Defining Custom Foot Orthoses with Advancing Technology

PEDORTHIC ASSOCIATION OF CANADA

The Pedorthic Association of Canada would like to clarify how we define custom made foot orthoses with advancing technologies. We won't be discussing or analyzing the technologies themselves, what we want to address is the fundamental principles in the process of creating a custom-made orthotic and ensure that they are not lost when using technologies.

It is important to know that these are the standards of practice that we hold our members accountable to as required by the College of Pedorthics of Canada regarding the technologies used in clinics to manufacture custom-made foot orthotics.

"Custom-made foot orthotics are medical insoles worn inside footwear. They are designed and manufactured based on a specific individual's feet and footwear to address a need determined during a clinical assessment by a qualified footcare professional."

Especially at a time with continuous evolution in technology, we can't ignore the importance of clinician assessment and the design of the orthotic for the patient's needs. It would be equally incorrect to limit the definition to only one aspect of the manufacturing process, such as casting technique, or brand name of a scanner used.

As technology has been advancing rapidly in the last few years, Pedorthists ensure that the information gathered from the assessment provides the knowledge used to design the orthoses "custom" to each patient's needs and that nothing is lost in the technology.

There isn't software or a casting system that can know the range of movements of the joints of the foot. Alignments could be determined but as we know we may only correct with posting/wedging based on the mobility of these alignments. This information is gathered during the hands-on assessment, biomechanical exam, and gait analysis.

Whether the Pedorthist builds their own orthotics in an in-house lab or uses an external central fabrication facility, each pedorthist is responsible to authenticate and use their clinical discretion in the processes and technologies used when manufacturing and dispensing their patient's orthotics.

These are questions that we ask our members to keep in mind when vetting new technologies in their clinic for casting and/or manufacturing of CFO's.

Answering NO to any one of these questions will disqualify as "custom-made" unless reasonable medical justification can be provided.

1 **Is the patient assessment provided by an approved clinician/provider and in alignment with their College's Code of Ethics and Standards of Practice?**
Information gathered during the assessment provides the knowledge that the clinician uses to design the orthoses "custom" to patient need. Understanding the appropriate footwear that will optimize the intended outcome.

2 **Does the design provided in the work order medically meet the needs of the patient to appropriately manage and achieve the intended outcome of each patient?**
The orthotic description contained in the work order is formal communication from the clinician to the manufacturer that justifies the medical need unique to each patient. The design of the orthotic must offload and/or address the corrections outlined in the work order, as required.

3 **Does the negative casting process capture an accurate replica of the patient's foot in weight bearing, semi-weight bearing and/or non-weight bearing positions?**
The skillset of the person taking the negative cast of the patient's foot is much more influential on patient success than the actual type of cast taken. However, the clinician needs to use a casting process that captures the unique anatomy of the patient's foot, and that cast must be utilized throughout the full manufacturing process.

When looking at traditional Root-based theory, if digital technology is used when taking the negative cast, the laser or scanning system must create a 3-dimensional foot image from points read directly from the foot itself or from a direct model of the foot, such as a plaster slipper cast or foam impressions.

The scanning technology must not use computer algorithms, extrapolations, or interpretations to calculate shapes and contours from two-dimensional pressure readings, ink impressions, single aspect photographs, or any other two-dimensional methods for the goal of creating a 3-dimensional cast.

We want to make sure that there aren't technologies used in the systems and processes to create a custom-made orthotic that eliminate steps or streamlines the process that affect the desired outcome and design based on the distinctive observations found during the assessment.

4 Does the positive casting process allow all needed correction to be added to the negative cast?

This manufacturing stage is paramount to being able to provide a device that is custom to the patient's need, unique to their anatomy, and is a crucial step to ensure compliance with clinician's work order. This is one of the most important steps of the manufacturing process. It is imperative that the software in the CAD/CAM systems allow the technicians in an outside lab or in our in-house lab to modify the cast based on the clinician's work order. Due to the various factors that determine the required final product, it is the clinician's job to make the decisions not the computer.

Here is an example of an explanation of a technology provided to insurance when asked this question.

"The diagnostic software program isolates and tracks eight key landmark points along the plantar surface of the foot which identifies whether abnormal foot function exists. The software specifies the appropriate functional design algorithms necessary ...."

The question here is who is designing the orthotic? The clinician or the software.

5 Does the shell fabrication process utilize raw materials shaped to the positive cast of the patient's foot?

This manufacturing stage is critical to provide a device that is custom to the patient's need, unique to their anatomy, and is vital step to ensure compliance with the clinician's work order. Technologies that can only mill one type, thickness or durometer of material would limit the diversity to provide the most medically justified design for their patients.

6 Does the assembly process allow all needed corrections to be added to the final orthotics?

This manufacturing stage is fundamental to being able to provide a device that is custom to the patient's need, unique to their anatomy and is a crucial step to ensure compliance with the clinician's work order.

7 Was a fitting and follow-up provided?

A vital stage to increase patient care and compliance, as it serves to improve patient education, reinforce expectations, verifies orthotic/footwear interfacing, and formally addresses the possibilities of adjustments and fine tuning of the orthotics.