Validation of a computer navigation system and a CT method for determination of the orientation of implanted acetabular cup in total hip arthroplasty: A cadaver study

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Abstract

Background. Successful hip reconstruction to restore the normal hip biomechanics requires precise placement of implants. Computer assisted navigation in total hip arthroplasty has been proposed to have the potential to help achieve a high accuracy in implant placement. The goal of the study was to evaluate the accuracy of an imageless computer navigation system on cadavers and to validate a non-invasive computed tomography method for post-operative determination of acetabular cup orientation.

Methods. Total hip arthroplasty was performed on seven cadaver hips with the aid of an imageless computer navigation system. The achieved cup orientation were recorded using three methods, (1) intra-operatively using the imageless computer navigation system, (2) post-operatively with direct bone digitization and (3) with a computed tomography based three dimensional model interpreted by three raters. Measurement from the direct bone digitization was taken as the gold standard to evaluate the other two methods. The intra-rater and inter-rater consistency of the computer tomography-model method were assessed by Cronbach’s alpha determination.

Findings. Compared with the cup orientation obtained from the direct bone digitization, the average difference for anteversion and abduction were 3.3 (3.5)° (P = 0.045) and 0.6 (3.7)°, respectively, for navigation reading. The average differences for computer tomography-model for three raters were 0.5 (2.1)°, 0.8 (1.5)° and 3.2 (3.3)° (P = 0.043) for anteversion and 0.4 (1.6)°, 0.3 (1.6)° and 2.1 (2.7)° for abduction. The intra-rater consistency ranged from 0.626 for a novice rater to over 0.97 for experience raters. The inter-rater consistency (including novice and experienced raters) was over 0.90.

Interpretation. While the values for cup orientation determined with imageless computer navigation were comparable to those from direct bone and implant digitization, the measurement for anteversion obtained was not as accurate as that for abduction. The proposed computer tomography-model method has an excellent intra-rater consistency for experienced raters, as well as an excellent overall inter-rater consistency. The study confirms that a non-invasive computed tomography based model analysis can be used in clinical practice as a valid method for post-operatively evaluating the orientation of the acetabular component.

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Keywords: Computer navigation; Total hip arthroplasty; Implant placement; Cadaver hips; Computed tomography; Acetabular cup orientation

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1. Introduction

The risk for a hip dislocation after a total hip arthroplasty (THA) depends on a number of implant related factors including acetabular cup abduction and anteversion, presence or absence of an elevated rim, head size, femoral neck shape and size and the degree of femoral neck anteversion (Barrack, 2003; Biedermann et al., 2005; Del Schulte et al., 1998; DeWal et al., 2003; D’Lima et al., 2000; Jolles et al., 2002; Kennedy et al., 1998; Kummer et al., 1999; Lewinnek et al., 1978; McCallum and Gray, 1990; Paterno et al., 1997; Pierchon et al., 1994). Of all the factors associated with hip dislocation, component malposition is the most manageable and its improvement usually predicts a good result (Daly and Morrey, 1992; Dorr et al., 1983). More accurate positioning of the implants, through the use of computer assisted navigation, has been shown to have the potential to improve surgical outcomes (DiGioia et al., 2002; Grutzner et al., 2004; Hube et al., 2003; Jaramaz et al., 1998; Kalteis et al., 2006; Kiefer, 2003; Leenders et al., 2002; Nogler et al., 2004; Saxler et al., 2004; Widmer, 2004; Zheng et al., 2002) for a THA.

Computer assisted hip navigation relies on a pelvic coordinate system to determine the acetabular cup orientation. Commonly, this coordinate system is defined with pelvic bony landmarks, the anterior superior iliac spines (ASIS) and the pubic tubercles (PTs). The landmarks define the anterior frontal plane of the pelvis (Lewinnek et al., 1978; DiGioia et al., 1998). For image based computer navigation, these points are determined by matching the measurement on intra-operative images to those on preoperative images. For an imageless computer navigation, where no intra-operative radiographs are taken, the bony landmarks are determined by digitizing the location obtained via manual palpation through the overlying soft tissues without the help of imaging. (Kalteis et al., 2004; Kiefer, 2003; Nogler et al., 2004; Zheng et al., 2002). With this dependence on manual palpation, there is a concern about the reliability of imageless navigation. Therefore, there is a need to evaluate the accuracy of the intra-operative readings for the implant orientation from the imageless computer navigation method.

A number of researchers (DiGioia et al., 2002, 2004; Dorr et al., 2005; Grutzner et al., 2004; Haaker et al., 2003; Hube et al., 2003; Jaramaz et al., 1998; Kalteis et al., 2004, 2006; Nogler et al., 2004; Saxler et al., 2004; Zheng et al., 2002) have shown that the computer assisted cup positioning allowed for more consistent placement compared with the conventional manual procedure. However, the studies were generally focused on the comparison of the acetabular cup orientation achieved using the navigation method with that using a conventional manual method. There is a lack of information on the accuracy of the navigation system itself evaluated using an objective method. For post-operative follow-up, radiographic measurements of the acetabular cup orientation have been shown to have wide variation (DiGioia et al., 2002). Although a variety of methods have been proposed (DiGioia et al., 2002), the reliability of such measurement is still limited due to the 2D limitations of radiography (Lewinnek et al., 1978; Visser and Konings, 1981; DiGioia et al., 2002). Radiographic measurement for evaluating cup orientation is not a reliable method, particularly for cup anteversion (DiGioia et al., 2002). The use of computed tomography (CT) has the potential to provide more reliable assessment of acetabular cup position with a three dimensional (3D) analysis.

Therefore, the objectives of this study were to use a cadaver model (1) to evaluate the accuracy of the imageless navigation for THA and (2) to validate the use of a 3D model constructed from computer tomography images as an accurate and non-invasive tool for determination of acetabular cup orientation in in vivo application.

2. Methods

2.1. Specimens

Seven intact fresh frozen cadaver hips (females: mean 68.5 (15.0) years) were used in this study. A total hip arthroplasty was performed on each of the cadaver hips. The implants used were uncemented titanium alloy cups fixed with screws (Trident Acetabular Implant, Stryker Corporation, Kalamazoo, MI, USA) and uncemented titanium alloy femoral stems with chromium cobalt metal heads (Accolade Femoral Implant, Stryker Corporation, Kalamazoo, MI, USA).

2.2. Computer hip navigation system (NAV)

An imageless computer navigation system (Stryker® navigation system, Stryker Corporation, Kalamazoo, MI, USA) was used for all surgery. “Imageless” means that this computer navigation system does not rely on images (CT or fluoroscopic) that are matched to the patient’s anatomy for planning and intra-operative guidance. With an imageless system, the relevant bony points to establish a coordinate system are determined by manual palpation. With the Stryker navigation system, “trackers” are rigidly fixed to the pelvis and femur. The trackers are active devices that communicate with infra-red signals to a camera system and computer. Using the bony landmarks that define the coordinate system and the position of the instruments and implants, the computer software calculates the position and orientation of the implants. The orientation of the acetabular cup, i.e. the anteversion and abduction, is then determined in real-time and provided to the surgeon.

2.3. Coordinate system

A pelvic coordinate system was used to identify the orientation of the acetabular component. Shown in Fig. 1, this coordinate system had its origin at the midpoint between the bilateral ASISs and its X and Z-axes lied in the anterior frontal plane of the pelvis (AFPP). The AFPP was defined by the bilateral ASISs and pubic symphysis (PS). The com-
puter navigation system used in this study has the option to use the midpoint between the bilateral pubic tubercles (PTs) to replace the PS; however, in this study, only the method of using the PS to determine the coordinate system was used to keep consistent measurement across the cadavers. The Z-axis was in AFPP pointing superiorly, while the X-axis pointing to the right ASIS and the Y-axis pointing ventrally, perpendicular to AFPP. The method to obtain these bony landmarks is described later for each experimental method.

2.4. Acetabular cup orientation

According to Murray’s (Murray, 1993) definition, the anatomical abduction was the angle formed between the normal vector of the acetabular surface (acetabular axis) and the transverse plane of the body, while the anatomical anteversion was the angle between the acetabular axis and the coronal plane of the body. While Murray’s definition was in the body coordinate system, we adapted his definition to the pelvic coordinate system defined above. In this way, the acetabular anteversion was relative to the AFPP (X–Z plane) and the abduction was to the pelvic transverse plane (X–Y plane).

2.5. THA surgery

With the aid of the imageless computer navigation system, a THA was performed for each cadaver hip. At surgery, the cadavers were placed in a lateral decubitus position supported firmly for the pelvis and the trunk to remain stable. A navigation tracker was attached to the distal–lateral femur through two self-tapping bicortical pins while another one was placed on the iliac crest approximately 5–8 cm posterior to the ASIS of the operative side. Using a pointer with an active tracker, the two ASISs and center of the pubic symphysis (PS) were palpated through the drapes and soft tissues and their locations were registered with the computer. Surgeries were performed by the senior surgeon Dr. Wixson with the guidance of the navigation system using a posterior approach. A bone ingrowth cup was implanted with press–fit fixation. Since the study was to validate cup orientation readings from different methods, the placement of the acetabular cup was not targeting a specific value of orientation as long as the cup orientation was within the range of 35–55° of abduction and 15–30° of anteversion.

2.6. Measurement of acetabular cup orientation

Three methods were used to measure achieved acetabular cup orientation. They were (1) intra-operatively using the computer navigation system (imageless-NAV), (2) post-operatively with direct bone digitization (direct digitization), and with (3) a 3D model constructed based on CT images (CT-model). Among them, data from the direct digitization was used as the gold standard for evaluating the other two methods. In the direct digitization, after dissecting away the soft tissues, the tip of the palpating probe was placed directly on the bone surface at the location of each bony landmark, providing a measurement with the least interference from other structure such as soft tissue.

2.6.1. Intra-operative reading from the computer navigation system

At the beginning of the navigated surgery, the location of both ASIS and PS was obtained through manual palpation to establish the pelvic coordinate system. The real-time intra-operative reading of the acetabular cup orientation was based on this coordinate system and they are in the group of “imageless-NAV”.

2.6.2. Post-operative direct digitization

After the surgery, soft tissues overlying the ASISs and PTs were removed to expose the bone. Small titanium screws (2.3 mm in diameter; Styker Leibinger GmbH & Co. and KG, Freiburg, Germany) with Phillip’s head were placed into the bone to mark the exact location of the bony landmarks. The center of each screw head was then digitized directly using the pointer probe (Stryker® navigation system, Stryker Corporation, Kalamazoo, MI, USA). These values were assumed to represent the true location of the bony landmarks and they were used as the gold standard for evaluating the other two methods.
To calculate the orientation of the implanted acetabular cup, multiple points were collected while sliding the tip of the probe on the acetabular rim surface. A plane was fitted to these data by using a least-square error algorithm. The cup anteversion and abduction were then determined by the orientation of this acetabular plane. This group of data was the “direct digitization”.

2.6.3. Determination from a 3D model including pelvis and the prosthesis reconstructed from the CT images (CT-model)

All specimens had post-operatively a CT scan (Fig. 2A and B) of the pelvis and the proximal femur in a GE-9800 scanner with 1.25 mm cuts from above the pelvic crests to below the ischial tuberosities with the specimens lying supine. The CT images were used to create a 3D model for the pelvis and prosthesis (Fig. 2C) by using software developed for a CT based hip navigation system (CT-Hip System, Stryker Leibinger GmbH & Co. and KG, Freiburg, Germany). On this 3D pelvis–prosthesis model, one point was selected at each of the location of the bilateral ASISs and PTs to define the pelvic coordinate system. Using the implant placement planning function, a virtual acetabular cup was superimposed over the implanted cup component (Fig. 3). By adjusting the location and tilting angle of the virtual cup in transverse plane (Fig. 3A), frontal plane (Fig. 3B) and in a plane perpendicular to cup axis (Fig. 3C), the virtual cup was aligned closely to the implanted cup. Then the reading of anteversion and abduction of the virtual cup was considered to represent that of the implanted cup (Fig. 3D). Data obtained using this method was in the group of “CT-model”.

Additionally, intra-rater and inter-rater consistency was assessed for CT-model method by calculating Cronbach’s alpha for measurements from three independent raters. Among the three raters, rater A was an experienced researcher on THA-related projects for 3 year and had used the CT-hip software for 6 months, rater B was an experienced orthopaedic surgeon who had been performing THA for over 25 years and had used the software for 5 years, and rater C was a novice researcher who just started to learn the software for less than a week.

2.7. Statistical analysis

For each hip, a difference between the cup orientation from imageless-NAV and that from direct digitization was calculated. A similar difference was obtained between the measurements of CT-model and direct digitization for each of the three CT-model raters. A *t*-test (2-tailed) of these differences versus a value of zero difference was performed to determine whether the differences were significant. The Cronbach’s alpha was calculated among three raters and within the three measurements of each individual rater, for inter-rater and intra-rater consistency, respectively. Statistical analysis was performed using SPSS 15.0 (SPSS Inc., Chicago, IL, USA). A *P*-value below 0.05 was considered significant.
3. Results

In direct digitization, it was found that the average distance between the two ASISs was 216.5 (9.5) mm. The average distance between the midpoint of the two ASISs and the midpoint of the two PTs was 94.5 (5.6) mm.

The differences for acetabular cup anteversion and abduction obtained using imageless-NAV, direct digitization and CT-model from those using direct digitization are summarized in Table 1. A negative value indicates that the measurement was smaller than that of direct digitization.

**Anteversion:** The average difference of anteversion for imageless-NAV from that of direct digitization was significant \((P = 0.045)\). The range of this difference for the tested 7 cases was over 10°. Anteversion obtained using CT-model method deviated from that of direct digitization by less than 1° for raters A and B, but more than 3° for rater C. The range of this difference was over 7° for rater C with significance.

**Abduction:** The average difference of abduction for imageless-NAV from that of direct digitization was not statistically significant, although the range of this difference for the tested seven cases was over 10°. Abduction obtained using CT-model method was different from that of direct digitization by less than 1° for raters A and B but more than 2° for rater C. None of these differences was statistically significant.

**Intra-observer reliability in applying CT-model measurement** (Table 2): The Cronbach’s alpha for intra-rater reliability using CT-model to measure anteversion was over 0.9 for raters A and B but was only 0.626 for rater C. That for abduction was over 0.9 for all raters. When the measurement of anteversion and abduction was pooled together, the Cronbach’s alpha was over 0.98 for all three raters.

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**Fig. 3.** This figure shows that a virtual acetabular cup was used to obtain the acetabular cup orientation. (A) The transverse view of the CT scan of the implanted prosthesis and the superimposed virtual cup. (B) The frontal view of the CT scan of the implanted prosthesis and the superimposed virtual cup. (C) A view which was perpendicular to the axis of the implanted acetabular cup of the CT scan of the implanted prosthesis and the superimposed virtual cup. (D) A 3D view of the CT-model of the pelvis, femur, the implanted prosthesis, and the superimposed virtual cup.
The range of the difference is given as the range from the most negative to the most positive values of the differences. Data for CT-model method are given for three different raters. A positive value indicates the measured value is larger than that from the direct digitization.

Table 1
Differences (mean (SD)) of acetabular anteversion and abduction measured by using imageless navigation system (imageless-NAV) and CT-model methods from those obtained from direct bone digitization (direct digitization)

<table>
<thead>
<tr>
<th></th>
<th>Imageless-NAV</th>
<th>CT-model Rater A</th>
<th>CT-model Rater B</th>
<th>CT-model Rater C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anteversion (°)</td>
<td>-3.3 (3.5)</td>
<td>-0.5 (2.1)</td>
<td>-0.8 (1.5)</td>
<td>-3.2 (3.3)</td>
</tr>
<tr>
<td>P</td>
<td>0.045</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
<td>0.043</td>
</tr>
<tr>
<td>Range (°)</td>
<td>-8.4 to 2.2</td>
<td>-3.0 to 2.7</td>
<td>-3.0 to 1.0</td>
<td>-7.7 to 0.3</td>
</tr>
<tr>
<td>Abduction (°)</td>
<td>-0.6 (3.7)</td>
<td>0.4 (1.6)</td>
<td>-0.3 (1.6)</td>
<td>-2.1 (2.7)</td>
</tr>
<tr>
<td>P</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Range (°)</td>
<td>-6.6 to 4.0</td>
<td>-2.3 to 1.9</td>
<td>-2.4 to 1.6</td>
<td>-6.0 to 0.6</td>
</tr>
</tbody>
</table>

Data for CT-model method are given for three different raters. A positive value indicates the measured value is larger than that from the direct digitization. The range of the difference is given as the range from the most negative to the most positive values of the differences. P is the statistical significance of the difference from values obtained using direct digitization.

Table 2
Reliability test results for CT-model method. Cronbach’s alpha for intra-rater and inter-rater consistency is given for measuring anteversion, abduction and overall

<table>
<thead>
<tr>
<th></th>
<th>Rater A</th>
<th>Rater B</th>
<th>Rater C</th>
<th>Inter-rater</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anteversion</td>
<td>0.985</td>
<td>0.979</td>
<td>0.626</td>
<td>0.901</td>
</tr>
<tr>
<td>Abduction</td>
<td>0.994</td>
<td>0.992</td>
<td>0.962</td>
<td>0.958</td>
</tr>
<tr>
<td>Overall</td>
<td>0.998</td>
<td>0.997</td>
<td>0.989</td>
<td>0.992</td>
</tr>
</tbody>
</table>

In “overall” option, data for anteversion and abduction are pooled together.

Inter-observer reliability in applying CT-model measurement: The inter-observer reliability for Crohnbach’s alpha was over 0.9 for all measurements.

4. Discussion

This study evaluated an imageless computer navigation system for THA on seven cadaver hips for the accuracy of the cup orientation measurements. In addition, a method for determining cup orientation post-operatively using a CT based computer model was validated. Specifically, the measurements for acetabular cup orientation obtained from the imageless navigation system intra-operatively and from the CT based method post-operatively were both compared with those from a direct bone surface measurement, which was considered the gold standard for this evaluation. The purpose of this study was to evaluate the potential clinical outcomes of using a navigation system for total hip arthroplasty. By using a single group of cadavers we were able to first validate the CT based method of post-operative assessment and then use the same data set to evaluate the accuracy of the navigation system. The two portions of the study have been reported together since they had the same ultimate purpose, were done together and were based on the same set of specimens.

The use of a cadaver model allowed direct comparison of the imageless-NAV method used to position the cup, the CT-model used to measure its position and direct bone digitization which gave the absolute values for cup orientation. Since the direct digitization used the probe tip to physically touch the bone surface and the implanted acetabular cup rim, the measurements were not influenced by manual palpation through the soft tissues, which occurs with imageless-NAV. It also lacked the potential variation between different observers of the interpretation of the images on the CT-model. For this study the direct digitization values were used as the gold standard for determining cup orientation. The CT-model method provides a non-invasive method to evaluate the accuracy of acetabular implant placement following total hip arthroplasty done with, or without, computer assisted navigation.

Results from the determination of cup orientation in this study showed some differences from the imageless-NAV and CT measurements compared to the values obtained from direct digitization. The average discrepancy for the indirect methods was within 3.5° with the largest average variation seen for the imageless-NAV (−3.3°) of cup anteversion. The largest variation on interpretation was also for anteversion with the novice rater (rater C, −3.2°). Both these errors were statically significant. For the rest of the data, the average error was within 2.5° without statistical significance. For each of the methods and for each rater using the CT-model, the error on cup orientation was greater for anteversion than for the abduction. In addition, the error of the readings between imageless-NAV and direct digitization was greater than that from the CT-model. While anteversion appears to be less precise than the abduction, the average error and ranges are well within the “safe zone” of ±10° described by Lewinnek et al. (1978).

Two factors may have contributed to this difference between abduction and anteversion. First, there may be an effect from the body position the cadaver was placed when the measurements were taken. Both the direct digitization and CT-model were performed in supine position with the bony landmarks well exposed, while the imageless-NAV readings were taken in a lateral position which used to perform the THA surgery. The use of a lateral position may have introduced inconvenience for palpating the ASIS on the non-operative side, which may have contributed to the slightly smaller values for both anteversion
and abduction in imageless-NAV data, compared to those from the other two methods. Further analysis incorporating the cadaver's pelvic posture is needed to understand the influence of body position on the measurement.

Second, during surgery, the soft tissues were intact except for the location of the incision. With intact skin, subcutaneous tissue and fibrous tissue overlying the bony landmarks, the digitized point was a variable distance above the bone surface. Any variation in that distance between the points would introduce a cup orientation calculation error for the imageless-NAV readings. This may also account for the relatively larger error seen in imageless-NAV readings of anteversion than that of abduction. Abduction would be influenced by the distance between the two ASISs, which was of 216.5 (9.5) mm. By comparison, the distance between the midpoints of the ASISs and the PS, which influences anteversion was smaller with an average of 94.5 (5.6) mm. Therefore, for a similar error of palpating ASISs and the PS, the abduction calculation would be less affected than that for the anteversion. This may have resulted in the intra-operative digitization of the bony landmarks deviating from the true location and contributed to the error of the cup orientation reading from the imageless-NAV method.

The validity of the CT-model compared to the direct digitization showed good intra-rater and inter-rater reliability. The inter-rater consistency was high with a Cronbach's alpha over 0.900, which implies that the non-invasive CT-model method described in this study is a valid tool for accurately determining the anteversion and abduction of the implanted acetabular cup. However, the lowest Cronbach’s alpha for intra-rater consistency was with a novice rater who had been exposed to the method for less than a week. At the same time, for experienced raters A and B, the intra-rater reliability reached at least 0.979 and correlated well with the average error data. Rater C had average errors above 2° for cup angles while the more experienced raters A and B had less than 1°. This suggests that training and practice are necessary to achieve reliable determination of the cup angles using the CT-model method.

A variety of methods have been proposed for measuring the acetabular orientation using single or bimanual radiography. However, assessment of the anteversion of the acetabular component is limited due to the 2D limitations of radiography (Lewinnek et al., 1978; Visser and Konings, 1981; DiGioia et al., 2002). In this study with cadaver specimens, there was close agreement, for both cup abduction and cup anteversion, among these 3D methods, i.e. the navigation reading, CT scan analysis, and direct digitization. The high inter-rater reliability and intra-rater consistency for experienced observers indicate that there were no significant inter-observation variation nor intra-observation variation in the acetabular cup orientation determined based on the CT-model analysis. Therefore, it suggests that this CT-model method may be a valid method for use as the definitive measure for non-invasive post-operative assessment of the acetabular cup orientation with experienced and trained observers.

One limitation of this study is the relatively small sample size of only seven cadaver hips. A further study with a larger sample size may provide better insights into the accuracy of imageless navigation system on THA surgery, and the various factors affecting the accuracy of acetabular cup placement. Another limitation is that this study did not provide data on the absolute error of the landmark digitization of imageless-NAV from that of the standard values provided in direct digitization method. This was due to the fact that these two measurements were taken in two different times so the numbers obtained from two different measurements were not able to be compared directly. Therefore, the comparison was performed for the final product of each method, i.e. the orientation of the acetabular cup, to evaluate the influence of errors from imageless-NAV and CT-model on acetabular cup orientation determination.

In summary, this study has demonstrated acceptable accuracy in the measurement of the acetabular cup orientation using an imageless computer navigation THA system. A CT based 3D model method for determining the orientation of the hip prosthesis was found to be valid as a non-invasive method for accurately analyzing acetabular cup position. However, training and experience are necessary to use the method reproducibly.

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References