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Three-Dimensional Manufacturing of Personalized Implants in Orthopedic Trauma Surgery—Feasible Future or Fake News?

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Until recently, producing medical-grade osteosynthesis devices was solely done by (mostly large) orthopedic medical device companies. Although a wide variety of osteosynthesis devices are commercially available, in reality, hospitals are bound by legal contracts, production and supply issues, and a need to reduce costs, which limits flexibility and availability. IJpma et al[1] report on the feasibility of on-demand patient-specific osteosynthesis plates and drilling guides for acetabular fracture surgery that are designed in house and regionally produced. In a cohort of 10 patients with complex acetabular fractures, they managed to plan, design, and manufacture the implants within 4 days and reported easy handling and no need for additional intraoperative contouring of the plates. Each patient's computed tomography (CT) data were used to create a 3-dimensional (3-D) model that was virtually reduced and then used as a template to design patient-specific plates. Fracture reduction and implant position were evaluated by postoperative CT scans, and clinical outcomes were assessed by Short Musculoskeletal Function Assessment questionnaires. Excellent results in both domains were reported. Details regarding legal legislation and cost efficacy of this procedure were not provided. The question that remains after reading this article is: is this a gimmick for the happy few or is it the future? Will we soon all move to an era of self-designed and locally (ie, in-house) produced patient-specific osteosynthesis implants? Particularly for complex skeletal reconstructions—but also in austere environments or mass casualty situations—a readily available, affordable, and always-appropriate implant can make the difference between failure and success.

The surgical benefits of 3-D visualization and fabrication of bone models are beyond dispute, and their use during the last decade has gained popularity in orthopedic trauma surgery. Particularly for the complex anatomy in reconstructive intra-articular acetabular procedures, preoperative printed pelvic models are regarded as valuable supplements to standard medical imaging techniques.[2] The physically printed bone models can also be used for preoperative planning and practicing, such as for fracture reduction techniques and precontouring of commercially available implants. This allows for reductions in operating time, which is financially attractive and might result in better outcomes.[3,4] It would be interesting to compare this outcome to the results of the study by IJpma et al[1]; however, costs of surgery and time reduction were not part of their study. Technical possibilities have progressed toward the production of personalized implants. This is done not only for fracture surgery but also, for example, for revision of arthroplasties and skeletal stabilization of congenital deformities or after tumor resections in various clinical scenarios.[5] All these indications demonstrate potential for these new techniques to stay and conquer a specific area in standard medical care.

It seems that personalized care within trauma surgery has no downsides; however, it must be noted that compared with conventional methods, these new techniques necessitate additional actions by the surgical team. The preparation of anatomical models, the design and planning of the surgical intervention, and the production of the implants all require added commitment and training and some extra costs. There is a delicate balance between the needed investment for software, materials, equipment, and the personnel to operate it on the one hand and the added treatment quality or reduced surgery time on the other. These key factors will ultimately determine whether these new techniques are here to stay and for which indications they are used.

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Apart from the feasibility and costs of local (ie, in-house) production facilities, another major challenge for the treating team is obtaining regulatory approval for the production of patient-specific surgical implants, including sterilization certificates. The pathways for navigating these regulations are often unclear, frequently bureaucratic, and always time consuming.[6] It is clear that there has to be a system in place that represents patients' interests and allows for the safe production and use of medical implants. However, these regulations currently form a very worrisome barrier for the use of personalized fracture care in clinical practice. In trauma surgery, we simply do not have the luxury of elaborating a complex route for procedures that need to be done in a timely fashion. If we learned anything from the COVID-19 pandemic, it is that with the right perseverance, medical legislation can be accelerated when necessary.

Therefore, it is commendable to IJpma et al[1] that they managed to plan, produce, and use these patient-specific implants in an actual, day-to-day trauma surgical setting. The study's concept of personalized fracture care is very interesting because it is also widely applicable in various subdisciplines of surgery. However, to further determine whether fast-track osteosynthesis is a gimmick for the happy few or the future for trauma surgery, we need well-designed and sufficiently powered prospective studies that compare patient-specific osteosynthesis implants targeting clinical outcomes and patient safety with a transparent impression of the costs.

ARTICLE INFORMATION

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REFERENCES

1. IJpma FFA, Meesters AML, Merema BBJ, et al. Feasibility of imaging-based 3-dimensional models to design patient-specific osteosynthesis plates and drilling guides. *JAMA Netw Open*. 2021;4(2):e2037519. doi:10.1001/jamanetworkopem.2020.37519

2. Fang C, Cai H, Kuong E, et al. Surgical applications of three-dimensional printing in the pelvis and acetabulum: from models and tools to implants. *Unfallchirurg*. 2019;122(4):278-285. doi:10.1007/s00113-019-0626-8

3. Maini L, Sharma A, Jha S, Sharma A, Tiwari A. Three-dimensional printing and patient-specific pre-contoured plate: future of acetabulum fracture fixation? *Eur J Trauma Emerg Surg*. 2018;44(2):215-224. doi:10.1007/s00068-016-0738-6

4. Ballard DH, Mills P, Duszak R Jr, Weisman JA, Rybicki FJ, Woodard PK. Medical 3D printing cost-savings in orthopedic and maxillofacial surgery: cost analysis of operating room time saved with 3D printed anatomic models and surgical guides. *Acad Radiol*. 2020;27(8):1103-1113. doi:10.1016/j.acra.2019.08.011

5. Ma L, Zhou Y, Zhu Y, et al. 3D printed personalized titanium plates improve clinical outcome in microwave ablation of bone tumors around the knee. *Sci Rep*. 2017;7(1):7626. doi:10.1038/s41598-017-07243-3

6. Willemsen K, Nizak R, Noordmans HJ, Castelein RM, Weinans H, Kruyt MC. Challenges in the design and regulatory approval of 3D-printed surgical implants: a two-case series. *Lancet Digit Health*. 2019;1(4):e163-e171. doi:10.1016/S2589-7500(19)30067-6