Transactions on Additive Manufacturing Meets Medicine
Trans. AMMM, Vol. 4, No 1, Suppl. 1, Article ID 651, 1 Page

Infinite Science Publishing

Abstract

3D printed trials and short-term devices

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Through qualified FDA-approved workflows and regulations 3d printed patient-specific implants like cranial plates printed from PEEK become reality. But besides implants also trials sizes, spacer, surgery tools or other short-term devices follow these success stories more and more often.

Printed from commonly used materials in the medical industry like PPSU, PEEK and carbon fiber enhanced PEEK a brought range or application field can be covered by filament-based additive manufacturing. Through DIN EN ISO 10993 approved materials in combination with the qualified Kumovis R1 printing technique medical devices for the whole orthopedic market are already possible. From joint reconstruction over spine to trauma market applications, way beyond orthosis or cutting guides, can be experienced a disruptive change.

Using 3d printing to manufacture short-term devices from high-performance polymers enable a huge range of benefits in terms of material as well as overall cost-effectiveness. Substituting current metal-based devices with plastics like PPSU leads to a huge reduction in weight per part and therefore for whole trays of trials and instruments. Using additives like barium sulphate for x-ray visibility a complete substitution without losses in terms of performance or medical needs can be ensured. But even more important, next to natural given material benefits, are the enormous cost efficiency that are achieved throughout FFF printing also against machining or injection molding especially for small series or special sizes. Additive manufacturing even opens further advantages in term of geometries or integration of functions and develops its full potential if devices specially designed for 3d printing to add functions and structures that are only possible by using an additive instead of subtractive manufacturing techniques.

For putting above-mentioned arguments in facts two well-knows applications shows following exactly these benefits. Spine trial spacer or stoppers for lumbar or cervical insertion, currently most common produced in metal molding, can now easily replaced by using Kumovis R1 3d printed components made from PPSU with BaSO4 available in different colors for all different sizes. With each instrument weight savings can implemented, by being x-ray detectable to adjust the right positions and angles and leads to overall cost savings in production around 60 percent. Another application mentioned from the trauma market are osteosynthesis trial plates. To adjust the right size and length of the final implant trials are used to save costs and prevent costs of defective performance. These trials for body regions like distal radius or tibia/fibula can be produced as actual plates for fitting tests or as x-ray template with length notch features. Compared to metal molding or machining based on quantity and massive reduction of material waste cost reduction around 60 resp. 85 percent are applicable.

Bottom line multiple-use short-term devices and tools applicable up to 500 sterilization cycles with 3d printing become more and more efficient in functionality and production costs.

AUTHOR'S STATEMENT

Conflict of interest: N. Marquardt is employee of Kumovis GmbH a 3DSystems Company, Munich , Germany. Informed consent: Informed consent has been obtained from all individuals included in this study.

DOI: 10.18416/AMMM.2022.2209651