Author
Rosicky, Jiri (Ostrava-Pustkovec CZ) | M.E., PhD
Invent Medical Group s.r.o. - Management

Title
Additive Manufacturing in the O&P industry: Benefits, Challenges, Practical Considerations.

Coauthors
None

Summary
It is expected that 35% of patient-specific O&P devices will be 3D printed by 2027. 3D printing is not just a manufacturing method. The Direct Digital Manufacturing process (3D scanning, CAD SW, 3D printing) represents a new opportunity to introduce product, process and business model innovation.

Introduction/ basics
This paper reacts to an introduction of 3D printing technology in the O&P industry and should contribute to a better understanding of the possibilities that 3D printing can bring and also its challenges, limitations and meaningful adoption. 3D printing is an opportunity to raise not only the O&P profession, but solutions for our patients, to the next level.

Material method; implementation/ process
An evaluation of DDM in O&P is based on our personal experience with the standard manufacturing process (30 years), CAD/CAM process (12 years), DDM process (9 years) and our long-term interest in applying digital technologies such as 2D/3D scanning, CAD/ computational modeling, 3D printing, automation and algorithm-based solutions to different clinical areas of O&P. R&D, QA and regulatory teams worked together to assess the technology and its implications. Various 3D printing technologies, materials, post-processing steps and design approaches were assessed in an iterative design process and verified and validated in computation analysis, mechanical testing in in-house lab, with patients and early-adopter customers and partners. Systematic validation and verification framework was developed to provide actionable quantitative and qualitative data.

Results

3D scanning and CAD surface modification are already familiar methods from the CAD/CAM process.

DDM process introduces 2 new methods: CAD modeling of 3D objects (product design) and 3D printing (a new manufacturing method).

CAD/computational modeling (product design) is the most important part of DDM in O&P as it enables using the full potential of 3D printing - design freedom.

Product design in O&P is more than just the shape.

The design process of 3D printed patient-specific O&P products has to take into consideration many parameters: clinical requirements, product requirements, 3D printing method, used materials.

DDM process needs to be controlled, systematic and repeatable. It has to comply with the regulatory requirements on 3D printed patient-specific O&P products (MDR) and ensure QA control.

DDM has to offer products with enhanced comfort, incorporated function and better appearance.

DDM needs to be developed into an affordable and easy to use process, enabling clinicians to benefit from new technology - to democratize 3D printing.

Major benefits in efficiency and stability are offered by DDM process to O&P facilities.

DDM opens a way to systematic controlled production of a new generation patient-specific products.

An efficient way to stay compliant with the new MDR regulatory requirements with full detailed components, device and process history and controls.

Discussion/ conclusion; conclusion for the practice

Direct Digital Manufacturing (DDM) is a new design and manufacturing process that even today represents an alternative to standard manual or CAD/CAM processes in some O&P products.

DDM has the potential to innovate the products, process, and business model in the O&P field.

Product innovation enables designers to develop lightweight, breathable, and highly aesthetic 3D printed products with integrated biomechanical function and properties. Process innovation

is based on a fully digital workflow. Business model innovation means global availability of O&P products because of the digital data mobility and more stability and efficiency for O&P providers especially in unstable pandemic situation.

The correct combination of design, technology, printer, material and post-process is crucial for success of additive manufacturing.

MDR implication for regulatory compliance of 3D printed patient-specific products is more strict. However with fully digital systematic process it is more efficient as all necessary documentation is generated along the process and more reliable and safe products can be produced.

References

1 SmarTech Analysis. New Report on Orthotics and Prosthetics Markets: “Opportunities for Additive Manufacturing in Medical Devices – Prosthetics, Orthotics, and Audiology“. Available at: https://www.smartechanalysis.com/news/orthotics-prosthetics-markets/

Image: Screen Shot 2021-09-15 at 8.17.27_209.png

Image: PHOTO-2021-05-20-22-32-47_210.jpg

Image: 1bf1ecc3d6cbf63bafae74611fc8ad2f-02_211.png

Image: 0416 Talee_Vyroba - 1125_212.jpg