
DAIHEI KIDA, HIROYA HASHIMOTO*, NORIKO ITO*, YUKARI KITO**, KOUICHI MORI, NOBUNORI TAKAHASHI† AND YASUSHI TOMITA‡

Department of Orthopedic Surgery and Rheumatology, *Clinical Research Center, National Hospital Organization Nagoya Medical Center, Nagoya 460-0001, **ArthroDesign. Ltd, Kawaguchi 332-0001, †Department of Orthopedic Surgery, Nagoya University Graduate School of Medicine, Nagoya 466-8550, ‡Department of Cardiology, National Hospital Organization Nagoya Medical Center, Nagoya 460-0001, Japan

Received 25 December 2017, accepted 30 April 2018
J-STAGE advance publication 10 September 2018

Summary: In total hip arthroplasty (THA), it is generally accepted that the bones of the acetabular cup and femur of hip joint must be accurately cut and components (artificial joint parts) be implanted in exact positions at exact angles to achieve improvement of daily living (ADL) and quality of life (QOL). However, with the conventional surgical method, it is difficult to grasp and measure the acetabular cup and femoral stem precisely during surgery, making some kind of reliable guide necessary. Although it was reported that an accurate angle was achieved in acetabular cup implantation by support instruments for surgical planning, an effective support instrument is now being developed for stem implantation on the out-of-reach femur side. This is the first clinical study to assess the efficacy and safety of anterolateral approach THA using an extracorporeal patient-specific femoral guide (PSG) for stem implantation with three-dimensional (3D) surgical support software in patients with hip joint disease.

Key words total hip arthroplasty, three-dimensional surgical support software, patient specific guide, cup, stem

INTRODUCTION

About 50,000 cases of total hip arthroplasty (THA) are performed each year in Japan, mainly for hip osteoarthritis, rheumatoid arthritis, and femoral head necrosis. Together with 60,000 cases of bipolar hip arthroplasty (BHA) targeting femoral neck fracture, it is estimated that more than 130,000 patients receive THA every year.

It is important in THA to precisely cut the bones of the acetabular cup and femur and to implant components at an accurate position and angle. This is believed to improve patient’s activities of daily living (ADL) and quality of life (QOL) by allowing them to obtain good load distribution, obtain a good range of motion (ROM), reduce the occurrence of wear and looseness of parts, and to prolong the life and replacement timing of the artificial hip joint.

According to the conventional surgical method, the parts are implanted mainly based on the experience of the doctor using two-dimensional information from front and side view X-rays. However, it is difficult to grasp and measure the cup and the stem precisely during operation, so some kind of reliable guide...
is necessary [1, 2, 3].

Three-dimensional (3D) surgical methods using a surgery support robot and a navigation system can help to address these problems. Although several methods have been developed with good results [4], there are still many disadvantages, including the high cost of initial introduction and maintenance, additional invasive procedures like antenna installation, operational complications like eyes’ leaving the surgical field to check the intraoperative monitor, and long operational hours. Thus, the penetration rate of these methods is still low [5].

The drop in prices of high performance computers has made it possible to simulate surgery by creating a surgical plan in 3D virtual space on a computer, based on preoperative computed tomography (CT) data, including performing bone cutting and implanting parts for THA in the virtual space. This could improve the accuracy of surgery by a 3D operation plan with surgical support instruments and by reproducing the plan during surgery (intraoperative support), based on a simulation of the preoperative plan in virtual space. The postoperative CT data and the preoperative data can be compared (postoperative evaluation) in the same virtual space, and a simulation of motion analysis is also possible. 3D surgical support software allows consistent performance of such preoperative planning, intraoperative support, and postoperative evaluation.

At the Nagoya Medical Center, simple instruments for surgical planning support (HipCOMPASS, TARGET, and acetabular reamer with depth gauge) and 3D surgery support software (ZedView) are used to implant the acetabular parts (cups) at an accurate angle, position, and depth. Recently it was reported that HipCOMPASS achieves an accurate angle in acetabular cup implantation [6].

In contrast, the reported accuracy of stem implantation on the femur side using a navigation system, and the selection of a coordinate system for evaluation varies depending on the reporters [7, 8].

As with the acetabulum side, there is no system yet to reproduce and guide 3D surgery plan by methods other than the surgical support robot and navigation in implanting parts (stems) on the femur side. A simpler surgical support instrument is needed. Recently, stem implantation accuracy in posterolateral approach THA using a patient-specific instrument for the femoral bone was reported [9].

Separately, we jointly developed a new extracorporeal patient-specific femoral guide (PSG) for THA with 3D surgical support software (ZedView) in collaboration with ArthroDesign. Ltd., and have applied for a patent. This PSG (a guide for osteotomy matching the thigh bone of each patient) produces a 3D operation plan from a model in which individual bones of a patient are reproduced with a 3D printer. One of the relative angle gauges installed in this guide is then used as an indicator of stem implantation, and another relative angle meter is attached to a surgical instrument such as a rasp (a tool to cut the femur) or a stem implantanter (to implant the stem at an appropriate position) to align with the relative angle meter on the PSG side. Finally, the 3D surgical plan is reproduced to guide (navigate) and facilitate surgery.

METHODS/DESIGN

Study Design

This is a single-center, open-label, single-arm interventional study.

Intervention procedures

1) Preoperative planning: First, CT imaging of the candidate for THA is performed. CT data is imported to the 3D surgical support software (ZedView), xyz coordinates of the pelvis and femur are set three-dimensionally, and STL data (3D shape data) are output. Based on the CT data and 3D data, the type and size of the acetabular cup and the femoral stem of the hip joint are determined on ZedView, each implantation position and angle is planned, surgical instruments for HipCOMPASS and TARGET are set, and the implantation and adjustment parameters are calculated.

2) Intraoperative support (for the acetabulum side): surgical instruments (HipCOMPASS, TARGET, and acetabular reamer with depth gauge) measured from a surgical simulation result on the computer are prepared, adjusted, and sterilized for use during surgery. The acetabular cup is implanted using these as reference indicators.

3) Intraoperative support (for the femoral side): the PSG for the femoral side prepared from a pre-cut bone model based on a full-scale thigh bone, a rasp, and the stem implantation guide are used with the relative angle meters. The implantation position and angle are then measured, and stem implantation is conducted with the measurement result as a reference indicator.

4) Postoperative evaluation: CT imaging is performed after surgery and before discharge. The accuracy of implantation position and angle of the cup and the stem are evaluated by 3D matching of compo-
nents before and after surgery, using 3D surgery support software (ZedView).

The following items were confirmed according to the observation and examination schedule (Table 1), and the data were used for this study. All of these items are checked in routine practice for artificial joint diseases.

1) Basic patient information: age, sex, diagnosis, body height and body weight
2) X-ray (two directions of hip joint)
3) CT (hip joint)
4) Measurement of ROM of hip joint by motion capture

Participants

Patients with hip joint diseases (osteoarthritis, rheumatoid arthritis, femoral head necrosis, and femoral neck fracture) who are scheduled to undergo THA.

Eligibility criteria

Inclusion criteria
1. Presence of hip joint disease and scheduled to undergo THA.
2. Aged over 20 years at the time of consent.
3. Patient freely provided written consent after receiving sufficient explanation for participation in this study.

Exclusion criteria
1. Judged inappropriate as a participant in this study by the principal investigator.
2. Registered in this study in the past.
3. Posterior pelvic incline of 20 degrees or more.
4. Has or suspected to have Creutzfeldt-Jakob disease.

Endpoints

Primary endpoint

Accuracy of postoperative implantation by 3D preoperative planning (by antetorsion [neck axis])

Secondary endpoints
1) Accuracy of postoperative stem implantation by 3D preoperative planning (by antetorsion [stem axis], varus/valgus, flexion/extension, depth from center of the stem, and spatial position differences of the stem in x [coronal]-axis, y [sagittal]-axis, and z [axial]-axis)
2) Accuracy of postoperative cup implantation by 3D preoperative planning (by radiographic inclination [RI], radiographic anteversion [RA], and spatial position differences of the cup in the axes of x, y, and z)
3) Leg length discrepancy (before and after surgery)
4) Adverse events

Sample size

The sample size calculation was based on the results of an observational study conducted from June 2013 to March 2016 at the Nagoya Medical Center. In 18 cases using a combination of HipCOMPASS, TARGET, and PSG, the mean of the absolute value of the difference between the preoperative plan and postoperative values of antetorsion (neck axis) was 4.6 degrees with a standard deviation of 3.4 degrees, whereas in 27 cases using the freehand method the median of the absolute value of the difference between the preoperative plan and postoperative values of antetorsion (neck axis) was 7.2 degrees. We assumed that the absolute value of the difference was 4.6 degrees with a standard deviation of 3.4 degrees and set a threshold.
value of 7.2 degrees. A sample of 20 cases was required to give an upper 95% confidence limit less than 7.2 with a statistical power of 90%. Assuming a dropout rate of 15%, 23 cases were needed.

Statistical analysis

Analysis of primary endpoints

In order to confirm the distribution of the primary endpoint, summary statistics will be calculated for the preoperative plan and postoperative values and their differences. For the absolute value of the difference from the preoperative plan, the 95% confidence interval is estimated and compared with the threshold value. The p-value for null hypothesis that the absolute value of the difference is greater than 7.2 is calculated from the t-test. A one-tailed p-value of less than 0.025 is considered to indicate statistical significance.

Analysis of secondary endpoints

For the accuracy of stem implantation by 3D preoperative planning, the absolute value of the difference between preoperative plan and postoperative values, the summary statistics, and the confidence interval will be calculated for antetorsion (stem axis), varus/valgus, flexion/extension, depth from center of stem, and spatial position differences of stem in the x (coronal)-axis, y (sagittal)-axis, and z (axial)-axis. The same will be calculated in cup implantation for RI, RA, and spatial position differences of the stem in the x, y, and z axes. For leg length discrepancy, the absolute value of changes before and after surgery, the summary statistics, and the 95% confidence interval will be calculated, together with the incidence of adverse events.

DISCUSSION

This is the first clinical study to test the concept of anterolateral approach THA using an extracorporeal PSG for stem implantation with 3D surgical support software in patients with hip joint disease.

THA using an extracorporeal PSG for stem implantation with 3D surgical support software is easier and cheaper to perform than the conventional method. In addition, accuracy should be improved compared with the conventional method (i.e. the freehand method), operation time should be shortened through better navigation, and the amount of bleeding should also decrease. Moreover, additional invasion by antenna installation for navigation surgery becomes unnecessary, and it becomes possible to compare the accuracy between the preoperative plan and actual postoperative implantation with consistent CT standards before and after surgery.

DECLARATIONS

Ethics approval

This study was approved by the Clinical Research Ethics Committee of Nagoya Medical Center on 25 November 2016 (Serial Number: 2016-66). This study has been registered in the Clinical Trial Registry (UMIN-CTR) on January 20, 2017 (UMIN000025768).

Competing interests

DK jointly developed a new extracorporeal PSG with 3D surgical support software (ZedView) in collaboration with ArthroDesign.Ltd., and applied for a patent. YK is the Representative Director of ArthroDesign.Ltd. For the other authors, there are no conflicts of interest to declare.

Authors’ contributions

DK will approve the final protocol and supervise the entire study. HH is responsible for statistical analysis. NI supported preparation of the protocol. YK is in charge of creating PSG. KM and NT are involved in the study. YT oversees medical treatment.

REFERENCES

navigation system. *Int Orthop.* 2013; 37:1