Special Issue: Surgical Innovation: New Surgical Devices, Techniques and Progress in Surgical Training

Journal of INTERNATIONAL MEDICAL RESEARCH

Journal of International Medical Research
0(0) 1–9
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DOI: 10.1177/0300060519887299
journals.sagepub.com/home/imr
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Value of three-dimensional printing of fractures in orthopaedic trauma surgery

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Abstract

Objective: Information technology-based innovation is playing an increasingly key role in healthcare systems. The use of three-dimensional (3D)-printed bone fracture replicas in orthopaedic clinical practice could provide a new tool for fracture simulations and treatment, and change the interaction between patient and surgeon. We investigated the additional value of 3D-printing in the preparation and execution of surgical procedures and communication with patients, as well as its teaching and economic implications.

Methods: Fifty-two patients with complex articular displaced fractures of the calcaneus, tibial plateau, or distal radius were enrolled. 3D-printed real-size models of the fractured bone were obtained from computed tomography scans and exported to files suitable for 3D-printing. The models were handled by trauma surgeons, residents, and patients to investigate the potential advantages and procedural improvements. The patients' and surgeons' findings were recorded using specific questionnaires.

Results: 3D-printed replicas of articular fractures facilitated surgical planning and preoperative simulations, as well as training and teaching activities. They also strengthening the informed consent process and reduced surgical times and costs by about 15%.

Conclusion: 3D-printed models of bone fractures represent a significant step towards more-personalized medicine, with improved education and surgeon–patient relationships.

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Keywords
3D-printing, fracture, rapid prototyping, surgery, planning, education, informed consent

Date received: 11 April 2019; accepted: 17 October 2019

Introduction

Three-dimensional (3D) printing is a low-cost technology that can create solid objects from computerized 3D-imaging files.[1,2] 3D-printed models of healthy or fractured bones can be used in orthopaedic and trauma surgery to study detailed patterns of deformities and fractures, with potentially important impacts on surgical practice.[3–6] In line with the increased sophistication and availability of commercial 3D-printers, orthopaedic surgeons have started to use 3D-printed replicas of traumatic articular bone lesions (wrist, elbow, tibial plateau, talus, calcaneus) to improve their tactile and visual understanding of the fracture.[7,8] However, the potential advantages of 3D-printing in orthopaedics and traumatology have not been fully investigated.

3D-printing technology could improve the patient's understanding of their injury and proposed surgery in relation to acquiring informed consent, as well as facilitating the surgical preparation procedures and reducing costs. To the best of our knowledge, no prior studies have analysed these above aspects of 3D-printing technology in a teaching setting. We therefore proposed that 3D-printing in orthopaedics and traumatology could improve patient understanding, improve the surgical preparation process, improve the quality of training in the residency program, and reduce procedure times and their direct and indirect costs.

We accordingly reported on the 3-year results of the application of 3D-printed replica articular fractures at the Orthopaedic and Trauma Surgery Unit, University of Verona, Italy. The 3D models were evaluated by surgeons and residents for educational purposes and used for preoperative planning and simulation to inform the surgical approach, type of fixation, and optimal hardware size and location. 3D prints were then used to describe the fracture features to the patients and inform them about the planned surgical technique.[9,10] The patients' and surgeons' opinions regarding the perceived advantages and reliability of the models' applications were recorded by questionnaires. This new technology could help to reduce healthcare costs.[11,12]

Materials and methods

Patients

Consecutive patients admitted to the Orthopaedic and Trauma Surgery Unit at the University of Verona, Italy, from May 2013 to April 2016 with articular fractures of the calcaneus, tibial plateau, and distal radius were selected. It is often difficult to obtain a complete understanding of the fracture pattern at these sites, even with 2D or 3D computed tomography (CT) screening, because of their location in small, articular, anatomically complex regions, with displaced fragments. These fractures were thus suitable for study using 3D, real-size, 'full-touch' replicas. The study was performed in accordance with the relevant guidelines and regulations of the Integrated University Hospital of

Verona. All the enrolled patients in the study provided informed consent.

Reconstruction and 3D modelling

After plain X-ray, all the fractures were investigated by CT scan with slices of 0.625 mm (Philips iCT 256 CT Scanner; Philips Healthcare, Best, the Netherlands). The obtained DICOM files were uploaded to an OsiriX Dicom Viewer (Pixmeo© SARL, Bernex, Switzerland; 2003–2016).[13] 'Multiplanar Reconstruction' (axial, sagittal, coronal) and '3D Volume Rendering' were carried out, and the fractured bone was then cropped using the digital 'scissor' tool. A 'Surface Rendering' model was created and exported to a .stl file, which was analysed and prepared for 3D-printing using dedicated software (Mesh Lab, SourceForge Media, LLC dba Slashdot Media, La Jolla, CA, USA). A post-processing step was sometimes necessary to create artificial bridges to connect seriously displaced fragments to maintain the realistic integrity of the replica. The models were finally exported in .obj format and sent to a 3D-printer (HP Design Jet 3D, Hewlett-Packard, Palo Alto, CA, USA). The models were then printed using acrylonitrile/butadiene/styrene (ABS) and autoclaved if necessary for use in the surgical field (Figure 1). Printing times were recorded.

All the models were handled and examined by the senior surgeons and residents for preoperative planning and educational surgical simulation prior to the surgery (Figure 2). Once the fracture pattern was understood, the artificial bridges connecting the displaced fragments could be removed to facilitate reduction. This allowed the necessary manoeuvres and sequence in which the fragments should be reduced to be simulated, and the appropriate selection of the type and size of fixation device needed. The models were also shown to the patients when obtaining informed consent, to increase their understanding of the pattern, severity, and prognosis of their fracture, together with details of the proposed surgery. In most cases, the surgeons used the models in the surgical field as a template for fracture reduction and fixation, particularly in the case of minimally invasive surgical techniques without direct vision of the fractured site.

Patient and surgeon feedback

In all cases, questionnaires were submitted to obtain a feedback from the senior surgeons who performed the surgery and from the patients regarding the use of the models. Each form included five questions to the surgeon and five questions to the patient aimed at grading the usefulness and advantages of handling the models compared with the preliminary information obtained by X-rays and 2D and 3D CT scans. The level of understanding was assessed on a score of 1–10. In the surgeon-related questionnaire, the influence of the 3D-printed model on the preoperative decision-making processes was assessed in two separate sections.

The difference in quantitative data before and after the application of the 3D models based on the questionnaires were analysed by Wilcoxon's signed-rank test. Surgical times were recorded and compared with the durations of similar procedures carried out in the previous 2 years and recorded in the hospital's electronic databases.

Cost analysis was conducted using an activity-based costing approach considering direct and indirect costs related to surgical interventions.[14,15] The number of sterilized instruments was considered as a direct cost and surgical time as an indirect cost.

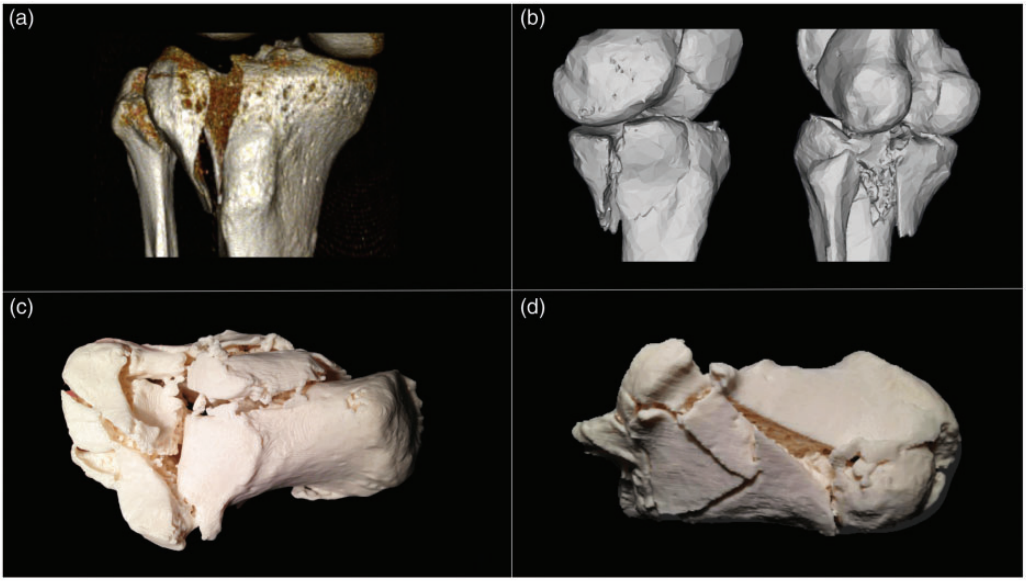

Figure 1. 3D-printed fracture models. (a) Computed axial tomography scan with 3D reconstruction of a tibial plateau fracture. (b) Creation of a .stl file using specific software. (c, d) 3D-printed acrylonitrile/butadiene/styrene model of a calcaneal fracture showing articular comminution (c) and extension through the entire vertical aspect of the calcaneal body (d).

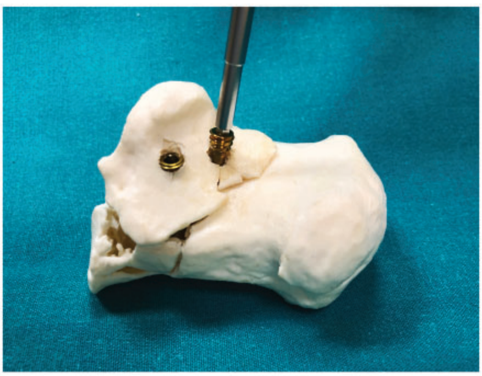

Figure 2. Simulation of reduction and fixation using the printed model the day before the surgical intervention.

Results

Patients and fractures

Fifty-two patients were enrolled in the study, including 23 with articular fractures of the calcaneus, 19 with tibial plateau fractures, and 10 with distal radius fractures.

3D models

Printing of the 3D ‘full touch’ 1:1 models took between 4 and 12 hours, depending of the anatomical location (average 4 hours for distal radius and 12 hours for tibial plateau). The average cost of producing a calcaneus or distal radius model was 50 €, while the cost of a tibial plateau fracture model was 100 €.

Surgical procedures

The fracture replicas were used the day before surgery to test the most suitable reduction steps and fixation hardware (e.g. plate shape and size, screw length and orientation) allowing resident training surgeons to simulate the surgical procedure directly on the models, thus improving their learning curve (Figure 2). This teaching tool has been included in the university postgraduate residency program for orthopaedic and trauma surgery.

This process ensured that only the preselected fixation devices deemed most suitable for the specific fracture based on the simulation were set up for the definitive surgery, thus reducing the need to procure and sterilise a wide range of potential devices, and saving the time of the operating theatre personnel.

Questionnaires

The results of the questionnaires and their distributions are reported in Table 1 and Figure 3. The 3D models significantly increased both the surgeons' and patients' understanding of the lesion pattern (Figure 4). The surgeon-related score (mean $\pm$ standard deviation) increased from 8.19 ± 0.84 without the use of the models to 9.15 ± 0.6 after introduction of the models, with an increase of 0.96 (+11.72%, $P < 0.05$). The surgeons also favoured the routine use of this tool in 82% of cases, and reported that the 3D-printed model provided useful additional information for planning and operative procedure in 63% of cases. The mean patient comprehension score increased from 6.26 ± 1.26 to 8.21 ± 0.84 after introduction of the 3D models, with an average increase of 1.95 (+31.15%, $P<0.05$). None of the patients had ever seen a 3D model of part of their body before. Use of the models improved patient trust in the proposed treatments to 6.76 ± 1.71. Most patients (88%) were in favour of the routine use of 3D-printing for explaining the proposed intervention (Yes 46, No 6).

The availability of the 3D-printed replicas thus helped to collect improved informed consent from the patients by showing and explaining their specific situation, the risk of complications, and the planned surgical procedures and expected outcomes.

Surgeons kept the sterilized models in the operating field, and reported an improved sense of spatial orientation using the percutaneous tools for the reduction of displaced fragments in selected cases of planned minimally invasive or percutaneous surgery (23 calcaneal and 9 tibial plateau fractures, 61.53% of cases). The durations of these surgical procedures were reduced by an average of 15% compared with previous procedures reported in the hospital's electronic databases, mostly due to better advanced knowledge and prevention of challenging situations, as well as the selection of the most suitable hardware.

Considering that the gross cost per hour of a surgical room in our institution was 1000 €, the use of this technology reduced the cost of a single surgery by a minimum of 150 €, including direct savings as a result of surgical tool preparation.

Discussion

Personalized medicine using 3D-printing technology is likely to become an important research field in the future. 3D-printing can be developed to allow physicians to deal with skeletal deformities, traumatic injuries, tumours and congenital diseases. The use of 3D-printed replicas for maxillofacial surgery and neurosurgery is already well known and used worldwide;[16,17] however, the application of this technology for traumatic articular bone injuries is less widespread and common. This discrepancy may be due to difficulties in organising the workflow of 3D-printing organisations (emergency room, radiologic and orthopaedic departments), as well as in the availability of the equipment. CT scans must first be performed with appropriately thin slices (ideally 0.625 or 0.9 mm for fractures) to prevent low-quality reproduction. The conversion to a .stl file should be carried out immediately after CT scan using the CT workstation or with

Table 1. Summary of questionnaire results.

n=52 (radius, n=10; calcaneus, n=23; tibial plateau, n=19)	Mean	Median	SD
PATIENTS			
Survey of novelty			
1. Have you ever seen a 3D-printed model of any part of your body before? (Yes/No)	Yes = 0 (0%) No = 52 (100%)		
Traditional imaging –level of understanding			
2. How well could you understand the severity of your fracture based on computerized images and the surgeon's explanation? (1–10)	6.26	6	1.26
3D-printing imaging –level of understanding			
3. How well could you understand the severity of your fracture after handling the 3D-printed model? (1–10)	8.21	8	0.84
Comparative analysis			
4. How important/critical has it been to see a physical model of your fracture and the implant that will be used for fixation during surgery? (1–10)	6.76	7	1.71
5. Would you suggest that other patients ask for a 3D-printed model of their fracture before surgery? (Yes/No)	Yes = 46 (88.5%) No = 6 (11.5%)		
SURGEONS			
Traditional imaging – level of understanding			
1. How reliable was the diagnosis of the articular damage (comminution and number of fragments) based only on computerized images? (1–10)	8.19	8	0.84
3D-printing imaging – level of understanding			
2. How reliable was the diagnosis of the articular damage (comminution and number of fragments) after handling the 3D-printed model? (1–10)	9.15	8	0.6
Comparative analysis – planning			
3. Did the availability of the 3D-printed model influence your surgical indication? (Yes/No)	Yes = 0 (0%) No = 52 (100%)		
Comparative analysis – implant selection			
4. Did the 3D-printed model influence the implant selection? (Yes/No)	Yes = 29 (55.8%) No = 23 (44.2%)		
Comparative analysis – usefulness			
5. Would you use 3D-printed models for other fractures, and would you suggest their use to any of your colleagues? (Yes/No)	Yes = 43 (82.7%) No = 9 (17.3%)		

Mean, median, and standard deviation (SD) of scores are reported. Number and percentage of positive/negative answers in dichotomous questions are shown.

commercial software like OrisiX®, Mimics®, or Horos® by trained personnel, and then sent directly sent to a 3D-printer in the hospital or at a nearby service provider. This system should mean that the model can be available within 12 hours, allowing time to use it to plan and perform early surgery when needed.

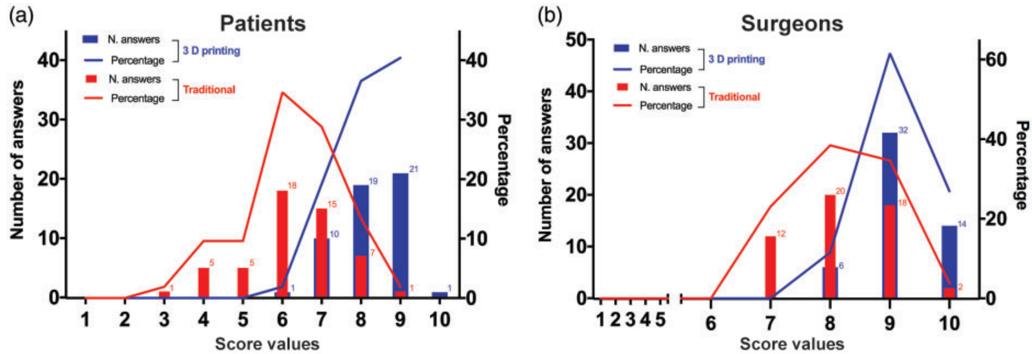

Figure 3. Questionnaire results for traditional imaging (red) and 3D-printing technology (blue) in patients (a) and surgeons (b).

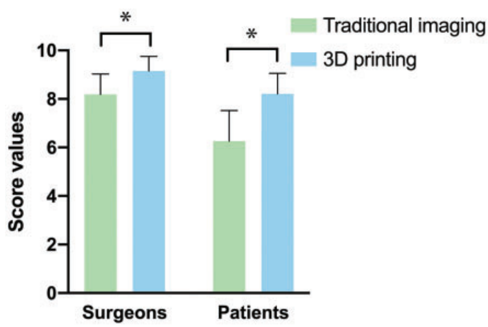

Figure 4. Difference in levels of understanding using traditional and 3D-printed imaging (*$P < 0.05$).

Professional 3D-printers use various materials for medical models, usually ABS, polylactic acid, or VisiJet® (3D Systems, Rock Hill, SC, USA), with possible different colours (Figure 2) to differentiate among anatomical parts and pathologies (e.g. bone, cartilage, hematoma).

We recently found that VisiJet® (coloured or not) provided more detailed models of bone fractures than the other materials, but has the disadvantage that it cannot be sterilized in a common autoclave. White ABS, as used in the current study, thus offers an excellent compromise for producing surgical real-size, 'full-touch' renderings.

Experienced surgeons and radiologists might consider that there is no need for this novel application given their acquired knowledge of the injury patterns and the high-quality performances of currently available imaging techniques. However, the physicians in the current study reported a significant improvement in preoperative information and skills, and better overall management of the patient's treatment. Moreover, this tool has been adopted for educational and training purposes by the University of Verona residency program.[18]

In light of the responses of surgeons and patients to these 3D models, our institution is currently considering introducing the use of 3D-printed replicas as a routine step for surgical planning and informed consent in patients with selected injuries. Considering all kinds of treated fractures, the 3D models present the greatest advantage and benefit in cases with more complex articular and comminuted fractures, by providing a better understanding of their pattern. Moreover, improved informed consent could also possibly reduce costs associated with medico-legal litigations. Reduced surgical times were recorded, with a potential proportional indirect impact on operating costs. In effect, surgical time-sparing was evident in all surgical steps, including instrument sterilisation and setting, trial and choice of the most appropriate fixation device, as well as the use of fluoroscopy rather than pure fracture reduction and fixation.

Further studies and cost analyses are needed to investigate the systematic feasibility of the use of 3D-printed models in hospitals.

In conclusion, 3D-printed replicas of articular fractures could be considered an innovative procedure and useful tool. This application represents a small step towards the implementation of personalized medicine and health technology assessment quality, as well as potentially reducing health care costs. 3D-printed prototypes can effectively improve the spatial definition of fracture patterns, thus giving surgeons the opportunity to refine their surgical strategies.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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