VIRGINIA PROSTHETICS
THE ORTHOTIC & PROSTHETIC CENTER

UPDATE

Current Developments in Prosthetics & Orthotics No. 63

Delivering on the Promise Of O&P Design Excellence

Ever wonder what goes on in the "back office" of an orthotic-prosthetic practice? Most health care professionals involved in the care of physically challenged patients and those who wear prosthetic and/or orthotic devices have never ventured into an O&P fabrication lab or witnessed the decision-making and craftsmanship that goes into the creation of current-generation prosthetic limbs and orthopedic braces. Were they to do so, they would gain a good appreciation of the three essential ingredients of orthotic-prosthetic fabrication:

Fabrication

- **Technology**—The science and know-how we employ to build the optimum levels of function, comfort and durability into every device;
- **Materials**—The advanced plastics, metals, fabrics, and other raw components we use to create advanced, functional limbs and braces for every patient; and
- **People**—The trained and highly skilled personnel whose talent, compassion and experience fulfill the promise of great orthotic and prosthetic designs and thereby help patients realize their lifestyle and vocation goals.

To produce a superior outcome for amputees and individuals requiring orthopedic braces, O&P assistive devices must: (1) fulfill the functional potential of their design, (2) fit intimately and wear comfortably on the patient's anatomy, and (3) be sufficiently durable to withstand the stresses of daily use.

Present-day prosthetists/orthotists are well-trained to determine their patients' capabilities, needs and functional desires and to design a prosthetic limb or brace to maximize mobility and lifestyle within those parameters. It remains for the device built to that design to deliver on the promise of the clinician's vision, a result that inevitably depends on careful, accurate fabrication.

Because of the critical role of the prosthetic socket as the connecting link between human anatomy and prosthesis, most all prosthetic limbs today are custom-fabricated. Althought some bracing needs can be solved with prefabricated products, the majority of orthosis designs depend on a precise, total-contact fit and thus require custom manufacture.

An off-the-shelf device is modified and adjusted to achieve the best result possible, given that its fit is, at best, an approximation. Custom prostheses and orthoses, on the other hand, are one-of-a-kind devices molded intimately to a cast or computer-generated model of the patient's anatomy to deliver the best result possible.

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Doctor, Are You Registered?

The PECOS system was officially enacted in July 2010 and is now operational. The deadline for rejection of prescriptions from physicians not registered with PECOS is Jan. 1, 2011.

Please remember: After that deadline, neither we nor any other facility can accept prescriptions from non-registered physicians for Medicare patients to receive prosthetic or orthotic care, supplies or durable medical equipment.

Information on PECOS and how to enroll is available at:
www.cms.hhs.gov/MedicareProviderSupEnroll

How Great Prosthetic Limbs and Orthoses Come to Life

(Continued from page 1)

Technology

Molds and Measurements

In standard casting, a plaster of Paris bandage or water-activated synthetic casting tape is wrapped around the affected limb or torso to create a three-dimensional mold. Upon hardening, the mold is carefully removed, sealed and filled with plaster to create a positive model of the body segment on which the prosthetic socket or orthosis will be formed.

A contemporary alternative, computer-aided design (CAD), allows practitioners to design and modify O&P components with mouse and monitor. Once completed, the design can be exported to a computer-aided manufacturing (CAM) carver to generate a foam positive model. A hybrid option utilizes a laser scanning device to digitize the interior contours of a traditional mold, allowing the practitioner to then rectify the model electronically.

After initial casting or digitizing, the prosthetist-orthotist modifies the design to build in therapeutic strategies, provide focused additional support as needed, accommodate anatomical irregularities and enhance patient comfort.

The more intimate the fit and the greater the comfort, the better the functional outcome, so the importance of an accurate and properly modified model cannot be overstated…

CAD/CAM system creates positive limb mold digitally. *Courtesy Fillauer Inc.*

And Now to the Lab...

...nor can the actual fabrication process. Many prosthetist/orthotists choose to be directly involved in turning their designs into reality, while others rely on trusted technical support personnel for fabrication (see People article at right), allowing the practitioners to focus their attention on direct patient care.

A well-equipped O&P laboratory incorporates workbenches, specialized tools and equipment, a supply of plastics, metals, fabrics, foams, leather and other raw materials, and safety mechanisms to ensure fabrication is performed in a safe environment for staff and surrounding areas.

The introduction of sheet thermoplastics and thermoset plastic laminations has revolutionized the fabrication of limbs and braces, providing a total-contact fit and superior strength in a lightweight package (see Materials article at left).

In both upper- and lower-extremity prosthetic limbs, custom sockets form the key interface between anatomical remnant and replacement limb. Getting the socket right is critical to functional success; thus, one or more check, or test, sockets of transparent plastic may be fabricated to ensure an optimal fit. When the definitive (final) socket is ready, the limb is completed with various pre-made components (feet, knees, pylons, hand units, etc.) chosen specifically for that patient.

Plastics are used to an even greater extent in orthosis construction, notably in ankle-foot orthoses (AFOs), spinal braces, upper-extremity orthoses and cranial remolding helmets. Various foams and fabrics are added for enhanced comfort and skin protection.

Fabrication time can vary considerably depending on design complexity and patient characteristics. Some devices can be made in hours; others take many days. Our intention is to take whatever time is necessary—but no more—to fabricate every limb/brace as "right" as we possibly can.

We welcome your questions and comments regarding the fabrication process.

Building Blocks of O&P Fabrication

Materials

Strength, light weight, durability and comfort are paramount requisites for modern prosthetic and orthotic devices. From space-age plastics and high-tech composites to advanced metal alloys, today's O&P fabricators enjoy tremendous flexibility to choose materials that will produce the best combination of these variables for each patient's individual needs.

High-temperature sheet plastics provide varying degrees of rigidity, thickness and color for use in prosthetic sockets and a wide range of orthotic devices. Polyethylene, for example, is a highly flexible soft thermoplastic frequently used as the inner, interface, layer of a flexible socket, while polypropylene is quite rigid and thus appropriate for the outer socket structure. Numerous other 'blended" thermoplastics offer varying degrees of strength and flexibility for particular needs.

These plastics are heated in high-temperature ovens, then formed over a positive model of the affected body segment under vacuum and allowed to cool to retain the desired shape.

Heating thermoplastic prior to shaping over positive mold.
Courtesy Fillauer Inc.

Plastic laminates (thermosets), consisting of one or more fabric layers (carbon fiber, Kevlar, nylon, fiberglass, etc.) impregnated with a liquid resin and formed over a positive model under vacuum, are also widely used in the fabrication of prosthetic sockets and lower-limb orthoses (AFOs and KAFOs). When a catalyst is introduced, the resin bonds the reinforcing fabric layers together creating a lamination that is both lightweight and strong. Different selections of fabrics and resins provide significant latitude in the rigidity, strength and thickness of the finished product, which can thus be fabricated to reflect the weight, physical capabilities and lifestyle of the user.

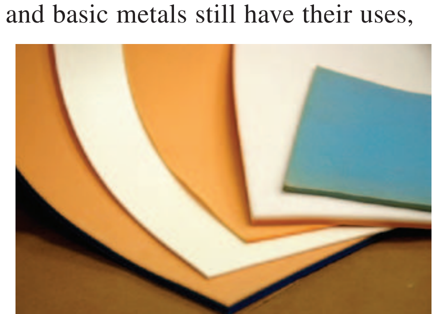
Carbon composites are increasingly being used in prosthetic and orthotic fabrication due to their extremely high strength and low weight. In addition to sockets, carbon composites are used extensively in AFOs and KAFOs (including sidebars), prosthetic pylons, knee joints, and dynamic response feet.

Reinforcing fabrics for O&P laminations

Metals—Steel, long used for making AFO and KAFO sidebars and prosthetic knee, pylon and ankle components, provides superior strength but with a significant weight penalty. Aluminum is now commonly used as a lightweight alternative when deemed strong enough to meet O&P design criteria. Titanium alloys, though relatively costly, provide perhaps the best combination of high strength and low weight and are increasingly being used in lower-extremity applications.

Others—While these newer plastics and metals have become the building blocks of choice in O&P fabrication, traditional alternatives such as leather, wood, foams and basic metals still have their uses, notably in devices for long-time orthosis or prosthesis wearers who are comfortable with their older device design and composition and do not wish to change.

Whatever the needs and desires of our patients, we are prepared to fabricate the most appropriate materials into each device we create.



Selection of foams used in fabricating and adjusting O&P devices

The Folks in the Back

People

The descendants of today's O&P practitioners can be traced back many hundreds of years to the town blacksmith, armorer, or "brace-maker." Though "uneducated" in the classroom sense, those craftsmen used their knowledge and ability to process and shape the materials of the time to provide their neighbors with assistive devices (splints, braces and artificial limbs) with which to carry on after bone-setting or amputation surgery.

Courtesy Ohio Willow Wood

The role and scope of orthotic and prosthetic practice have advanced significantly since those days, now requiring formal education (generally at least a bachelor's degree), board certification and licensure in many states.

As the effectiveness and complexity of the specialty have grown, today's orthotists and prosthetists now spend increasingly more time in the clinician role—interacting with patients, evaluating their condition, needs and desires, then designing the most appropriate rehabilitation device for those variables.

While many prefer to translate their designs into a finished brace or limb by constructing it personally, others find they are more productive in collaborating with and supervising the "brace-makers" of today—prosthetic and orthotic technicians—in the fabrication of the finished appliance.

O&P techs function under the direction of board-certified orthotists and prosthetists in bringing both routine and technically advanced limb and brace designs to reality. Some have amassed ample experience in their specialty and define career fulfillment as maximizing their contribution at the technician level. Others are motivated to further develop their education and talent on the path to becoming board-certified prosthetist-orthotists. In either case the abilities of these valued personnel can now be recognized by their own credential granted by the American Board for Certification in Orthotics and Prosthetics—Certified Orthotic and/or Prosthetic Technician.

Courtesy Fillauer Inc.

Whatever their career goals, rest assured O&P technicians are some of the most creative and talented individuals in our business.

Courtesy Otto Bock Health Care

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Creating a 21st Century Prosthetic Socket

Down to Cases

Transfemoral amputee John T., 45, presented with a seven-year-old, outdated prosthetic leg, which no longer fit or functioned properly.

Like many traumatic amputees, John maintains an active lifestyle and expects a lot from his replacement limb, including comfort, performance and endurance. For those expectations, an intimate socket fit is essential. John's prosthetist recommended an all-new limb design and components featuring a rigid laminated socket with suction suspension, polycentric knee unit and dynamic response foot.

The process began with a CAD scan and digitizing of John's residual limb contours, from which his prosthetist performed the initial socket design and subsequently produced a positive model in the exact shape of John's remaining limb segment. Next, the mold was selectively modified to build up specific spots subject to focused weight-bearing pressure and provide added protection for sensitive areas.

A check socket to evaluate the efficacy of the design and modifications was then created from a sheet of clear thermoplastic heated to 425 degrees F., draped over the mold, allowed to cool under vacuum, and trimmed. This diagnostic form allowed his prosthetist to observe John's residual limb within the socket environment and evaluate the intimacy of fit. After minor resulting adjustments to the mold, the process advanced to fabricating the definitive socket.

Forming the check socket.

John's socket began with layers of carbon fiber and fiberglass fabric chosen by the prosthetist to achieve desired strength and rigidity. These reinforcing materials were placed one by one over the rectified positive model and saturated with a thin coat of resin.

When all prescribed layers were added, this "lay-up" was placed under vacuum, and a catalyst-pigment mixture was introduced via a funnel at the top of the outer bag.

The resulting chemical reaction hardened the lamination, which when cooled was removed from the mold, trimmed and smoothed. Voilà: Finished socket!

Adding catalyst-pigment mixture to activate socket lamination.

Once the soundness and fit of the socket were confirmed, John's new leg was completed with attachment of the remaining prescribed componentry: knee, pylon, foot and ultimately a cosmetic cover.

Outcome: John is now able to work, play and "go" harder, longer and with more enjoyment of life. He readily credits his new socket fit and the effort and technology that went into it.

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 involved in compiling this issue:

Charles Coulter • Fillauer Inc. • Ohio Willow Wood
Otto Bock Health Care