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Personalized image-based templates for precise acetabular prosthesis placement in total hip arthroplasty: a pilot study

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Abstract: Objective: In order to achieve accurate implantation of the acetabular prosthesis in total hip arthroplasty (THA), we designed individual templates based on a three-dimensional (3D) model generated from computed tomography (CT) scans. Methods: Individual templates were designed for 12 patients who underwent THA. A physical template was designed to conform to the contours of the patient's acetabulum and to confirm the rotation of the acetabular center. This guided the acetabular component orientation. Results: The preoperative and postoperative X-ray and CT scans were obtained to assess the location with respect to the accuracy of the acetabular component. For all patients, the abduction angle of the acetabular component was 46.7° to 54.3° and the anteversion angle was 11.3° to 18.5°. Conclusions: The assessment of postoperative CT scans demonstrated higher accuracy of the acetabular component bore when used with the individual template. Therefore, the individual template can be an alternative to the computer-assisted navigation systems, with a good cost-performance ratio.

Key words: Total hip arthroplasty, Templates, Acetabular prosthesis

1 Introduction

In recent years, total hip arthroplasty (THA) has been widely used. Accurate implantation of the acetabular prosthesis is a key factor for the success of the operation. Many researches showed that the safe spot for installation of the acetabular prosthesis is at the abduction angle of 40° to 60° and the anteversion angle of 5° to 25° (D'Lima et al., 2000; Patil et al., 2003; Muller et al., 2006). In the past, the installation angle for an acetabular prosthesis was determined primarily by positioning the equipment or from the experience of the surgeon, but it often resulted in inaccuracy when the prosthesis installed did not fall within the range of the "safety spot". This is usually the major reason for instability of the joint after surgery. The transplant position of the acetabular pros-

thesis is not only a key factor for its articular stability, but can also influence lysis of bone materials in the pelvis, abrasion of internal polyethylene materials, and prosthesis slackening. When the average anteversion angle of the acetabular prosthesis declines to 49.3° from 56.9°, the quantity of bone material lost from the pelvis can be reduced by 11% (Hayakawa *et al.*, 2009). Kennedy *et al.* (1998) believed that ideal positioning of the acetabular prosthesis can provide the best unit surface for weight support to reduce wear in polyethylene materials as well as limit the production of granules. These factors will result in reduced bone loss.

Although there are many types of positioning equipments to assist the surgeon in placing the acetabular prosthesis in its ideal position, none of these are satisfactory. Most of the equipments for positioning the acetabular prosthesis will use the surgical table as a reference point, which makes it difficult to accurately determine the position of the

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pelvis during surgery, or even whether pelvic position may shift during the operation (Cross and Newell, 2000). Therefore, the change in a patient's position on the surgical table can result in the erroneous determination of acetabular articulation during surgery.

As computerized software has become more widely available over the past ten years, computerized technology has been used more frequently to design and develop acetabular prosthesis. Object implantation and preparation of the designated region can be performed under computerized guidance, which verifies anatomy as well as lesions of the joint. Precise contrast study before and after surgery can be used as a reference for the appropriate selection of prostheses in order to design and guide surgical modality. As well, real-time surgical supervision can improve the accuracy of the operation (Langlotz et al., 2007). This paper deals with preoperative computerized design and the use of rapid-prototype techniques to outline and individualize an acetabular template, which can be used to improve surgical accuracy.

2 Materials and methods

2.1 Patient data

From March to August 2008, 12 consecutive patients with hip disease underwent a THA with the use of preoperative simulation and a custom-made template. Inclusion criteria included those who suffered from unilateral developmental dysplasia of hip, fracture of the femur neck, and aseptic necrosis of the femoral head, and thus required acetabular replacement in THA, as well as those with bilateral developmental dysplasia of hip (type IV) who required restoration in THA. These patients included four cases of necrotic femoral head, two cases of osteoarthritis, two cases of developmental dysplasia of hip, and four cases of fracture at the femoral head. There were five male and seven female patients with a mean age of 59 years (range 42-78 years) at the time of surgery. Clinical manifestations included pain in acetabular articulation and/or walking disability, which influenced quality of life. For the Harris assessment, scores fell between 22 and 34 points, with an average of 28.5 points. After informed consent was obtained from patients for participation in the study, preoperative simulation, corrective acetabular prosthesis with use of the custom-made template, and physical and radiographic examinations were carried out. All subjects were followed for more than 12 months (range 12–18 months, mean 15 months).

2.2 Data acquisition

All patients received preoperative X-ray examination, complete pelvic computed tomography (CT) scan (Toshiba, Japan), and 3.0 T magnetic resonance imaging (MRI). The sectional thickness of CT was 0.5 mm and the surface resolution was 0.5 mm. In the 3.0 T MRI machine for scanning, image resolution rate is 256×256. When image interpolation and segmentation had been done, the image resolution rate increased to 512×512. All imaging data were in the format of DICOM (digital imaging and communications in medicine).

2.3 Acetabular center of rotation and guidance hole designs

According to the subject's CT and MRI data, an individualized template was designed. In the welldeveloped contralateral hip, we reconstructed threedimensional (3D) model of acetabular bone from CT data and drew the outline of cartilage from MRI data in the contralateral hip. By fitting a suitable sphere, we calculated the spherical center that was the acetabular center of rotation in the normal hip. We used mirror theory to determine the ipsilateral acetabular center of rotation. In bilateral developmental dysplasia hip, the calculation of hip center is the subject of a future study, and there were no cases of bilateral dysplasia hip in this group (Flecher et al., 2008; Kaneuji et al., 2009; Zheng et al., 2009). The template, with sub-acetabular notch and acetabular lip as the orthopedic markers, was matched up with the internal surface of acetabular culmination of acetabulum. The guidance hole was at an abduction angle of 48° and was slightly inclined forward by 14° (Fig. 1). These parameters were all computer-generated in the standard template library (STL) format.

2.4 Rapid formation of a template

Prepared data were loaded into rapid-prototype equipment (3D System, SLA-3500). By using heated plastic material [acrylonitrile-butadiene-styrene (ABS)], the template was rapidly formed on the machine. The flexural modulus of ABS is 300000 psi with an

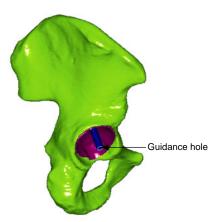


Fig. 1 Installation for the rapid formation model of acetabular articulation

elongation at break 11%. System parameters were set up as follows: thickness of processing layer at 0.1 mm, processing speed at 500 mm/s, and temperature at (40 ± 2) °C. The entire process of formation took about 6–20 h, with an average of 9.5 h. The reconstruction model was sterilized for 4 h with steam of glutaral-dehyde and the model could be used directly on the surgical table for upfront guidance of the operation.

2.5 Surgical modality

A conventional posterolateral incision into the hip joint was made, with acetabular fossa clean up of the soft tissue in and around the joint capsule. The template, with sub-acetabular notch and acetabular lip as the orthopedic markers (Fig. 2), was matched up with the internal surface of acetabular articulation. Its edge matched parallel to the acetabular lip (Fig. 3), while the guiding needles along the guidance hole were nailed on for fixation. The abduction angle was 48° and the anteversion angle was 14°. The acetabular template was then taken out and the hollow acetabular reamer was used to polish the acetabular articulation along the guiding needles (Fig. 4). The acetabular prosthesis could then be installed along the track that had been ground.

2.6 Postoperative assessment

After surgery, postoperative X-rays and CT images were measured by Mimics software (Figs. 5, 6, and 7). The accuracy of length was detailed to 0.1 mm, while the angle was precise up to 0.1°. Measurement indices were as follows: (1) The anteversion angle of acetabular articulation was the angle between the

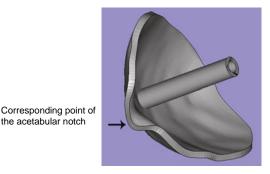


Fig. 2 Rapid-modeling template



Fig. 3 Needle through the guidance hole During surgery, after installation of the acetabular template, Kessler's needle is fixated on the acetabular articulation through the guidance hole. The abduction angle of the needle is 48° and the anterior inclination angle is 14°



Fig. 4 Acetabular reamer along the needle Using an acetabular reamer, along the direction and the angle of the needle, the acetabular cup is installed

acetabular central axis and the projection of the coronary surface. The acetabular metallic marker loop formed an oval shape as projected on the coronary surface; its longer axis was set as 'a' and the shorter axis was 'b'. The anteversion angle ' β ' of acetabular articulation was calculated as β =arcsin(b/a). For the

non-cement prosthesis, its longer axis must be confirmed first before matching with the oval shape simulated by the uncovered arch of the acetabular head. (2) The abduction angle of acetabular articulation was the angle between the lowest connecting line of bilateral sciatic nodules and the long axis of the metallic edge of articulation. (3) The height of the femoral head center of the hip was measured perpendicular to the inter-teardrop line (H_1 : operative, H_2 : contralateral) (Fig. 8). (4) The horizontal location of the femoral head center was the distance along the inter-teardrop line from the inferior point of the teardrop (W_1 : operative, W_2 : contralateral) (Fig. 8). All data were presented in the form of mean \pm SD and the t-test was performed using SPSS 10.0 software.



Fig. 5 Postoperative X-ray for abduction and anteversion angles of acetabular prosthesis

Postoperative X-ray shows good positioning of the acetabular prosthesis, while its abduction and anteversion angles are 48° and 17° , respectively

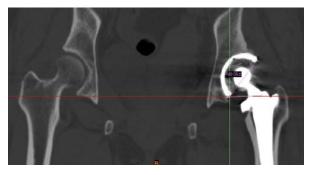


Fig. 6 Postoperative CT scan for abduction angle of acetabular prosthesis

Postoperative CT scan shows good positioning of the acetabular prosthesis, while its abduction angle is 49.05°

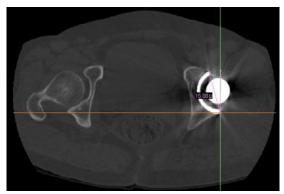


Fig. 7 Postoperative CT scan for anteversion angle of acetabular prosthesis

Postoperative CT scan shows good positioning of the acetabular prosthesis, while its anteversion angle is 15.88°

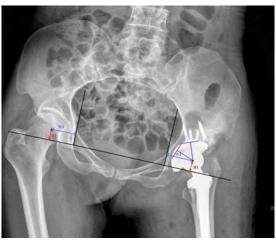


Fig. 8 Measurement of the height of the hip center (H) and the horizontal location of the hip center (W) by postoperative radiographic analysis

 H_1 : operative; H_2 : contralateral; W_1 : operative; W_2 : contralateral

3 Results

After application of the personalized image-based templates, the anteversion angle of acetabular articulation was $(14.2\pm2.29)^{\circ}$ and the abduction angle was $(50.5\pm3.22)^{\circ}$ (Table 1). In the operative hip, the height of the hip center to the inter-teardrop line was (25.8 ± 7.5) mm; in the contralateral it was (25.4 ± 4.7) mm. In the operative hip, the horizontal location of the femoral head center as the distance along the inter-teardrop line from the inferior point of the teardrop was (36.4 ± 3.7) mm; in the contralateral, it was (36.1 ± 2.9) mm. The results indicated that the hip center in the operative side and the contralateral side had no significant difference (P>0.05) (Figs. 9 and 10).

Case	Gender	Age (year)	Pathogen	Preoperative score	Score after one year (Harris)	Radiographic evaluation anteversion/abduction angle (°)			
1	Male	66	Fracture		86	13.7/52.6			
2	Female	68	Fracture		97	13.0/51.4			
3	Male	56	Osteoarthritis	32	88	13.2/54.3			
4	Female	52	Necrosis	43	71	14.1/46.7			
5	Female	70	Necrosis	34	83	16.1/55.1			
6	Female	55	Osteoarthritis	41	99	12.7/53.8			
7	Female	48	DDH	28	58	11.3/48.4			
8	Male	59	Fracture		87	18.5/52.1			
9	Female	78	Fracture		91	10.6/44.6			
10	Male	42	Necrosis	37	88	16.5/49.6			
11	Male	54	DDH	35	76	15.9/49.1			
12	Female	57	Necrosis	40	82	15.2/48.7			
AVG		58.8		36.3±5.0	83.8±11.3	(14.2±2.29)/(50.5±3.22)			

Table 1 Results of personalized image-based templates for acetabular prosthesis implantation

AVG: average; DDH: developmental dysplasia of hip

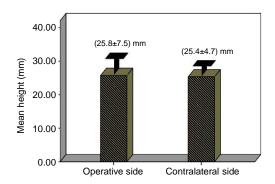


Fig. 9 Height of the hip center in operative and contralateral sides

Data are expressed as mean \pm SD. There is no significant difference (P>0.05)

4 Discussion

As THA becomes more widely practiced and both the theory and technique for artificial joints develop over the years, the demand for acetabular prosthesis installation is increasing rapidly. The accuracy of artificial prosthesis implantation is an important index for assessing surgical quality, prognosis, and functional recovery. Each of these parameters describes prosthesis function and life-span. Gait, recovery of the length of the diseased extremity, stability, wear, loosening, and osteological lysis are all determined by the position and direction of the transplanted prosthesis (Ichmann, 1997; Jasty *et al.*, 1997; Echeverri *et al.*, 2006).

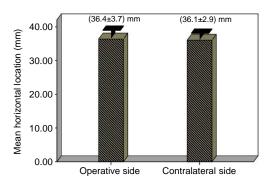


Fig. 10 Horizontal location of the hip center in operative and contralateral sides

Data are expressed as mean \pm SD. There is no significant difference (P>0.05)

Accurate positioning of the acetabular prosthesis is extremely important for the stability of artificial acetabular articulation. Because the acetabular abduction angle is smaller, resulting in directional force toward the superior medial side, the acetabular prosthesis is less likely to be struck when abductive motion is performed. The acetabular prosthesis is stable and dislocation is less likely to happen. However, an angle that is too small can limit the abduction and flexion of the acetabular joint. If the angle is too wide, it can minimize the motions of rotation and retraction, which interferes with acetabular articulation, resulting in over-concentration of force toward the superior lateral side, instability of the joint, and dislocation in the upward direction. Only appropriate abduction

angles can result in a better and wider coverage of the femoral head by the acetabular prosthesis. The force will be homogeneously distributed in a more stable joint. The existence of an anterior inclination angle of acetabular articulation allows slower transformation of the abduction angle during the motion of flexing the acetabular joint, ensuring better coverage to the femoral head by acetabular articulation. An increase in anterior inclination angle at the acetabular joint can greatly enhance the motion of flexion, even though stretching will be limited (Nadzadi et al., 2002; Padgett et al., 2005). Therefore, the appropriate acetabular angle can prevent interference with and dislocation of the acetabular joint, and maintain the degree of motion and stability required by the artificial articulation. An inappropriate acetabular angle will cause changes in stress at the contact surface between the femoral head and acetabular joint and increase the wearing speed, which further reduces the long-term stability and life-span of the prosthesis (Wan et al., 2006). Lewinnek et al. (1978) believe that the safest position for installation of an acetabular prosthesis is an anterior inclination angle of 5° to 20° and an abduction angle of 30° to 50°.

Centralization of the prosthesis can prevent aseptic loosening and lengthen the life-span of the prosthesis, as well as enhance reliability. Regardless of whether the prosthesis is cement or non-cement type, its position in bone marrow should fulfill the requirement of "centralization". Good centralization allows homogeneous distribution and transmittance of stress through the prosthetic body and maximally reduces abnormal stress. Loosening of the prosthesis is closely related to incomplete coverage by cement, and centralization can increase the completeness of coverage by cement surrounding the prosthetic body. This will ensure maximum biological function of the cement, in order to allow the most effective "pressure and matching" between the prosthesis and the bone.

Although in recent years scholars have identified the importance of prosthesis centralization for the success of surgery, actual practice of ideal centralization remains difficult. In traditional surgery, there is a challenge that accurate positioning of the pelvis will be impossible, due to constant changes in body position. There are also limitations due to the incision and erroneous subjective observation on the part of the surgeon. This usually results in greater differences

between the original physiological angles of the acetabular joint, the abduction angle and the anterior inclination angle after transplantation of the acetabular prosthesis. Traditional positioning equipment for the acetabular joint will usually cause further anterior inclination rather than a standard lateral position due to a non-fixated pelvis and changes in body position. This results in installation of the acetabular prosthesis in an overly posterior inclined position. Although the use of positioning equipment for acetabular joints can provide a certain location reference, it also brings a false sense of safety to the surgeon, especially when the positioning equipment cannot securely install the acetabular template on the bed. The safety range set by traditional surgery can vary by as mcuh as 20° and can be inadequately accurate for a given patient. Therefore, inaccuracy in positioning of the prosthesis after surgery is usually the primary reason for postoperative articular instability, and may even result in osteological lysis, as well as wearing and loosening of the prosthesis (Temmerman et al., 2007; Williams et al., 2008). Minoda et al. (2006) reported that 27.8% of acetabula were not able to hold the safety position during surgery without assistance.

Rapid-prototype technique is a new digital modeling technique based on the principle of separation and the accumulation of materials to create a prototype. It uses computerized control and is based on the computer-aided design (CAD) model or imaging data from CT or MRI. Rapid modeling is a comprehensive and collective application of subjects and techniques such as CAD, laser processing, digital control, and research and development (R&D) of new materials. Its basic procedure includes repetitive layered processing of a 3D model of the object to obtain its 2D sectional data, which are then used to generate a "slide" of the acquired 2D data, until the accumulation of these slides "grows" into an actual model. The manufacturing technique is precise to the point of 0.1 mm or less. The uniqueness of rapid-prototype technique is its suitability for the production of complex, single-unit, or large-batch objects. Because the data scanned by CT or MRI are similar to the data from the rapid-prototype slide, accurate replications of biological objects with similar morphology can be performed through vector transformation of CT data and reverse calculation of the biological object's surface (Ono et al., 2000; Brown et al., 2003; Galantucci et al., 2006).

This study, using the rapid-prototype technique, employed CT to acquire pelvic data from subjects. These data were calculated in consideration of the acetabular rotational center on the computer. Specifically for the subject with acetabular dysplasia, the acetabular center was accurately calculated before surgery. The acetabular rotational center was used for precise control of the anterior inclination angle and flexion angle. During surgery, surgical installation of the template must be performed such that the template can tightly adhere to the acetabular joint. The acetabular notch is an essential anatomical marker for template adherence. Our results showed that the angles of the experimental group were closer and more tightly grouped than those of the control group. Also, the comparison of the angles between the experimental group and the control group showed statistical significance (P<0.01). The rapid-prototype template is user-friendly and avoids the required complicated processes such as surgical positioning and matching. Also, the change of prosthetic position during surgery is not related to the change in body position of a patient. In addition, expensive guidance equipment is no longer required, so only a week is required for preparation of the template.

In this study, errors derive mainly from the following factors: (1) CT data. This kind of error is about 0.01 mm; (2) Design. When loading CT data, articular cartilage is not imaged by CT, so we delineated the thickness of articular cartilage via MRI of the corresponding acetabular joint; (3) Rapid laser prototyping. This kind of error is related to the rapid-prototype equipment and materials, and we took 0.1 mm as the error in the rapid formation; (4) Intraoperative factors. Because the acetabular notch is the essential osseous marker for localization, the guiding template should adhere tightly to the osseous marker during the operation. This type of error represents the largest source of error in the entire process and thus ought to be controlled precisely.

This is a pilot trial with a limited number of cases and a very short period of follow-up. In order to extrapolate from these findings, further investigations will be necessary to determine the appropriate values for clinical application. The computer-aided 3D template prototyping technology may signifi-

cantly facilitate precise acetabular prosthesis implants in THA.

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