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THE ACADEMY TODAY

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ACADEMY FABRICATION SCIENCES SOCIETY

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THE ACADEMY **TODAY**

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MESSAGE FROM THE PRESIDENT

Kate Allyn, CPO, LPO, FAAOP
2019–2020 President

As I write this, I am on my way home from a fantastic American Academy of Orthotists and Prosthetists Board of Directors strategic planning meeting. The meeting took place at the Academy's offices in Bethesda, Maryland. What a vibrant city. I can think of no better location to debate strategy for the coming year. Your board members are enthusiastic, smart, and professional. They are the perfect group of people to represent the Academy—your professional home.

The board embraced a plan that will take the Academy into new and exciting territory. It is my privilege and honor to work with these leaders who dream big. We have worked together to conceive, design, and execute lofty goals that will have a meaningful impact.

Together, we will identify and critically appraise membership benefits and value, identify trends for future development, enhance member engagement, target membership growth, and ensure that all involved in the provision of O&P care identify the Academy as their professional home.

As you may already know, the Academy Board of Directors has proposed changes to Academy membership categories. When the Board was discussing the proposed membership categories, I took my "Academy president" hat off and replaced it with my "O&P practitioner" hat. The following questions immediately popped into my head.

Why is my Academy proposing new membership categories?

The Academy is dedicated to advancing the O&P profession. In order to be the professional home to all O&P practitioners who are certified, licensed, or affiliated with the profession, the organization's membership criteria need to be evaluated through the lens of inclusion.

What is wrong with the way things are?

Looking at the profession as a whole, all O&P practitioners strive to provide their patients with the best treatment plan possible. Providing all clinicians with access to the best tools and resources will only further our collective mission to ensure patients receive exceptional care.

Does this mean it will cost me more to be a member of the Academy?

The Academy currently has no plans to increase membership dues.

If the membership votes in favor of this, when will it go into effect?

If approved, the proposed membership categories will be employed for the 2020–2021 membership year.

Voting members have until October 10 to submit their ballots. Thank you in advance for sharing your voice with the Academy.

Regardless of the results of this election, fall is the season for back to school, crisp mornings, and enjoying the bounty of an abundant fall harvest. Your fall harvest can be collecting your much-needed CECs. Fall is the perfect time of year to review your CEC requirements, and your Academy is ready help. The Online Learning Center (OLC) has fresh content from which you may earn your credits.

Please plan on joining us in Chicago, March 4–7, 2020, for the 46th Academy Annual Meeting & Scientific Symposium. I look forward to meeting new friends and catching up with classmates and fellow clinicians.

One last announcement I would like to include is about an enormous accomplishment our executive director has completed. Chellie Hollis Blondes has earned the Certified Association Executive (CAE) credential from the American Society of Association Executives (ASAE). The CAE designation is the highest professional credential in the association industry. We are fortunate to have Chellie leading our organization, and I look forward to working with her on our mission to promote professionalism and advance the standards of patient care through education, research, literature, advocacy, and collaboration.

Kate Allyn, CPO, LPO, FAAOP
2019–2020 President

CAD/CAM SOCIETY of the American Academy of Orthotists and Prosthetists

FABRICATION SCIENCES SOCIETY of the American Academy of Orthotists and Prosthetists

Introduction

Any amount of time spent in the O&P profession will quickly give evidence to the interconnectivity of the different aspects that are required for clinical and/or technical success. With this understanding, the American Academy of Orthotists and Prosthetists (the Academy) CAD/CAM and Fabrication Sciences Societies have partnered to provide four articles that show advances in materials science or fabrication techniques that are continuing to evolve within O&P.

- The Role of 3D Printing in the Fabrication Process for Partial-Hand Prostheses

Abby Hoffman-Finitsis, Crystal Cassetori, Matthew Mikosz, and Carol Rivera provide a look into a novel approach toward integrating CAD/CAM to simulate various aspects of the traditional fabrication process for partial-hand prostheses.

- Using Hybrid Manufacturing to Design and Fabricate a Canine Running Prosthesis

Michael Madden utilizes a case study to outline the methods and processes of additive manufacturing and rapid tooling to restore function to a unique prosthesis user.

- Dynamic Characteristics of Fitted AFOs

David Knapp describes an analysis across a spectrum of carbon AFOs to provide a level of quantified data with the end goal of providing a reference for clinicians in selecting the appropriate intervention for their patients.

- Evaluation of Carbon Composite AFOs for Product Strength and Durability: A Discussion of Void Content

Justina Appel illustrates a methodology for the structural evalution of composite material and how it relates to material integrity and discusses related industry standards.

We are grateful to the contibutors for taking the time to formulate their expertise in a format that can be shared with the membership of the Academy. It is the intention of the Academy's Fabrication Sciences and CAD/CAM Societies to generate discussion and engagement in an effort to advance the O&P profession. It is our hope that the information contained here will benefit your clinical practice, stimulate your mind, and open a conversation. We encourage you to read and comment so that your experience and expertise can help your colleagues. If you would like to have an even greater role, please join one or more of the Academy's nine Scientific Societies.

David Knapp, CPO
Chair, Academy
CAD/CAM Society
President, Connecticut
Brace and Limb

Duffy Felmlee,
MSPO, CPO, FAAOP
Chair, Academy
Fabrication Sciences Society
Associate Professor
University of Hartford
felmlee@hartford.edu

THE ROLE OF 3D PRINTING IN THE FABRICATION PROCESS FOR PARTIAL-HAND PROSTHESES

Creating 3D-printed diagnostic sockets for partial-hand prostheses and 3D-printed molds for the direct application of silicone can help streamline modification and fabrication standards and ensure consistency among clinicians and technicians. By using scanning and software modification tools, the Hanger Fabrication Network (HFN), under the guidance of National Clinical Specialist Upper Extremity Matthew Mikosz, is developing a protocol to improve consistency in modification outcomes. Although we frequently use traditional plaster modifying techniques, Hanger's process allows us to easily adapt a model for variations in residual limb volume and maintain a record of each patient's digitized residual limb for future clinical comparisons, adjustments, and insurance justifications. This technique merges traditional patient casting methods to capture the unique shapes and alignments of the partial-hand residual limbs with scanning of the plaster mold to create a digitized 3D file, modifying with software, and 3D printing either diagnostic sockets or molds to go straight to creating inner sockets with silicone.

Standardizing Partial-Hand Modifications

In this process, the clinician uses silicone rubber casting material or an equivalent molding agent to take an impression of his or her patient's residual limb in the desired hand position. The negative impression is sent to the Hanger Fabrication Lab, where it is poured with porous plaster to make a positive mold. Once the positive molds are poured and stripped, they are scanned with a high-resolution 3D scanner. The scans are saved as STL files and are then imported and modified in a software program. Typical modifications include adjusting for volume reductions and adding pressures in defined areas. If a diagnostic socket needs to be created, an inner flexible socket using flexible resin and an outer rigid socket using durable resin are printed in the stereolithography (SLA) resin printers. Two printers are used for this process so the inner and outer sockets can be printed simultaneously. The printers cure the resin with light layer by layer and provide a smooth surface finish compared to traditional fused deposition modeling printers. However, if a diagnostic socket is not needed, the modified 3D model can be printed and used for the direct application of silicone to fabricate the inner socket, upon which the outer prepreg carbon fiber frame is formed.

Figure 1. Hydrographics applied to a socket.

Potential Misconceptions of 3D Printing in the Fabrication Process

It is important to dispel any myths or misconceptions that 3D printing is an easy-to-master, automated technology that anyone can do without significant training. Often there is no manual or long-established protocol or system for this type of fabrication process. Consequently, users need to employ more flexibility and versatility in their approaches and devise novel protocols and practices along the way. Troubleshooting these processes can be complicated and multifaceted, ranging from issues with finicky software updates to using or combining new materials in ways that haven't been previously tested. As such, being creative, tech savvy, vigilant, and patient are essential attributes for modification and fabrication teams.

Benefits of CAD and 3D Printing in the Fabrication Process

The HFN partial-hand department receives hand impressions from clinicians across the United States, as well as from international clinics. Working electronically opens up the possibility for access to remote specialized modifications and long-distance fittings. It also allows us to send electronic files to colleagues for opinions, suggestions, or collaborations. Since 3D printing, also known as additive manufacturing, is built layer by layer, there is less material waste. More traditional processes typically remove material from a larger object as in carving or thermoforming sheets of plastic and discarding the unused material beyond the socket trimlines.

Figure 2. Scanning a plaster mold.

Figure 3. Electronically modifying the mold.

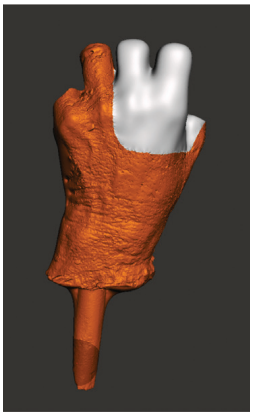


Figure 4. 3D-printed inner flexible socket and outer durable diagnostic sockets.

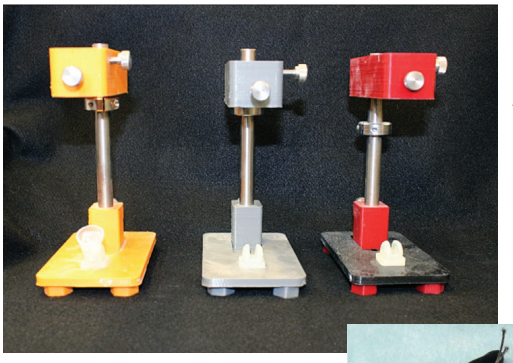


Figure 5. 3D-printed alignment transfer jigs for partial fingers.

Figure 6. A sample of a finished mechanical design.

Figure 7. A sample of a durable resin 3D print of a mold with silicone directly applied.

As mentioned previously, using CAD and 3D printing in the modifying and fabrication process allows the clinical and fabrication teams to maintain a record of the patient's electronic files and document residual limb volume changes over time. This enables clinicians to return to previous design iterations to learn from the patient's history or modify a previous design so that it continues to work for the patient's evolving needs.

In terms of analyzing the clinical and fabrication teams' success over time, it is possible to identify modification trends in order to determine what is working across similar patient scenarios and create consistency across clinicians' modifications. Having an electronic history of scans and 3D design files makes it is easier to track and analyze success, compared to looking over old plaster molds. Our goal is to establish a consistent, predictable, and successful process in which we are quantifying what we are actually doing by being precise in our modifications. As the process becomes more streamlined, we hope to maintain product consistency, save time, and decrease material waste.

Additionally, since the partial-hand molds are relatively small, we can also print out supporting materials and structures for our process. For instance, we are able to create our own transfer vertical alignment jigs specifically designed for partial fingers and our fabrication method. The addition of the transfer alignment jigs allows us to precisely transfer alignment from the diagnostic phase to a definitive prosthesis in a similar manner as a lower-limb prosthetic device.

In the diagnostic fitting phase, having the means to easily adjust the volume of a socket with electronic software, reprint a check socket relatively inexpensively, and quickly print out a new model or multiple models can be extremely advantageous. Finally, material selection with 3D printing is continually evolving. Materials are becoming more versatile and durable. Prints can be polished and customized with hydrographic designs for a high-quality finished product.

Abby Hoffman-Finitsis, MA, CP
University of Hartford, Assistant Professor
Department of Rehabilitation Sciences
Hanger Clinic, Staff Prosthetist
hoffmanfi@hartford.edu

Matthew Mikosz, CP, LP
Hanger Clinic
National Clinical Specialist Upper Extremity
mmikosz@hanger.com

Coral Rivera
Hanger Fabrication Network
Partial Hand Lab, Technician
crivera@hanger.com

Crystal Cassetori
Hanger Fabrication Network
Partial Hand Lab, Technician
ccassetori@hanger.com

Using Hybrid Manufacturing to Design and Fabricate a Canine Running Prosthesis

A Case Study

When a dog requires limb amputation, complete limb disarticulation is generally considered a common practice if the dog has three or more limbs and can compensate with the remaining limbs. If complete limb disarticulation is indicated, the amputation should be made as proximally as possible so the residuum does not become subject to injury.[1] During quadrupedal ambulation, the forelimbs and hindlimbs set down and exert forces in unison, controlling the rotation of the body about the transverse (pitch), vertical (yaw), and longitudinal (roll) axes.[2] In tripedal ambulation, this dynamic is altered, forcing compensatory motions to maintain balance and a stable and straight pattern of locomotion.[2] This results in significant kinematic changes to the remaining limbs during the stance and swing phases of gait.[3] These compensatory mechanisms also force changes to the joint excursions of the remaining limbs[3] and lead to joint breakdown, arthritis, and premature disability. To make prosthetic management more viable, recent trends in veterinary medicine favor salvaging as much of the involved limb as possible, challenging the common practice for canine limb amputation described above.[1]

This case study article discusses managing a canine forelimb amputation with a running-style prosthesis. The amputation of the dog's right foot, the result of trauma, was executed just distal to the carpals at the pastern. The determination to fabricate a running prosthesis was predicated on the increased loading parameters of the forelimbs during quadrupedal locomotion. Forelimbs bear approximately 60 percent of the vertical forces during locomotion.[2] The passive elastic qualities of running blades, which compress to absorb, store, and release ground reaction forces, are advantageous,[5] especially in the case of a canine forelimb amputation.

Hybrid Manufacturing

The goal for the fabrication of this dog's running prosthesis was to use additive manufacturing (AM), otherwise known as 3D printing, as the primary fabrication process to create a bivalve socket and attachment plate for the running blade (Figure 3). Subtractive manufacturing (SM) methodologies (the process of creating objects by removing material from a block or form) were only used when necessary. During the design stage of the prosthesis, it was determined that hybrid manufacturing[7] would be the solution to the material limitations of AM and fused deposition model (FDM) printing. Hybrid manufacturing would augment the redesign and remanufacturing of components, based on limitations identified during prototyping. One limitation was the likelihood of the FDM material undergoing thread stripping during loading at the interface of the running blade and the socket attachment plate. The structural integrity of an FDM-printed running blade and its performance under repetitive loading was also a concern. Strength-related issues are of critical importance when 3D-printed parts are going to be load bearing.[8] The ability to replicate design features that had positive outcomes and modify features that were less than desirable was enhanced using hybrid manufacturing and prototyping.[7]

Though current perceptions are that AM is not well suited for direct component and product manufacturing[7] and that material choices are limited,[8] advances in AM techniques and materials make it a viable option for direct digital manufacturing and rapid tooling.[5] The inferior mechanical properties and anisotropic (an object that has a different value when measured in different directions) characteristics of FDM printing[5] made it necessary for the running blade to be fabricated using SM with composite materials. The layer-by-layer nature of FDM printing creates variations in the microstructure of the material and the boundaries between each layer,[5] resulting in anisotropic characteristics. Print orientation affects the tensile strength of the printed object considerably.[5] The print orientations as prototyped proved ineffective under the anticipated loading. The running blade was fabricated using SM techniques common to prosthetic fabrication. A form was modeled with CAD software and fabricated using an FDM printer to produce the desired size and curvature of the running blade (Figure 1). All tooling for the running blade was modeled using CAD software and printed using an FDM printer. This included a drill guide, which duplicated the hole pattern on the attachment plate and was used to drill the holes in the running blade. SM and AM processes typically require some post-production processing.[7] The printed running blade lamination form and various FDM-printed componentry required the removal of support material in a solution bath; the attachment plate required the bonding of threaded inserts; the running blade, socket, and anterior shell required trimming and tooling.

Image Capture and CAD

Although production efficiency could be improved by scanning the forelimb for image capture, the ability to compress fur and soft tissues during traditional casting provided a more accurate model of the residuum. The cast was modified, and a 3mm firm EVA foam liner was fabricated over the cast to serve as an interface. The liner was then scanned with an OMEGA Scanner to produce a 3D image. The scan was imported into the OMEGA software for final rectification and exported as a stereolithography (STL) file so that the socket could be printed from the scanned 3D image.

The scanned image appeared hollow when viewed in the OMEGA software; however, when the STL file was exported and converted to G-code, to a 3D printer, or to a computer numeric control (CNC) machine it was a solid object. To "hollow" the CAD model, the STL file was imported into the Blender 3D Creation Suite.

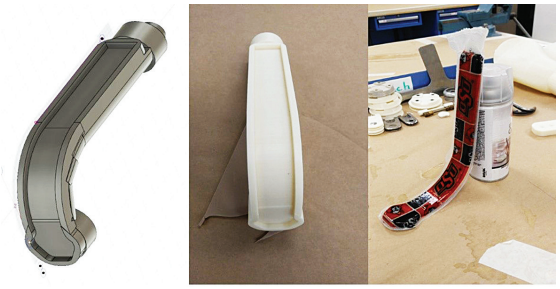


Figure 1. Lamination Tooling. Left: Fusion 360 rendering. Center: FDM printed form. Right: Running blade.

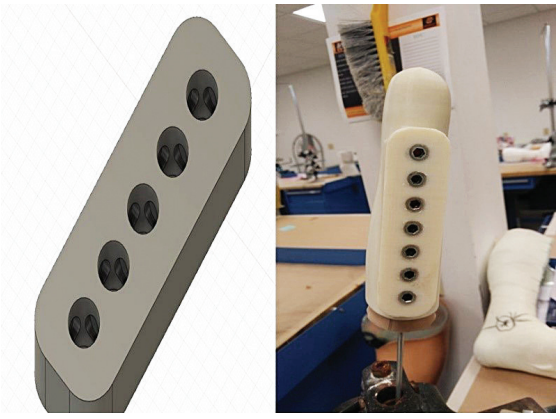


Figure 2. Attachment Plate. Left: Attachment plage in Fusion 360. Right: Attachment plate with threaded inserts.

The vertices were removed from the model, leaving a single layer *mesh* (i.e., the outer wall of the model). Using a solidification process within Blender, the thickness of the socket walls was determined (3mm–5mm) and a socket created. The socket was exported from Blender as an STL file and imported into Autodesk Fusion 360.

The STL file imported into Fusion 360 was imported as a *mesh body*. The imported mesh body was converted to a *boundary representation body* (BRep) so that it could be modified within the software. Fusion 360 CAD software was used to design the attachment plate for the running blade. The attachment plate was aligned, extruded, and joined to the socket, forming a solid BRep body. That body was then exported as an STL file, converted to G-code, and printed as a single socket/attachment plate component. The FDM-printed socket and attachment plate were scanned and used to design and fabricate the anterior shell for the prosthesis.

The attachment plate was designed with symmetrically aligned recesses into which metal-threaded inserts were bonded during SM production. Vertical and horizontal channels were designed within each recess to decrease the potential of the threaded insert being pulled from the attachment plate under loading (Figure 2). The dynamic forces applied to the running blade required attachment with stainless steel fasteners threaded into metal inserts to prevent stripping of the threaded holes.

Figure 3. Canine Running Prosthesis. Left and right: Fitting a prototype. Center: The canine running. prosthesis.

The inserts were bonded in place using a two-part epoxy. Hole placement was designed so the running blade could be positioned proximal and distal on the attachment plate for height adjustments (Figure 2).

The running blade was fabricated using a shell of Spectra and Kevlar wrapped around a unidirectional carbon warp with 90-degree fiberglass weft tape. The carbon was the core stiffening structure for the running blade. A cosmetic fabric was used over the Spectra/Kevlar/carbon wrap and laminated using a two-part epoxy resin. Positional posts were bonded into the posterior aspect of the bivalve socket to orientate the anterior shell. The anterior shell was secured using dacron straps (Figure 3).

References are available at www.oandp.org/page/ATcurrent.

Acknowledgement

I would like to thank Jennifer Block for her lead in making this project possible, for her contributions to making it a success, and for her editorial assistance.

Michael P. Madden,
CPO, LPO, FAAOP
Orthotic & Prosthetic Technologies Program,
Oklahoma State University Institute of Technology
mike.madden@okstate.edu

DYNAMIC CHARACTERISTICS of FITTED AFOs

Introduction

AFOs that flex during gait, augmenting the patient's muscle function, can be used to restore mobility and improve gait efficiency for patients with neuromuscular and musculoskeletal challenges. These passive-dynamic AFOs (PD-AFOs) store elastic spring energy when flexed and release it as kinetic energy when they return to their original shape. All custom-fitted carbon fiber AFOs mentioned in this study are PD-AFOs. There are numerous designs on the market today; they differ in three key characteristics: stiffness, neutral angle, and the amount of energy they return. The purpose of this study is to quantify those parameters for an assortment of custom-fitted carbon fiber AFOs that are commercially available.

Custom-fitted carbon fiber AFOs are widely prescribed to improve swing clearance due to foot drop and to effectively lengthen the toe lever after transmetatarsal amputation. These devices are well utilized for their proficiency in improving swing phase, but they affect stance phase as well.

The most effective AFO is stiff enough to provide support during midstance yet flexible enough to allow energy return in third rocker, or push-off.[1]

AFO function is influenced by the patient's body weight, passive ankle range of motion, spasticity, and whether he or she is able to generate force at the hip and ankle.[2] Selecting the appropriate AFO should be done through a comprehensive evaluation of each individual patient. This evaluation should include medical history, manual muscle testing, range of motion, and gait analysis. If a PD-AFO is prescribed, Figure 1 can be used to help select the most appropriate custom-fitted carbon AFO or to provide insight on how to build the most effective custom-fabricated AFO.

Methods/Procedure

Each AFO was fitted to a biomimetic surrogate limb that was moved through one stance cycle by an electric motor. The kinematic and kinetic parameters of the resulting "step" were recorded and analyzed for comparison.

Kinematic data was captured using an Optotrak 3020 motion analysis camera system. Kinetic data was captured with an AMTI force plate.

The surrogate limb used in this study had seven segments (shank, talus, calcaneus, two tarsometatarsals, and two phalanges) all made from ultra-high molecular weight polyethylene. The surrogate limb had seven articulations (knee, talocrural, subtalar, talonavicular, calcaneocuboid, and two metatarsophalangeal). The joints had anatomically accurate orientations and ranges of motion. The goal was to simulate flaccid paralysis, so there were no muscles. The limb also included a simulated plantar aponeurosis to provide some arch height. The articulated skeleton was encased in ballistic gel to create a limb-shaped model. Care was taken to ensure that the thickness of the gel matched that of a human limb. The gel thickness was about 0.25 inch on the anterior shin and more than 3 inches posteriorly to allow for displacement of the orthosis associated with normal tissue compression. The total weight and the distribution of mass within the surrogate were controlled to ensure that the inertial properties were similar to an actual limb. A standard AFO sock covered the surrogate limb during all the tests to provide a realistic interface.

The surrogate limb was a right leg proportioned anthropometrically to match a 180 lb. person who wears a

Figure 1. Dynamic Characteristics of Fitted AFOs
Stiffness, neutral angle, and relative energy return of 18 commonly prescribed PD-AFOs.

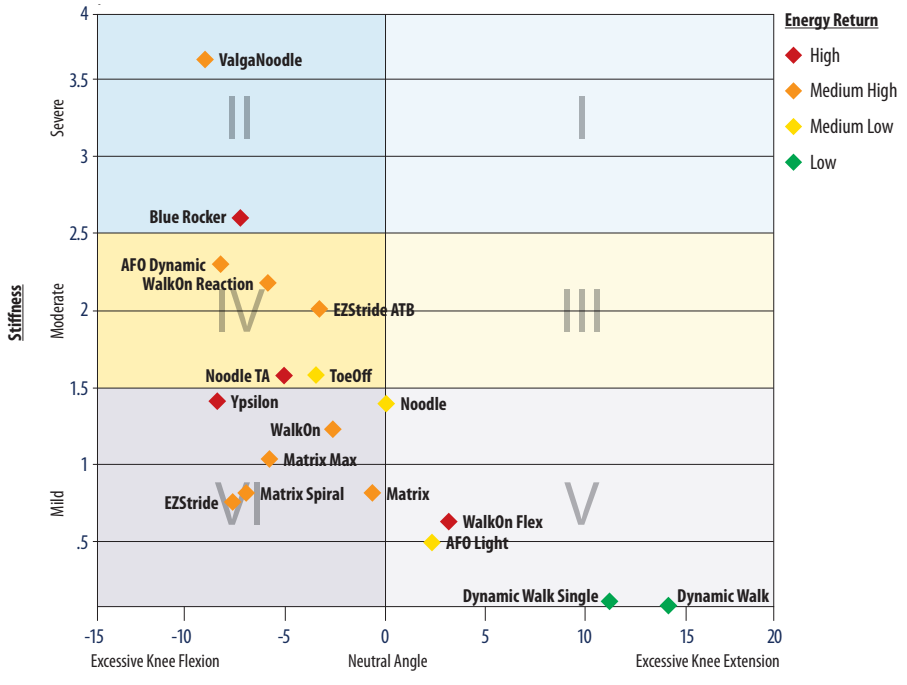
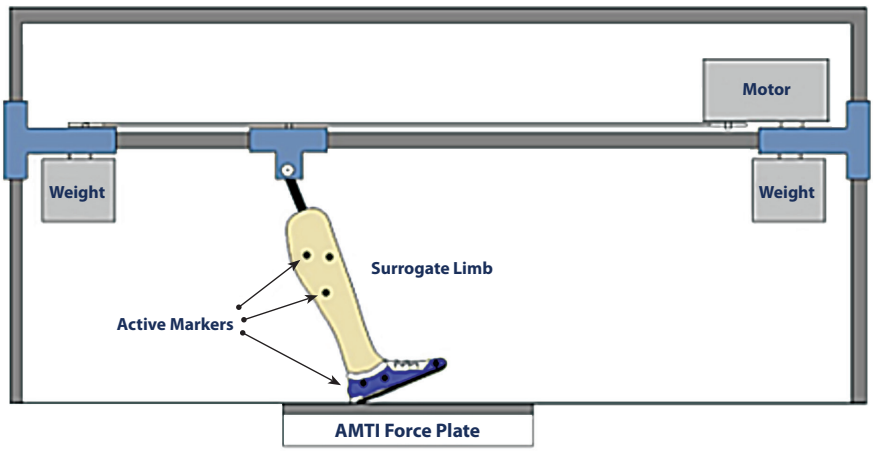


Figure 2. Major Components of the Test Rig



men's size 9.5 shoe. Each AFO was fitted as directed by the manufacturer, and the orthopedic shoe was donned and tightened to the same tension for each test. The same limb, shoe, and sock were used for every test.

Eighteen different custom-fitted carbon AFOs from seven different manufacturers were tested under the same loading conditions. The tests began with the surrogate leg positioned to simulate the moment just prior to initial contact. Then, as the knee joint was driven forward, the limb made contact with the ground and was rapidly loaded to full body weight. The height of the knee apexed in midstance and then began to move downward through terminal stance. The limb was then rapidly unloaded by a second electric motor to simulate the contralateral limb during pre-swing. Data collection stopped as soon as the surrogate entered swing phase. Figure 2 illustrates the main components of the test rig.

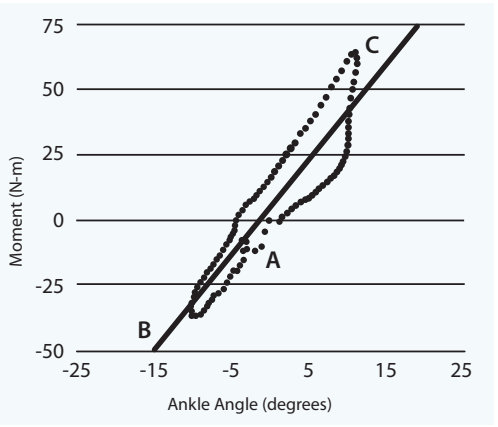
Results

AFO stiffness can be visualized by plotting net ankle moment against the angle of the ankle joint and observing the slope of the resulting plot. The net angle moment was calculated through inverse dynamics using the observed acceleration of the segments (foot and shank) and solving for the forces that are causing the acceleration. Since the surrogate limb has no muscles, it was assumed that the AFO was responsible for creating those forces.

Each AFO produced a characteristic shape when the angle was plotted against the net moment. A typical plot is shown in Figure 3. The loop represents one full stance cycle. The data was collected in a clockwise manner, with more energy stored during loading than is released during unloading, indicating a net energy loss. Point A represents initial contact, point B is the beginning of midstance, and point C is the end of terminal stance. Since the slope constantly changes throughout the test, the stiffness of the AFO was defined as the slope of the linear regression line that best fit the data.

Figure 3. Characteristic Shape of the Angle Plotted Against the Next Moment

Typical plot of deflection as a function of the applied moment during one simulated stance phase. (The straight line is the linear regression line whose slope was used to estimate overall stiffness.)



Clinical Application

Figure 1 is designed to help clinicians differentiate between the variety of custom-fitted carbon AFOs that are commercially available.

Stiffness, represented on the vertical axis in Figure 1, is a critical element of proper orthotic treatment. In this study, the stiffness of each AFO was determined to be the slope of the line that divided the loading region from the unloading region of the hysteresis curve (Figure 3). Many factors must be considered to determine the optimal stiffness of an AFO, starting with the patient's

Figure 4. Stiffness by AFO

Average stiffness based on linear regression lines.

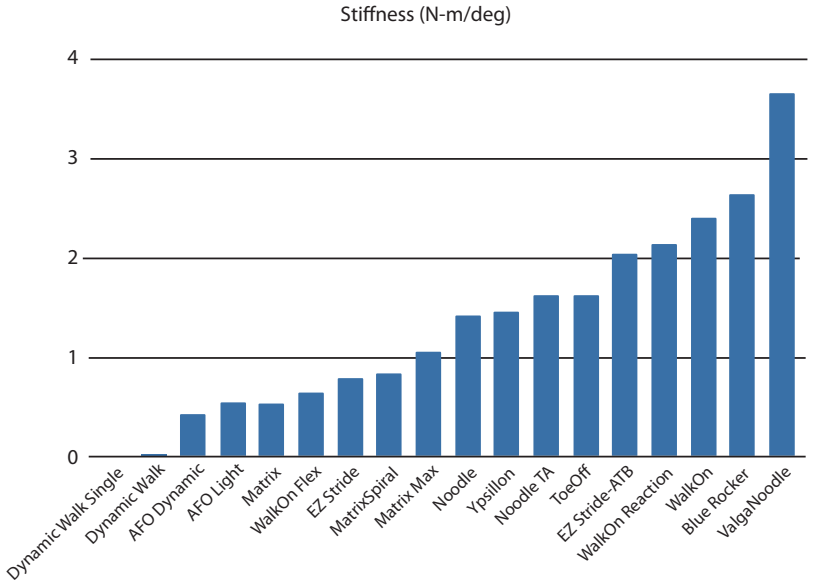


Figure 5. The Neutral Angle
Neutral angle based on each AFO fitted to the surrogate limb with shoe off.

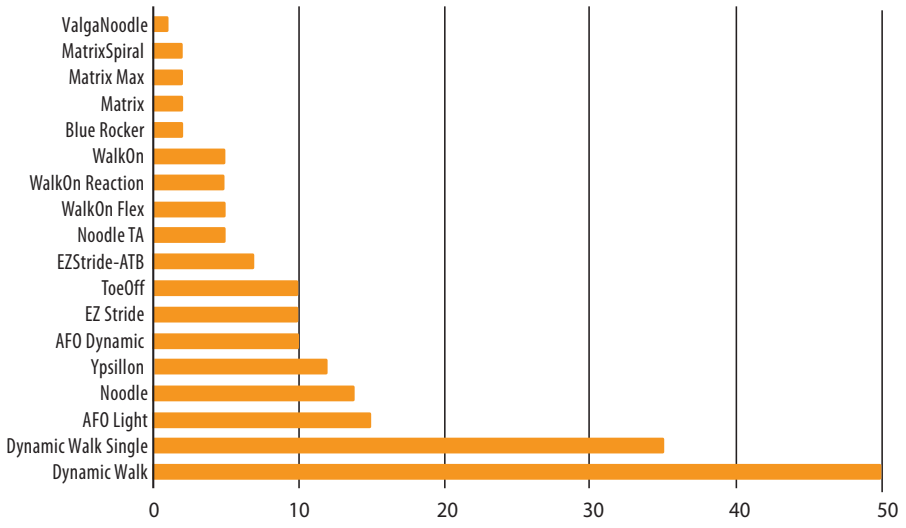
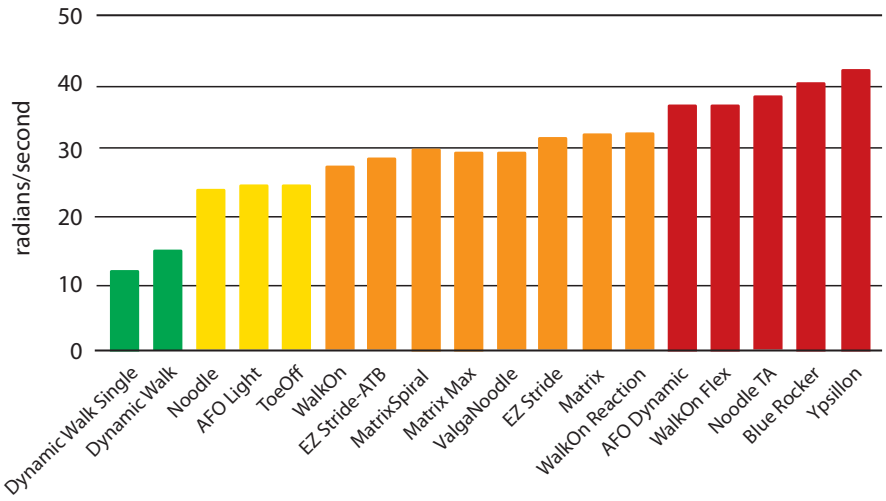


Figure 6. Average Angular Velocity During Pre-Swing
Angular velocity of plantarflexion during pre-swing. This is an indictator of the relative amount of energy that is returned by the AFO.



weight and muscle strength. The greater the patient's weight, the stiffer the AFO must be to generate the higher torques required. Similarly, a decrease in muscle strength indicates the need for greater AFO stiffness. Negative consequences can occur from improper AFO stiffness; excessive stiffness can lead to slower gait speed, excessive knee extension, and increased energy consumption, while insufficient stiffness will not correct the patient's gait deficiencies.

The horizontal axis of Figure 1 depicts the neutral angle that is built in to all fixed-angle AFOs (Figure 4). The neutral angle is the angle at which no moment is produced by the AFO, or, put more simply, the angle of the AFO when it sits on the shelf. Neutral angle will influence knee stability; therefore, it is important to tune the AFO in the sagittal plane. Shank vertical angle (SVA) is the net angular position when the orthosis, shoe, and terrain interact. Thus, it is important to evaluate the patient's shoes with particular attention to the heel height, as it will affect the patient's SVA. It is equally important to talk with the patient about his or her hobbies and vocation as the terrain will also influence the SVA.

Energy return is represented in Figure 1 by the color of the diamond-shaped marker for each AFO. Energy return levels were measured by comparing the average angular velocity of the ankle joint as it plantarflexed during pre-swing (Figure 6). Increases to angular velocity above the baseline are caused by the energy that is returned by the AFO during the pre-swing phase. Higher levels of energy return are typically beneficial and will lead to increases in gait efficiency. One exception to this is the presence of severe alignment irregularities, especially in the transverse plane. If the patient has transverse plane deformities (for example, excessive toe-in or toe-out), the energy return can be skewed to the frontal plane, which could exacerbate gait abnormalities.

It is useful to consider stiffness, neutral angle, and energy return to determine the best custom-fitted carbon fiber AFO for your patiPent based on a comprehensive clinical evaluation. Figure 1 also shows that there are no AFOs with a moderate or high stiffness that have a neutral angle built in dorsiflexion. Patients who need that type of support are more likely to benefit from treatment with a KAFO.

Further Research

The study focused specifically on custom-fit carbon AFOs. Further research should be conducted to include newer offerings and/or custom AFOs of all varieties.

Also, this study simplified classification by representing the stiffness of each AFO with a linear approximation. Further study should be undertaken to develop a stiffness profile for each AFO that more closely matches its dynamic properties.

References are available at www.oandp.org/page/ATcurrent.

David Knapp, CPO
Chair, Academy CAD/CAM Society
President, Connecticut Brace and Limb

Evaluation of Carbon Composite AFOs for Product Strength and Durability: *A Discussion of Void Content*

By investigating the mechanical properties of the materials used in the fabrication of O&P devices, the goals of optimizing outcomes and addressing the need for evidence-based practice in the current reimbursement environment can be met. The purpose of this paper is to raise awareness for the need to establish mechanical standards for the materials used to fabricate devices. By establishing specific standards using outcomes research, the industry can then justify reimbursement. Composite materials have proven their relevance in the fabrication of O&P devices. Properties can be tailored to individual needs, and an extra layer or two can be added for optimum strength and durability with minimal impact on weight. However, quality control in the manufacture of all orthoses and prostheses plays a major role in optimizing outcomes, addressing the demands of our current reimbursement system, and minimizing the costs associated with additional office visits as well as added labor and material costs required for remakes or refitting.

Several issues can affect the level of quality of a cured laminate. Such issues include wrinkles, dry spots, improperly oriented fibers, and resin problems. However, void content is a major concern when it comes to determining the overall quality level of composite laminate materials. Industries outside of O&P, such as aviation, renewable energy, and marine biology, are also concerned with the issue of void content and its effect on final product quality. Using x-ray microtomography to test several different orthotic devices that are considered for the same prescription criteria usage, this study examined the presence of void content in the finished product. The study, although somewhat limited, measured the porosity levels of the composite materials and how the mechanical properties of this material can be differentiated in various ankle-foot devices by using x-ray microtomography. This research is considered a benchmarking exercise to establish baseline quality levels of the devices constructed in the O&P industry.

Orthoses are normally manufactured out of composite materials since these types of materials offer many favorable properties. However, to obtain durable, damage-resistant orthoses, it is important to maintain a minimum number of defects in the material. A common type of defect in composite materials is voids. High void content may affect the static and the fatigue strength, as well as cause greater sensitivity to environmental conditions. The interlaminar shear strength[1] and the compressive strength[2] are severely degraded by voids.

Voids or pockets of air within the material are among the most common manufacturing-induced defects in a composite orthosis or prosthesis.

A high void content can cause issues with several mechanical properties, including fatigue strength, the overall strength of the materials, and the lifespan of a composite.[3]

For the reasons previously stated, the measurement of void content was chosen as the criteria provided to an independent testing facility to investigate the current quality levels of the specific group of composite AFOs and to generally compare those results to other industry norms, thus establishing the quality status of composite AFO fabrication. X-ray microtomography (XMT) was chosen as the measurement tool to determine the percentage of void content in each of the samples.[4]

Testing Methods

The XMT-studies were carried out using a Zeiss Xradia 510 Versa at Luleå University of Technology in Sweden. Eight AFOs were studied; all were made of fiber-reinforced resin. No special specimen preparation was done in terms of cutting and/or polishing. The pieces for scanning were cut out from the AFOs using an ordinary band saw. The typical tube voltage and output effect for the XMT scanning was 60kV and 5 W, respectively, and the exposure time varied from six to 20 seconds. The typical field-of-view was approximately 12x12mm, and the spatial resolution approximately 12 µm. The resulting images from the XMT studies were high contrast, and details of microstructure (for example, voids and fiber bundles) were clearly visible. The application of an appropriate software package was used to calculate the void content percentage from the images produced.

XMT is an efficient technique to determine the void content in composite orthoses. A great advantage is that the technique gives information about shape, size, and location of the voids. This information is important because the stress distribution in composite orthoses is highly non-uniform. As XMT is a non-destructive test, it could be used for quality control in individually made AFOs.

Results

The XMT scanning used to capture the images from each product that was tested produced high-resolution scans across three planes. Up to 1,000 images were taken from each product at a predetermined location. A selection of 20 images was taken evenly throughout the thickness of each product specimen to determine the average value of void content. Some of the AFOs examined were of high quality, with void content less than 0.5 percent, while others showed void content as high as 5 percent. The contrast between fiber and matrix (polymer) is not as high for carbon fibers as for glass fibers, but it is still possible to distinguish different

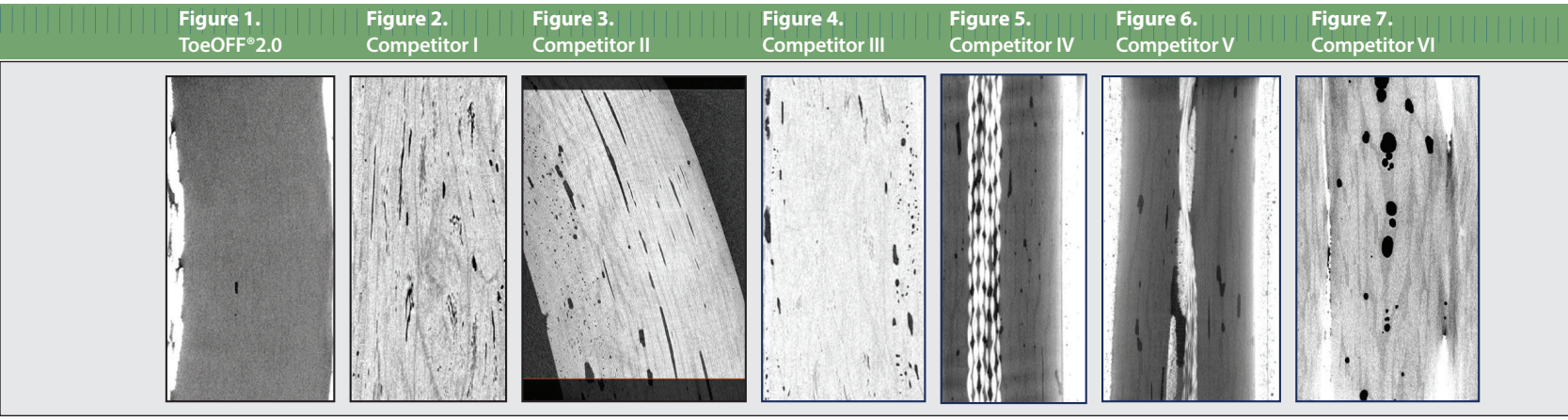


Figure 8

Device	Average Void Content (%)
ToeOFF2.0	0.2
BlueROCKER	0.1
Competitor I	2.7
Competitor II	2.7
Competitor III	2.3
Competitor IV	2.1
Competitor V	2.6
Competitor VI	3.0

constituents. High contrast between voids and fibers/matrix made it easy to evaluate the void content in the orthoses as seen in Figures 1–7. The associated calculated void content can be seen in Figure 8.

Discussion

The influence of voids on the service life of a composite orthosis is a complex problem due to the large number of variables involved. Investigations of void content in other industries that also use structural composite components, such as aircraft wings and wind turbine blades, have led to limits for maximum void content to ensure that the components do not compromise safety. Generally, it is accepted that a good quality composite laminate should have a void content below 0.5 percent.[5] If the void content is below this level, the mechanical properties are not especially affected by the voids. Research done by Bhat et al. noted that the interlaminar shear strength is reduced by more than 50 percent in materials that test with greater than 0.5 percent voids.[6] At this level, a lower shear strength of the material will result.

If a composite AFO intended for foot drop was only about dorsiflexion, a discussion about void may not have been so interesting. Layers of fibers could be added to support load in the sagittal plane. However, most stroke victims and patients with similar neurological deficits present with weakness in the surrounding structures or exhibit impaired control and pain. To manage their daily activities, compensatory movements are also common. To make a composite AFO durable and damage resistant during use, it must be able to withstand loads in several directions. Any damage, whether incurred by overload or through impact force, must be isolated and resistant to propagation. If damage starts in a laminate with air pockets, it is likely to increase and further reduce the mechanical properties.

Conclusion

The test results show a wide range of void content between similar devices encountered in today's market. An average void content of 0.1 percent to 0.2 percent is considerably lower than the established threshold value for a premium quality laminate of 0.5 percent as has been established in scientific literature.[5] Void content above 1.0 percent will have a negative effect on the laminate, reducing the product's strength and durability. Future research that incorporates robust methods and valid reliable outcome measures is needed to evaluate the effect of material properties on quality assurance in manufacturing processes in relation to the intended outcome. There is a need to integrate evidence from the literature into clinical practice. Lastly, standardized fabrication material testing and reporting guidelines should be established to ensure AFO device characteristics are sufficiently communicated and allow comparison across studies. With future studies providing a high level of documentation and using reliable and valid measures, we would better understand the effects of the impact of the quality of materials used in fabrication methods on specific devices and thus be able to provide valuable information to improve patient outcomes.

References are available at www.oandp.org/page/ATcurrent.

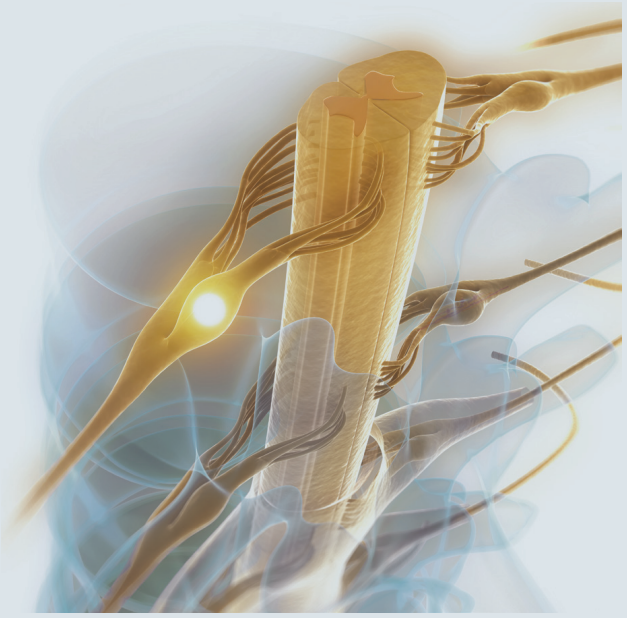
Justina Appel, PhD, CO, LO, BOCP, LP, FAAOP
Director of Education and Clinical Support
Allard USA
justi.appel@allardusa.com

DRG Stimulation:
Relieving the Burden of Chronic Pain Following Limb Loss

Between 30 percent and 85 percent of patients experience chronic residual limb pain following amputation,[1] which can make it difficult to experience the full benefits of a prosthesis. Patients who continue to experience pain beyond the normal healing time (six months or more) may need to consider chronic pain treatment options. Abbott has developed dorsal root ganglion (DRG) stimulation, a new non-opioid technology for treating chronic pain following limb loss in patients with causalgia. It works by sending mild electrical pulses to the nerves responsible for the painful sensations.

Neurostimulation

Conventional tonic spinal cord stimulation (SCS) has been successfully utilized since 1967 as a treatment modality for the management of chronic, intractable pain in the trunk and/or limbs.[2] But for pain locations outside of, or more focal than, the trunk and/or limbs—as seen in chronic intractable pain conditions such as complex regional pain syndrome (CRPS)†—conventional tonic SCS has been less successful or has resulted in extraneous stimulation.[3]



By stimulating the DRG, it is possible to achieve therapeutic coverage and pain relief in difficult-to-treat focal chronic intractable pain conditions. Research has demonstrated that the DRG plays a critical role in the development and maintenance of chronic pain. The DRG's unique pathophysiological response to pain makes it an ideal target for interventional therapies like neurostimulation, providing a greater opportunity for therapeutic benefits to be isolated only in the patient's primary area of pain.[4]

ACCURATE Study

DRG stimulation has been proven clinically superior to conventional tonic SCS in treating lower-limb pain associated with CRPS.* Patients in the ACCURATE study reported focal chronic intractable pain in anatomical locations such as the foot, knee, hip, and groin.[3]

At three months, 81.2 percent of patients receiving DRG stimulation achieved effective pain relief and greater treatment success compared to 55.7 percent of patients receiving traditional tonic stimulation.[3] Durability of pain relief was seen after 12 months, with 74.2 percent of DRG stimulation patients achieving meaningful pain relief and greater treatment success when compared to 53 percent of patients receiving conventional tonic SCS.[3] Data from the ACCURATE study suggests that DRG stimulation may offer a meaningful option for patients suffering from chronic intractable pain conditions that are currently underserved by conventional tonic SCS.

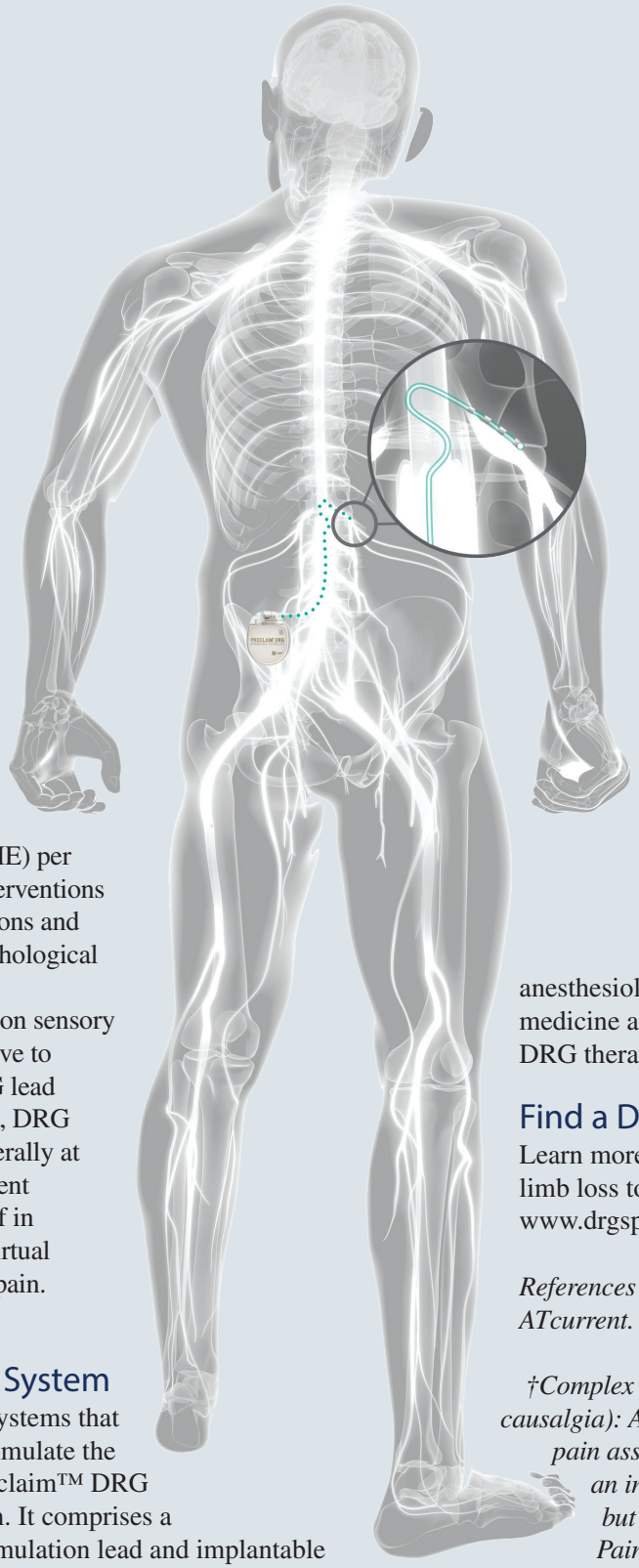
The Science Behind the DRG

The DRG is a key epidural, intraspinal nerve structure that houses primary sensory neurons (PSNs) cell bodies.[5] These PSNs embody the primary source of sensory information flow from the periphery to the central nervous system and also represent an important processing point of sensory information.[4] Pain is one type of sensory information that flows and is processed by PSNs within the DRG.[4]

Normally, pain represents an important protective sensory experience, but in pathological conditions, pain becomes a chronic condition. Research has shown that PSNs in the DRG are critically involved in the development and maintenance of chronic pain.[4]

Similarly, these neurons exhibit altered membrane properties, such as increased excitability as well as abnormal and ectopic activity.[6,7] While these pathophysiologic changes contribute to the chronic pain state, they also likely leave those cells more susceptible to influence by neuromodulation (stimulation) therapies.[4]

Additionally, the DRG itself is a robust structure with a predictable intraforaminal location in the epidural, intraspinal space.[5] The ganglia are encapsulated in a dural sleeve with minimal cerebral spinal fluid (CSF) surrounding it. This minimal CSF layer, in turn, may allow for a closer and more stable neuronal-electrode interface. The DRG's unique pain processes and its anatomical considerations make it an ideal interventional target to treat various focal chronic intractable pain conditions due to CRPS.



Case Study

A 59-year-old male veteran suffered a transfemoral amputation resulting from an indirect mortar attack in Afghanistan. The patient experienced phantom pain sensation and residual limb pain in addition to post-traumatic stress disorder.

The patient was prescribed opioids at 40 morphine equivalents (ME) per day. Other attempted interventions included multiple injections and robust physical and psychological rehab regimens.

Radiofrequency ablation sensory stimulation was conclusive to determine the ideal DRG lead location. During the trial, DRG leads were placed unilaterally at L4, L5, and S1. The patient reported 85 percent relief in residual limb pain and virtual elimination of phantom pain.

Proclaim DRG Neurostimulation System

Abbott offers the only systems that are FDA-approved to stimulate the DRG, including the Proclaim™ DRG neurostimulation system. It comprises a specially engineered stimulation lead and implantable pulse generator (IPG) that interfaces with wireless programmers via Bluetooth® technology. This therapy system is designed to precisely deliver stimulation in order to communicate with the DRG and optimize a patient's unique pain therapy requirements. A simple trial procedure allows patients to evaluate whether DRG therapy works for their chronic pain before committing to another surgery.

DRG stimulation has been successfully studied for CRPS and causalgia following nerve injury.[3] It is covered by Medicare and many medical insurance providers, and the procedure is performed by interventional anesthesiologists, neurosurgeons, and physical medicine and rehabilitation physicians trained in DRG therapy.

Find a DRG Expert in Your Area

Learn more about managing chronic pain following limb loss today. Find a local Abbott DRG expert at www.drgspecialist.com.

References are available at www.oanp.org/page/ATcurrent.

†Complex regional pain syndrome (CRPS I/II, causalgia): According to the National Health Service, pain associated with CRPS is typically caused by an injury and is usually confined to one limb, but it can spread to other parts of the body. Pain symptoms include burning, stabbing, or stinging, but may also include a tingling sensation and numbness. Many CRPS patients also report symptoms of hyperalgesia (extreme sensitivity to pain) and/or allodynia (experiencing pain from a very light touch).

**As studied in the ACCURATE clinical trial.*

APPENDIX

Using Hybrid Manufacturing to Design and Fabricate a Canine Running Prosthesis Page 7

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Additional Information

Rx Only

Brief Summary:

Prior to using these devices, please review the User's Guide for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use:

US: Spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable* pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II.**

*Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least 2 prior pharmacologic treatments from at least 2 different drug classes and continued their pharmacologic therapy during the clinical study.

**Please note that in 1994, a consensus group of pain medicine experts gathered by the International Association for the Study of Pain (IASP) reviewed diagnostic criteria and agreed to rename reflex sympathetic dystrophy (RSD) and causalgia, as complex regional pain syndrome (CRPS) types I and II, respectively. CRPS II (causalgia) is defined as a painful condition arising from damage to a nerve. Nerve damage may result from traumatic or surgical nerve injury. Changes secondary to neuropathic pain seen in CRPS I (RSD) may be present, but are not a diagnostic requirement for CRPS II (causalgia).

International: Management of chronic intractable pain.

Contraindications:

US: Patients who are unable to operate the system, who are poor surgical risks, or who have failed to receive effective pain relief during trial stimulation.

International: Patients who are unable to operate the system, are poor surgical risks, are pregnant, or under the age of 18.

Warnings/Precautions:

Diathermy therapy, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), computed tomography (CT), electrosurgery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery and equipment, pediatric use, pregnancy, and case damage.
Adverse Effects: Painful stimulation, loss of pain relief, surgical risks (e.g., paralysis). User's Guide must be reviewed for detailed disclosure.

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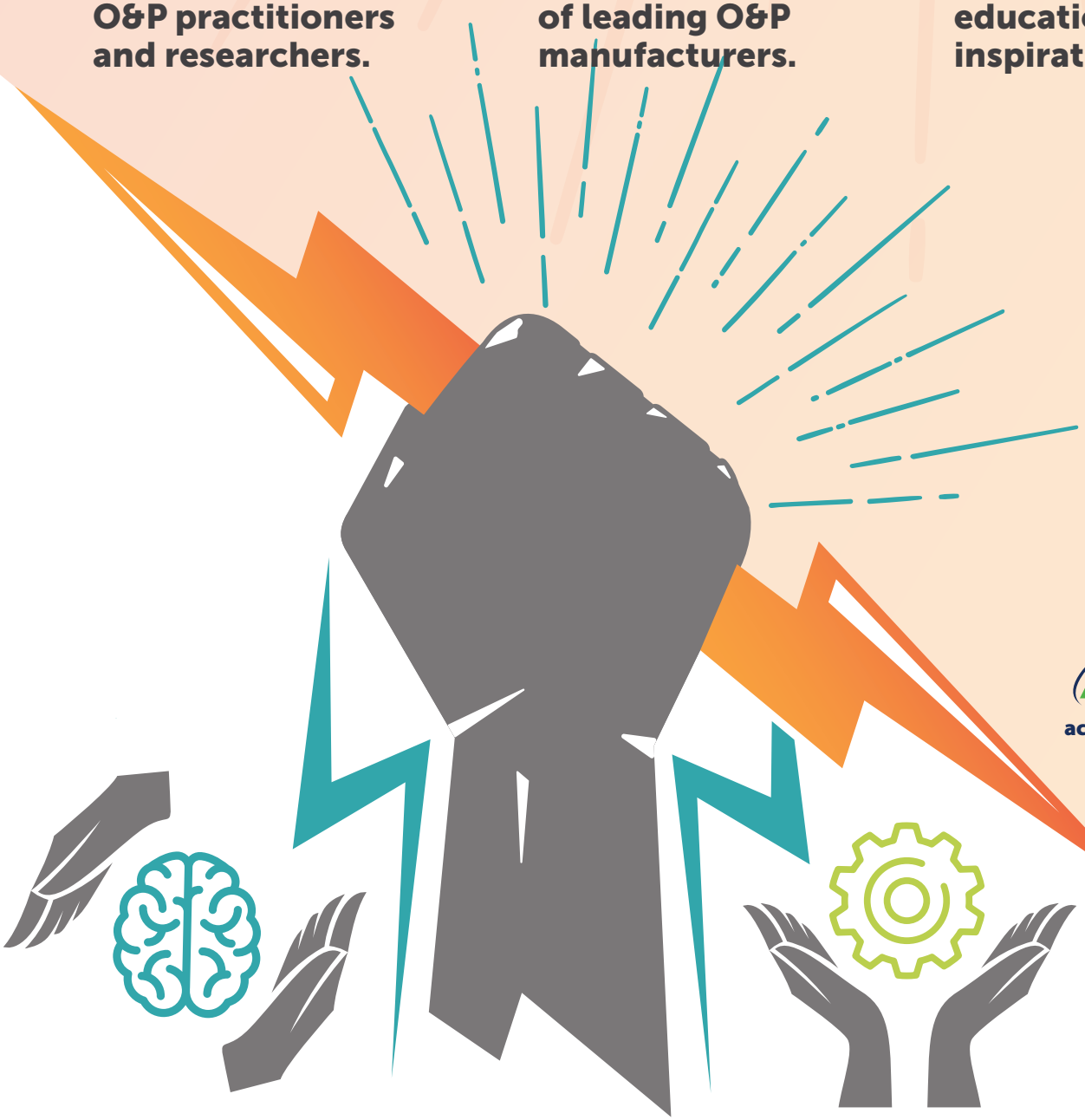

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