



Clinical White Paper #2

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Part II: Refining the Solution

ORTHOTIC TREATMENT CONCEPTS

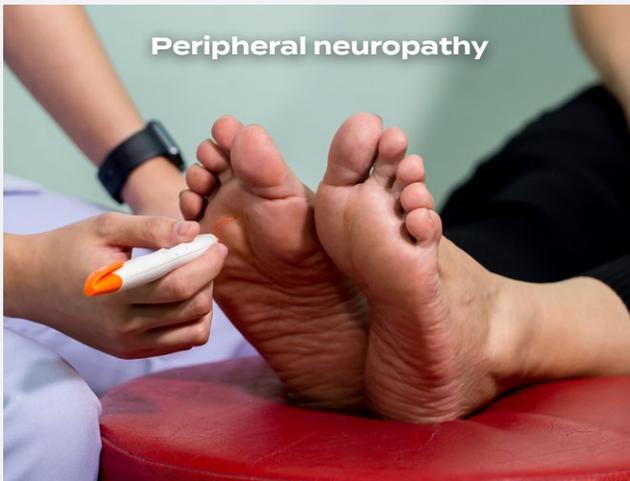
Part I was written to define the problems and outline the relationship of peripheral neuropathy, Charcot foot syndrome (CFS) and wound development. Operative and non-operative treatment options are implemented to manage these conditions, and Part II of this series will focus on non-operative orthotic 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 proper footwear to prevent recurrence of the trauma or wound. Allowing patients to return to the previous footwear that allowed or did not prevent the injury is rarely advised. Considerations include: extra-depth shoes, stiff rocker sole modifications, custom inserts, custom diabetic insoles, and custom shoes.

CROW

More than 30 years ago, the 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 status, 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.



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



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

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)



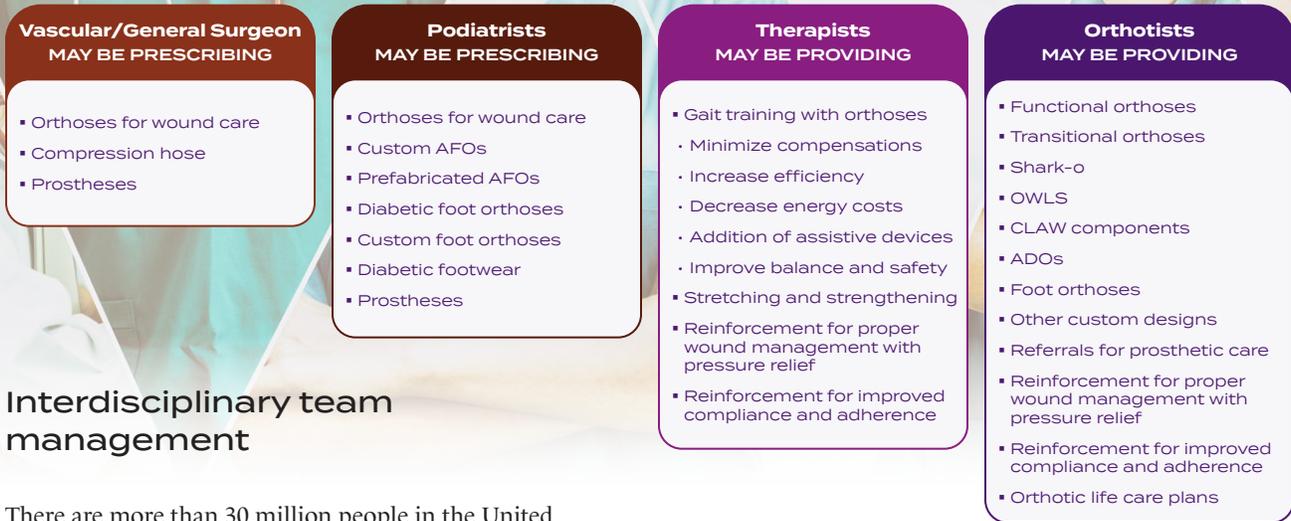
Figure 12. The advanced diabetic orthosis (ADO).

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	<ul style="list-style-type: none"> Chronic condition 	<ul style="list-style-type: none"> Custom AFO 	<ul style="list-style-type: none"> Stabilize structure Improve function
CHARCOT FOOT SYNDROME	<ul style="list-style-type: none"> Stages 2–4 Post-healing 	<ul style="list-style-type: none"> shark-o 	<ul style="list-style-type: none"> Offloading Immobilization
	<ul style="list-style-type: none"> Severe deformity Referred pain 	<ul style="list-style-type: none"> CLAW 	
FOOT ULCER	<ul style="list-style-type: none"> Wagner 2–4 Heel, midfoot and forefoot ulcers Severe deformity 	<ul style="list-style-type: none"> OWLS 	<ul style="list-style-type: none"> Offloading Decelerate loading Optimize timing Improve balance
	<ul style="list-style-type: none"> Severe deformity Referred pain Heel, midfoot and forefoot ulcers 	<ul style="list-style-type: none"> CLAW 	
	<ul style="list-style-type: none"> Wagner 1+ Transitional after OWLS Post-operative Night time 	<ul style="list-style-type: none"> ADO 	
	<ul style="list-style-type: none"> Post-healing Transitional 	<ul style="list-style-type: none"> 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.



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)

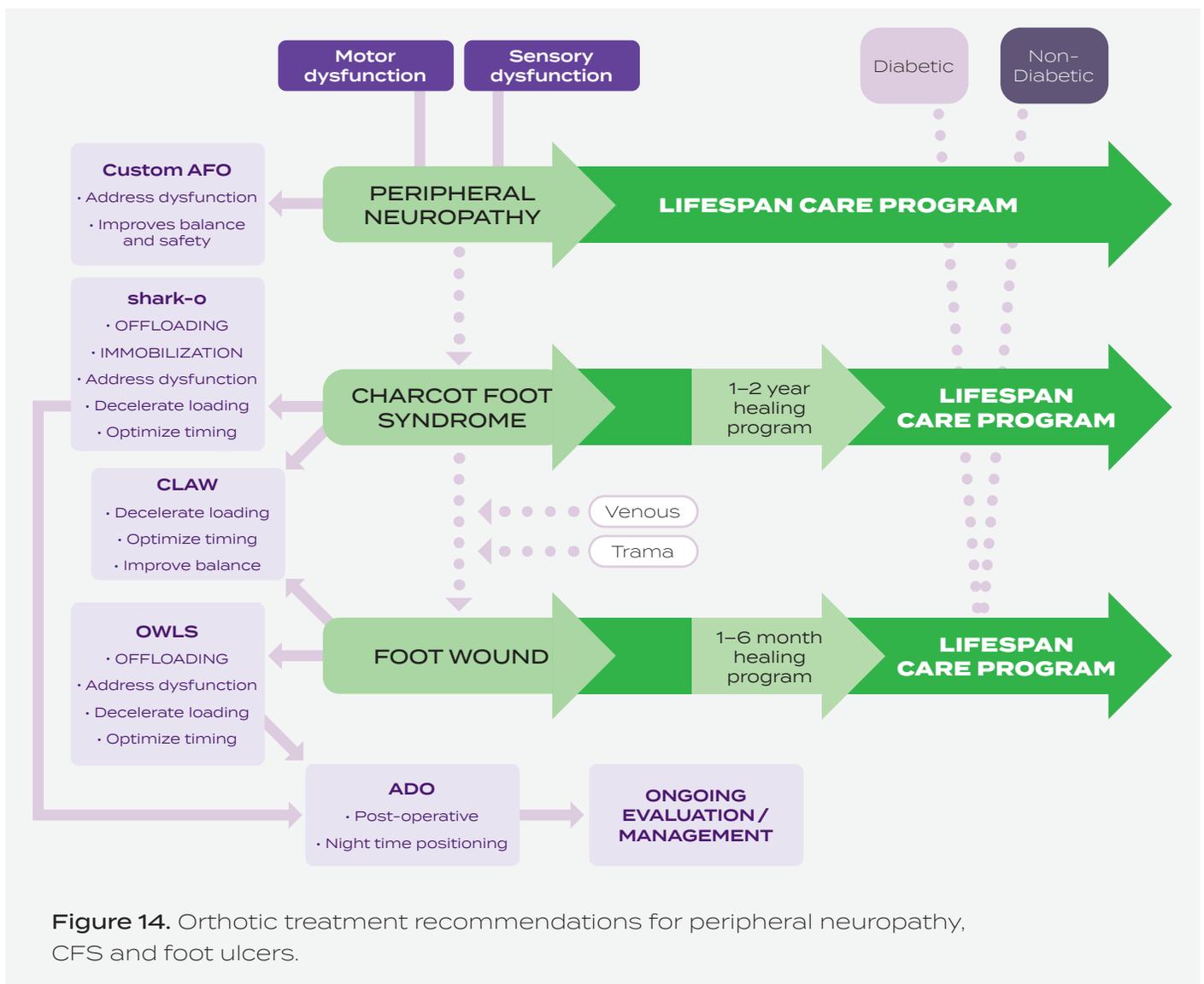


Figure 14. Orthotic treatment recommendations for peripheral neuropathy, CFS and foot ulcers.



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