Application of 3D printing in orthopedics: status quo and opportunities in China

Hong Cai

Department of Orthopedics, Peking University Third Hospital, Beijing 100191, China

Correspondence to: Hong Cai, MD. Department of Orthopedics, Peking University Third Hospital, 49 North Garden Rd., Haidian District, Beijing 100191, China. Email: hongcai@bjmu.edu.cn.

Submitted Jan 22, 2015. Accepted for publication Jan 23, 2015.

doi: 10.3978/j.issn.2305-5839.2015.01.38

View this article at: http://dx.doi.org/10.3978/j.issn.2305-5839.2015.01.38

The 3D printing technology is penetrating the healthcare field at an astonishing rate. Although there is still a long way to go to realize organ printing and despite the constantly existing ethical and technical changes (1), the 3D printing can form 3D supporting structures in a controllable manner and has shown charms in fields such as tissue engineering and regenerative medicine along with the advances in cell printing and bio-printing and the innovation of printing materials (2-4). In the clinical settings, 3D printing, as a novel additive manufacturing technique, is mainly applied in orthopedics and stomatology (5). A group of 3D printing-based patient-specific osteotomy instruments, orthopedic implants, and dental implants have been licensed by the US Food and Drug Administration (FDA) and Caritas Europa (CE) for clinical use. The orthopedics in China does not lag behind the Western countries in terms of patient number, operation volume, and surgical skills; however, the Western countries have much advanced orthopedic devices, in particular the implants, than China. The 3D printing technology may provide a chance for the Chinese orthopedists and technicians to independently develop innovative medical devices to catch up with their Western counterparts.

Using the rapid prototyping manufacturing (RPM) to facilitate surgery design

Based on imaging techniques such as computed tomography (CT) and magnetic resonance imaging (MRI), the 3D images of the bones can be re-constructed; then, the prototypes of the bones can be obtained using the layered manufacturing technique (LMT) for teaching, presentation, and surgical design. Based on the symmetry of the human anatomy, or by using the human anatomy data in database, we can also reverse or mimic the 3D images of the bones at the missing parts, so as to assist the conventional mechanical processing to manufacture bone prostheses that can be implanted into human body. These two rapid prototyping manufacturing (RPM) techniques have been quite mature and commonly applied in surgery design. By using the RPM techniques, the Ninth People's Hospital of Shanghai Jiaotong University School of Medicine has applied the custom-made prosthesis for the hemipelvic reconstruction after hemipelvectomy and for the reconstruction of serious acetabular bone defect in hip revision surgery (6,7). They took a lead in this field; however, confined by the 3D metal printing technology, the implanted prostheses were still manufactured by conventional techniques. Along with the advances in 3D printing technology and the drop of forming equipment prices, an increasing number of doctors began to use 3D printing for the medical education and for the design and presentation of complex surgeries.

Design and application of 3D printing-based instruments

While the role of patient-specific instrumentation in total knee replacement remain controversial (8,9) (particularly, no evidence on its effectiveness in improving the long-term outcomes has been available), it does have some notable advances such as shorter operative time, improved the accuracy of alignment, and simplified complex surgical procedures. All the major international artificial joint companies have marketed their corresponding products for clinical use. In China, however, the higher cost (an addition USD 1,000 is needed for each case) and longer duration

(it takes 4 weeks from imaging to instrumentation) limit its application. Currently, some domestic artificial joint manufacturers have initiated R&D in this field, and some products have been piloted in some hospitals. Obviously, the patient-specific instrumentation also has a learning curve and is designed for experienced surgeons; thus, it can not completely replace the traditional surgical tools. In addition to the field of artificial joints, the design and application of 3D printing-based instruments in fields including spinal surgery, trauma, and orthopedics have shown special values. Researchers from Kunming General Hospital have demonstrated the efficacy and accuracy of a novel rapid prototyping drill template for cervical pedicle screw placement in cadaver spine specimens (10); also, satisfactory effectiveness has been achieved in their clinical practices (11).

R&D of 3D printing-based orthopedic metal implants

Development of metallic implants and personalized prostheses is the most important and most valuable direction when applying the 3D printing in the field of orthopedics. This is determined by the materials, equipment, and manufacturing capabilities available for 3D printing. The commonly used metal materials including Ti6Al4V, cobalt-chromium alloy, and stainless steel can be used for 3D printing and manufacturing. The preciseness and efficiency of high-energy 3D printing equipment such as electron beam and laser beam can meet the requirements for manufacturing small parts or achieving high-scale production. Under the computer-aided design, the 3D printing can rapidly manufacture shaped implants; meanwhile, it can also produce size-controllable micro-pore structures. These micro-pore structures can lower the elastic modulus of metal materials and decrease the stress shielding at the solid parts of the implants and can promote the integration between metal and bones at the surface of the implants. The unique feature makes R&D of orthopedic implants become more promising. Researchers from Peking University Third Hospital have developed an artificial vertebral body fabricated by electron beam melting using the microporous 3D printing; animal study has demonstrated that the artificial vertebral body can be well integrated with the surrounding bones (12). Also, research has shown that the roughened titanium screws prepared with 3D printing demonstrated a high degree of osseointegration and increased torsional resistance to extraction over smooth titanium screws (13). In 2010, FDA approved the InteGrip®, an acetabular cup manufactured by Exactech with a titanium alloy with a porous surface manufactured using 3D printing; in 2013, FDA approved the Tesera® Standalone anterior lumbar interbody fusion cage, which was manufactured by Renovis using 3D printing. However, the actual outcomes of the use of porous structures (instead of the conventional bone grafting) and the bone integration efficiency still require further verifications in long-lasting studies, in particular when they are used for the interspinous fusion.

Basic research

Due to their innate biological inertness, the metal materials can not be easily integrated with the host bones. Currently, one of the hot research topics is the modification in the nature of the porous surfaces of the 3D printing-formed metals. The aims of these studies are to promote the osseointegration efficiency of the porous surfaces of the metals; or, they may be used as stent materials to be loaded with other functional materials and drugs (e.g., producing anti-bacterial surfaces). The research teams from the Fourth Military Medical University Affiliated Xijing Hospital and the Shanghai Jiaotong University (14,15) have successfully promoted the osteointegration under diabetic conditions using chitosan/hydroxyapatite composite coating on 3D printing-based porous titanium surfaces. These studies have overcome the weakness of 3D printing materials and the manufacturing techniques, and thus expanded the application of 3D printing in orthopedics. Indeed, while the 3D printing of biodegradable materials is another hot research topic, there is still a considerable distance to go before clinical translation.

In summary, the application of 3D printing in orthopedics is experiencing a rapid translation from bench to bedside. Only a "real world" clinical translation can reveal the value and future of 3D printing. Currently, a major limiting factor may be the policies and regulations from the government, particularly those on the manufacturing of the 3D printing-based patient-specific implants. Luckily, the government has made great efforts on this issue, and some improvements have occurred. Nevertheless, 3D printing provides a great opportunity for the orthopedic implantable medical devices manufacturing in China to catch up with the advanced countries.

Acknowledgements

Disclosure: The author declares no conflict of interest.

References

1. Maruthappu M, Keogh B. How might 3D printing affect clinical practice? BMJ 2014;349:g7709.
2. Derby B. Printing and prototyping of tissues and scaffolds. Science 2012;338:921-6.
3. Murphy SV, Atala A. 3D bioprinting of tissues and organs. Nat Biotechnol 2014;32:773-85.
4. Michalski MH, Ross JS. The shape of things to come: 3D printing in medicine. JAMA 2014;312:2213-4.
5. Liu Q, Leu MC, Schmitt SM. Rapid prototyping in dentistry: technology and application. Int J Adv Manuf Technol 2006;29:317-35.
6. Dai KR, Yan MN, Zhu ZA, et al. Computer-aided custom-made hemipelvic prosthesis used in extensive pelvic lesions. J Arthroplasty 2007;22:981-6.
7. Li H, Wang L, Mao Y, et al. Revision of complex acetabular defects using cages with the aid of rapid prototyping. J Arthroplasty 2013;28:1770-5.
8. Voleti PB, Hamula MJ, Baldwin KD, et al. Current data do not support routine use of patient-specific instrumentation in total knee arthroplasty. J Arthroplasty 2014;29:1709-12.
9. Thienpont E, Schwab PE, Fennema P. A systematic review and meta-analysis of patient-specific instrumentation for improving alignment of the components in total knee replacement. Bone Joint J 2014;96-B:1052-61.
10. Lu S, Xu YQ, Chen GP, et al. Efficacy and accuracy of a novel rapid prototyping drill template for cervical pedicle screw placement. Comput Aided Surg 2011;16:240-8.
11. Lu S, Xu YQ, Lu WW, et al. A novel patient-specific navigational template for cervical pedicle screw placement. Spine (Phila Pa 1976) 2009;34:E959-66.
12. Yang J, Cai H, Lv J, et al. In vivo study of a self-stabilizing artificial vertebral body fabricated by electron beam melting. Spine (Phila Pa 1976) 2014;39:E486-92.
13. Yang J, Cai H, Lv J, et al. Biomechanical and histological evaluation of roughened surface titanium screws fabricated by electron beam melting. PLoS One 2014;9:e96179.
14. Ma XY, Feng YF, Ma ZS, et al. The promotion of osteointegration under diabetic conditions using chitosan/hydroxyapatite composite coating on porous titanium surfaces. Biomaterials 2014;35:7259-70.
15. Li X, Ma XY, Feng YF, et al. Osseointegration of chitosan coated porous titanium alloy implant by reactive oxygen species-mediated activation of the PI3K/AKT pathway under diabetic conditions. Biomaterials 2015;36:44-54.

Cite this article as: Cai H. Application of 3D printing in orthopedics: status quo and opportunities in China. Ann Transl Med 2015;3(S1):S12. doi: 10.3978/j.issn.2305-5839.2015.01.38

