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U **PROSTHETIC & ORTHOTIC** UPDATE

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No. 46

Prefab Braces— When, Where, Why?



*Talon
wrist-driven
wrist-hand
orthosis.*

*Courtesy
Becker Oregon*

An enduring debate in the rehabilitation specialties centers on the feasibility and applicability of prefabricated, aka “off-the-shelf” or “OTS,” orthopedic braces.

From decades ago when virtually all orthotic components were custom-made, the field has evolved to today’s state in which an estimated 35 percent, perhaps more, of all orthoses are prefab, spurred by advanced materials and fabrication technology, aggressive cost containment measures, and Americans’ desire for convenience.

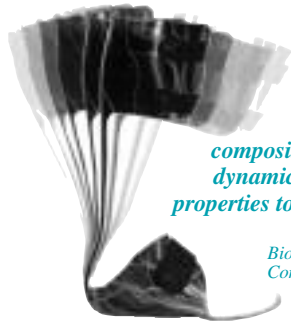
A whole new delivery system has emerged, encompassing pharmacies, shoe stores and other retail entities, affiliated rehabilitation providers such as physical and occupational therapists, and even physicians. The question is, when are these alternative delivery options appropriate for the patient’s needs.

The orthoses illustrated with this article are some common prefabricated products available today. For each device, a custom counterpart can be created for individual patients.

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New Day Dawning in Orthosis Fabrication

A new day is dawning in the fabrication of lower-extremity braces—ankle-foot orthoses (AFOs) and knee-ankle-foot orthoses (KAFOs). When the full potential of this new technology is realized, the outcome will be stronger, thinner, and lighter devices, some of which will deliver dynamic response to facilitate ambulation. For good measure, the fabrication process will be shorter and easier on the patient and potentially more cost-effective.

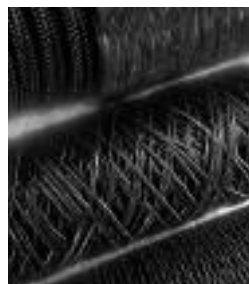


*Pre-preg
composites extend
dynamic response
properties to orthoses.*

*Courtesy
Bio-Mechanical
Composites Inc.*

For the past 30 or so years, AFOs have been fabricated primarily of polypropylene and other thermoplastics; KAFOs have been enhanced with metal struts.

Thermoplastics are durable and allow orthotists to build in required flexibility by varying thickness and geometry. However, they also present certain drawbacks, including a thick profile that can limit footwear choices, heat discomfort (thermoplastic is an insulator), and a sometimes lengthy fabrication process. With KAFOs the weight of the orthosis can be a deterrent to patient tolerance and effective ambulation, as well.



*Pre-preg carbon
fiber composite*

Courtesy Becker Orthopedics

Just as the introduction of plastics to orthotic fabrication several decades ago was a quantum improvement over the then-prevalent leather, wood and metal, so now is the emerging application of advanced composite materials—layers of carbon or other fabric bound with a resin—promising to at least partially supplant plastic construction.

(Continued on page 4)

O&P Veteran Joins Nobbe Team

Nobbe Orthopedics is pleased to welcome experienced practitioner Richard Feldman, CPO to our Santa Maria office staff.

Rick, a veteran of more than 20 years of private practice in southern California, has built an expertise in burn scar and contracture management. He was instrumental in developing transparent facial masks for the management of hypertrophic scarring at Sherman Oaks burn center. Most recently before joining our practice, he has served as a consultant, given expert witness testimony on behalf of prosthetic facilities and provided locum tenens services to private orthotic and prosthetic facilities. Rick has also served on various committees for both state and national O&P organizations.

He earned a bachelor of arts degree from Antioch University and has completed postgraduate O&P studies at UCLA, Northwestern, and New York universities. Rick brings a depth of expertise and commitment to his new role, and his presence will allow us to expand further the scope of our services.

When Are Off-the-Shelf Orthoses Appropriate?

(Continued from page 1)

To be sure, some types of “soft goods”—e.g. spinal corsets, soft cervical collars, elastic knee supports and wrist gauntlets—don’t



OrthoLux lumbosacral orthosis

Courtesy Hope Orthopedic

require the training and experience of a certified orthotist. These are generally short-term applications in which precise fit and control are not required. In the right circumstances these OTS devices provide satisfactory support and control and produce cost savings for patients and/or their insurance companies.

But...in various other situations or in the hands of unqualified providers, prefabricated orthoses not only fail to achieve their intended results but can also be detrimental to patients. The trick is in recognizing when optimal fit and custom design are required to achieve the desired results.

Custom Fit vs. Custom Fab

Custom fit and custom design and fabrication are two different things. An off-the-shelf device can be modified and adjusted to achieve the best possible result, given that it was not constructed to a custom mold of the patient’s anatomy. Such alterations and accommodations require a degree of training...minimal for basic fabric corsets, soft collars and other soft goods,



Jewitt spinal orthosis

Courtesy Otto Bock Health Care

Orthotics Today

considerably greater for AFOs, advanced spinal and cervical orthoses, therapeutic knee braces, and others.

The certified orthotist is uniquely trained for this function, as well as all aspects of custom fabrication. The experienced orthotist can both recognize patients and conditions for which prefab bracing is appropriate and work closely with the referring physician, therapists and others involved in the patient’s care to obtain the desired therapeutic outcome.

Regardless of anatomical location and purpose of bracing, some patients are simply not candidates for a prefabricated orthosis. Manufacturers of custom-fit devices typically offer a range of sizes based on statistical norm, which may fit 60-65 percent of the population. Patients outside the norm cannot wear that brace model effectively.

The custom orthosis, on the other hand, is a one-of-a-kind device molded intimately to a cast or computer-generated model of the patient’s anatomy, or with the adoption of new materials technology (see page 4) directly to the patient.

After initial casting or digitizing, the orthotist then modifies the design to incorporate therapeutic strategies, provide needed support, accommodate anatomical irregularities and enhance patient comfort. Such modifications are sometimes possible with prefab orthoses but usually to a significantly lesser degree.



Ankle-foot orthoses

Courtesy Otto Bock Health Care

Whether or not off-the-shelf products can fill a meaningful therapeutic bracing role, they frequently can be used to predict the efficacy and patient acceptance of a custom orthosis and thus help justify medical necessity. Again, the trained orthotist plays an essential role in making such an evaluation.

Pediatric Considerations

One orthotics classification that does not lend itself to prefabricated

products is pediatric bracing. The growth and development issues posed by children require specialized designs and sizes that are not conducive to mass production. A child’s smaller stature offers reduced surfaces on which corrective and supportive forces can be applied and thus less error tolerance; moreover, designs must allow for bone and muscle growth and the reality that such growth does not necessarily occur synchronously.

“Children are not small adults,” is a common watchword in our business, and it particularly applies to prefabricated products. You cannot simply downsize an orthosis designed for adults and expect it to work on a child.

The Compliance Issue

Obviously, all efforts at orthotic management, whether custom-fabricated or off-the-shelf, are essentially worthless if the patient refuses



Pacific Collar

Courtesy Becker Orthopedic

The Orthotist Advantage

Whether prefabricated or custom-made, most orthopedic braces require finishing, patient instruction, and follow-up modifications and maintenance. In our prevailing reimbursement climate, the “system” tends to seek out the “least-expensive” option. Seldom does this practice work to the benefit of the patient.

When another practitioner is asked to assume the role of the certified orthotist, the patient is deprived of the expertise offered by a dedicated specialist in biomechanics, orthotic evaluation, component design, materials, and fabrication technology, not to mention in most cases the availability of a full on-site fabrication laboratory. Typically such short cuts produce suboptimal prefabricated or “semi-custom” orthoses or components made in a remote facility based on a prescription and measurements provided by an individual underqualified to perform that role optimally.

There are exceptions to every rule, of course; but generally speaking, the best outcome results when a certified orthotist is allowed to exercise the expertise he/she brings to the table.

to wear the brace. Compliance involves three primary factors: comfort, self-image, and ease of application and removal. The experienced orthotist pays an important role in all three.

Comfort—It stands to reason that a brace formed from an anatomical model will fit more comfortably than a several-sizes-fit-all approximation. Fine adjustments to correct for minor discomfort, add padding, and/or compensate for perspiration are typically easier to complete on a custom-made device.

Self-image—Some patients refuse to wear their orthosis simply because it is embarrassing to them. Prefab braces are usually more bulky and therefore are frequently more obvious to others than custom orthoses. Spinal braces provide a good case in point: Most off-the-shelf models are too large to wear under clothing, whereas many custom spinal jackets can be designed to worn under reasonably fashionable clothes and thus remain largely hidden.

Donning and doffing—With a custom orthosis, we can design a custom brace to match the needs and abilities of the patient, but prefabricated braces often incorporate an amazing number of straps and buckles to achieve as close a fit as possible with a general-sized product. The more closures and adjustments, the more difficult for the patient and caregiver to apply the device correctly and with maximum effectiveness. Add the potential for improper initial fitting of the device by an undertrained provider, and you have a recipe for noncompliance.

In Conclusion

Properly employed, prefabricated braces definitely have their place in today’s rehabilitation milieu.

While we respect and value our relationship with all providers of clinical rehabilitation services, we also believe that a certified orthotist is the practitioner best prepared and experienced to select, design, fit and maintain orthotic devices, whether prefab or custom.



GII osteoarthritis knee brace

Courtesy Össur

Orthotic Management of Charcot Foot Deformities

The most prevalent medical disorder seen in American orthotic and prosthetic practice today is diabetes, usually involving peripheral neuropathy affecting the feet. Insensitivity to pain and proprioception leaves diabetic individuals at increased risk of developing Charcot foot (also known as Charcot joints or Charcot changes) deformities of the foot and ankle, resulting from repetitive, undetected insult and abnormal stresses. Charcot foot is also associated with chronic renal disease, alcohol abuse, myelomeningocele, and other conditions that produce nerve damage.

A Charcot process often begins with a fracture produced by a misstep or stumble that initially goes undetected. By the time non-pain symptoms (e.g. inflammation, hyperemia and edema) appear, the Charcot evolution is well under way. Left unmanaged, Charcot foot generally leads to progressive joint destruction and significant deformity; however, experience has shown that timely intervention can interrupt the Charcot activity and preclude amputation.

The Charcot process generally occurs in three stages: Stage I, the proliferative or acute stage, is characterized by foot redness, heat and advanced swelling; in Stage II joint destruction and dislocation is most likely; Stage III is the consolidation or healing stage.

Management for Stages I and II typically involves joint immobilization and non-weight-bearing in a total contact cast or comparable orthosis to stabilize and protect the foot and ankle from further destruction and deformity. Surgery may be indicated to deal with infection, a deformity that cannot be accommodated in an orthosis, or ulcers that will not heal.

Stage III management may also involve surgery, or the patient can be fitted with therapeutic footwear, an ankle-foot orthosis or a Charcot Restraint Orthotic Walker (CROW), a cross between an AFO and a custom boot, to provide ongoing, probably lifelong, protection for the at-risk foot.

The CROW is a custom-fabricated, bivalved, total contact orthosis incorporating a custom foot insert, soft liner, and rigid outer shell with a solid ankle cushion heel (SACH) and rocker bottom. It is designed specifically to reduce shear and stress forces acting on the foot, equalize weight-bearing, and minimize axial loading of the plantar surface.



CROW Boot

Courtesy O&P

The primary difference between this orthosis and a pure cast is that the CROW may be removed for dressing changes, bathing and sleeping. Many patients learn to drive while wearing the boot. The CROW is easy to don and remove and exhibits a high level of patient acceptance.

Upon wound healing some patients benefit from a transition to an AFO, notably a floor-reaction design. This less-cumbersome option gives the wearer some additional freedom, while the anterior force applied in stance phase provides an added measure of proprioception to compensate for that lost with the advancing Charcot process.

For some patients who have suffered severe Charcot-related deformities, a patellar tendon-bearing AFO may be necessary to contend successfully with recurring plantar ulcerations. This design incorporates prosthetic principles to redistribute weight-bearing forces away from the plantar surface.

These orthotic strategies for accommodating Charcot foot help us realize our primary goal in managing diabetic patients: preventing the need for limb amputation.



Floor-reaction AFO

'Pre-preg' AFOs—Stronger, Lighter, Dynamic

(Continued from page 1)

Composites have been applied in prosthetics for some time in socket fabrication and advanced ankle-foot construction. Now, a recent variation, pre-impregnating the composite with a thermosetting resin, gives the fabrication team some exciting new applications for orthotic components as well.

"Pre-pregs" as these new materials are coming to be known, provide high durability at low weight and can be designed to flex, providing dynamic response.



Pre-preg custom articulated AFO

Courtesy Custom Composite Mfg. Inc.

Compared to similar orthoses made from plastics, pre-preg AFOs and KAFOs offer a high strength-to-weight ratio, thin profile and enhanced patient comfort. While early applications appeared primarily in prefabricated devices, fully custom pre-preg braces are beginning to enter the mainstream.

Dynamic Response

Energy storing and release has become a mainstay characteristic of many prosthetic feet models but heretofore has not found major application in orthotics. Now, the dynamic properties of pre-preg composites make possible the same sort of gait assistance from an AFO.

A dynamic-response AFO can be designed to allow motion and a gradient resistance throughout the stance phase, capitalizing on the patient's strengths while supporting weaknesses. Customized dynamic forces throughout the gait cycle enable the patient to ambulate longer and farther before exhaustion.

An exciting pre-preg option still in development is interrupted cure processing, in which a partially



Dynamic-response AFO in place

Courtesy Bio-Mechanical Composites Inc.

Prefabricated KAFO incorporating pre-preg technology

Courtesy Becker Orthopedics



cured pre-impregnated composite pre-shaped into the general form of a particular AFO design can be custom-molded, trimmed and adjusted for the needs of a particular patient, sometimes in a single office visit. This technique could conceivably eliminate the casting, vacuum forming and extensive sanding commonly required in the fabrication of plastic orthoses. Pre-preg thermoformable composites may accept several fine adjustments before the material completely cures.



AFO Dynamic shows thin profile possible with pre-preg composites.

Courtesy Össur

Applications and Contraindications

Pre-preg lower-extremity orthoses can be prescribed to provide improved function and enhanced comfort for patients with drop foot secondary to stroke, multiple sclerosis, polio, spinal cord injury, and other neurological conditions, as well as various ankle instabilities. On the other hand, patients with spasticity or mild-to-severe clonus can be stimulated by a dynamic-response device and are thus not considered good candidates for a pre-preg brace.

Still in their infancy, pre-preg composite orthoses are just beginning to stir excitement and gain acceptance in the rehabilitation community. We can look forward to further news and advances about this technology in the near future.

Note to Our Readers

Mention of specific products in our newsletter neither constitutes endorsement nor implies that we will recommend selection of those particular products for use with any particular patient or application. We offer this information to enhance professional and individual understanding of the orthotic and prosthetic disciplines and the experience and capabilities of our practice.

We gratefully acknowledge the assistance of the following resources used in compiling this issue:

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