An Overview of Digital Workflows and 3D Printing in the Orthotics and Prosthetics Industry

Prosthetics and orthotics is the specialty within the healthcare industry that focuses on the development, design, manufacture, and application of prostheses and orthoses for patient care. Today, the industry's market size is approximately $6.5 billion dollars with an expected annual growth rate of 4.2%. The industry's growth is driven by the need to improve patient care through the provision of custom-fit solutions that ease the traditional challenges associated with their use. This is where 3D printed orthotics and prosthetics have crucial roles to play.

Majority of the traditional challenges associated with the use of prostheses and orthoses include discomfort with using generic items, compatibility with the skin/human body, and poorly-fitted designs. To ease these concerns, emphasis was placed on the importance of customization to meet the specific needs of individual patients and this also came with a new set of challenges – expensive customization costs and a time-consuming production process.

Today, the healthcare industry continues to explore new design, testing, and manufacturing option to reduce customization costs and speed up production cycles. Known for its rapid production and relatively affordable processes, 3D printing provides stakeholders in the prostheses and orthoses industry with a powerful customization solution. This overview will provide doctors, physical therapists, healthcare providers, and medical devices manufacturers with an extensive guide on getting started with 3D printing prostheses and orthoses.

Commonly Used Devices in the Orthotics and Prosthetics Industry

Orthotic devices are generally defined as external medical devices used for the support, immobilization, and treatment of muscular or skeletal injuries and deformities. Prosthetic devices refer to the medical devices developed to replace missing body parts or to support specific body parts and their functions. Going by definition, orthotic devices are always externally used and prostheses may be used either externally or internally depending on individual use cases.

Examples of common orthotic devices include:

- Shoe Inserts – to support balance and the locomotive process of patients
- Knee Braces – to reduce the pressure and force on the knees during physical activities
- Teeth Braces – to support and straighten the teeth
- Splint – to support broken or infirm bone structures
- Neck Braces – to support the neck or keep it in a prone position.

Examples of common prosthetic devices include:

- Leg Prostheses – these below-the-knee devices serve as replacement parts for patients with limb loss.
- Dental Implants – to support dental surgery procedures and to replace removed tooth
- Ocular Implants – to support eye sockets
- Joint Implants – to support collapsed or broken joints
- Hearing Aids – inserted in the ears to improve hearing
- Pacemakers – to support the heart and improve its functionality

These common solutions do not exhaust the list of orthoses and prostheses devices used across the healthcare industry. Other examples include ossicular implants, cochlear devices, urinary implants, voice prostheses etc. The use case for each implant also highlight the importance of customization and the need to take advantage of 3D printing to meet the varying physical attributes of every patient.

Traditional Workflows for Manufacturing Orthoses and Prostheses

Conventional manufacturing processes associated with producing prosthesis may vary according to the end-use part. In many cases, the following traditional manufacturing processes are utilized:

- Plaster Casting – The plaster mold casting process involves the use of a plaster, gypsum or calcium sulfate which is mixed with talc, sand, and other materials to form slurry. The slurry is then applied onto a patterned surface to form the mold. Molten metals or polymers are then poured into the mold to form the finished part.
- Conventional Machining – The machining process involves a human operator directing the machining tools to cut through materials to form the finished part. The operator is usually responsible for managing the location and intensity of the machining tool.

- Thermoforming – This involves the use of a thermoforming machine and a mold or pattern to transform plastic into a 3-dimensional part. Thermoforming is sometime used alone or alongside other manufacturing processes to produce externally used medical devices.
- Wax Casting – This involves creating a mold from a pattern using wax as the mold forming material. Molten metal is poured into the mold to form the finished part.

Despite the differences in these traditional orthoses and prostheses manufacturing processes, a common production workflow outlines the steps for developing end-use items. This workflow includes the following steps:

1. Developing a topography map of the compromised area – This involves the use of casts, technical drawing, and measurements to map out the area. The process takes approximately 30 minutes to an hour.
2. Model Formation – Developing a model from the topography map takes approximately 1 to 2 hours to accomplish.
3. Fitting and Sculpting – To ensure the mold fits the end-user, fitting and sculpting is required. This takes 2 – 7hours depending on the complexity of the design.
4. Post Processing and Finishing – This involves removing excess materials and prepping the orthotic or prosthetic device for use.

Traditional workflows come with diverse challenges that can be pinpointed to each stage of the workflow. Utilizing casts and other manual methods to develop a topography map provides tolerance errors that may affect the use of the end-used part. The time-taken to complete a single customization project is approximately 12 hours spread across a couple of days due to multiple return visits for fitting appointments.

Design errors, excess manual labor, an extended production timeline, and costs make the customization of orthoses and prostheses using traditional workflows a difficult process for manufacturers and healthcare service providers. Hence, applying traditional workflows for multiple customization production runs is not feasible from the economic and timeframe standpoint.

Most Common Applications for 3D Printing

Additive manufacturing is popularly known for its economical processes and production speed. The 3D printing process empowers service providers with an affordable rapid production technique for manufacturing 3D printed orthoses and prostheses. Research on the application of 3D printing highlights its two important use cases – producing ultra-affordable items and developing professional grade solutions.

1. Producing Ultra-affordable Prostheses and Orthoses – 3D printing's prototyping and production speed makes it ideal for producing ultra-affordable items at varying volumes for commercial or personal use. The healthcare industry takes advantage of this speed to produce easily affordable orthoses and prostheses such as:
    - POHLIG GmbH Orthosis Ring – The orthosis ring is used to reposition the talus or provide support for patients with equine foot. Here, SLS 3D printers are used to rapidly produce 3D printed orthoses rings at very affordable prices.
    - Wrist Orthosis – The wrist orthosis is used to support the wrist or hold it in positions that reduce the possibility of further injuries occurring to sprained wrists. 3D printing of wrist orthosis reduces the production costs associated with traditional manufacturing process by $3,500.
    - Orthopedic Insoles – 3D printed insoles are ultra-affordable solutions that provide patients with customizable orthosis for foot correction and support. The printing process enable orthopedic service providers quickly produce affordable insoles for diverse patients.
2. Professional Grade Prostheses and Orthoses – High-precision and accuracy levels are required to develop complex prostheses or orthoses used internally to improve patient health. In scenarios where high-precision levels are required, professional grade 3D printed orthoses and prostheses are used. The production process may be more complex due to the process of scanning and designing the CAD models. The application of 3D printing still speeds up production timelines and reduces production costs. Examples of professional grade prostheses include:
    - Prosthetic Hands and Fingers – Developing usable prosthetic hands involves recreating accurate joint movements, ensuring proper fitting, and the comfort of the end-user. Hence, the 3D printing process involves implementing high-precision levels and tight tolerances to develop professional grade prosthetics.
    - Orthoses for Traumatic Hand Conditions – Traumatic and chronic hand conditions limits a patient's ability to use the limbs and may cause considerable pain. Professional grade

orthoses have been proven to reduce the effects of traumatic injuries, reduce the chronic pain that comes with it, and improve hand functionalities.

Common Print Engines and Materials

The common print engines that support the printing of orthoses and prostheses designs includes fused deposition modeling (FDM), Stereolithography (SLA), Multi-jet fusion (MJF), and selective laser sintering (SLS) technologies.

- Fused deposition modeling – FDM involves the extrusion of thermoplastic material from a moving nozzle onto a build platform. The extrusion process occurs in layers specified by the CAD model fed into the 3D printer.
- Stereolithography – This process involves the use of light to cure resins into a solidified shape or geometry depending on the 3D models it intends to recreate.
- Selective laser sintering – The SLS process involves the use of a laser as the power and heat source for sintering powdered material into a solidified shape.
- Metal Jet Fusion – The MJF process involves the use of an inkjet array to apply fusing agents across a build platform with powdered material. The fusing agent and material is then fused into solid geometries by a heat source.

Patient's specific requirements generally determine the materials to be used when 3D printing custom or generic orthoses or prostheses. These requirements may include the patient's anatomy, the purpose of the print, the application of the end-use part, and the physical properties expected of the part such as durability, or flexibility. An extensive variety of 3D printing materials are available for the production of orthoses or prostheses and the most commonly used ones include:

- Thermoplastic Elastomers (TPE) – TPE is used for its flexibility, strength, and durability. Orthopedic and healthcare service providers also points at its high resistance to chemical, water, moisture, and abrasion as some of the major reasons why TPE is used in 3D printing orthoses and prostheses.
- Nylon – Multiple iterations of Nylon are utilized in the manufacture of prostheses and orthoses due to their physical properties. These properties include the durability, flexibility, and aesthetics of Nylon. Nylon is also highly resistant to chemical and abrasions. The commonly used nylon polymers are the PA11 and PA12 iterations.

- Acrylonitrile Butadiene Styrene (ABS) – ABS is a popular thermoplastic used across the 3D printing community due to its malleability and durability. ABS is used in 3D printing ultra-affordable prosthetic devices due to the affordability of the material.
- Acrylic Resins – Multiple resins types are utilized in 3D printing performance grade prostheses and orthoses by orthopedic service providers. The advantageous features attached to acrylic resins include durability, high tensile strength, aesthetic finish, and abrasion resistance.
- Polyethylene – The material provides features such as resistance to many solvents, resistance to abrasion and wear, resistance to chemicals, and approval by the FDA and USDA for the development of medical devices.

Overview of the Digital Process

The digital approach to 3D printing orthoses and prostheses for patients starts with scanning the affected body parts to determine the dimensions required for the end-use part. Digital scanners are used to accomplish this task.

Scan Acquisition

The wide acceptance of the application of 3D printing in healthcare has led to the development of powerful scanners that scan and produce accurate CAD models of a patient's anatomy without the need of computer-aided design software. Examples of these powerful hand-held digital scanners targeted at healthcare providers include:

- Structure Sensor – A powerful 3D scanner built with an iOS native SDK that enables the scanning of body parts using devices with the iOS operating system.
- **Peel 3D** – The series of hand scanners Peel 3D offers, may be used to scan body parts to capture the relevant data needed to produce accurate digital 3D representations. Peel 3D also offers complementary software for fine-tuning measurements to improve a model's accuracy.
- Amfit Solutions – The series of scanners Amfit offers include handheld 3D image scanners and desktop scanners for producing accurate 3D models of body parts. Amfit solutions also include computer-aided manufacturing software to ease the 3D printing of scanned anatomy.
- Materialise – Materialise converts patients imaging data into accurate 3D anatomical models. These models form the foundation for 3D printing orthoses and prostheses for patients.

The 3D models produced using the listed scanning devices provide the information required to modify the existing 3D model or design patient-specific solutions before the 3D printing process. This makes shape modification and designs the next step in the digital workflow.

Shape Modification and/or Design

In many cases, simple to extensive modifications to scanned models are required to produce accurate 3D models of orthoses and prostheses before the 3D printing process begins. The shape modification and design stage involves utilizing either a CAD or CAM software to put the finishing touches to your scanned models and prepping the model for the printing process. Examples of shape modification service providers and tools include:

- Spentys – The Spentys platform is equipped with digital workshop tools to automate the modification and design tasks associated with prepping scanned models. These tools support the personalization of CAD models and testing or validating designs before 3D printing. Spentys also validate digital workflows from the scanning process to ensuring the printed prosthetics meets its intended goals.
- Mecuris – The Mecuris platform is a powerful digital workspace that provides both CAD/CAM and 3D printing support services to the orthopedic device development industry. The CAD and CAM tools within the virtual workspace supports shape modifications and design repairs of scanned anatomical parts.
- nTopology – Offers a modern modeling engine that enables the intuitive modification of 3D models and designs from scanned object. The intuitive nature of the platform empowers both professional designers and individuals with little design knowledge to modify 3D models.

3D Printing

The next step in the digital workflow is 3D printing the modified designs or 3D models to produce the end-use orthoses or prostheses. Orthopedic and healthcare service providers can take advantage of the diverse 3D printing engines to produce the finished item. The application of the end-use part, its size, production volume, and design complexities are some of the important criteria to consider when choosing a printing engine.

In scenarios where premium grade orthoses and prostheses are required, SLS and MJF 3D printing engines are equipped with the technologies and materials to produce highly-accurate and quality items.

FDM printing engines are capable of producing low-cost and larger prosthetic designs due to the thermoplastics it relies on and the availability of larger FDM desktop 3D printers. The common print engines used in 3D printing prostheses and orthoses models include:

- Selective Laser Sintering – SLS printing engines are capable of producing high-quality prosthetics at very low tolerances making them optimal for developing professional grade solutions for patients. SLS engines are used in producing sensitive items such as ocular implants, joint inserts, and dental implants.
- Multi Jet Fusion – MJF printing engines are capable of producing premium grade solutions from nylon within a day for patients. They can be applied to rapidly produce complex solutions for unique anatomical parts with intricate geometries at high-precision levels.
- Stereolithography – SLA printing engines are commonly used to produce prosthetics that meet the quality recommendations of individual applications. Orthopedic service providers may choose to leverage SLA to produce low-cost items such as insoles or high-quality items such as hand aids or ocular implant prototypes.
- Fused Deposition Modeling – This material extrusion 3D printing engine is capable of producing low-cost solutions due to the negligible costs of its operational processes and materials. Healthcare service providers routinely utilize FDM to produce custom insoles, hand, leg, and joint support solutions without stringent design requirements.

Formlabs Role in the Orthoses and Prostheses Manufacturing Community

The digital workflow associated with 3D printing highlights the importance of leveraging a production ecosystem that supports the entire process from scanning to post-processing 3D printed parts. Implementing a production ecosystem in place that ensures scanning, modification, printing, and post-processing occur symmetrically without disruptions is crucial to reducing cost, eliminating material waste, and speeding up production timelines.

Formlabs provides orthoses and prostheses service providers with powerful tools and the technical experience required to build functional ecosystems. Service providers who intend to manufacture commercial anatomical support solutions must also consider the need for documentation to receive the product certifications required by many communities. To this end, Formlabs currently provides the orthoses and prostheses development community with:

- SLS printing engines – Formlabs Fuse 1+ 3D printer is a next-generation SLS engine equipped with the features and capability to produce custom premium grade orthoses and prostheses for the healthcare industry. Service providers continue to leverage the Fuse 1+ and nylon (P11, P12) to produce high-performing anatomical support devices for the industry.
- SLA printing engines – Formlabs' 3B+ and 3BL printing engines built specifically for the healthcare industry. Form 3BL is designed specifically for the high volume printing of dental devices and implants and 3B+ supports the development of customized solutions using biocompatible materials.

Formlabs also works in partnership with solutions providers that offer diverse services across the digital workflow. These collaborations ease the scanning and modification process before printing occurs. Partnerships across the digital process include:

- Scan Acquisition – Partnerships with Structure Sensor, Peel 3D, Amfit, and Materialise provide integrated support for scanning 3D printable anatomy models for Formlabs' printing engines.
- Shape Modification/ Design – Partnerships with Spentys, Mecuris, and nTopology platforms provide the healthcare industry with powerful CAD/CAM tools that complements Formlabs PreForm 3D printing software to automate the design modification and printing process.

Formlabs-specific Digital Process Recommendations

Insert the table here.

Post-Processing Recommendations

3D printed parts may require some forms of post-processing to meet the aesthetics of application requirements of individual patients. Multiple post-processing techniques are applied individually or together to ensure the orthoses or prostheses eases a patient's health challenges. These techniques involve:

- Vapor Smoothing – The vapor smoothing process involves the exposure of the printed part to vaporizing solvents. The process is conducted in a controlled environment with a heating chamber and egress points to remove vapor. The solvents remove blemishes such as layer lines, box-like finishing where smoothness is required, and leaves a glossy, smooth surface.

  Vapor smoothing comes highly recommended because it refines printed features without harming surfaces or affecting the mechanical structures of the printed part. The post-processing technique may be applied to a variety of 3D printing materials including nylon, TPU, TPE, ABS, and their polymers.
  A vapor smoothing unit such as the AMT PostPro SF100 costs approximately $3000. Healthcare providers can also choose to outsource the smoothing process to 3D printing service providers. This post-processing technique is executed within 1 to 5 days depending on the complexity of the printed part. The cost of vapor smoothing is approximately $7 per part for batches containing approximately a thousand pieces of 3D printed parts.

Formlabs vs. the Competition

Choosing the right 3D printing engine and brand for your prostheses and orthoses production runs require some in-depth cost analysis, features analysis, and knowledge about the support ecosystem of each vendor. The table below provides a competitor analysis for Formlabs Fuse 1+, HP Jet Fusion 3D Series, EOS, and 3DS SLS printers.

Printers	Cost	Materials	Support/Maintenance	Build Volume/Throughput	Printing Technology	Ease of Use	Software
Fuse 1+	Starting at $27,999. Complete setup	Nylon 12, Nylon 12 GF,	Extended 3-year after sales support for maintenance and	16.5 x 16.5 x 30 cm 6.5 x 6.5 x 11.8 in. Capable of	SLS	Plug and Print utilizati	Available for Windows and Mac

	starting from $39,243	Nylon 11, Nylon 11 CF, and TPU	repair activities.	round-the-clock printing that minimizes downtime.		on process.	
HP Jet Fusion 3D Series	Price range is $270,000-$430,000 for the 4200 series and $350,000-$500,000+ for the 5200 Series.	Nylon 12, Nylon 11, glass-filled Nylon 12, and TPU.	Paid after sales support that comes at a huge financial cost.	38 x 28.4 x 38 cm 15 x 11.2 x 15 in. Optimized for high throughput with recommended periodic cool-down durations.	MJF	Complex setup and utilization process	Proprietary software powered by 3rd party providers.
EOS P Series	Opaque pricing but approximately $300,000	TPE, PA, PP, nylon, PS	Paid after sales support.	13 x13 x 26 in. Optimized for high throughput.	SLS 3D printing	Requires extensive setup but easy to use once setup.	Open OPC UA software compatible with Windows and Mac devices
3DS SLS Printers	Opaque pricing	Nylon, TPE, TPU	Paid after sales support.	15 x 13 x 18 in. High throughput wit recommended	SLS	Requires some setup process	Relies on proprietary software

				cool-down durations.		es but easy to use.	.

Extending Orthoses and Prostheses Manufacturing with 3D Printing

Advancements in 3D printing technology currently coincide with current progresses across the healthcare sector. Next-generation 3D printers provide orthoses and prostheses service providers with powerful manufacturing tools to bring your most complex and innovative solutions to life. Commercial medical device manufacturers looking to take advantage with the projected growth within the industry can also take advantage of digital manufacturing processes powered by 3D printing. Learn more about improving your orthoses/prostheses R&D and manufacturing processes with 3D printing by speaking with the experts today.