PRESCRIPTION CUSTOM FOOT ORTHOSES

Standards of Practice for Members of the College of Chiropodists of Ontario

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I. Introduction

Prescription Custom Foot Orthoses (**PCFO**) are an integral part of patient care in the management of pedal pathologies and are used to improve gait and alleviate pain and discomfort from abnormal foot function or structure.

The College has developed this Standard of Practice to ensure that the public of Ontario has access to safe and effective foot care, including safe and effective PCFO. This Standard of Practice reflects what is required by Members with respect to the prescribing and dispensing of orthotic devices. As set out in this Standard of Practice, it is the responsibility of a Member to comply with all aspects of this Standard of Practice. This responsibility includes, without limitation, ensuring continuity of care for the patient and, in particular, that a Member who prescribes a PCFO is also responsible for dispensing that PCFO to the patient as set out in this Standard of Practice.

II. Definitions

In this Standard of Practice, the following terms mean as follows:

- **Accommodative Prescription Custom Foot Orthosis (Accommodative PCFO)** – An orthotic 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.
- **College** – The College of Chiropodists of Ontario.
- **Customized Foot Orthosis (CFO)** – A 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.[1]
- **Custom Made/Custom Molded Foot Orthosis** – Synonym for the preferred term PCFO.
- **Dispensing** – Inspecting the PCFO to ensure it meets the prescription, fitting the PCFO on the patient, and educating the patient on the proper use of the PCFO.
- **Foot Orthoses** – Plural of foot orthosis.
- **Functional Prescription Custom Foot Orthosis (Functional PCFO)** – A custom-made orthotic 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.
- **Member** – A member of the College (in the plural, "Members").

[1] **Explanatory Note:** 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. Additionally, adding a customized foot orthosis into a shoe does not make the shoe a prescription/custom made shoe (Refer to the College's Prescription Footwear Standard).

- **Orthosis** – A device utilized to assist, resist, facilitate, stabilize or improve range of motion and functional capacity.

- **Orthotic/Orthotics** – Synonym for the term Orthosis/Orthoses.

- **Orthotic Prescription** – 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 foot or medical condition or postural imbalance of the patient.

- **Plaster of Paris Bandage** – A casting product available as a plaster embedded gauze wrap used to obtain a negative mold of the foot and/or leg.

- **Prefabricated Insole** – Any mass-produced prefabricated shoe insole that is sold over-the-counter (OTC) without any particular user/wearer in mind.

- **Prescribing Member** – A Member who has prescribed a PCFO.

- **Prescription Custom Foot Orthosis (PCFO) –** An orthotic 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.[2]

- **STS Slipper Cast** – A casting product composed of a fast setting fibreglass resin embedded wrap used to obtain a negative mold of the foot and/or leg.

III. Background to Prescription Custom Foot Orthoses

Unlike the case with hearing aids, dental prostheses and eyewear, prescribing and/or dispensing foot orthoses are not controlled acts within the meaning of 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, practitioners in many different professions and with varying levels of competency recommend and/or sell "foot orthoses". Extended health benefits insurance plans are increasingly limiting coverage, or applying restrictions with respect to prescribing and dispensing orthotics. Consequently, it is therefore mandatory that Members adhere to the regulations and standards required by the College, including this Standard of Practice, in order to protect the public and to distinguish Members from other regulated and non-regulated practitioners.

Even though recommending and selling foot orthoses are acts in the public domain, Members are the only healthcare providers whose statutory scope of practice explicitly references orthotics: **"The practice of chiropody is the assessment of the foot and the treatment and prevention of diseases, disorders or dysfunctions of the foot by therapeutic, orthotic or**

[2] **Explanatory Note:** 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.

palliative means."[3] Accordingly, Members are expected to apply their unique scope of practice, competencies, and best clinical practices to prescribe and dispense the highest possible quality PCFO and demonstrate leadership in that regard within the healthcare community and within the healthcare delivery system.

Members have extensive knowledge of lower limb biomechanics and are required to uphold this Standard 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 optimal functioning of the foot joints and the lower extremity.

Over-the-counter prefabricated devices are readily available in the marketplace. Although prefabricated devices may be appropriate, or can sometimes be modified to resolve a patient's condition, these devices must not be offered, or conveyed to the public, or be represented by Members as a PCFO.

IV. Prescription Custom Foot Orthoses

A PCFO 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 PCFO

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/or lower extremity musculoskeletal symptomatology, and

- To prevent or reduce the development of abnormal forces by mechanical control in order to ameliorate the likelihood of developing musculoskeletal deformities, pathology or lesions.

ii. Indications for 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 within the foot and/or in other parts of the body.

- Overuse syndromes.

[3] *Chiropody Act, 1991*, S.O. 1991, c. 20, s. 4.

iii. **Prescription of a Functional PCFO** is required to include information that is specific to the patient and their needs. The assessments that are performed by a Prescribing Member to determine the patient's prescription shall be documented in the health record by the Prescribing Member and the assessments shall include the following:

- A thorough biomechanical examination with appropriate measurements taken and recorded in the patient's file (refer to the Records Standard) and, as necessary:

  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 when required

  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:
     - Spine
     - Hip
     - Knee
     - Ankle joint
     - Subtalar joint
     - Mid Tarsal Joint
     - Tarso-Metatarsal Joint
     - Fifth ray
     - First ray
     - 1st Metatarsophalangeal joint (MPJ)
     - Lesser MPJ's
     - Interphalangeal joints (IPJ's)

  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, joints of the foot 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 may be 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 nor does it replace the need for physical, biomechanical, and gait examinations.

iv. Construction of Functional PCFO

- The orthotic device must be constructed and fabricated from appropriate materials as directed by the Orthotic Prescription.

- The following patient information must be considered for the PCFO prescription:
    - Shoe size and width
    - Type of Footwear
    - Biomechanical data pertinent to the patient's deformity
    - Weight
    - Age
    - Intended use and Activity level
    - Occupation
    - Diagnosis
    - Previous orthotic use or bracing, strapping, taping, or offloading treatment
    - Systemic diseases that have podiatric manifestations
    - Proximal musculoskeletal pathology

- For an orthosis to be considered a PCFO, the prescription shall include at least the following:
    - Types of material to be utilized
    - Flexibility of device
    - Cast balancing technique (intrinsic vs extrinsic correction)
    - 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)

- The Prescribing Member must perform and document the necessary assessments required for the Orthotic Prescription. The Prescribing Member is required to clearly document in the health record the following information:
  - The need for the Orthotic Prescription
  - The therapeutic goal of the orthotic device in the overall management of the specific patient, and
  - How the efficacy of this intervention will be assessed.

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 in the subtalar joint neutral position or the most anatomically correct joint position.

- Casting/scanning must be done by the Prescribing Member, designated Member, *or* designated trained assistant, but the cast or laser scan must be reviewed and assessed by the Prescribing Member and compared against the patient's feet to ensure accuracy on the same day that they were obtained and before the patient is discharged from the office.

One Recommended Negative Casting Technique for PCFO

- 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 by the Prescribing Member on the same day before the patient is discharged from the office 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 PCFO

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. Indications for 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 is required to include information that is specific to the patient and their needs. The assessments that are performed by a Prescribing Member to determine the patient's prescription shall be documented in the health record by the Prescribing Member and the assessments shall include the following:

- 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 three-dimensional, non-weight-bearing scanning of the feet in the subtalar joint neutral position or the most anatomically correct joint position. The cast or laser scan must be reviewed and assessed by the Prescribing Member and compared against the patient's feet to ensure accuracy on the same day that they were obtained and before the patient is discharged from the office.

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

- The Prescribing 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.

PCFO 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[4]

A. Best practice requires that the PCFO is both prescribed and dispensed by the same Member in order to provide patients with a seamless continuum of care and to ensure that there is no fragmentation or confusion about the responsibility or liability for results. However, where the Prescribing Member is unable to dispense the PCFO to the patient, the Prescribing Member may request that another Member dispense to the patient. For clarity, in all circumstances, the PCFO must be dispensed by a Member. It is the responsibility of the Prescribing Member to ensure that the PCFO is dispensed to the patient by a Member.

B. The Member is required to 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

C. The requirements for follow-up to the dispensing of PCFO include:

- Provide short term instructions for usage of the devices.
- At least one follow-up appointment with the Prescribing Member must be offered within a reasonable period of time after dispensing the PCFO (such as 3 to 6 weeks). It is expected that the Prescribing Member will provide additional follow-up appointments as required working toward achieving optimal functioning with the orthotics and to review and/or amend the overall management plan as needed. This should be documented in the patient record.
- Advise the patient regarding the need for periodic long-term check-ups.

D. The Prescribing Member is required to address what the patient may expect regarding the outcomes of the treatment. Although a Member cannot guarantee the success of any treatment, a reasonable level of patient satisfaction is expected. The Prescribing Member is

[4] **Explanatory Note:** Applies to Functional PCFO and Accommodative PCFO.

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

E. A Member is required to 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 a PCFO, the Member is expected to expend best efforts in working with the patient to achieve the best results and compliance.

F. In appropriate circumstances, a Prescribing Member may re-dispense a PCFO to a patient within one year of the original Orthotic Prescription without the requirement for a full patient assessment.

VI. Conclusion

The College has developed this Standard of Practice to reflect the best available clinical evidence. Within the context of constantly evolving information, Members are encouraged to continually evaluate their orthotic prescription strategies and procedures to maintain currency with best practices and full compliance with the College's standards. In this way, Members can ensure that patients are achieving the most positive health outcomes possible and that Members are competent providers of PCFO.