trigger the development of contralateral CFS and/or recurrence on the ipsilateral side.

The features of CFS in the affected foot and ankle include distended joints, disorganization, dislocation, debris, increased density and destruction. Clinical findings and presentations are varied based upon the specific course of damage and may result in any combination of fractures (often without pain), ligamentous laxity, cartilage deterioration, dislocations, osteomyelitis, ulceration, infection, instability, bone deterioration and deformity. Brodsky et al proposed an anatomical classification of Charcot foot involvement based upon the affected joint(s). (Figure 4) The midfoot is the most often affected joint in the lower extremity, followed by the hindfoot, ankle, heel, forefoot and combinations.

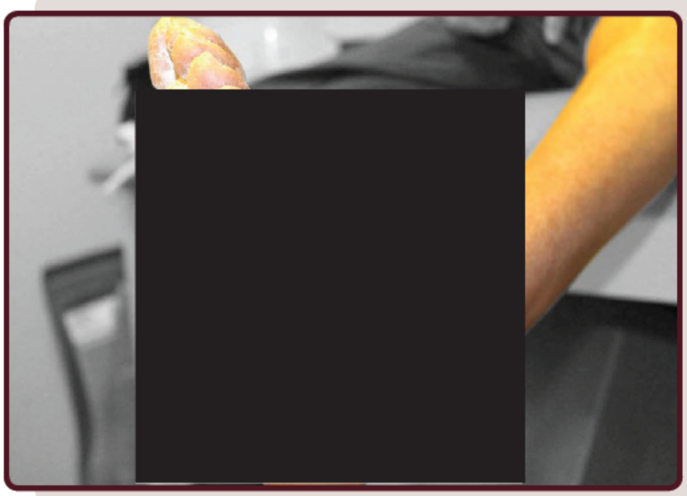
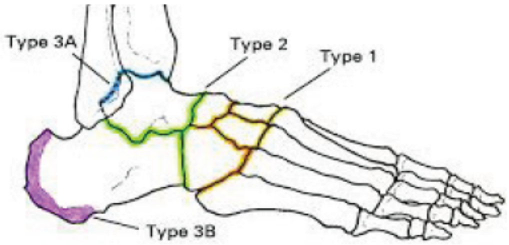


Figure 3. Charcot foot syndrome and rocker bottom foot.

- Charcot joint
- Charcot arthropathy
- Charcot foot
- Neuropathic joint
- Neurotrophic joint
- Charcot syndrome
- Charcot neuroarthropathy
- Charcot neuropathic osteoarthropathy
- Diabetic neuro-osteoarthropathy

Figure 4. Brodsky anatomic classification of Charcot arthropathy.



Type	Location / % of Patients	Involved Joints
1	Midfoot (60%)	Tarsometatarsal, naviculocuneiform
2	Hindfoot (10%)	Subtalar, talonavicular, calcaneocuboid
3A	Ankle (20%)	Tibiotalar
3B	Calcaneus (< 10%)	Tuberosity fracture
4	Multiple regions (< 10%)	Sequential and concurrent
5	Forefoot (< 10%)	Metatarsophalangeal

Structural abnormalities create exacerbated plantar pressures during loading; hammertoes, claw toes and other foot anomalies are common. The amount of bone and joint damage is often dependent upon the degree of sensory loss, activity level and degree of disruptions to the mechanical stresses transferred through the joint structures. In the worst scenarios, amputation and even death may occur. (Figure 5)

Although the exact pathophysiological processes are unknown, two major theories exist for the development of Charcot foot syndrome. The neurotraumatic theory proposes that CFS is the result of repetitive microtrauma to an insensate foot. The neurovascular theory proposes that bone resorption is triggered by an inherent vascular reflex and results in deterioration. While the pathogenesis may differ between patients, the sensory-motor neuropathy and autonomic involvement are key factors combined with even moderate stresses (i.e. walking) that serve to initiate this destructive disease process. Fractures, ligamentous laxity, dislocations, damage to cartilage, bone erosions and hypertrophic repair result in severe and progressive deformities.

The true prevalence of CFS in unknown, however, numerous risk factors exist such as: trauma, peripheral vascular disease, diabetes, ulceration, physical activity, excessive plantar pressures, repetitive abnormal loading, obesity, instability, age, contractures and sensory or

Figure 5. Progressive nature of peripheral neuropathy, Charcot foot syndrome and wounds.

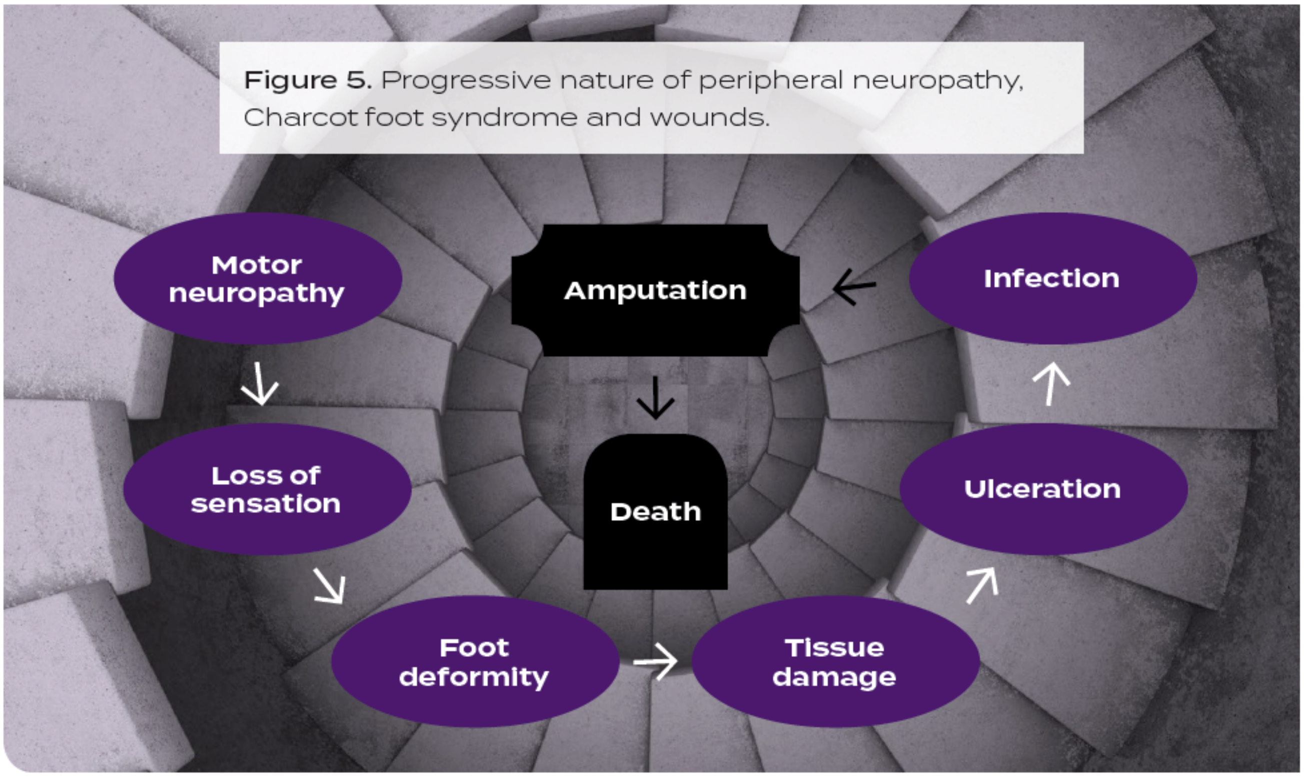
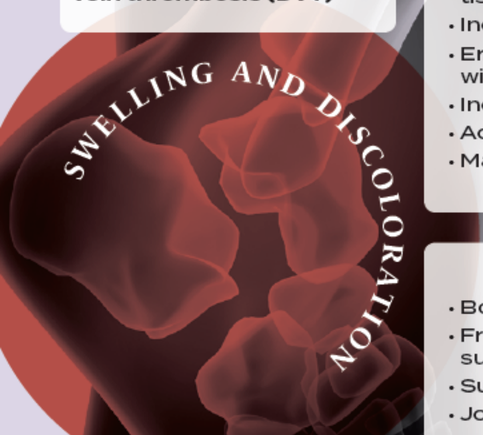


Figure 6. Staging and progression, Eichenholtz (1–3) and Shibata (0)

STAGE 0
Localized swelling

- Local warmth
- Mild erythema
- Clinical instability
- Minimal radiographic changes
- Clinical signs precede x-ray identification
- Joint edema

Frequently misdiagnosed as gout, cellulitis, or deep vein thrombosis (DVT)



Radiography

- X-rays may be negative
- Suggest bone scan and MRI

Treatment Program

- Non-weightbearing
- shark-o for offloading and immobilization
- Assess contralateral limb

STAGE 1
Development – Fragmentation Period

- Debris formation
- Fragmentation
- Subluxation
- Dislocation
- Erosion of articular cartilage
- Bone resorption
- Marked soft tissue edema
- Increased joint mobility
- Erythema (may reduce with elevation)
- Increased warmth
- Acute inflammation
- May last 6–12 months

Radiography

- Bone debris at joints
- Fragmentation of subchondral bone
- Subluxation
- Joint dislocation

Treatment Program

- shark-o® for offloading and immobilization
- Assess contralateral limb

STAGE 2
Coalescence Period

- Lessening of edema
- Absorption of fine debris
- Healing of fractures
- Fusion and coalescence
- Loss of vascularity
- Sclerosis of bone
- Decreased inflammation
- Decreased warmth / reduced temperature
- Decreased erythema

Radiography

- Absorption of fine bone debris
- New bone formation
- Coalescence of large fragments
- Sclerosis of bone ends

Treatment Program

- shark-o for offloading and immobilization
- Assess contralateral limb

STAGE 3
Reconstruction – Consolidation Period

- Further repair and remodeling of bone
- Fusion and rounding of large fragments
- Revascularization
- Increased bone density
- Ossification
- Residual deformity (prone to progression and may lead to ulcer)
- Normal temperature

Radiography

- Remodeling, consolidation and rounding of bone and fracture fragments
- Decreased sclerosis
- Bone healing

Treatment Program

- shark-o to prevent progression of deformity
- Transitional custom ankle-foot orthosis (AFO)
- Custom or orthopedic shoes
- Assess contralateral limb
- Lifespan care plan

autonomic neuropathies. Ultimately, any condition or pathology that leads to the development of an insensate foot may be a precursor to the development of CFS. Still, the staging and progression of the disease process proposed by Eichenholtz and Shibata follow a common and predictable path (Figure 6). It is important to note that the acute Stage 0 defined by Shibata is often misdiagnosed in up to 25% of cases as gout, deep vein thrombosis, posterior tibial tendon dysfunction or infection.

As a result, early intervention of Charcot foot syndrome is often delayed until it has progressed into Stage 1 and a definitive diagnosis is made. If acute CFS is suspected, immediate referral to a multidisciplinary foot care clinic is recommended for effective management of this complex condition. **It is important to note that the average duration of the destructive process varies from 2–3 months, however complete healing of the affected Charcot joint(s) may take up to 1–2 years.**

Once the process is initiated, a vicious cycle of destruction continues. Joint deviations lead to abnormal plantar pressures and ongoing microtrauma to the joints. Inflammation triggers osteoclast activation (i.e. pathological bone resorption), leading to lower bone density, fractures, deformity and wounds. Early diagnosis and effective orthotic management are imperative to reduce and avoid the rapid development of permanent foot deformity and the associated complications it presents (e.g. ulcer, difficulty with foot wear, disrupted ambulation ability, etc.) Recurrence rates for CFS vary from 10% to 30%, making the post-treatment transitional orthotic program as important as the initial orthotic design for offloading and immobilization. Ulceration may result from bony deformity or instability, and may lead to chronic or recurrent soft tissue infection or osteomyelitis. Clinical management of Charcot foot syndrome is briefly outlined in Figure 7.

Figure 7. Clinical management will be discussed in Part II: Refining the Solution

Considerations for orthotic treatment programs include pathogenesis (diabetic, non-diabetic, etc.), location of joint(s) affected, degree of dysfunction, deformity, contractures, ligamentous laxity, potential for progression, acute vs. chronic, potential for wound development, and prognosis. ***Preventive care is focused on the contralateral side.***

Key concepts for orthotic design not only focus on **OFFLOADING and IMMOBILIZATION** during Stages 0 - 3, but also include controlling and decelerating initial loading, strategic progression of the center of pressure during weight bearing, and improving balance. **Prevention of the progression of joint deformity and repetitive microtrauma is critical.**

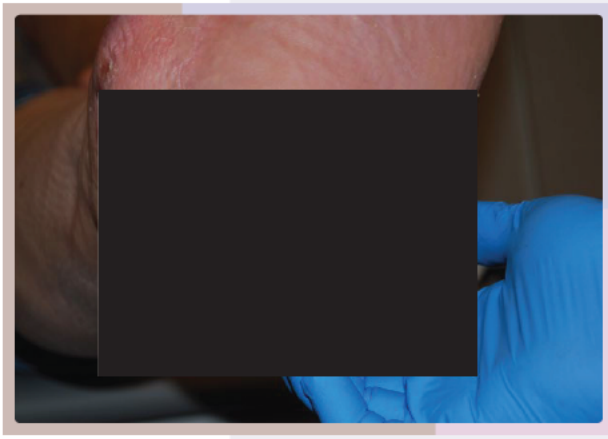
Charcot joint destruction may occur anywhere in the body and the location is highly suggestive of the primary diagnosis. Vascular management, infection control and pressure relief must be managed, and considerations for offloading and/or immobilization must occur when appropriate. Ultimately, outcomes will vary depending on the location of the involvement, severity, degree of damage, surgical intervention and compliance with the recommended treatment program. (Figure 8)

Figure 8. Location of Charcot joints and primary pathologies.

Wounds

Foot ulcers are the result of repetitive stresses from weight bearing, pressures, friction, peripheral neuropathies, structural changes, ischemia, functional deficits (e.g. foot slap) and other factors. These ulcers are especially prone to progression in patients with insensate feet. Even for patients with adequate perfusion, the healing of a foot ulcer will be delayed unless early interventions with effective offloading efforts are employed. After healing, patients still face up to a 40% recurrence rate over the next few months. Wound care clinicians must understand the devastating effects of unresolved pressures, shear forces and repetitive loading or injury. Effective treatment programs must balance individual patient factors along with the opportunity to provide optimal pressure offloading treatments.

Figure 9. Symptoms of foot ulcers.



- Presence or absence of pain
- Swelling of foot
- Bleeding
- Discharge from ulcer
- Difficulty moving foot
- Skin discoloration
- Thickened or hardened areas on the skin

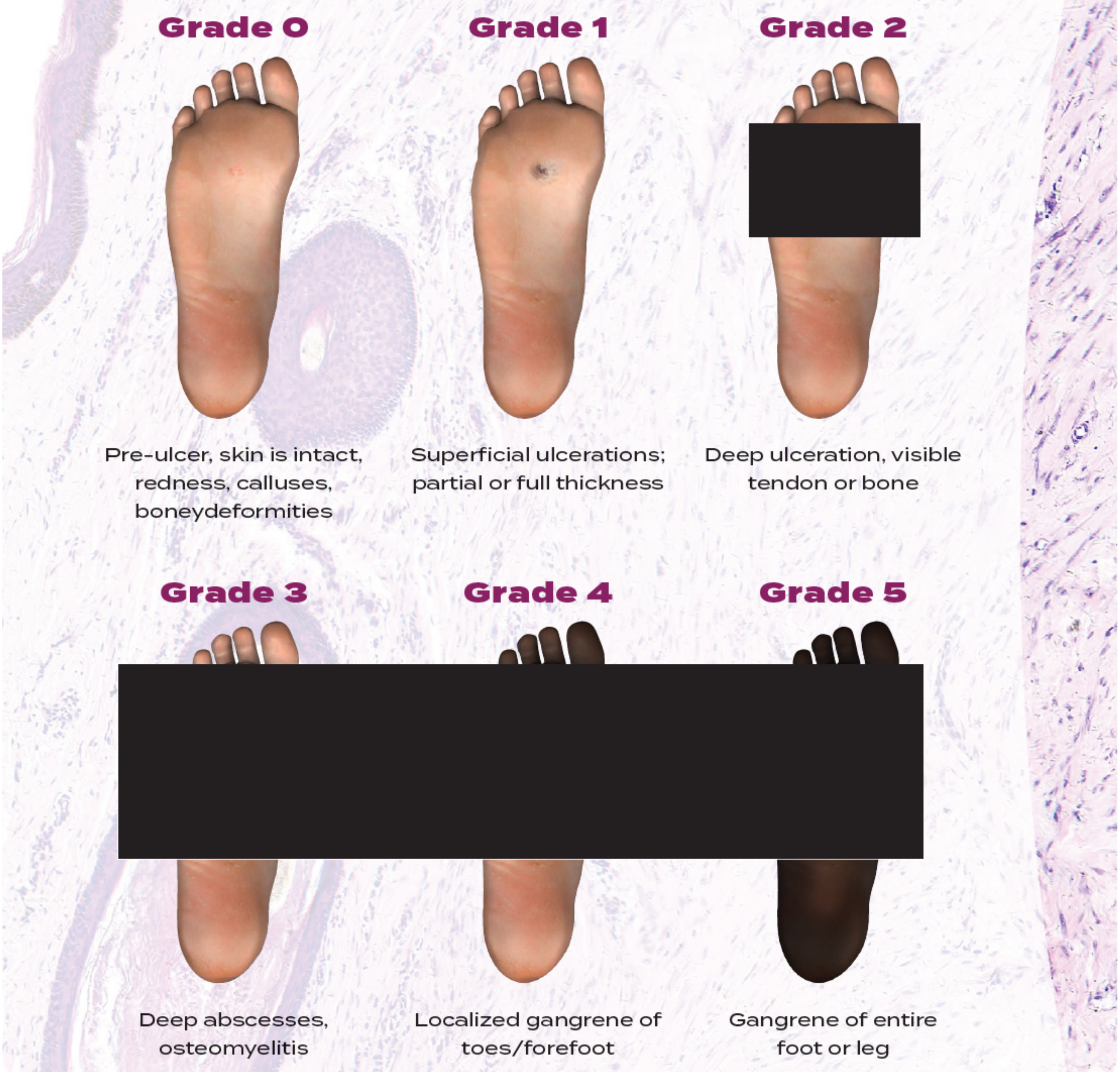
Wounds are especially prevalent in patients with diabetes due to the potential combination of loss of protective sensation, bony deformities, impaired circulation, lack of self-care and obesity that may contribute to ulcer formation. Symptoms of foot ulcers are shown in Figure 9. Prevention is the key to effective management of the diabetic foot, and early intervention with effective multidisciplinary treatment programs is critical. For all patients, determining the appropriate treatment program requires identification of the pathogenesis and causation. Common diagnoses associated with foot wounds include posterior tibial tendon dysfunction, varus and equinovarus deformity, joint instability, Charcot foot syndrome and dropfoot dysfunction. Unresolved pressures, arterial disruptions, ischemia and/or neuropathies may also cause ulcers. Combined with an existing or developing deformity, instability, trauma and/or contracture, patients present very challenging profiles and require the need for unique orthotic management systems. Clinical considerations for diabetic populations are shown in Figure 10.

Figure 10. Clinical considerations for diabetic populations.

- 30 times more likely to experience a lower limb amputation
- 10 times more likely to be hospitalized for bone and soft tissue infections
- Up to 25% will develop a foot ulcer, 15% will require hospitalization for foot complication, and 20% will require an amputation
- Average cost of a major amputation is $45,000
- Average cost to heal a single ulcer is $8,000 to $10,000; and the average cost to heal an infected ulcer is double
- 40% re-ulceration within the first three years; and 70% re-ulceration over five years
- Approximately 80,000 amputations are performed each year in the US with:
  - High incidence of recurrence in same area
  - Up to 50% will develop wounds/ulcers on contralateral side with resultant amputation
  - High 2–3 year mortality rate after first amputation

While there is no universally accepted wound classification, the Wagner Grade Scale is commonly used to classify the severity of wounds and is summarized on page 8 (Figure 11). Clinical factors include but are not limited to: wound size, wound depth, presence of sinus tracts, probing to bone, amount of granulation tissue, presence of fibrotic or dysvascular tissue, drainage, hyperkeratotic tissue, and signs of infection. With good circulation and consistent medical attention, healing of a superficial ulcer may occur within three to six weeks. Deeper ulcers may take up to 20 weeks to heal. Wounds that do not heal within three months are considered chronic and surgery may be considered. Many patients experience recurrence of the ulceration, especially those with peripheral neuropathies, abnormal foot pathomechanics and peripheral arterial disease (PAD). While PAD is not a direct cause of the wound, it is a contributing factor to delayed healing.

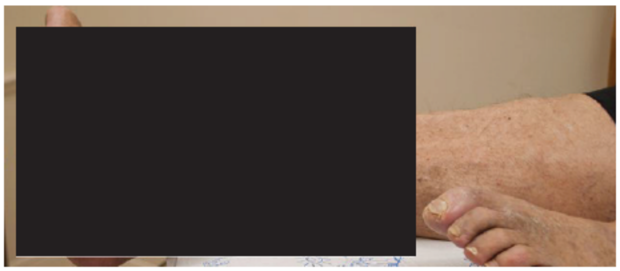
Figure 11. Wagner classification of diabetic foot ulcers.



Risk factors for the development of ulcers for all patients include foot deformities, obesity, loss of protective sensation, motor neuropathies, and inadequate offloading (Figure 12). Hammertoes, hallux valgus and other foot deformities may result from the medical condition or poor fitting footwear, and may progress with increased pressures and risk the development of ulcers.

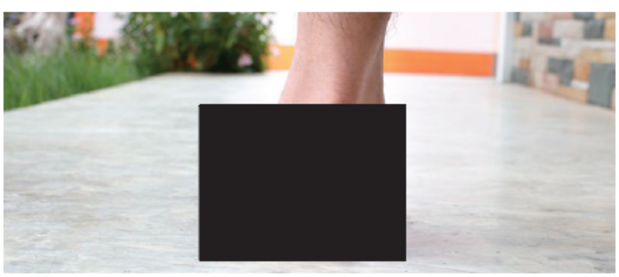
The time between the onset of symptoms, diagnosis, and effective treatment may be several weeks or months, during which time the severity of the condition progresses. Wounds evolve and change over time, and effective healing requires dynamic team management with frequent patient follow-up visits. A lifespan care program is necessary to prevent the devastating effects and consequences of tissue damage, ulceration, infection, amputation and even death.

Figure 12. Three primary factors associated with diabetic foot ulcers.



Peripheral sensory neuropathy: burning pain, stabbing pain, numbness, sensitivity to touch

Deformity: claw toes, hammer toes, hallux valgus



Trauma: inappropriate footwear, foot slap

Effective medical treatment for peripheral neuropathy, Charcot foot syndrome and foot wounds demands a comprehensive team approach and extensive lifespan care program. Debridement, offloading and infection control are key treatments to successful healing. Both the wound causation and underlying pathology must be identified and addressed in a comprehensive treatment program. Peripheral neuropathies may be acute or chronic and effective orthotic treatment may prevent the progression to more serious medical conditions. Charcot foot syndrome is especially prevalent in the diabetic population, and immobilization and offloading during the first few months must be followed by protective weight bearing programs for up to two years. Simply allowing the patient to return to previous footwear and walking conditions may trigger the recurrence of the Charcot condition or lead to the development of a new foot wound. The healing time for wounds varies considerably relative to the individual, and post-healing treatment programs must continue indefinitely. (Figure 13.)

Figure 13. Three phases of wound healing.

INFLAMMATORY PHASE

- Up to 3 days
- Bleeding stops
- Inflammation
- White blood cells attack bacteria and debris
- Growth factor stimulation

PROLIFERATION PHASE

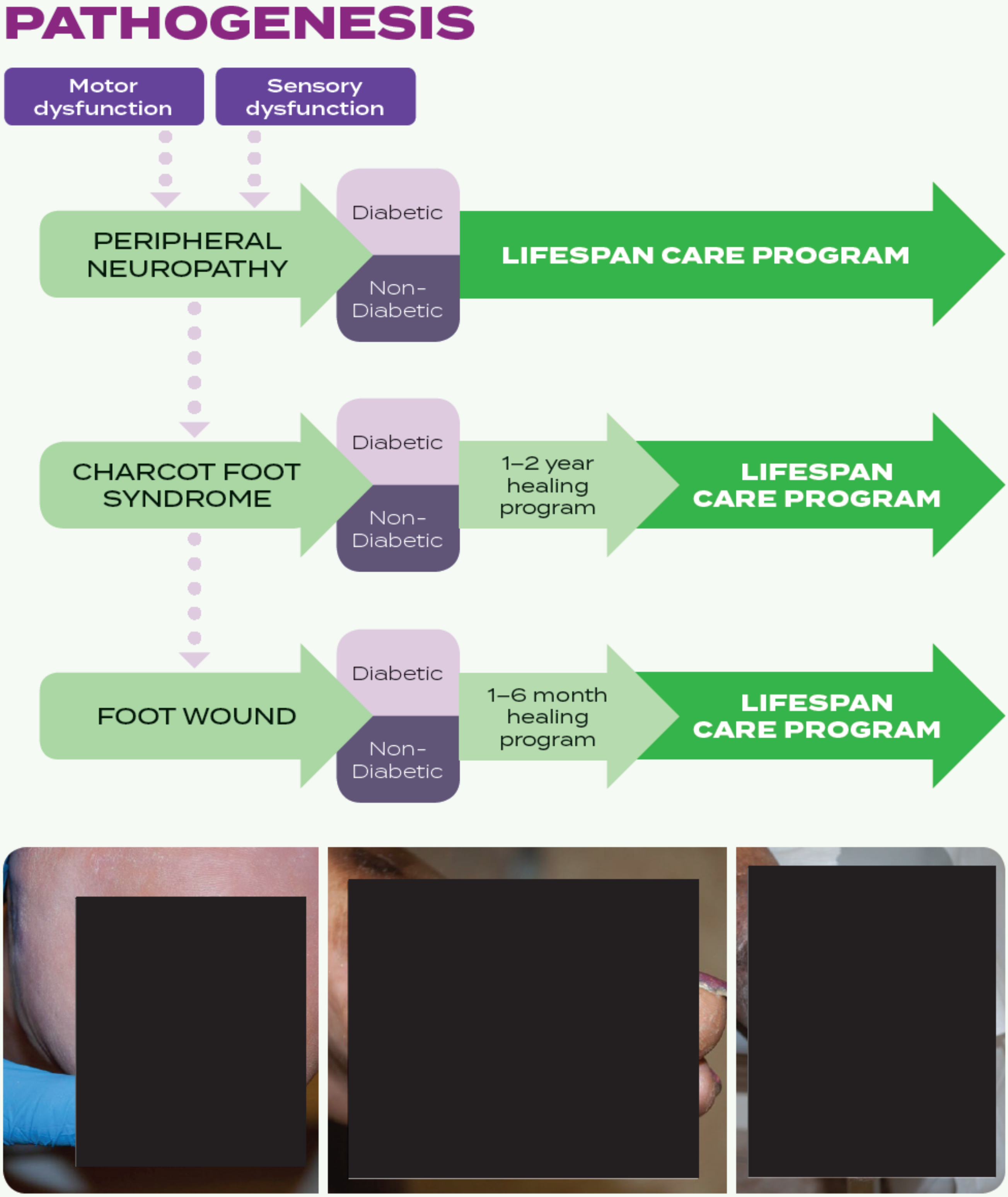
- 3 days to 3 weeks
- New blood vessels develop
- Collagen synthesis
- Granulation
- Epithelialization

MATURATION PHASE

- Up to 2 years
- Reorganization of collagen

Management may include offloading, daily dressings, debridement, antibiotics, control of blood glucose, and evaluation and correction of peripheral arterial insufficiency. Long-term healing and maintenance strategies must follow initial healing efforts to prevent recurrence of the wound or joint trauma. (Figure 14)

Figure 14. The pathogenesis of lower limb dysfunction, deformity and wound development.



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Clinical White Paper #2

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OWLS Clinical White Paper #2

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Part II: Refining the Solution

ORTHOTIC TREATMENT CONCEPTS

Part I was written to define the problems and outline the relationship of peripheral neuropathy, Charcot foot syndrome (CFS) and wound development. Operative and non-operative treatment options are implemented to manage these conditions, and Part II of this series will focus on non-operative orthotic treatments. Orthotic care programs are developed based upon the medical history of the patient and individual goals and needs. Many factors must be considered to optimize the orthotic design for each patient and some of the significant clinical considerations are listed in Figure 1.

Among the many individual structural and functional deficits that are identified and addressed in the design of orthotic medical devices, four primary concepts will be discussed in detail: offloading (for CFS and wounds), immobilization (for CFS), altered timing of the center of pressure during stance phase, and deceleration and control of limb loading (e.g. initial contact) (Figure 2).

Figure 2. Four primary concepts for effective orthotic designs.

Figure 1. Clinical considerations for orthotic treatment programs.

- Stage of the condition
- Function / activity levels
- Vocation and avocation
- Amount of edema
- Degree of compliance
- Presence, depth and likelihood of wound/infection
- Self-care abilities
- Motivation
- Commitment
- Degree of foot/ankle deformity
- Influence on proximal joints
- Location of wound
- Vascular function
- Volume of exudate
- Skin integrity
- Follow-up care program
- Social support
- Lifestyle
- Charcot foot syndrome and ulcer

Total contact casting (TCC)

TCC is often referred to as the "gold standard" of wound care as it has been shown to redistribute plantar pressures, prevent additional trauma to the limb, reduce edema, and immobilize the affected joints and surrounding soft tissues. It has been recommended for Charcot foot syndrome (stages 0 and 1). A trained and skilled team member must apply the total contact cast with weekly cast changes for optimal effect during the initial treatment period that may last up to 4 to 6 months. The downside of this process is the inability to inspect the wound, possibility of secondary skin pressures, considerable time and skill required to apply the TCC, and inadequate reimbursement for this clinical procedure. Patients also report walking difficulties, difficulty sleeping and disruptions with independent self-care tasks such as bathing. In reality, fewer than 2% of wound care clinics utilize total contact casting, calling into question the continued labeling as the gold standard (Figure 3).

Figure 3. Total contact casting

Pros

- Forced compliance
- Documented pressure reduction and wound healing

Cons

- Time-consuming
- Steep learning curve
- Prevents inspection
- Contraindicated for infections and Wagner 3 and 4 wounds
- Impaired ADLs
- Sleeping difficulties
- Hygiene difficulties
- Walking instability
- Secondary skin issues and pressures
- Weekly visits/cast changes
- Inadequate reimbursement

Prefabricated walking braces

Prefabricated walking braces may be able to address immobilization, altered timing and deceleration of the foot contact period. A critical concept missing from most of these medical devices is the ability to effectively offload the extremity during walking. These devices are contraindicated for patients with severe deformities, severe wounds, and questionable compliance with the wearing schedule and overall treatment program.

Shoes, pads and inserts

Footwear should be evaluated throughout the course of treatment, and final recommendations made after complete healing has occurred and transition to the final orthotic design has been made. Insensate feet require long-term management in prop prevent recurrence of the Allowing patients to retur footwear that allowed or c the injury is rarely advised include: extra-depth shoes sole modifications, custom diabetic insoles, and custo

CROW

More than 30 years ago, th Charcot restraint orthotic walker (CROW) was developed to specifically address this patient population. (Figure 4) Designed as a total contact custom ankle-foot orthosis (AFO), the CROW consists of a clamshell ankle-foot orthosis with a rocker bottom sole. The removability of the device allows for inspection and often promotes more efficient ambulation. Frequent adjustments are required by the orthotist to address changes in edema, and to ensure proper fit and function. The CROW is most often used for CFS stages 2 and 3, and may also be used as part of a post-operative treatment program. As with all removable devices, patient compliance must be managed by ongoing follow-up, education and discussions.

Figure 4. Charcot restraint orthotic walker.

REFINING THE SOLUTIONS

Advances in material science and integrated patient management programs have led to the development of today's current orthotic designs for effective treatment of Charcot foot syndrome and foot ulcers. The challenge remains to combine an effective orthotic design with easy donning/doffing to enhance compliance, use and adherence to the treatment program. Other factors considered during the orthotic consultation include but are not limited to: age, gender, weight, presence of a wound, presence of infection, integrity of the skin, vascular status, neurological static, compliance history, history of amputation, degree of deformity, general medical status/stability, vocation and avocation. Key design concepts for lower extremity orthoses are briefly discussed (Figure 5).

Effective & Efficient Orthotic Designs

- Offloading
- Immobilization
- Deceleration during loading
- Altered timing during stance
- Improved balance
- Address limb length discrepancy
- Decreased referred pain
- Increased function
- Increased compliance
- Limb protection
- Decreased gait compensations

Figure 5. Orthotic design concepts for the treatment of peripheral neuropathy, Charcot foot syndrome and foot wounds.

OFFLOADING: Interventions such as diabetic insoles and shoes rarely achieve complete healing for chronic wounds. Offloading is a critical component of effective treatment along with wound care and debridement. While bed rest, crutches, wheelchairs and other methods may seem to be ideal, they are disruptive to the patient's daily function and activities. The shark-o™ and OWLS® are custom medical devices and adaptable to daily changes in patient limb volume. This ensures optimal load transfer through the orthosis and away from the affected areas of the foot and ankle. The key to effective pressure reduction via offloading designs is patient adherence, proper fit, effective function, and correct donning of the orthosis. Offloading devices should be considered for the prevention and treatment of foot ulcers, as well as the primary treatment of Charcot foot syndrome during stages 0–3.

IMMOBILIZATION: Immobilization of the affected joints is critical in treating CFS and, in some cases, wounds. Custom orthoses are designed to address each joint in the necessary coronal, sagittal and transverse planes. Effective alignment is maintained with the application of three-point force systems, and effective immobilization is then maintained with circumferential and hydrostatic pressures.

DECELERATE LOADING: Many patients with peripheral neuropathy and CFS have an altered loading pattern during initial contact. Orthotic designs to address foot drop and foot slap will decrease the speed and manner in which the foot impacts the ground.

DECREASE TIME SPENT ON FOOT:
Peripheral neuropathy and poor balance alter the normal mechanics of the foot, often resulting in disrupted swing and stance ratios during walking. Foot deformities further alter the mechanics and function of the foot leading to disruptions in the pathway and timing of the center of pressure as it translates across the plantar surface of the foot. For example, midfoot collapse creates a prolonged stance phase secondary to loss of the anterior forefoot lever and reduced propulsion. Custom orthoses are design to improve balance, gait mechanics and translation of the center of pressure.

DECREASE CORONAL PLANE DEVIATIONS/ IMPROVE BALANCE: Many patients develop altered gait patterns secondary to peripheral neuropathy, CFS or wounds. Coronal plane compensations are identified by the side-to-side sway of the upper trunk during walking. Lateral trunk deviations allow 70% of the body mass to deviate perpendicular from the line of progression and significantly increase the energy costs associated with walking. These gait deviations combined with poor balance may also deter the patient from maintaining an appropriate activity level after healing of the wound or Charcot joints have occurred. Considerations for the use of external walking aids such as a cane, walker or crutch should be made.

ADDRESS LIMB LENGTH DISCREPANCY: Limb length discrepancies (LLD) introduced with lower limb orthoses for immobilization and offloading should be addressed. The EvenUp™ device is used to address the LLD and can be transferred to a variety of shoes worn on the contralateral side (Figure 6A).

Figure 6A. EvenUp™ device for limb length discrepancies.

DECREASE REFERRED PAIN: Most effective orthotic designs for offloading will introduce a limb length discrepancy. Referred pain may develop in proximal joints, the contralateral limb and/or the spine. Physical therapy training may be recommended for patients with dysfunctional walking patterns, poor balance and generalized weakness or instability. Developing an effective and efficient pattern of walking with the lower extremity orthosis will reduce the chance for referred pain.

INCREASE FUNCTION/COMPLIANCE: Patient education is an essential component of the long-term management of patients with peripheral neuropathy, Charcot foot syndrome and wounds. The interdisciplinary team must collaborate to reinforce and monitor effective donning/doffing of the orthosis and daily wear time as prescribed.

PROTECTION: Patients with decreased sensation require education on ways to protect their feet from mechanical trauma. Four danger signs of damage include swelling, pain, color change and skin changes. Any of these signs should prompt a return to the specialty clinic for further assessment.

shark-o™

The shark-o is an advanced orthotic device and has been developed to specifically address Charcot foot syndrome. (Figure 6B) The unique orthotic design strategically focuses on offloading and immobilization and can be used during all stage of the Charcot process. The rocker sole design also decelerates the foot during initial loading, promotes smooth translation of the center of pressure as it travels anteriorly, and allows for a smooth rollover at terminal stance. This precisely contoured design decreases the amount of time that would be spent on a structurally unstable foot and promotes a more symmetrical gait pattern. The anterior shell of the shark-o is designed to maintain total contact over the foot section and accommodate volume changes in the calf area. Patients can easily adjust for daily calf volume changes by sliding the anterior shell inside the posterior boot structure (Figure 6C) and tightening with simple strap adjustments. The shark-o orthosis is specifically designed to reduce soft tissue motion, address or accommodate foot and ankle deformity, provide smooth and decelerated loading and provide smooth transition and rollover during walking.

Figure 6B. The shark-o is used for the prevention and management of Charcot foot syndrome and ulcers caused by ischemia, direct trauma and/or repetitive stresses.

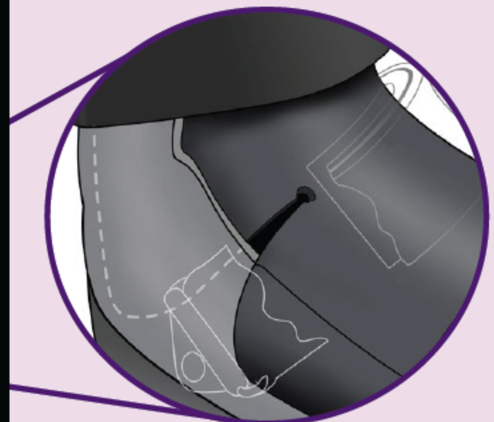

Figure 6C. Patent pending design feature to enhance patient adjustability for volume changes.

POST-HEALING PROGRAMS

May continue up to 2 years for complete healing

Focus on protective and gradual weight bearing

- **Month 1 post-healing:** 90% with shark-o during weight bearing activities; 10% with appropriate shoe wear, inserts and/or transitional orthosis during limited household ambulation
- **Months 2–3 post-healing:** 75% with shark-o during weight bearing activities; 25% with appropriate shoe wear, inserts and/or transitional orthosis during limited household ambulation
- **Months 4–6 post-healing:** 50% with shark-o during weight bearing activities; 50% with appropriate shoe wear, inserts and/or transitional orthosis during limited household and community ambulation
- **Develop individual life span orthotic care program**

Figure 7. Post-treatment considerations of Charcot foot syndrome with the shark-o.

Treatment programs with the shark-o must be individualized for each patient. The shark-o is worn full-time from the time the patient gets out of bed to the time they bathe and go back to bed. Initial healing of the Charcot foot syndrome may last from 60–100 days, depending upon the timing of the diagnosis and initiation of the orthotic treatment program. It is important to continue to manage the patient after Stage 3 healing has occurred and post-healing considerations are outlined in Figure 7.

OWLS®

Orthomerica's whole limb solutions (OWLS) is a line of custom AFOs designed to treat a variety of orthopedic anomalies of the foot and ankle (Figure 8). The OWLS system is designed to address the primary condition that caused the wound, is able to accommodate for multiple wounds, and provides exceptional limb stabilization while unloading the affected areas. The sole of the orthosis is specifically modified to further enhance unloading efforts for forefoot, midfoot and hindfoot contouring. Benefits of the OWLS system include fewer trips to the wound care center, no risk of compartmental syndrome, daily wound site inspection and treatment of Wagner 3 and 4 wounds, and may also be designed for use with a wound VAC system. Similar to the shark-o orthosis, the OWLS system is specifically designed to reduce soft tissue motion, address or accommodate foot and ankle deformity, provide smooth and decelerated loading, and provide smooth transition and rollover during walking.

Figure 8. OWLS designs for hindfoot, forefoot and midfoot wounds, and partial foot amputation.

As discussed with the shark-o treatment program, wounds also require a stringent post-healing strategy. General recommendations are outlined in Figure 9.

POST-HEALING PROGRAM

- **Month 1 post-healing:** continue with existing OWLS
- **Month 2 post-healing:** continue with OWLS, consider transitional design such as ADO
- **Month 3 post-healing:** focus on transitional orthosis such as ADO, continue with OWLS during periods of high or prolonged weight bearing activity
- **Develop individual lifelong care program with appropriate footwear, inserts and/or transitional AFO**

Figure 9. Post-healing considerations for wounds treated with OWLS designs

CLAW®

Orthomerica's carbon laminate alignment walker (CLAW) technology was developed to enhance OWLS and shark-o design functions by improving the fit and function of orthotic treatment programs for patients with CFS and/or wounds. The CLAW allows triplanar adjustments easily made by the orthotist in the patient treatment room to accommodate and optimize the many unique variables of a patient's walking pattern. Specifically, 360 degrees of rotation in the transverse plane allows the CLAW footplate to be aligned effectively relative to the line of progression for patients with severe foot deformities and misalignments. (Figures 10 & 11)

Figure 11. CLAW is designed to address foot deformities and line of progression discrepancies

Figure 10. The CLAW allows 360 degrees rotation in the transverse plane to address each individual's line of progression and foot deviations.

ADO™

The advanced diabetic orthosis (ADO) is a custom AFO design for post-operative wound care. The ADO is designed to accommodate volume changes, allow full heel relief and prevent plantarflexion contractures. An extended footplate helps to prevent toe ulcerations and contusions, and the non-skid sole allows the patient to ambulate short distances in the home. Indications for use include Wagner 1+ heel ulcerations, post-operative wound care, and post-calcanectomy. The ADO will easily accommodate a wound vacuum if needed, and can be designed to address wounds on the forefoot, malleoli or proximal ankle and leg. (Figure 12)

Figure 12. The advanced diabetic orthosis (ADO).

General indications and orthotic treatment programs for the devices discussed on the previous pages are outlined in the table below. (Figure 13)

Pathology	Indications	Orthotic Device	Orthotic Principles
PERIPHERAL NEUROPATHY	• Chronic condition	• Custom AFO	• Stabilize structure • Improve function
CHARCOT FOOT SYNDROME	• Stages 2–4 • Post-healing	• shark-o	• Offloading • Immobilization
	• Severe deformity • Referred pain	• CLAW	
FOOT ULCER	• Wagner 2–4 • Heel, midfoot and forefoot ulcers • Severe deformity	• OWLS	• Offloading • Decelerate loading • Optimize timing • Improve balance
	• Severe deformity • Referred pain • Heel, midfoot and forefoot ulcers	• CLAW	
	• Wagner 1+ • Transitional after OWLS • Post-operative • Night time	• ADO	
	• Post-healing • Transitional	• Relative to orthopedic condition(s) and functional deficit(s)	

Figure 13. General indications, orthotic devices and orthotic principles for peripheral neuropathy, Charcot foot syndrome and foot ulcers.

Figure 14. Partnering with wound care treatment team members.

Vascular/General Surgeon
MAY BE PRESCRIBING

- Orthoses for wound care
- Compression hose
- Prostheses

Podiatrists
MAY BE PRESCRIBING

- Orthoses for wound care
- Custom AFOs
- Prefabricated AFOs
- Diabetic foot orthoses
- Custom foot orthoses
- Diabetic footwear
- Prostheses

Therapists
MAY BE PROVIDING

- Gait training with orthoses
  - Minimize compensations
  - Increase efficiency
  - Decrease energy costs
  - Addition of assistive devices
  - Improve balance and safety
- Stretching and strengthening
- Reinforcement for proper wound management with pressure relief
- Reinforcement for improved compliance and adherence

Orthotists
MAY BE PROVIDING

- Functional orthoses
- Transitional orthoses
- Shark-o
- OWLS
- CLAW components
- ADOs
- Foot orthoses
- Other custom designs
- Referrals for prosthetic care
- Reinforcement for proper wound management with pressure relief
- Reinforcement for improved compliance and adherence
- Orthotic life care plans

Interdisciplinary team management

There are more than 30 million people in the United States diagnosed with diabetes, and approximately 15% of these patients will develop foot ulcerations over the course of their lifetime. Two to five percent of these patients will undergo amputation at various levels of the lower extremity. Partnering with physician, surgeons, nurses and therapists allows orthotists to develop comprehensive care programs that include: (1) immediate orthotic management with early intervention for peripheral neuropathies, (2) a variety of elite orthotic designs for CFS and wounds, (3) transitional orthotic designs after initial healing has occurred, and (4) education about both orthotic and prosthetic care programs as needed. (Figure 14)

Adherence to the wound care program plays a significant role in the healing of foot ulcers. Team management must focus on continual education and support for patients with CFS and foot ulcers. It is important to keep in mind that protective weight bearing should include transitional orthotic programs for up one to two years after an episode of Charcot foot syndrome or after wound healing has occurred. This may include the continued wearing of the shark-o or OWLS designs or the development of a transitional orthosis to provide protection, structural stability and functional tasks. Transitional orthoses may be lower profile than the shark-o or OWLS designs depending on the needs and activities of the patient. Simply allowing the patient to return to the footwear and/or unprotected activity patterns that that the patient experienced prior to CFS or that created the foot wound will increase the likelihood of recurrence. As with all orthotic care programs, patients may experience difficulty with donning/doffing, the size of the orthosis, independence, ability to return to work, self-care and other factors that may discourage them from continued use of the orthosis post-healing. Effective wound healing is a dynamic process and requires frequent follow-up for all aspects of the treatment program. Team members must work together to create a new mindset of improved compliance and adherence if new results are to be obtained.

Patients with ulcers are instructed to undertake some major lifestyle changes and reduce their daily activity level while healing occurs, and the duration of offloading and immobilization program may range from 8 weeks to 1 year. With these types of extended care programs, it is not uncommon for the patient to present with some muscle atrophy, loss of bone density, joint stiffness and contralateral overuse. Protective rehabilitation efforts continue under the supervision of the physician, continued maintenance programs and transitional orthotic designs provided by the orthotist, and general physical exercise and gait training provided by the physical therapist. All team members should continue to monitor the limbs to prevent recurrence. Ultimately, the goal is to maintain a stable and plantigrade foot that accepts appropriate footwear to be worn, transitions to the lowest profile orthotic designs, prevents amputation, and provides a functionally and structurally sound foot for continued ambulation.

Figure 14 outlines the orthotic recommendations and treatment programs associated with peripheral neuropathy, Charcot foot syndrome and foot wounds.

Successful management of limbs affected by peripheral neuropathy, Charcot foot syndrome and ulcerations depend on the collaborative expertise of an interdisciplinary care team. Care programs must be developed and monitored to both address and prevent complications and further dysfunction. Patients require rapid access to care for early diagnosis and immediate treatment regimens. Education is a cornerstone to successful outcomes; patients must understand the life- and limb-threatening nature of the pathology, adhere to the wearing schedule, comply with lifestyle modifications and altered activity levels, understand the required offloading and immobilization strategies, attend all scheduled follow-up visits with different members of the medical team, and monitor their limb in between visits with healthcare professionals. Once the dysfunction, deformity and/or wound have been effectively addressed, six to 12 month follow-up programs are scheduled. Lifelong care plans must be developed to prevent progression, recurrence and complications of the various pathologies. Good team management addresses a complex pathology; great team management prevents further complications and/or recurrence.

(References and additional readings on back page)

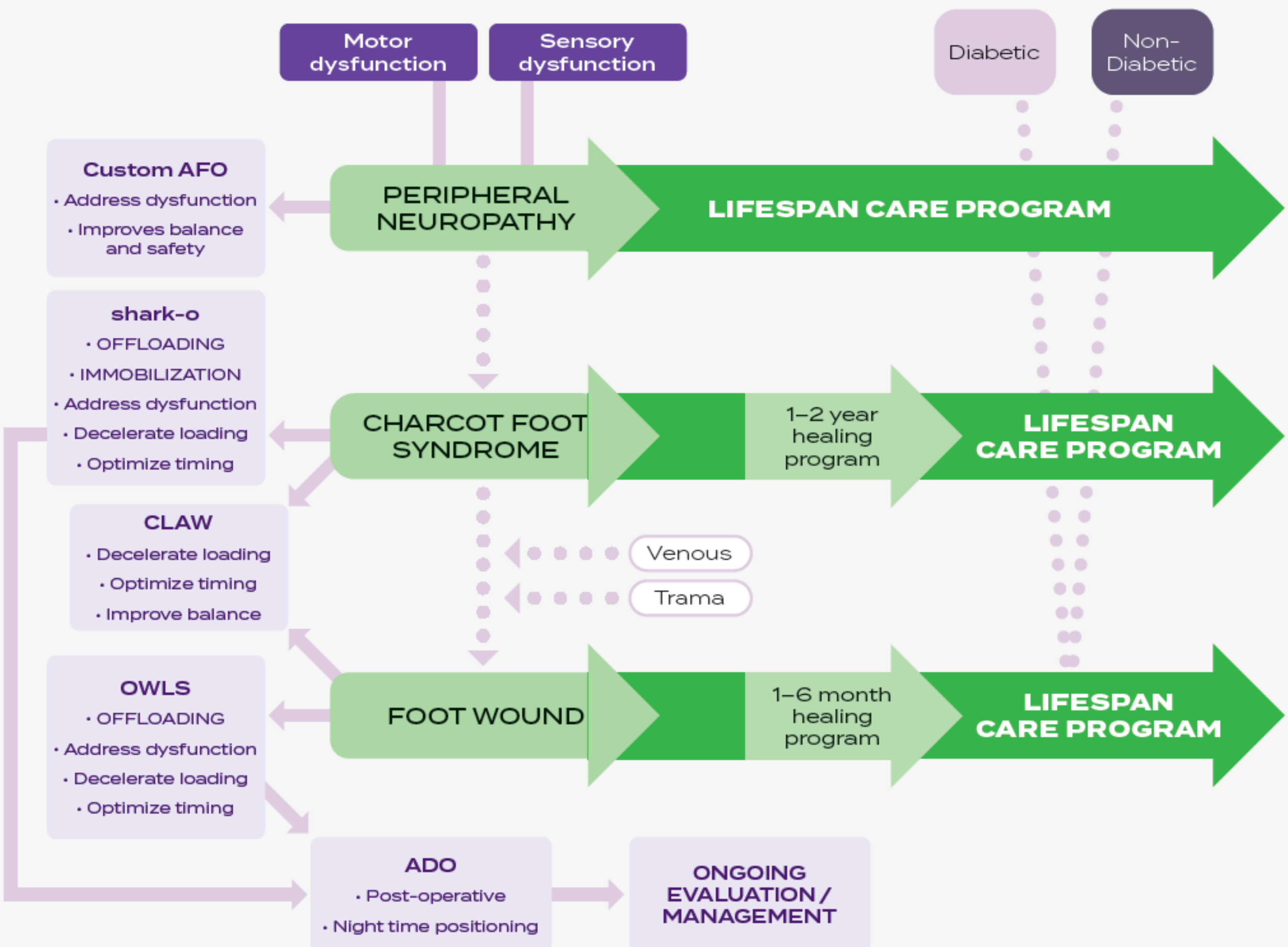

Figure 14. Orthotic treatment recommendations for peripheral neuropathy, CFS and foot ulcers.