Bio-Design and Manufacturing (2020) 3:122–132
https://doi.org/10.1007/s42242-020-00070-y

RESEARCH ARTICLE

Three-dimensional printing for the accurate orthopedics: clinical cases analysis

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Received: 16 February 2020 / Accepted: 2 April 2020 / Published online: 13 April 2020

Abstract

As an emerging technology to promote the combination of medicine and industry, the three-dimensional (3D) printing has developed rapidly in the fields of orthopedics, while its unique advantages in improving precise treatment still need to be further popularized. In this report, our team have exhibited several classic cases of integrating 3D printing into orthopedic clinical application, thereby further elaborating thoughts and opinions on the significance of 3D printing in the orthopedic clinical application, technical advantages, existing main problems and coping strategies.

Keywords 3D printing · Orthopedic clinical application · Additive manufacturing · Guide plate · Metal 3D printing prosthesis

As one of representative technologies in the third industrial revolution, 3D printing is becoming a high-speed engine to promote the orthopedic clinical application due to its precise medical characteristics at the macro level [1–3].

3D printing is a precise medical technology with low threshold

The combination of augmentation manufacturing technology and current imaging technology has derived a vital branch of digital orthopedic technology, the orthopedic 3D printing. Macroscopically, it can realize the whole process of precise medical treatment, which contains the accurate reproduction of injury anatomy, accurate injury classification, treatment scheme, individual customization of surgical instruments, precise manufacturing of implant materials, sophisticated control of surgical risks and accurate prediction of surgical efficacy.

The basis of 3D printing applied in orthopedic clinical application is to obtain the data for modeling of injured sites. Currently, the simplest and most accurate data for modeling are the data of hard tissue collected by computed tomography (CT) scanning. Furthermore, the orthopedics is a subject for the diagnosis and treatment of entire human body bones, joints and attached ligaments, muscles, blood vessels, nerves and other soft tissues, except the skull, sternum and ribs. Thus, the orthopedics is the simplest subject to collect the data of hard tissues and the earliest subject to apply the 3D printing in clinical application. Currently, the 3D printing has been applied in the all sub-specialties in orthopedics, such as the trauma, joint, spine, bone oncology, pediatric orthopedics, foot and ankle, hand, sport medicine, repair and reconstruction.

However, the current application threshold of 3D printing in orthopedics is relatively low. As the most commonly used device for 3D printing data collection in orthopedics, the CT has been widely used in secondary hospitals in China, and even many primary hospitals also possess it, which creates a good prerequisite for the popularization of 3D printing in orthopedics. As long as the patient's personal CT data can be collected accurately and transmitted to the third-party organizations, even without the 3D printing technology and

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devices, the basic hospitals can also use the 3D printing to obtain precise medical treatment.

The levels of 3D printing in orthopedic clinical application

From the perspectives of development, depth and breadth, the 3D printing in orthopedic clinical application can be divided into four levels. As the morphology of pyramid, the first level is printing the models, which is used for preoperative planning and drilling. However, the first level is the basic foundation, the earliest application, the least difficult to perform, and the currently most widely used one. In this level, the printed models belong to the lowest class of medical devices according to medical device management laws and regulations. The second level is printing the guide plates, which is used to assist the precise surgery, while the application difficulty is significantly improved, and the corresponding application value is also significantly enhanced. In this level, the printed guide plates belong to the second-class medical devices according to medical device management laws and regulations. The third level is the implant materials, such as the printed prosthesis and fixtures, which are used to reconstruct the mechanical structure and function. In this level, the printed implants are included into the third-class medical devices according to medical device management laws and regulations, and the access conditions, clinical value and economic benefits have been significantly enhanced compared with the guide plates. The fourth level is printing the biological tissues, which are used to reconstruct the anatomical structure and biological function of tissues and organs. As the tip of pyramid, although the biological printing is still in the initial stage of researches, its application prospect is the best and the most valuable, which can maximize the advantages of 3D printing in future.

Unique advantages of 3D printing in orthopedic clinical application

In terms of the macro structure, 3D printing has unique advantages in orthopedic clinical applications, which can achieve the target of 'think is what you want', and the following aspects are specifically reflected.

(1) *Break through the bottleneck of product manufacturing.* 3D printing is not only particularly suitable for the individual customization, rapid manufacturing and low-cost manufacturing, but also the only technology that can realize the controllable porous structure and lightweight manufacturing currently. The bone invasion effect obtained by a prosthesis with a porous structure on surface makes the strength of bond between the prosthesis and host bone significantly better than the strength of bone on rough surface of a traditional subtractive manufacturing prosthesis. The porous surface is the best surface structure for the prosthesis to obtain the permanent biological fixation.

(2) *Break through the bottleneck of orthopedic surgeries.* In the orthopedic surgeries, drilling and osteotomy are often needed, and these operations are often the key to the success of surgeries. 3D printing can effectively improve the quality and efficiency of drilling and osteotomy, so as to reduce the risk of operations. The higher the accuracy of drilling and osteotomy, the more difficult and the higher risk of operations, the greater the value of 3D printing guide plates application. Although the current surgical navigators and robots can also achieve the accurate guidance of intraoperative drilling and osteotomy, due to its flexible guidance mode of image guidance, it will lose effect on some operations with complex osteotomy shape. Nevertheless, this situation is just the advantage of the rigid 3D printing guide plates. As long as the guide surface is constructed according to the irregular osteotomy surface before surgery, the preoperative osteotomy planning can be easily and accurately realized during operation. In addition, 3D printing guide plates can also accurately and conveniently assist the minimally invasive reduction and fixation of fractures and assist the accurate osteotomy and correction alignment of deformity osteotomy [4–7]. For the special joint replacement surgeries with complex shape and structure, with the combination of 3D printing osteotomy and drilling guide plates, it can obtain a proper and accurate outcome [8–10].

(3) *Break through the imagination.* 3D printing has the advantages of breaking through the bottleneck of product manufacturing and orthopedic surgeries. As long as the 3D printing is used properly, it can break through the imagination space of surgeons and challenge the cognitive impossibility.

Clinical cases analysis of 3D printing in orthopedic application

The following 6 typical cases involving the trauma, orthopedics, ankle, spine, joint and other orthopedic sub-specialties implemented by our team have exhibited the organic combination of 3D printing and orthopedic clinical application.

Case 1: Male, 34 years old, with the comminuted fracture of the right calcaneus, which realizes the anatomical reduction of calcaneus destructive fracture without the sequelae. In case 1, our team used 3D printing model to fully grasp the morphology of calcaneus crushed into 27 pieces and deformed in all directions, so as to avoid that the conventional open reduction and internal fixation (ORIF) can only restore the visible part of fracture shapes [11], but not obtain the anatomical reduction of whole calcaneus. During this process, we collected the CT scan data of patient from the dual-source 64-slice spiral CT system (SIEMENS, Berlin, Germany) in our hospital. The specific scan parameters were 120 kV voltage and 0.625-mm pitch. The original CT data were stored in Digital Imaging and Communications in Medicine (DICOM) format and imported into the Mimics 19.0 software (Materialise, Leuven, Belgium) for the 3D reconstruction, and the structural features of calcaneus were accurately separated by functions of Thresholding and Split Mask. After the Boolean operation, the restored fracture blocks were spliced together, and the noise reduction and smoothing were further performed. The fracture blocks were then virtually reset by the Move and Rotate operations. The design data were then imported into the 3D printing software (Cura 15.02) in STereoLithography (STL) format. After forming 3D digital model, the data were saved in Gcode format and exported to a 3D printer (Waston Med, Inc., Changzhou, China), and a 1:1 physical model of injured ankle joint was then fabricated with the materials of photosensitive resin (XiaoMan Tech, Inc., Nanchang, China), with the superiorities of smooth surface, high accuracy, waterproof and moisture proof, fast delivery cycle and attractive price. Then, our approach was to use the complete skin percutaneously for calcaneal prying and traction. Through the soft tissues such as periosteum attached to each bone fragment, it will drive the bone fragments to return and restore the calcaneal length and height. Then, the calcaneus was squeezed in both directions to press the widened calcaneus back to the original shape. Ultimately, a conventional lateral incision was made. Under the direct vision, according to the serial number of bone fragments marked on 3D printing models, the bone fragments were identified and pieced together for reduction, as well as bone grafting and internal fixation with the steel plates, so as to obtain the anatomical reduction and internal fixation of calcaneal destructive fracture and restore the normal foot function. The ankle joint flexion and extension function of the patient were normal 6 months after operation, and he can bounce freely 2 years after the operation (Fig. 1). This case fully shows that the simplest first level technology can also achieve the amazing clinical efficacy.

Case 2: Male, 44 years old, with a comminuted fracture of the right tibial plateau, which realizes the percutaneous reduction, bone grafting and internal fixation of comminuted fracture of the tibial plateau. In case 2, our team have designed the percutaneous 3D printing guide plates to accurately establish the channels for the percutaneous kyphoplasty (PKP) balloon reduction and bone grafting of collapsed lateral platform of tibia. Then, we have planned and accurately established the fixation channels for all screws and performed a minimally invasive percutaneous reduction, bone grafting and internal fixation of the tibial plateau comminuted fracture [12, 13]. With only five incisions about half a centimeter long, the operations of bone removal, reduction, bone grafting and internal fixation with 3 screws were completed quickly and well, which laid a solid foundation for the rapid rehabilitation of injured knee. Postoperative reexamination of CT showed the fracture reduction, the joint surface was flat, and the screw fixation was appropriate, and the patient can bounce freely 2 years after the operation (Fig. 2).

Case 3: Female, 53 years old, with ankle fracture deformity healing and traumatic joints. Malunion of intra-articular fracture to obtain the anatomical reduction according to irregular original fracture line osteotomy. Case 3 was an elderly female patient who had ankle fracture deformity healing and traumatic joints for more than 7 months; our team have creatively applied the relay-type 3D printing guide plate to find the healed fracture line that had not been recognized by the naked eye. During this process, three fracture surfaces were identified accurately according to the 3D printing model of the fracture, and then the positioning guide plates and the osteotomy guide plates with tensile property were further designed. Subsequently, under the guidance of the preset three osteotomy surfaces, the in situ osteotomy of the deformed healing bone mass following the *Z*-shape fracture line of the articular surface was accurately realized, thereby realizing the anatomical reduction of the articular surface fracture and the internal fixation of steel plate. Postoperative CT showed that the ankle was normal, and the articular surface was smooth. Moreover, 4 months after the operation, the function of ankle mobility was almost normal (Fig. 3).

Case 4: Female, 47 years old, with the necrosis of the left femoral head. Accurate core decompression for multifocal necrosis of the femoral head. In case 4, for the focus that was difficult to be clearly found and identified by the X-ray in the early stage of femoral head necrosis [14], even with the latest technology such as the surgical navigators and robots, it is even impossible to perform the focus repair operation accurately in early stage. Our team have established the femoral head necrosis model by using the combined technology of CT and magnetic resonance imaging (MRI) and found three necrosis foci accurately. According to this model, a positioning channel guide plate with 3 necrotic foci was designed and 3D-printed. The precise and rapid positioning of all necrotic foci was obtained during surgery, and the operations of curettage, decompression and bone grafting were successfully completed (Fig. 4). Postoperatively, the patient was generally in good condition, and the imaging examination did not indicate the occurrence of necrosis of left femoral head.

Case 5: Male, 42 years old, with cervical tuberculosis (C5–C6). Single approach for the cervical tuberculosis lesions removal and single-segment bone grafting and fusion.

Fig. 1 Male, 34 years old, with the comminuted fracture of right calcaneus. **a** X-ray of right calcaneus showed the calcaneal comminuted fracture, and the posterior articular surface was completely collapsed; **b** CT of calcaneus showed comminuted and collapsed articular surface, and the calcaneus was widened; **c** The 3D printing model had four directional views, and the serial number of each fracture fragment was written in sequence; **d** CT showed the anatomical reduction of fracture and flattened articular surface; **e** Postoperative calcaneal lateral X-ray showed the anatomical reduction of the fracture with proper internal fixation; **f** The ankle joint flexion and extension function were normal 6 months after operation; **g** The patient bounced freely 2 years after operation

Single-segment cervical tuberculosis (such as C5–C6) originally invaded only an intervertebral disk and adjacent upper and lower vertebrae (C5, C6). However, the current conventional surgical method is anterior debridement and titanium mesh, cage bone graft fusion and internal fixation. This operation is to remove the upper edge of the upper cervical vertebra (C5), lower edge of the lower cervical vertebra (C6) and two adjacent healthy intervertebral disks (C4–C5, C6–C7) and support the implanted bone block or prosthesis between the healthy vertebral bodies (C4, C7) above and below the injured cervical vertebra. This surgical method must fix the three motion segments with four cervical vertebrae together to restore the stability of cervical spine. However, with the assistance of 3D printing, our team have designed and printed the cervical anterior pedicle screws guide plate, lesion osteotomy guide plate and personalized anterior bilateral pedicle screws fixation of artificial vertebral body within only 48 h. After obtaining the ethical approval,

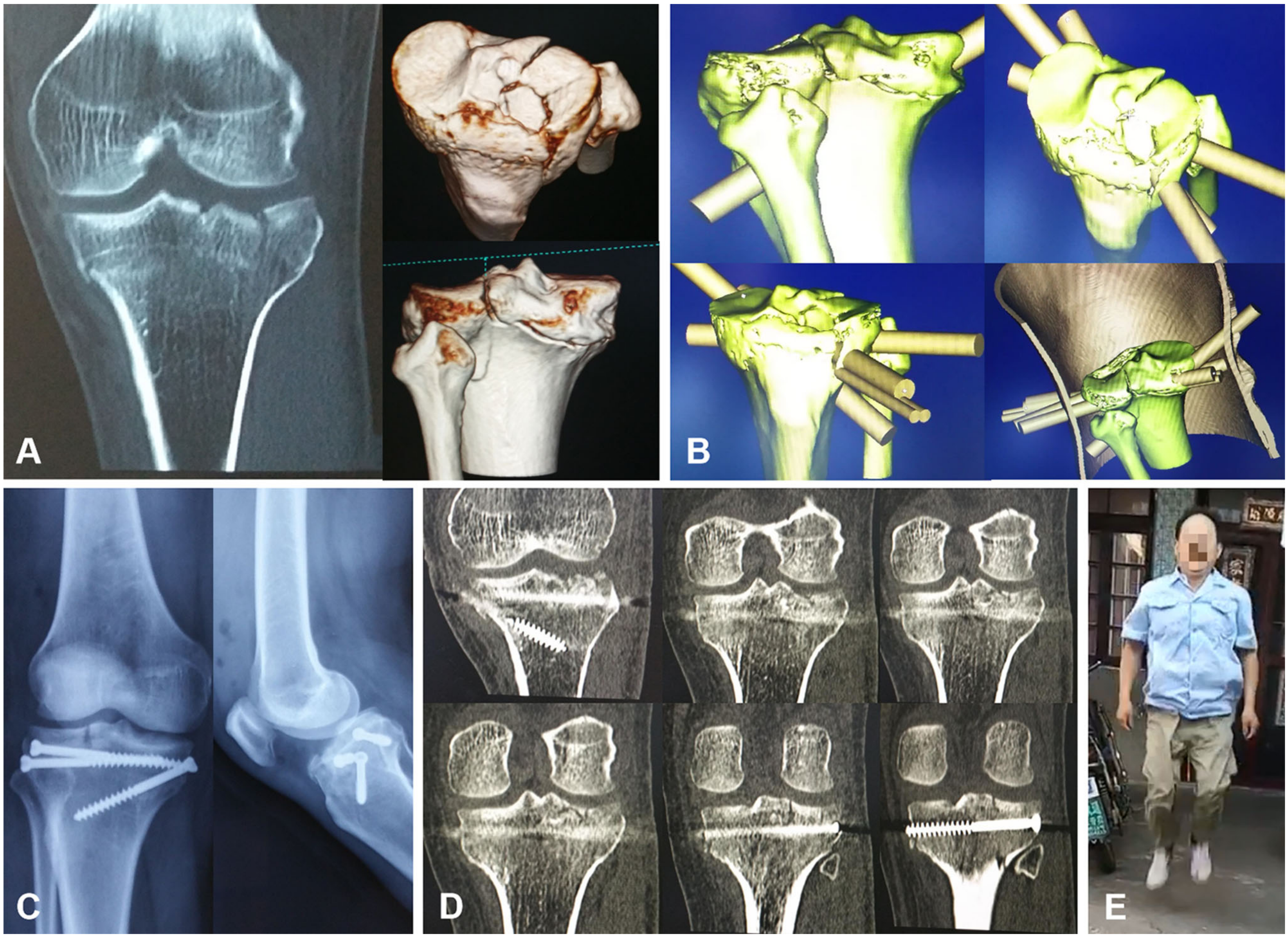

Fig. 2 Male, 44 years old, with a comminuted fracture of the right tibial plateau. **a** CT showed the fractures of inner and lateral platforms of right tibia, and lateral platform was collapse; **b** The design of a PKP balloon reduction with the tibial plateau collapsed bone mass, bone grafting channels and three fixation screw channels; **c** postoperative reexamination of the X-ray of knee joint showed the fracture reduction, and the screw fixation was proper; **d** Postoperative reexamination of CT showed the fracture reduction, the joint surface was flat, and the screw fixation was appropriate; **e** The patient bounced freely 2 years after operation

the patient has successfully undergone the surgery of single-segment cervical tuberculosis lesion removal and cervical reconstruction (Fig. 5). Meanwhile, the finite element analysis (FEA) results and 2.5-year follow-up of the patient showed that the single-segment cervical fixation method can not only cure the tuberculosis lesions and reconstruct the stability of cervical spine, but also reduce the stress concentration of adjacent segments and the degeneration of adjacent segments [15]. Postoperatively, the X-ray and MRI showed that the position of artificial vertebral body and pedicle screws were good; there was no tuberculosis signal, and the degeneration of adjacent segments was not aggravated (Fig. 6).

Case 6: Male, 27 years old, ankylosing spondylitis with severe osteoporosis of the proximal femur. Joint replacement for severe osteoporosis of the proximal femur. Case 6 was a young patient with ankylosing spondylitis and severe osteoporosis of proximal femur, and the bio-prostheses were prone to sink and rotate during the joint replacement, and the initial stability was also insufficient. When the cement prosthesis was considered, it was also prone to cause the loosening of cement–bone interface and lead to the fixation failure. Thus, with the assistance of 3D printing, our team have designed and fabricated a stemless prosthesis with the consistent shape and structure of patient and also had a porous surface. It can not only obtain the immediate stability, but also facilitate the bone growth, and conform to the biomechanical principle. Subsequently, the patient has successfully undergone the surgery of 3D printing-assisted personalized stemless prosthesis replacement. After 2-year follow-up, the patient was generally in good condition and had no significant limitation of hip mobility, the imaging examination also revealed that the prosthesis was fixed in place and there was no sign of

Fig. 3 Female, 53 years old, with ankle fracture deformity healing and traumatic joints. **a** The CT of ankle joint showed fracture healing at 7 months after injury; **b** The ankle joint space was narrow and severe osteoporosis at 7 months after injury; **c** The 3D printing model showed that the ankle fracture line was Z-shape on articular surface; **d** three fracture surfaces were identified according to 3D printing model of fracture; **e** according to the 3D printing model and three fracture surfaces identified, the positioning guide plates and the osteotomy guide plates with tensile property were further designed; **f** simulate the operation with the 3D printing models and guide plates; **g** the X-ray of the ankle joint showed that the fracture fixed by steel plate was in the anatomic reduction condition; **h** postoperative CT showed that the ankle was normal, and the articular surface was smooth; **i** 4 months after the operation, the function of ankle mobility was almost normal

loosening, and the bone density shadow in proximal femur was stronger than that before surgery (Fig. 7).

The existing main problems and coping strategies of 3D printing in orthopedic clinical application

Because 3D printing is an engineering-based technology, the current understanding of clinical orthopedic surgeons is not thorough. In recent years, although many engineering talents are engaged in medical 3D printing fields, and several medical graduate students and young surgeons have also gradually mastered the 3D printing technology, most of them can only carry out the first level of work or just set foot in the second level. In addition, the innovative design and application of orthopedics depend on the experts with abundant clinical experience, and factors such as surgical incision, approach, visual field, operating space, obstacles of peripheral blood vessels and nerves, and temporary fixations also need to be taken into account.

Furthermore, limited by the training system of Chinese medical students, most of orthopedic experts who equipped with abundant clinical experience lack the experience and skills of engineering. Moreover, most of orthopedic experts currently work in the clinics, scientific research and teaching fields at the same time. They are hard or unwilling to take the time to work closely with young engineering technicians to carry out the innovative design. Hence, the popularity of 3D printing in orthopedic clinical application in China is not high, and only a small number of units can make full use of the unique advantages of 3D printing.

How to accelerate the popularization, application and technological innovation of 3D printing in clinical application of orthopedics? We think that we should start from cultivating consciousness, stimulating motivation and providing convenience.

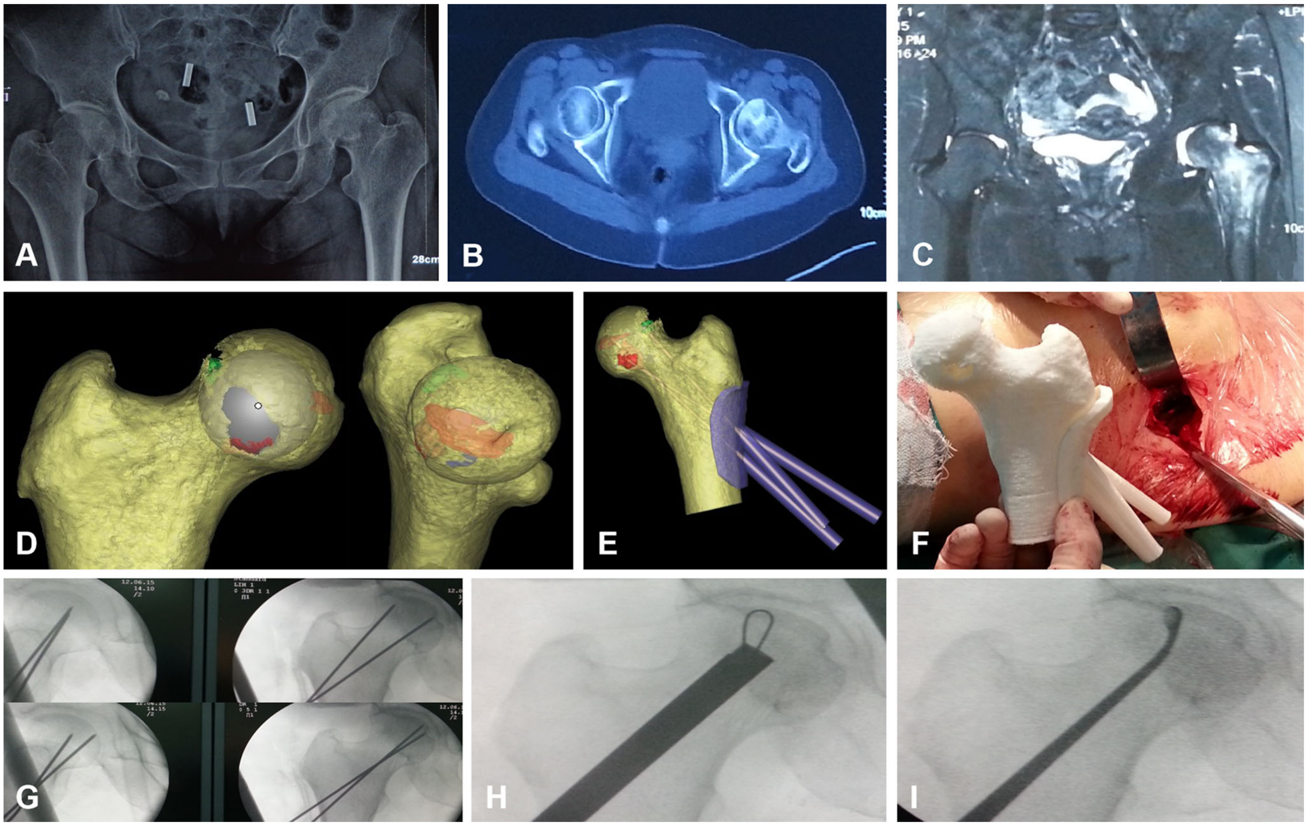

Fig. 4 Female, 47 years old, with the necrosis of the left femoral head. **a** Pelvic X-ray showed normal left femoral head without density changes and deformations; **b** pelvic CT showed the increased left femoral head density with cystic changes in the upper front; **c** pelvic MRI showed the high signal image of left femoral head and the bone marrow edema of trochanter; **d** a model created by combined technology of CT and MRI showed that there were 3 necrotic foci in the left femoral head; **e** a 3-channel necrotic foci positioning channel guide designed based on a virtual model of the proximal femur; **f** the cooperation between 3D printing model and the guide plate during operation; **g** the location of necrotic focus indicated by the tip of guide needle was observed by fluoroscopy during operation; **h** clear the lesion with a reversing scraper after the path was opened with a circular saw guided by the guide needle; **i** use an elbow curette to scrape the lesion further

(1) *Cultivating consciousness* Currently, the most urgent and effective approach is to strengthen universal education and cultivate the awareness of orthopedic surgeons, so that the most orthopedic surgeons will be able to understand that 3D printing can contribute to the surgeries that cannot be performed, cannot be performed well, and difficult to perform in the past, which can be performed, can be performed well, and easy to perform currently. As long as the concepts, demands and CT scan data exist, the work can be carried out even without the 3D printing devices. Meanwhile, 3D printing can also help the surgeons in small hospitals to perform the expert-level operations in large hospitals (of course, this is on the premise of personnel and technical access). Similarly, 3D printing can also help the experts in large hospitals to challenge the operations that are difficult to perform in the past.

Academic lectures and exchanges with shocking real cases as teaching materials are the best entry point, which can most attract the attention of orthopedic surgeons. Meanwhile, it can also strike while the iron is hot and provide the help to orthopedic surgeons in various ways by starting with the relatively simple model and guide plate, so that they can find the effect, eliminate the sense of confidentiality and enhance the interest and confidence. Ultimately, they will rapidly promote the popularization of orthopedic 3D printing application.

(2) *Stimulating motivation* It is necessary to fully explore the advantages of 3D printing in orthopedic clinical application, so that majority of orthopedic surgeons can taste the sweetness. Our team have summarized the premise and key points of the exploration and utilization, including learning to accept modestly, mastering methods and techniques, abandoning stereotypes, establishing a sense of innovation, inspiring the creative inspiration, cherishing all sources, analyzing the clinical pain points, finding the points of challenge, designing rigorously and comprehensively, and practicing boldly.

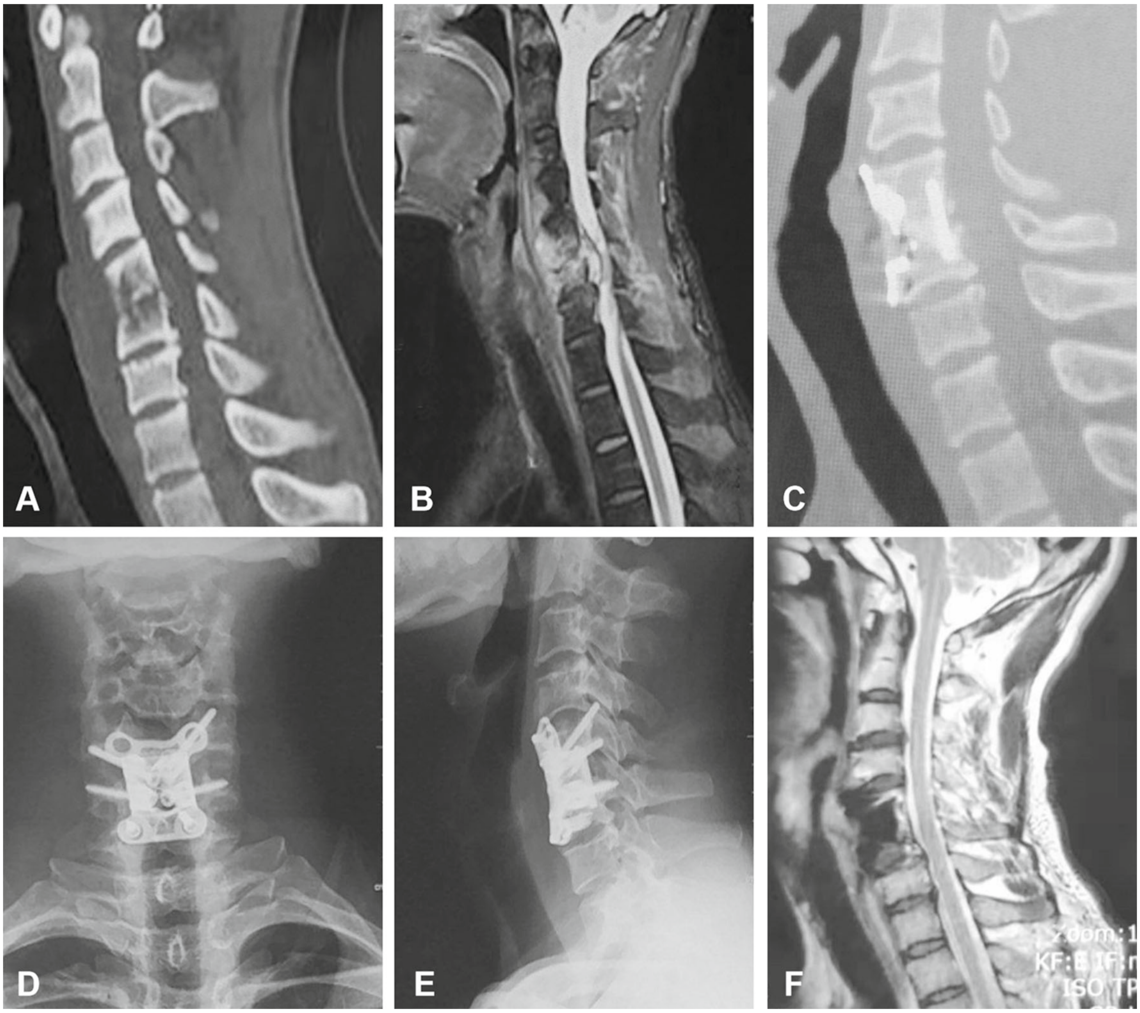

Fig. 5 Male, 42 years old, with cervical tuberculosis (C5–C6). **a** The CT of the cervical spine showed bone destruction and intervertebral space disappearance in the adjacent areas of C5 and C6 vertebrae; **b** the MRI of the cervical spine showed destruction of C5, C6 vertebrae and C5–C6 intervertebral disk, abscess formation and protruding into the spinal canal; **c** half a year after the surgery of single-segment cervical tuberculosis lesion removal and cervical reconstruction, the CT of cervical spine suggested that the tuberculosis lesions were eliminated and osseous fusion was obtained; **d**–**f** after 2.5-year follow-up, the X-ray and MRI showed that the position of artificial vertebral body and pedicle screws were good, there was no tuberculosis signal, and the degeneration of adjacent segments was not aggravated

(3) *Providing convenience* It is necessary to accelerate the training of medical–engineering talents, including encouraging a large number of engineering students to enter the medical 3D printing field, training medical students and young surgeons to learn the 3D printing-related knowledge and measures, so that the surgeons and engineering personnel can have a smoother technical exchange. In this way, orthopedic surgeons, especially the experts, may inform the designer of disease condition and surgical plan nearby or even face-to-face. As long as two parties have a simple communication, they can understand the intentions of each other. Thus, the design efficiency and the quality of guide plate can be improved, and the risk of surgery being unusable or misleading by the surgeons due to poor consideration can be reduced. After all, face-to-face communication is much more efficient and effective than any form of online communication. Hence, providing convenient application conditions and environment for the majority of orthopedic surgeons, especially the experts, will greatly mobilize the enthusiasm of all staff, so that 3D printing, as a step and shortcut to promote the revolutionary progress of orthopedics, and quickly improve the overall technical level and medical quality of orthopedics, and eventually benefit the numerous patients in China.

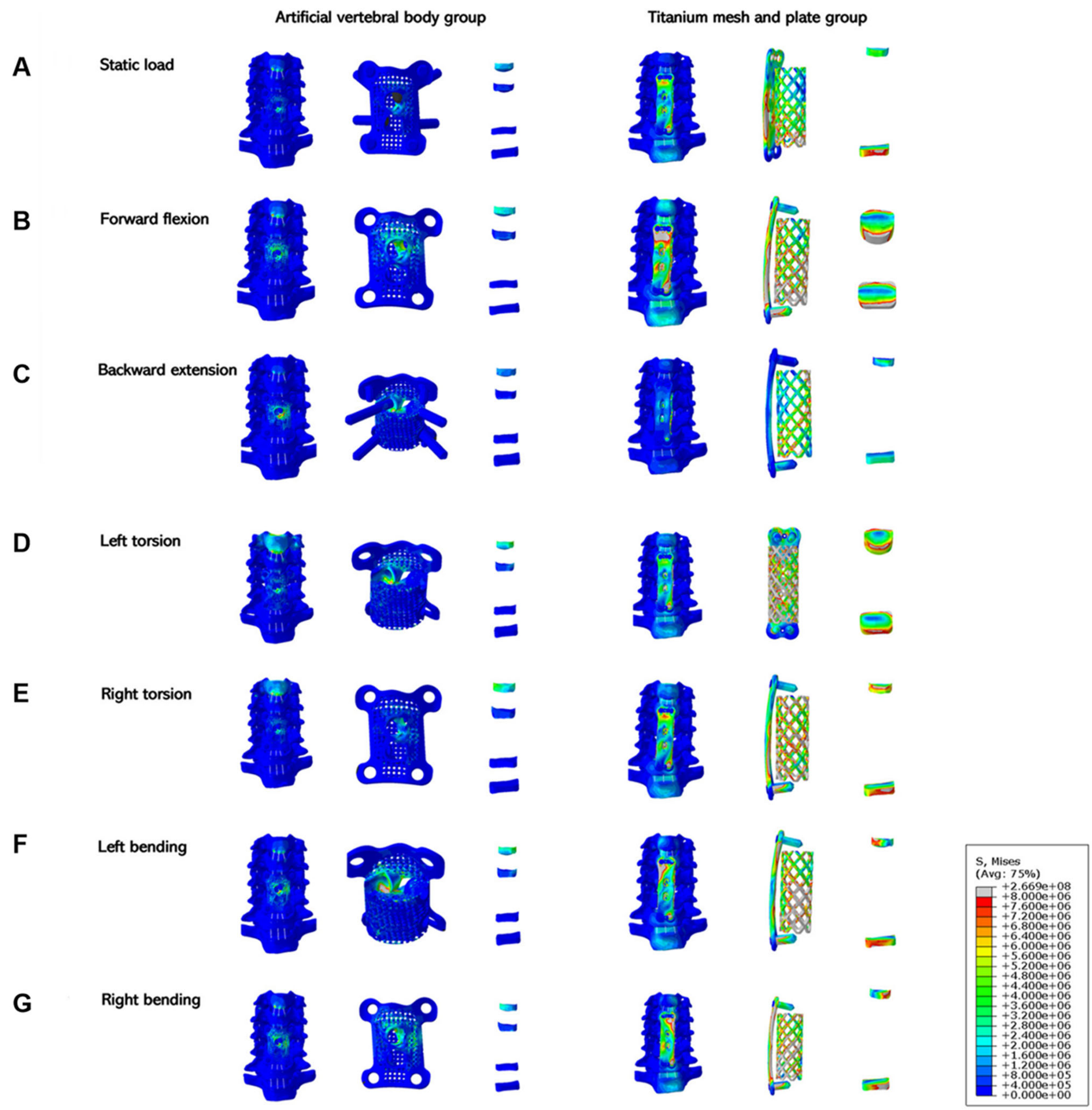

Fig. 6 Finite element stress cloud diagram comparison of artificial vertebral body group and titanium mesh plus steel plate group under different working conditions. **a** Static load; **b** forward flexion; **c** backward extension; **d** left torsion; **e** right torsion; **f** left bending; **g** right bending. The results showed that the fixation stress of the artificial vertebral body group was more uniform than that of the titanium mesh and steel plate group

Defects and considerations of 3D printing in orthopedic clinical application

3D printing is neither universal nor foolproof. In addition to enhancing awareness and confidence, orthopedic surgeons should also pay attention to the shortcomings and pitfalls in the clinical application process, especially during the process of design, which is more likely to be abandoned and misled due to the deviation between the design and actual situation.

First of all, the 3D printing in orthopedic clinical application is based on medical imaging data obtained from preoperative imaging examination, which is supposed to

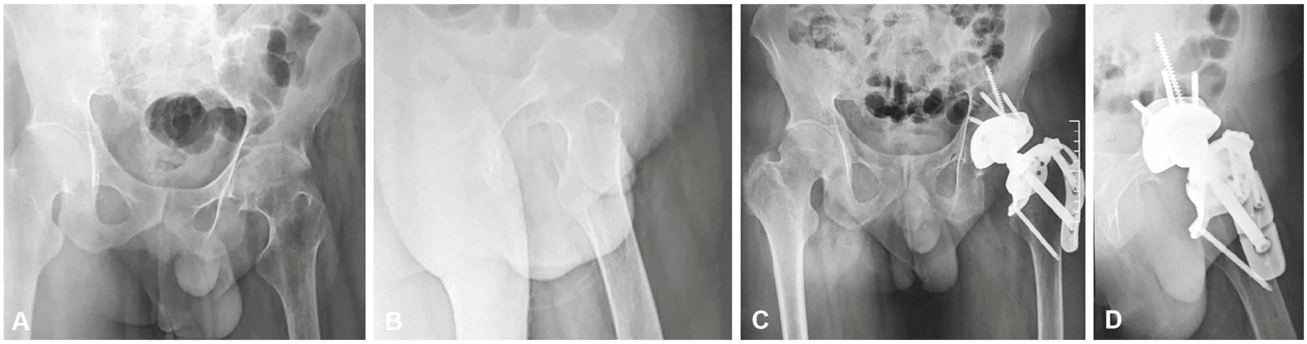

Fig. 7 Male, 27 years old, ankylosing spondylitis with severe osteoporosis of the proximal femur. **a**, **b** Preoperative X-ray radiographs showed severe osteoporosis, thin cortex, wide medullary cavity and intermittent hip stenosis in his left proximal femur; **c**, **d** 2 years after the surgery of 3D printing assisted personalized stemless prosthesis replacement, the X-ray radiographs showed that the prosthesis was fixed in place without signs of loosening, and the bone density shadow in the proximal femur was stronger than that before surgery

possess the qualifications of qualified equipment, standard software, precise imaging acquisition methods, parameters and data transmission approaches. It is the premise of application that the accurate imaging examination method, scope and position requirements issued by the surgeons and the active cooperation of imaging departments. Therefore, when carrying out 3D printing in orthopedic clinical application, it is necessary to fully understand the relevant situation and personnel cooperation of related departments, which may ensure the accuracy of data and models. However, in areas where osteoporosis and osteogenesis coexist, even if the above-mentioned basis and prerequisites meet the requirements, the surface morphology of established model may still be quite different from the actual situation during the operation, which requires the close cooperation between surgeons and designers. Moreover, in order to ensure the stability of the bonding surface between the guide plate and bone, the bone density which is allowed to be exposed and not prone to modeling deviation is selected as the bonding surface of the guide plate.

In addition, during the design process, it is also essential to further consider the incision and steps of operation to ensure that the guide plate can be placed into the incision and fit the bone surface, and the operation will not be hindered. For the percutaneous guide plate, it is necessary to ensure that the position during the operation is consistent with the preoperative design. Moreover, when collecting imaging data, a number of markers, such as cod liver oil pill, that can be developed without artifacts can be spread on the skin of the operation area, and the marker projection can be drawn with a marker that is not easy to fade. When designing fitting surface of percutaneous guide plate, a number of hollow windows are made according to the shape of marks, which can ensure the approximate fitting between the guide plate and the skin after the swelling of affected limb is reduced. This is because even if swelling has disappeared, the guiding puncture point will not change much, and the guiding direction has been determined in a 3D space, so only one direction needs to be fine-tuned under the verification of perspective, and the other direction will be determined accordingly. In this way, although it is not as accurate as bone guide plate, it still has a great advantage over the puncture operation without the guide plates.

In summary, it is necessary to make full use of and rely on the precise guidance of the guide plate, but not to blindly follow the guidance of guide plate. As long as the operation is based on the conventional operation procedures, with the assistance of the experience and hand feeling of surgeons, and the spherical probe and intraoperative perspective are used to verify the correction, it can avoid falling into the trap when the 3D printing guide plate is applied to overcome the orthopedic clinical difficulty.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Human and animal rights statement This manuscript does not contain any studies with animal subjects performed by any of the authors.

Informed consent Written informed consents were obtained from the patients included in the manuscript.

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