Int J CARS (2009) 4:157–162
DOI 10.1007/s11548-009-0286-1

ORIGINAL ARTICLE

Robot-assisted primary cementless total hip arthroplasty using surface registration techniques: a short-term clinical report

Nobuo Nakamura · Nobuhiko Sugano · Takashi Nishii · Hidenobu Miki · Akihiro Kakimoto · Mitsuyoshi Yamamura

Received: 30 April 2008 / Accepted: 29 December 2008 / Published online: 13 February 2009

Abstract
Purpose The purpose of this study was to compare non-fiducial based surface registration technique (DigiMatch) with the conventional locator pin-based registration technique in performing cementless total hip arthroplasty (THA) using ROBODOC system.
Methods Eighty-one THA were performed using pin-based technique and forty-three were performed using the DigiMatch technique. The average follow-up term was 38 months.
Results Postoperatively, the Japanese Orthopedic Association hip scores were significantly better in the DigiMatch group than in pin-based group. The accuracy of postoperative stem alignment of the DigiMatch technique was comparable with that of pin-based method.
Conclusions No need for prior pin implantation surgery and no concern for pin related knee pain were the advantages of DigiMatch technique. Short-term follow-up clinical results showed that DigiMatch ROBODOC THA was safe and effective.

Keywords Total hip arthroplasty · Cementless · Robot assisted · ROBODOC · Surface registration

N. Nakamura (✉) · A. Kakimoto · M. Yamamura
Center of Arthroplasty, Kyowakai Hospital,
1-24-1 Kishibe-kita, Suita-city, Osaka 564-0001, Japan
e-mail: nnakamu@abox2.so-net.ne.jp

N. Sugano · T. Nishii · H. Miki
Department of Orthopedic Surgery,
Osaka University Medical School, Osaka, Japan

Introduction

The ROBODOC system (Integrated Surgical Systems, Davis, CA, USA) was first designed to reduce potential human errors in performing cementless total hip arthroplasty (THA). The initial ROBODOC system used a pin-based registration system. The procedure consisted of presurgical locator pin implantation, computed tomography (CT) scanning, preoperative planning on the ORTHODOC workstation (Integrated Surgical Systems, Davis, CA, USA), surgical setup of the ROBODOC in operating room, surgical exposure, pin location, registration, and robotic milling of the femoral cavity [9]. In order to provide the information about the spatial orientation of the bone to the ROBODOC system, the pin-based registration was developed. This pin-based registration system has been proved to be accurate [10]. However, two locator pins must be implanted, one each in the proximal and the distal femur prior to surgery under local anesthesia. During the surgery, the surgeon must locate and expose the pins to the robot. As Nogler et al. [11] reported, postoperative pain at the site of pin implantation is a potential disadvantage of the pin-based registration method.

To eliminate the requirement for presurgical locator pin implantation and its potential pin-related complications, a proprietary non pin-based surface registration technique (DigiMatch) was developed by the manufacturer in 2000. There have been some reports on comparison of pin-based ROBODOC THA and conventional method [9,10,14], but none have been reported on the clinical results and accuracy of ROBODOC THA using the DigiMatch registration technique until today.

The purpose of this study was to compare the DigiMatch registration technique with the locator pin-based registration technique in THA procedure using ROBODOC system.

Materials and methods

From September 2000 to December 2003, 124 robot-assisted primary cementless THA were performed on 111 consecutive patients who had secondary osteoarthritis. Eighty-one THA were performed using the locator pin-based technique on 75 patients. Forty-three were performed using the DigiMatch technique on 36 patients. The indications were the same as those of cementless THA. In detail, patients with good bone quality (Dorr Type A or B) [4] and of Crowe Class I, II, or III (0 to 100% subluxation of the hip) [3] were the indication of robot-assisted THA. For patients with poor bone quality, we used cemented femoral stem with conventional manual technique. For patients with Crowe Class IV subluxation, we combined femoral shortening osteotomy with manual technique as robot-assisted THA was not indicated for these patients. All patients provided informed consent before undergoing the operation. The procedure was also approved by the institutional review committee. The average age was 57 (39–84) years. The average follow-up term was 38 (26–52) months. Preoperatively, we planned the position and the size of the VerSys FM Taper stem (Zimmer, Warsaw, IN, USA) three-dimensionally on the ORTHODOC workstation (Integrated Surgical Systems, Davis, CA, USA).

The ROBODOC pin-based technique has been described previously [9,10]. The ROBODOC DigiMatch technique was as follows. First a CT scan of the affected femur was taken according to the manufacturer's specified protocol. The CT data was imported to the ORTHODOC workstation and surface models of the proximal femur and the distal femur were created for surface registration. Then, the pre-operative plan was developed by selecting the optimal size and position of the prosthesis in each case. The prosthesis used for this study was the VerSys FM Taper stem (Zimmer, Warsaw, IN, USA). Trilogy cup (Zimmer, Warsaw, IN, USA) with a highly crosslinked polyethylene liner (Longevity; Zimmer, Warsaw, IN, USA) was used for the replacement of the acetabulum. Once the surface bone model was successfully created and the image of the optimal size implant was optimally positioned within the bone CT image on the computer screen, the surgeon transferred the surgical plan data onto a CD.

Prior to each surgical procedure, the surgeon loaded the patient surgical plan data from this CD into the robot system and performed routine setup and diagnostic checks. We used posterolateral approach for surgery. During the surgery, the surgeon secured the patient's leg in the femoral fixator of the robot. The surgeon oriented the robot by selecting points on the femoral surface using a digitizer (Integrated Surgical Systems, Davis, CA, USA) (Fig. 1a). Fourteen points from the proximal femur and 3 points from distal femur were taken (Fig. 1b). The ROBODOC computer recorded the spatial information of surface points and compared and matched them to the coordinate surface model that had been created preoperatively in the ORTHODOC. This procedure is called registration. When the registration was completed, the surgeon verified its accuracy by touching bone surfaces with the digitizer. If difference between the digitization-based surface contour and the CT-derived surface contour was within 1 mm, the registration was accepted (Fig. 1c).

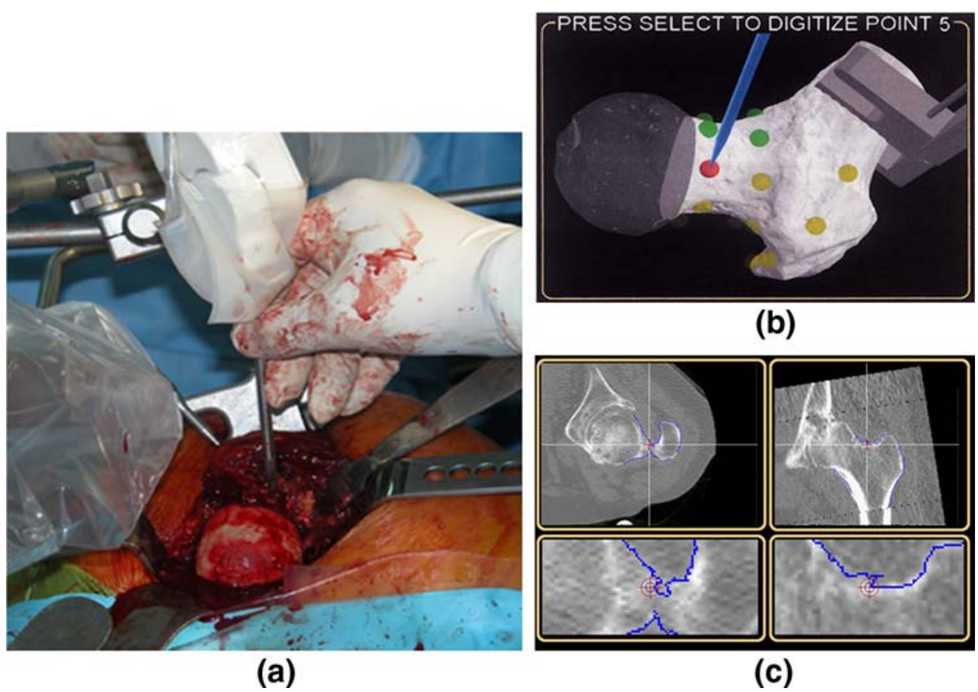

Fig. 1 The procedures of DigiMatch technique. **a** During the surgery, the surgeon oriented the robot by selecting points on the femoral surface using a "digitizer". **b** Registration of the proximal femur. Fourteen points were taken as shown on the monitor. **c** The surgeon verified the registration accuracy by touching bone surfaces with the digitizer. If their locations coincided with the bone surface points on the monitor, the surgeon accepted the registration

A cutter bit was installed at the tip of the robot arm and it was guided in front of the bone to begin the milling of the femur. After milling was completed, the surgeon manually inserted the implant.

Full weight-bearing was permitted 24 hours after the surgery and physiotherapy was carried out for three weeks in the hospital. The Japanese Orthopedic Association (JOA) clinical score [15] was measured preoperatively as well as at three, six, twelve, and twenty-four months after surgery. The JOA score has a maximum of 100, of which pain score has a range from 0 to 40 points, range of motion score ranges from 0 to 20 points, walking ability score ranges from 0 to 20 points and activities of daily living score ranges from 0 to 20 points. Knee-related pain and abductor muscle function (as indicated by the Trendelenburg sign and limping) were also assessed. The surgical duration (time from incision to closure) were measured for each patient. Radiographs made at three, six, twelve and twenty-four months were analyzed for evidence of fixation [6], loosening, subsidence, stress shielding [5], and heterotopic ossification, which was classified with the system described by Brooker et al. [2].

Radiographic evaluation of the stem alignment using reconstructed CT images was performed at 3 weeks after surgery according to the manufacturer's specified protocol (GE Yokogawa Medical Systems, Tokyo, Japan). We reoriented the proximal femur according to the axis of the stem on the coronal and sagittal plane on ORTHODOC (Fig. 2a, b). For local coordination, we adopted the vertical axis of the stem as the line that linked proximal screw hole and distal tip. For the third axis, we adopted the line that bisected the femoral head in the horizontal plane (Fig. 2a, b). This procedure was feasible because the VerSys FM Taper stem was symmetric, straight design. To standardize the image scales, we set the zoom level of ORTHODOC to 1.00. After

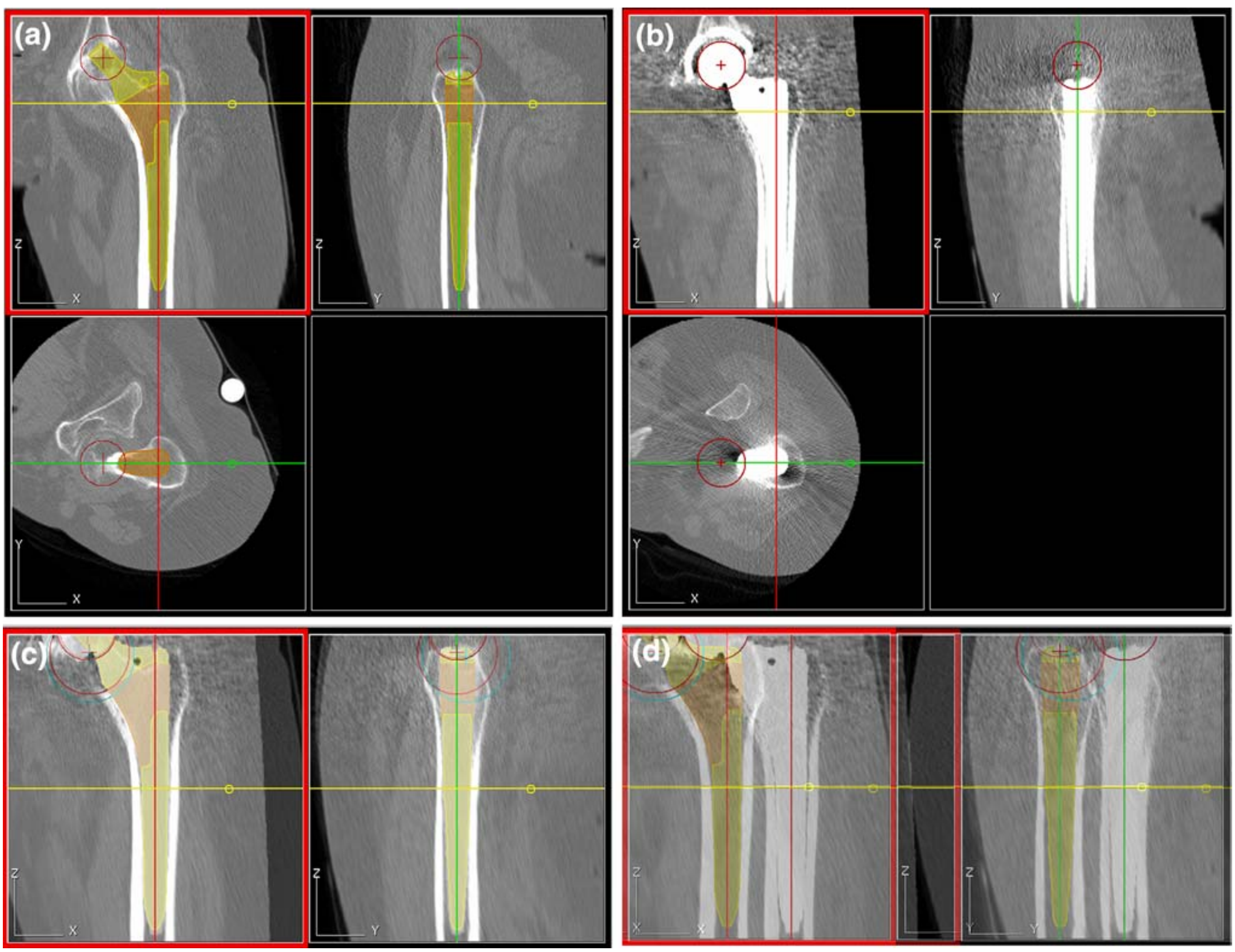

Fig. 2 Methods of stem alignment evaluation. **a** The preoperative proximal femur was reoriented according to the axis of the planned stem on the coronal and sagittal plane. **b** The postoperative proximal femur was also reoriented according to the axis of the stem. **c** Then the images of the both stem were completely overlapped. **d** We made parallel translation of the one image, and measured the angles between the contours of preoperative and postoperative cortex of the femoral shaft between the tip and the center of the stem level

capturing the images of the preoperative plan and that from postoperative CT data, they were overlaid on the image software (Photoshop Elements 2.0; Adobe systems, San Jose, CA, USA) using its layer function. When both the coronal and sagittal axis of the stems were completely overlapped (Fig 2c), we measured the angles between the contours of preoperative and postoperative bone cortex of the femoral shaft between the tip and the center of the stem level. Practically, we made parallel translation of the one image, and measured the angles (Fig. 2d). The AP views were used to evaluate the medio-lateral alignment and the lateral views were used to evaluate AP alignment of the femoral stem. Axial images of the femur were used to evaluate vertical seating. The DigiMatch and pin-based groups were compared with respect to the differences in those radiographic measurements between values from preoperative planning and measurements from postoperative CT images.

The unpaired t test, the Mann–Whitney U test, and the Chi-squared test were used for statistical analyses. Differences were considered significant when the P value was less that 0.05.

Results

Two patients (three hips) and three patients (three hips) for the DigiMatch and pin-based groups, respectively were lost to follow-up. So the net subjects included in the DigiMatch and pin-based groups were 34 patients (40 hips) and 72 patients (78 hips) respectively. There were no significant differences between the two groups with regard to the distribution of patient age, height, and weight except for the patient gender (Chi-squared test $P < 0.05$). The ratios of female/male were 33/1 for the DigiMatch group and 57/15 for the pin-based group.

The average duration of the surgery was significantly longer in the DigiMatch group (146 minutes) than in the pin-based group (121 minutes) ($P < 0.001$) (Table 1). However, the difference in the average blood loss during operation was not significant between the groups (Table 1).

In the DigiMatch group, there was one sciatic nerve palsy (2.5%), which recovered within six month and there were two intraoperative femoral fissures (5%) during insertion of the stem, which were successfully treated with cable wires. No dislocation, deep vein thrombosis or infection was seen. There was no thigh pain or knee pain that was seen in the pin-based group. However, none of the complications were statistically significant between the two groups (Table 1).

Preoperatively, there were no significant differences in the JOA hip scores between the two groups (Fig. 3). Three months, one year, and two years postoperatively, JOA hip scores were significantly better in the DigiMatch group than pin-based group (Mann–Whitney U test; $P < 0.01$) (Fig. 3).

Table 1 Intraoperative parameters and perioperative complications

	DigiMatch	Pin-based
No. of hips	40	78
Surgical time* (min)	146 ± 33	121 ± 26
Blood loss (ml)	654 ± 290	559 ± 286
Nerve palsy (%)	1 (2.5%)	0
Dislocation (%)	0	2 (2.6%)
Thigh pain (%)	0	1 (1.3%)
Knee pain (%)	0	2 (2.6%)
Femoral fissure (%)	2 (5%)	0

statistically not different exept * $P < 0.001$ (Student t test)

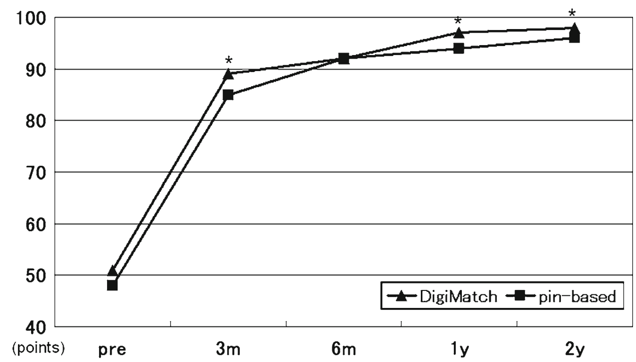

Fig. 3 Comparison of Japanese Orthopaedic Association Hip Scores of each surgery at preoperative and postoperative periods

At the final follow-up, one patient in each group showed slight limping but no Trendelenburg gait. The difference was not significant.

Plain radiographs at two years showed bone ingrowth fixation for all the stems and cups of both groups. There were no signs of mechanical loosening in any implant. Stem subsidence was seen in one hip (5 mm) in the DigiMatch group and one hip (3.5 mm) in pin-based group. Both subsidences stopped within three month postoperatively. There was no difference in stress shielding of proximal femur [5] or heterotopic ossification between the two groups.

Postoperative CT images were available in 28 hips of DigiMatch group and 35 hips of pin-based group. Using CT data, we compared postoperative stem alignment of DigiMatch and pin-based groups with preoperative planning. The average angular differences of the anterior-posterior stem axis were $0.02 \pm 0.17°$ in the DigiMatch group and $0.11 \pm 0.15°$ in the pin based group. The average angular differences of the lateral stem axis were $0.17 \pm 0.22°$ in the DigiMatch group and $0.0 \pm 0.21°$ in the pin based group (Table 2). The average difference of axial seating of the stem was 1.2 ± 3.2 mm in the DigiMatch group and $1.1 \pm 0.9°$ in the pin based group (Table 2). There were no statistical differences between the two groups (Student t-test). We further evaluated intra- and interobserver variability. For

Table 2 Comparison of postoperative stem alignment between DigiMatch and pin-based group

	DigiMatch	Pin-based	*P* value
AP alignment (°)	0.02 ± 0.17	0.11 ± 0.15	0.66
(Absolute value)	0.74 ± 0.49	0.75 ± 0.47	0.91
ML alignment (°)	0.17 ± 0.22	0 ± 0.21	0.57
(Absolute value)	1.08 ± 0.44	1.05 ± 0.59	0.83
Vertical seating (mm)	1.2 ± 3.2	1.1 ± 0.9	0.85
(Absolute value)	1.2 ± 3.2	1.1 ± 0.9	0.85

Statistically not significant (*t* test)

angular measurements, these differences were $0.0 \pm 1.2°$, $0.19 \pm 0.69°$ (anterior-posterior) and $0.18 \pm 0.81°$, $-0.32 \pm 0.92°$ (lateral). For axial seating, Pearson correlation coefficient for intra- and interobserver variability were 0.70 and 0.85, respectively. These data showed that the accuracy of the DigiMatch technique was comparable with that of pin-based method.

Discussion

For robotic milling of the femur, a method for registration using fiducial marker has been known to be accurate both experimentally [12] and clinically [10]. However, in this procedure, locator pins must be implanted prior to surgery. The problems associated with fiducial marker registration technique are not only its increased invasiveness and cost, but also marker-related complications [16]. Nogler et al. reported that pain at the site of pin implantation sometimes occurred [11]. Schulz et al. recently reported that during pin insertion process, complications such as wire breakage, temporary nerve damage and knee effusion were seen in 3.1% of patients [14]. We also experienced transient postoperative knee pain in 2.6% of the patients who underwent pin-based surgery (Table 1). To overcome these problems, we adopted the non-fiducial based registration technique for robot-assisted surgery.

Clinically, in the current study, no patient in the DigiMatch group complained of knee pain related to pin insertion. Postoperative JOA hip scores were significantly better in the DigiMatch group than pin-based group. We believe that in addition to the same initial stable fixation of the stem in the robotic-milling of femoral cavity, the lower rate of pin-related knee pain may have contributed to the better clinical scores for the DigiMatch group.

Surgical time for the DigiMatch technique was longer than pin-based method primarily because the time required for registration including verification was longer in the DigiMatch group. Improvements of the registration and/or verification program to reduce the time may be needed. However, for other parameters such as intraoperative blood loss, perioperative complications, stem subsidence, stress shielding and heterotopic ossification, there were no significant differences between the DigiMatch and pin-based groups.

Surface registration methods are widely used in the navigation systems [1,8,13,16,17] and robot-assisted surgery [7]. Many experimental accuracy studies have been done by comparison with fiducial based registration as a gold-standard [1,8,13,16,17]. However, clinical accuracy evaluation of surface registration method in the robot-assisted surgery has not been reported so far. Hence, we decided to measure the clinical accuracy data of stem placement between the pin-based and DigiMatch methods and determine the difference. The results showed that there was no difference in the accuracy for any of the measured parameters. It can be concluded that the DigiMatch method is as accurate as pin-based method. However, it must be noted that this accuracy of the DigiMatch method might be compromised if the preoperative surface model creation and/or intraoperative registration were inaccurate.

The major limitation of this study is that DigiMatch THA was performed periodically later than pin-based method. So this was a retrospective, non-randomized study. Some learning curve effect might exist for the DigiMatch group. In addition, patient gender was significantly different between the two groups. These factors may have affected the clinical score. Hence, a prospective, randomized, multicenter clinical study of this procedure may be needed.

In conclusion, although the operation time was longer, DigiMatch ROBODOC THA had better clinical scores than pin-based method. In addition, the accuracy of stem implantation for the DigiMatch technique was comparable with that for pin-based method. No need for prior pin implantation surgery and no concern for pin related knee pain were distinct advantages of the DigiMatch technique over the pin-based technique. Short-term follow-up clinical results showed that DigiMatch ROBODOC THA was safe and effective.

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