

Prescription Custom Foot Orthoses

Standard of Practice for Chiropractors and Podiatrists

I. INTRODUCTION

Prescription custom foot orthoses are an integral part of patient care in the management of pedal pathologies and are used to improve gait and to alleviate pain and discomfort from abnormal foot function or structure.

This Standard of Practice reflects what should be performed by Chiropractors and Podiatrists with respect to the manufacturing and dispensing of orthotic devices. [For purposes of this Standard of Practice "dispensing" includes fitting the prescription custom foot orthoses and educating the patient on their proper use to maximize their effectiveness.] However, this treatment therapy is dependant on many variables including each patient's medical history, footwear, activities, and work environment. As a result of the personalized treatment plan and this multi-factorial and complex process, deviations from this Standard of Practice may be called for in certain circumstances. In these situations, the patient chart should clearly document the revised treatment process and the justification.

The College of Chiropractors of Ontario has developed its prescription custom foot orthoses standard to ensure that the public of Ontario has access to safe and effective foot care, including safe and effective foot prescription custom foot orthoses. The College defines an orthotic prescription (the "prescription") to be the set of instructions intended for the orthotic laboratory that very specifically outlines the parameters of design, composition and fabrication of the orthotic intended for the treatment of an underlying medical condition or postural imbalance of the patient.

II. BACKGROUND TO PRESCRIPTION CUSTOM FOOT ORTHOSES

Unlike the case with hearing aids, dental prostheses and eyewear, neither prescribing, nor dispensing foot orthoses is a controlled act under the *Regulated Health Professions Act* (RHPA). These functions are deemed to be "public domain acts", able to be lawfully performed by any regulated or unregulated practitioner. Accordingly, in today's marketplace, members of many different professions and practitioners with varying levels of competency prescribe and dispense foot orthoses. Extended health benefits insurers, employers and other stakeholders are increasingly concerned about the excessive utilization and sometimes outright fraud in prescribing and dispensing foot orthoses. Extended health benefits insurance plans are increasingly limiting coverage, or applying restrictions with respect to prescribing and dispensing.

Even though prescribing and dispensing foot orthoses are in the public domain, Chiropractors and Podiatrists are the only health care providers whose statutory scope of practice explicitly includes the provision of orthotic devices: **"The practice of chiroprody is the assessment of the foot and the treatment and prevention of diseases, disorders or dysfunctions of the foot by therapeutic, orthotic or palliative means."** *The Chiroprody Act, 1991 S.O. 1991, CHAPTER 20, s. 4.* Accordingly, Chiropractors and Podiatrists are expected to apply their unique scope of practice, competencies and best clinical practices to prescribe and dispense the highest quality prescription custom foot orthoses possible and to show leadership in that regard within the health care community and within the health care delivery system.

Members of the College of Chiropractors of Ontario have extensive knowledge of lower limb biomechanics, and must uphold standards of practice to ensure that they are providing the most functional devices possible, along with comprehensive orthotic case management. The desired outcome is to control and/or improve the function or stability of the foot by preventing or encouraging motion of the foot joints, thereby restoring equilibrium between the foot and the lower body kinetic chain.

Over-the-counter prefabricated devices are readily available in the marketplace. Although prefabricated devices can be helpful on their own, or can sometimes be modified to resolve a patient's condition, these must not be offered, or conveyed to the public, or represented as custom-made/custom-molded orthotic devices.

III DEFINITIONS

The following definitions are used in this Standard of Practice:

- **Orthosis** - A device utilized to assist, resist, facilitate, stabilize or improve range of motion and functional capacity.
- **Foot orthoses** – plural of foot orthosis
- **Custom made/custom molded foot orthosis** - A device derived from a three-dimensional representation of the patient's foot and also made of suitable materials with regard to the individual's condition. It is either accommodative or functional and is removable from the patient's footwear. A foot orthosis shaped via a self-molding (self-contouring) process is not a custom-made/custom-molded foot orthosis, nor is a modified, prefabricated device.
- **Prescription custom foot orthosis (PCFO)** - same as Custom made/custom-molded foot orthosis
- **Functional Prescription custom foot orthosis (PCFO)** - A custom-made foot device created specifically to address the pathomechanical features of a foot condition that may be structural or functional in nature by providing support or stability.
- **Accommodative Prescription custom foot orthosis (PCFO)** – a device designed with a primary goal of conforming to and re-balancing the individual's foot, allowing plantar-grade floor contact, which permits forces to be evenly distributed to the foot.
- **Customized foot orthosis** – any prefabricated appliance or device that requires modification or assembly to accommodate a condition or alter lower extremity biomechanical function and is removable from the individual's shoe. Cutting a prefabricated inlay to an indicated trimline does not constitute customizing a foot orthosis. A customized prefabricated device is **not** a custom-made/custom-molded foot orthosis.
- **Prefabricated foot care products** – any mass-produced prefabricated foot care item, appliance or device that is sold over the counter (OTC) and is readily available, including prepackaged and non-packaged products.
- **STS Slipper Cast** – a casting product with a fast setting resin used to obtain a quicker, accurate mold of the foot without the mess of plaster

IV CUSTOM-MADE FOOT ORTHOSES

Prescription custom-made foot orthoses can be functional or accommodative. A functional device that is custom-made/custom-molded is generally the prescription of choice for patient treatment. However, an accommodative device may be prescribed for patients for whom a functional device is not necessary or appropriate.

A. Functional Prescription Custom Foot Orthoses (PCFO)

Approved by Council – February 20, 2015

i. Objectives for Functional PCFO

- To control and/or improve the function of the foot to a specific degree as determined by a thorough biomechanical evaluation in order to alleviate pedal and lower extremity musculoskeletal symptomatology, and
- To prevent or reduce the development of abnormal forces and subsequent deformities by mechanical control.

ii. Causes for the need of Functional PCFO

- Structural weaknesses or deformities, most often inherited, or acquired through trauma, contributing to abnormal, imbalanced bone and /or soft tissue structure, which may result in compensatory changes in other parts of the body.
- Overuse syndromes

iii. Prescription of a Functional PCFO should include:

- A thorough biomechanical examination with appropriate measurements taken and recorded and may include:
 - a) Assessment of the range and quality of motion and the position of the rearfoot, forefoot, subtalar joint and ankle joint complex
 - b) Gross assessment of muscle strength (Testing of specific muscles is necessary in certain pathologies.)
 - c) An evaluation of the stance position
 - d) A clinical evaluation of the limb length in certain circumstances
 - e) Assessment of the position, range and quality of motion of the following structures may be necessary in certain pathologies:
 - Spine
 - Hip
 - Knee
 - Ankle joint
 - Subtalar joint
 - Fifth ray
 - First ray
 - 1st MPJ (metatarsophalangeal joint)
 - Lesser MPJ's
 - IPJ's (interphalangeal joints)
 - f) Gait evaluation may include:
 - Angle of Gait
 - Base of Gait
 - Stride length
 - Speed :
 - Timing of heel lift
 - Abnormal time periods, positions or motions of hip, knee, ankle, STJ, MTJ, MPJs and IPJs in each of the phases of the gait cycle during walking or running:
 - Contact:
 - Midstance:
 - Propulsion:
 - Swing:
 - Postural considerations:
 - Head:
 - Shoulders:
 - Arm swing:

- Hips/pelvis:
- g) The use of information from in-shoe pressure measurement or force plate pressure measurement is useful in assessing the loads being applied to the plantar surfaces of the foot and can be helpful in offloading pathological plantar pressures. This information should not be used to extrapolate the plantar contours of the foot.

iv. Construction of Functional PCFO

- The orthotic devices must be constructed from the prescription and fabricated from appropriate materials in consideration of the patient's diagnosis, footwear and activities.
- The following patient information is necessary to create an appropriate PCFO prescription:
 - Shoe size and width
 - Heel height of shoe (shoe style)
 - Biomechanical data pertinent to the patient's deformity
 - Weight
 - Age
 - Activity level
 - Occupation
 - Diagnosis
 - Tissue stress diagnosis(soft tissue or bony):
 - Identify the anatomical structure that is being overloaded due to poor foot function for example: plantar fasciitis, heel spur syndrome, hallux abducto valgus, shin splints, patello femoral syndrome
 - Foot Morphology Diagnosis
 - Forefoot varus
 - Forefoot valgus
 - Rearfoot varus
 - Rearfoot valgus
 - Ankle equinus
 - Sagittal Plane Facilitation Diagnosis for example
 - Functional hallux limitus
 - Ankle equinus
 - previous orthotic use or mechanical treatment
 - systemic diseases that have podiatric manifestations
 - proximal musculoskeletal pathology
- For an orthosis to be considered a PCFO, the prescription should include at least the following:
 - Type of material to be utilized
 - Flexibility of device
 - Cast balancing technique (intrinsic correction) and/or rearfoot/forefoot posting
 - Depth of heel seat
- Additional modifications may be prescribed based on the individual patient's needs:

- forefoot extensions and top covers
- post flaring
- heel lifts
- flanges
- length
- cutouts
- cast fill and accommodations
- location of lesion(s)

v. Methods for Obtaining 3D Anatomic Volumetric Foot Model for PCFO

- Non-weight-bearing plaster of paris casts, non-weight-bearing STS slipper casts or equivalent, or three-dimensional, non-weight-bearing scanning of the feet.
- Casting/scanning must be done by the Member, designated colleague (Chiroprapist or Podiatrist), or designated trained assistant or support personnel.
- All casts/scans must be evaluated by the Member or designated colleague (Chiroprapist or Podiatrist) before being sent to the lab, which evaluation must include a comparison of the patient’s foot to the cast/scan to ensure that it is an accurate reflection of the patient’s condition and the contours of the patient’s foot.

One Recommended Negative Casting Technique for Orthotics

- A plaster of paris negative suspension cast in the neutral position is ideal for the prescription of functional orthotics. To date, this method is the most effective. However, as more clinical evidence becomes available, the ideal casting technique recommendations may be amended.
- Plaster of paris is applied to the foot with a two-splint technique.
- The foot is then positioned so that the subtalar joint is held in the neutral position, without pronating or supinating the foot. While keeping the foot in subtalar neutral, the midtarsal joint should be pronated, and the ankle joint dorsiflexed to resistance or 90 degrees. Hold the cast in this position until the plaster dries sufficiently.
- Once the cast is removed, it should be evaluated to ensure that an accurate impression was taken reflecting the patient’s condition, and contours of the foot.
- The aim is to create an accurate replica of the forefoot to rearfoot relationship.
- It is important to remember that the quality and efficacy of the orthotic is dependent upon the accuracy and precision of the negative cast.

B. Accommodative Prescription Custom Foot Orthoses

An accommodative device is prescribed for patients for whom a functional device is not necessary or appropriate.

i. Objectives for Accommodative PCFO

- To provide a measure of control to the function of the foot in order to alleviate pedal and lower extremity musculoskeletal symptomatology,
- To prevent or reduce the worsening of pedal deformities by mechanical control
- Deflect pressure from ulcers, hyperkeratoses, and areas of excessive pressure, which permits forces to be evenly distributed to the foot
- Increase cushioning of the foot

ii. Causes for the need of Accommodative PCFO may include:

- Structural weaknesses or deformities, most often inherited, or acquired through trauma or surgery
- Complications as a result of systemic disease causing a high-risk foot with a potential for soft tissue breakdown.

iii. Prescription of an Accommodative PCFO should include:

- A thorough biomechanical examination with appropriate measurements taken and recorded (see section IV. A, iii, a-e)
- A stance and gait analysis (see section IV, A iii, f)
- Plaster of paris casts, non-weight-bearing STS slipper casts or equivalent, or three-dimensional, non-weight-bearing scanning of the feet.

iv. Construction of Accommodative PCFO (see section IV, A, iv)

- The Member must take reasonable action to ensure that the orthotic device is constructed from the prescription and is fabricated from appropriate materials in consideration of the patient's footwear, activities and circumstances.

PCFOs may also be a combination of functional and accommodative devices, not necessarily one or the other.

V DISPENSING PRESCRIPTION CUSTOM FOOT ORTHOSES TO THE PATIENT

(Applies to Functional and Accommodative Devices)

- A. Best practice would have would have the custom foot orthoses both prescribed and dispensed by the same practitioner in order to provide patients with a seamless continuum of care and to ensure that there is no fragmentation or confusion of responsibility or liability for results. However, another designated member (chiroprapist or podiatrist) may dispense the prescription custom foot orthoses to the patient.
- B. New prescription custom foot orthoses should be fitted by a chiroprapist or podiatrist to ensure that the fit of the device meets the prescription, and the contours of the patient's foot.
- C. The Member should provide the following advice/guidelines to the patient in a manner that can be understood by the patient:
 - Guidelines for developing tolerance and acceptance of the devices
 - Time frames to achieve potential results
 - Appropriate footwear for the patient's:
 - a. condition
 - b. activities
 - c. foot orthoses
- D. The requirements for follow-up to the dispensing of prescription custom foot orthoses include:
 - Provide short term instructions for usage of the devices.
 - Offer a follow-up appointment within a reasonable period of time after dispensing the orthotic devices (such as 3-4 weeks). This should be documented in the patient record. A telephone follow-up would suffice, if the patient does not require *or* attend a follow-up visit.
 - Advise the patient regarding the need for periodic long-term check-ups.
- E. The Member should address what the patient may expect regarding the outcomes from the treatment. Although the practitioner cannot guarantee the success of any treatment, a reasonable level of patient satisfaction is expected. The practitioner

should explain these expectations in advance, both at the time of obtaining consent (prior to casting for the prescription custom foot orthoses), and at the time of dispensing.

- F. Each practitioner should have an office policy to deal with patient dissatisfaction. This policy should be communicated to the patient before initiating treatment. While patient non-compliance may contribute to lack of success with prescription custom foot orthoses, the Member is expected to expend best efforts in working with the patient to achieve the best results and compliance.

VI. CONCLUSIONS

The College of Chiropodists of Ontario has developed its Standards of Practice for prescription custom foot orthoses to reflect the best available clinical evidence. Within the context of constantly evolving information, practitioners are encouraged to continually evaluate their orthotic prescription strategies and procedures to maintain currency with best practices. In this way, Members can ensure that patients are achieving the most positive health outcomes possible and that Chiropodist and Podiatrists are competent providers of prescription custom foot orthoses.

The College of Chiropodists of Ontario recognizes that there can be exceptions to these standards where all of the above conditions cannot be met (i.e. physical and/or psychological limitations of the patient or uncooperative patients, especially young children). In these situations, an explanation should be given to the patient or guardian as to why all the criteria were not met in prescribing and dispensing the orthotic devices and this explanation should be noted in the chart.