3D printing technology used in severe hip deformity

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Abstract. This study was designed to assess the use of a 3D printing technique in total hip arthroplasty (THA) for severe hip deformities, where new and improved approaches are needed. THAs were performed from January 2015 to December 2016. Bioprosthesis artificial hip joints were used in both conventional and 3D printing hip arthroplasties. A total of 74 patients (57 cases undergoing conventional hip replacements and 17 undergoing 3D printing hip replacements) were followed-up for an average of 24 months. The average age of the patients was 62.7 years. Clinical data between the patients treated with different approaches were compared. Results showed that the time to postoperative weight bearing and the Harris scores of the patients in the 3D printing group were better than those for patients in the conventional hip replacement group. Unfortunately, the postoperative infection and loosening rates were higher in the 3D printing group. However, there were no significant differences in femoral neck anteversion, neck shaft, acetabular or sharp angles between ipsilateral and contralateral sides in the 3D printing group (P>0.05). The femoral neck anteversion angle was significantly different between the two sides in the conventional hip replacement group (P<0.05). Based on these results, we suggest that the 3D printing approach provides a better short-term curative effect that is more consistent with the physiological structure and anatomical characteristics of the patient, and we anticipate that its use will help improve the lives of many patients.

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Introduction

Total hip arthroplasties (THAs) have been used in China since the late 1980s. Successful replacements in cases of severe hip disease have brought relief to many patients. THA does not only reduce the pain of patients, but also allows them regain their athletic abilities. After decades of clinical application, THAs have become a standard treatment for hip disease (1). In remote areas where the medical care system and the economic status of the population are not optimal, like in Xinjiang in Western China, many patients with hip tuberculosis (TB) in a young age develop a severe hip deformity in their adult life. In addition, developmental dysplasia of the hip (DDH) also has a high incidence in Xinjiang, resulting in many cases of severe hip deformity. Severe hip deformities, negatively affect the quality of life of patients and even their mental health, which is why they are important from a public health perspective. Hip deformity surgery programs are challenging, they need to optimize prosthetic model choosing, accuracy of the prosthesis placement, and the degree of deformity correction for each patient (2). The conventional THAs are not sufficiently individualized for particular cases, and this leads to frequent deviations of the implanted prosthesis (3-5).

In this study, 74 cases (mean age, 62.7 years) treated in the Xinjiang People's Hospital for severe hip deformity, during the period from January 2015 to December 2016 participated in the study. The cases were divided into a common biologic prosthesis group (conventional hip replacement group) and a 3D printing biologic prosthesis group (3D printing group). The short-term efficacy of the 3D printing approach for THA was compared to the conventional hip replacement standard, in order to evaluate the newer method aimed at improving clinical hip prosthesis selection.

Subjects and methods

A total of 74 cases of severe hip deformity caused by either hip TB or DDH were included in the study. There were 37 males and 37 females, aged from 40.4 to 85.0 years with an average of 62.7 years. Twenty-three cases of hip TB included 5 cases of bone TB and 18 cases of total hip TB. The 51 cases of DDH included 5 cases of Crowe type II, 36 cases of Crowe type III, and 10 cases of Crowe type IV (15 cases of Hartofilakidis type B, and 36 cases of Hartofilakidis type C).

Table I. Basic information.

Variable	Conventional hip replacement group (n=57)	3D printing group (n=17)	χ^2/t value	P-value
Sex			0.076	0.782
Male	28 (49.1%)	9 (52.9%)		
Female	29 (50.9%)	8 (47.1%)		
Age (years)	65.5±10.8	59.8±11.4	1.886	0.063
Case category			1.05	0.305
Hip TB	16 (28.1%)	7 (41.2%)		
DDH	41 (71.9%)	10 (58.8%)		
Follow-up time (years)	2	2	-	-

There were no statistically significant differences in terms of sex, age, or case category in this study (P>0.05).

Patients with pulmonary TB, primary hypertension, diabetes, chronic bronchitis or coronary heart disease were all treated to adjust and stabilize their conditions to a normal state before surgery (Table I).

Of the 74 cases followed-up for 24 months, 12 were excluded due to incomplete data or failure to be present for the follow-ups. Bilateral hip TB or DDH cases were infrequent enough that they were excluded from the study. Additionally, 2 cases had to be excluded because of hip pain during scanning, and refusal to be examined or go through with the CT scan from fear to radiation exposure.

3D printing production process. The CT scans were performed on a Toshiba 320 slice CT (Toshiba, Tokyo, Japan) and a Siemens dual-source CT scanner (Siemens Corp., Berlin, Germany), with a thickness of 0.625 mm, along the long axis of the body. The tube current was 200 mA and the voltage 120 kV. The pixel resolution, window width, and position of the CT image were 512x512, 1,800 and 600, respectively. The DICOM format images were saved in a Toshiba and Simens CT working station (version 10.0; Siemens Corp.), and subsequently exported into the JPG format. Also, the ACDSee software was used to convert the images into the BMP format, which could be read by the Mimics software (version 15.0; Materialise, Leuven, Belgium). The Mimics 15.0 program was used to convert CT data, and 3D STL files (Fig. 1). The magnetic coil of the 3D printing machine was operated to control the high-energy electron beam to scan the metal powder in the working chamber of the equipment. Titanium alloy powder was melted according to the digital information of the femoral prosthesis to form the linear and planar metal layer by layer, until the entire portion of hip was completed (Fig. 2).

Clinical evaluation. Every patient was evaluated for post-operative infections and loosening, also the postoperative time to weight bearing and the Harris score were evaluated. CT images were used to assess the femoral neck anteversion, neck shaft, acetabular angle and sharp angles.

Statistical analysis. All data were analyzed using the SPSS 17.0 statistical software (SPSS, Inc., Chicago, IL, USA). Mean ± standard deviations were used to represent measurement data. T-tests were used for analyzing enumeration data. A P<0.05 was taken to indicate a statistically significant difference.

Results

Fifty-seven cases undergoing conventional hip replacement, and 17 undergoing 3D printing replacements were followed-up for 24 months. The time to postoperative weight bearing in the patients of the 3D printing group was shorter than that in the conventional hip replacement group. Also the postoperative Harris scores in the 3D printing group were higher than the scores in the conventional hip replacement group. However, the postoperative infection rate and loosening rate were also higher than those in the conventional hip joint replacement group. The differences between the groups were statistically significant (P<0.05). There were no significant differences in terms of femoral neck anteversion, neck shaft, acetabular or sharp angles between both sides of the hip in the 3D printing group (P>0.05). But the femoral neck anteversion angle was significantly different between both sides of the hip in the conventional hip replacement group (P<0.05), (there were no significant differences in any of the other angles in this group) (Tables II and III).

Discussion

3D printing technology was born in the 1980s. Charles Hull developed the first commercial 3D printer in 1986. Liver cells were used to print artificial liver tissue in 2012 (6). 3D printing technology is a type of digital rapid prototyping technology based on a discrete and heap-forming principle. It integrates contemporary high-end technologies such as computer-aided design, numerical control technology and new material uses together. The basic principle has CAD software designing a three-dimensional digital model of prefabricated components, and then the model is divided into vertical or horizontal directions. Finally, a 3D digital model is transferred into an STL 3D printer, which uses metal or plastic powder and other special materials with a laser beam or hot melt nozzle to print

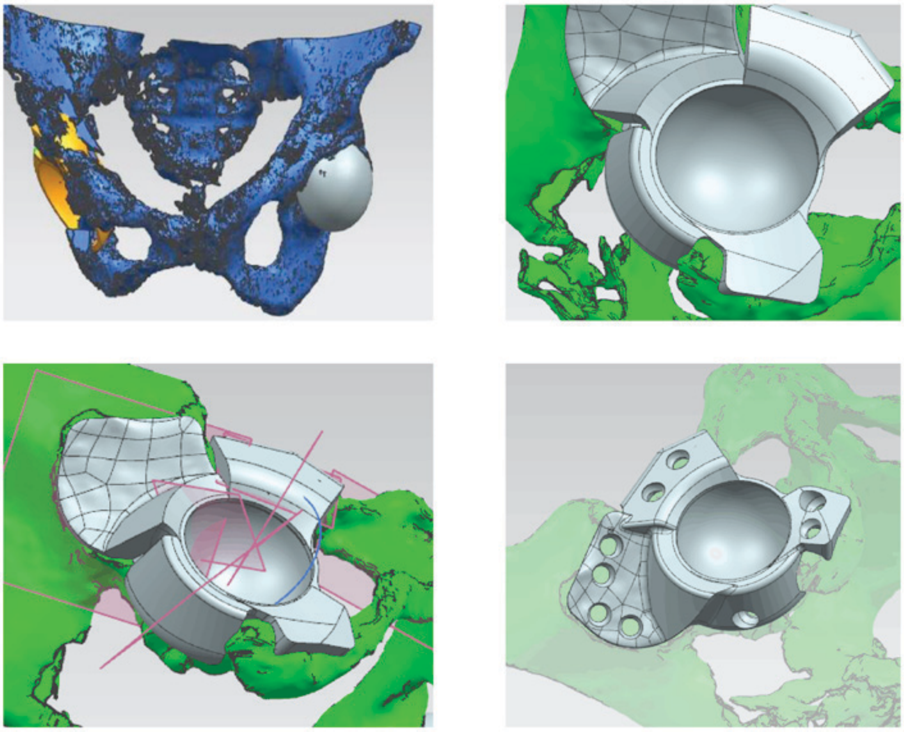

Figure 1. Reduction of 3D model in MIMICS.

Figure 2. 3D printed pelvic model and acetabulum prosthesis.

in the two-dimensional x-y plane bonded into a cross-sectional shape, and then in the z-coordinate layer stack, to ultimately result in the formation of three-dimensional structures. Unlike traditional 'cutting-off' methods on material, the 3D printing technology uses a 'layer-by-layer' material to create a 3D structure (3).

With the development of highly accurate medical digital images, the 3D printing technology has provided 'tailored' high precision implants for surgical solutions, improving the success rate of complex and difficult surgeries. Severe hip deformities, present many challenges for surgeons, who need to choose the right type of prosthesis, in order to achieve an accurate replacement with a high degree of deformity correction. Compared with CT or MRI images alone, a 3D model can provide more information to physicians, and the surgeon can even use the model to simulate the operation, so as to improve its success rate. A group of orthopedic surgeons have reported the successful development of a 3D hip replacement surgery-modeling program used on 21 patients with severe hip deformity (7). Postoperative imaging studies showed that

Table II. Clinical variables in patients after surgery.

Variable	Common hip replacement group (n=57)	3D printing group (n=17)	χ^2/t value	P-value
Postoperative time to weight-bearing (days)	2.1±0.3	1.5±0.2	7.73	<0.001
Infection			7.045	0.022
Yes	2 (3.5%)	4 (23.5%)		
No	55 (96.5%)	13 (76.5%)		
Loosening			9.855	0.009
Yes	1 (2.8%)	4 (23.5%)		
No	56 (97.2%)	13 (76.5%)		
Harris score	91.4±2.9	93.5±3.2	-2.559	0.013

Table III. Analysis of double side joint angle after hip replacement.

Angle	Ipsilateral side (degrees)	Contralateral side (degrees)	t-value	P-value
Common hip replacement group (n=57)				
Femoral anteversion angle	17.08±2.35	12.33±2.79	9.831	<0.001
Neck shaft angle	127.81±23.87	120.05±20.42	1.865	0.065
Acetabular angle	15.07±6.84	13.02±5.61	1.750	0.083
Sharp angle	40.07±7.53	39.08±6.24	0.764	0.446
3D printing group (n=17)				
Femoral anteversion angle	13.23±2.07	12.30±2.46	1.124	0.271
Neck shaft angle	123.13±20.06	121.18±19.49	0.288	0.776
Acetabular angle	11.90±3.80	10.06±2.90	1.587	0.122
Sharp angle	41.98±6.21	40.17±5.92	0.870	0.391

the implant components were accurately implanted and the surgical times were significantly shortened. Conventional methods do not allow for accurate judgments on the type of bone defects and the accurate positioning of the prosthesis. Sciberras *et al* was the first to apply a 3D printing technique to one case of complex hip arthroplasty, which resulted in prosthetic loosening and acetabular invagination after a THA (8). Nevertheless, the pelvic model was reconstructed according to the pelvic CT image of the patient, and a pelvic implant was 3D printed. The operation was successfully done and the approach served as proof of principle that 3D printing technology could effectively determine the type size and location of implants. Others have subsequently implemented such surgical programs providing individualized joint surgeries (9).

Bone cement prosthesis and bioprosthesis are commonly used in clinical hip prostheses (10). In this study, the time to weight loading in the 3D printing patients was less than that for the conventional hip replacement patients. Additionally, the postoperative Harris scores were higher in the 3D printing group. Indicating that the 3D printed prostheses are closer to patients' anatomical structures, and allow for better coordination to human biomechanics. Also, the 3D printing technology applied in hip arthroplasty speeded up the recovery of patients after surgery and improved their quality of life.

In China, failed hip replacements have different causes: infective and aseptic loosenings are the main culprits. A review of the literature summarizes the reasons for hip replacement failures as aseptic loosening of the prosthesis, osteolysis, and infection around the joints (11,12). Taking this into account, we used the infection and loosening rates as means to evaluate the postoperative period. In the present study, the infection and loosening rates were higher in the 3D printing group, (although there was only 1 case of infection and loosening in each group). It is quite possible that future studies with higher numbers of participants will show the 3D printing method carries no added risks for loosening and infections. Our 3D printing experience is just 2 years, and the number of cases in the 3D printing group was only 17, as compared to 57 cases in the conventional hip replacement group. More cases need to be analyzed in the future.

Xinjiang is a western province in China, where hip TB and DDH have high incidence rates. Patients with these diseases tend to present hip anatomical variations. In our study, no significant differences were found between the sides of a hip in terms of anterior and lateral femoral anteversion, neck-shaft, acetabular or sharp angles in in the patients of the 3D printing group. Importantly, the average anteversion angles of the ipsilateral and contralateral hip sides in patients of the conventional hip replacement group were significantly different, which indicated that the 3D prostheses were closer to the anatomies of patients. A study by another group showed results similar to these on surgeries performed on 22 DDH cases (13). In addition, others have used individual nails in cervical and thoracic spine, and other parts of the body, with the help of 3D printing preoperative design, improving the accuracy of operations and reducing surgical risks (14,15). Other researchers have performed individualized osteotomies on total knee arthroplasty by using a 3D guide, cadaveric tests demonstrated that individualized osteotomies were more accurate (16). Preoperative design was also used in this study (Fig. 1) with positive results.

In order for 3D printing technology for surgical applications to become mainstream, it is important for governments to regulate their application. There is no use for studies proving safety and efficacy of the methods if ultimately the law restricts their clinical application (15). In addition, in the manufacture of individualized prosthesis, the clinically useful material is limited to metal, ceramic and plastic. Research on other materials such as collagen, chondroitin sulfate, hyaluronic acid and hydroxyapatite is still in the laboratory stages. But with the development of tissue engineering and digital medicine, new materials and technologies, we anticipate the 3D printing technology will be widely used in the field of joint surgery (16-19).

In conclusion, based on our findings, the 3D printing technology has great potential to become a powerful tool for individualized and effective treatment in orthopedics.

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