The effect of fixation and location on the stability of the markers in navigated total hip arthroplasty

A CADAVER STUDY

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In navigated total hip arthroplasty, the pelvis and the femur are tracked by means of rigid bodies fixed directly to the bones. Exact tracking throughout the procedure requires that the connection between the marker and bone remains stable in terms of translation and rotation. We carried out a cadaver study to compare the intra-operative stability of markers consisting of an anchoring screw with a rotational stabiliser and of pairs of pins and wires of different diameters connected with clamps. These devices were tested at different locations in the femur. Three human cadavers were placed supine on an operating table, with a reference marker positioned in the area of the greater trochanter. K-wires (3.2 mm), Steinman pins (3 and 4 mm), Apex pins (3 and 4 mm), and a standard screw were used as fixation devices. They were positioned medially in the proximal third of the femur, ventrally in the middle third and laterally in the distal portion. In six different positions of the leg, the spatial positions were recorded with a navigation system.

Compared with the standard single screw, with the exception of the 3 mm Apex pins, the two-pin systems were associated with less movement of the marker and could be inserted less invasively. With the knee flexed to 90° and the dislocated hip rotated externally until the lower leg was parallel to the table (figure-four position), all the anchoring devices showed substantial deflection of 1.5° to 2.5°. The most secure area for anchoring markers was the lateral aspect of the femur.

In order to make bones visible to the camera of a navigation system and to ensure accurate referencing throughout the operation it is necessary to fix reference markers securely to the bones.1,2 In the Stryker imageless navigation system (Stryker-Leibinger, Freiburg, Germany) bi-cortical screws with a rotation locking mechanism or two or three pins connected together are used. In navigated total hip arthroplasty (THA) markers must be secured to the pelvis as well as the femur. The pelvic marker is usually placed in the area of the anterior superior iliac spine or the iliac crest. The femoral marker must be positioned distal to the tip of the planned stem, usually in the distal third of the femur.3,4

The fixation of a rigid body on bone usually requires that the surgical procedure is more invasive. In hip navigation, both markers are placed beyond the standard incision, particularly when minimally-invasive approaches are used.4 The markers should be attached as non-invasively as possible, without compromising their stability. In THA, where the leg is manipulated during the procedure, considerable forces are exerted on the fixation of the marker device.

In this cadaver study we compared the intra-operative stability of two types of marker namely a single standard screw with a rotational locking mechanism and a two-screw or connected two-pin structures. In a second experiment these devices were tested for structural stiffness.

Materials and Methods

Three fresh unfixed human cadavers were placed supine on an operating table. The navigation system was placed parallel to the cadaver on the side of the leg being tested. The Stryker Hipnav navigation software V1.0 (Stryker Leibinger) was used for all measurements.

All pins and screws were inserted percutaneously through a stab incision. A hole with a diameter 1 mm less than that of the fixation device was drilled into the bone. A depth gauge was used to ensure bicortical placement of the pins. When pairs of markers were used, the two devices were separated axially by 3 cm to ensure that the same distance was maintained every time a distance drill guide was used. The paired devices were connected with two Hoff-
magn clamps (Stryker-Leibinger) to a rod on which the marker was mounted. The active marker was always positioned caudally. All active markers were mounted to the rod, 5 cm above the level of the bone (Fig. 1).

The following fixation devices were tested (Fig. 2):

- P, bicortical standard screw with rotational stabilisation (Stryker-Leibinger);
- A3, a pair of Apex pins, 3 mm diameter (Stryker-Leibinger);
- A4, a pair of Apex pins, 4 mm diameter (Stryker-Leibinger);
- S3, a pair of Steinmann pins, 3 mm diameter;
- S4, a pair of Steinmann pins, 4 mm diameter;
- K, a pair of Kirschner (K)-wires, 3.2 mm diameter.

Stability was identified as the movement of the marker mounted on the pins relative to the femoral bone. This was determined by fixing a reference marker to the femur with a bicortical screw, equipped with a rotation locking mechanism (Stryker Leibinger). A marker was also placed proximally on the lateral side of the femur in the region of the greater trochanter. Soft tissue was removed in order to achieve tension-free placement of this device. Changes in the position of the distally placed marker relative to the reference marker were recorded in different positions of the leg. The reference marker was retained for all measurements on a specific leg. Measurements were first taken on the right leg and then on the left. All measurements were carried out in the same manner on the three cadavers by two examiners (GE, EM).

Six different positions of the leg were tested:
1. Starting from a neutral position of the leg, it was first held in the ‘figure four’ position, with the hip in external rotation and the knee in 90˚ flexion, thus crossing the ankle over the contralateral knee.
2. Flexion of the hip to approximately 90˚.
3. Flexion of the hip to approximately 100˚ in maximal external rotation.
4. Flexion of the hip to approximately 100˚ in maximal internal rotation.
5. The hip in 0˚ of flexion and maximal external rotation.
6. The hip in 0˚ of flexion and maximal internal rotation.

The positions of the markers were recorded with the leg held straight in the neutral position. The leg was then moved sequentially through the six positions and the final position recorded. This was repeated 30 times for each type of anchor.

The measurements were performed with the anchors attached at the following positions (Fig. 1):
1) On the anteromedial aspect of the proximal third of the femur (P-AM);
2) On the ventral aspect of the middle third of the femur (M-V);
3) On the lateral side of the distal femur (D-L).

A second set of experiments was performed to assess the stiffness of the anchors. These were mounted on to a tubular structure with the same material properties as bone, and loaded axially and radially. The deflection caused by the load was measured in the direction in which it was applied (Fig. 3). The arrangement of the anchors was identical to that in the cadaver experiments.

A mean of 19.8 (SD 5.1) baseline measurements in the starting position were performed for each leg, fixation (A3, A4, K, P, S3, S4) and fixation site (lateral, ventral, medial). Based on these mean values of the starting position measurements, displacement (mm) and deflection (degrees) were computed for all movements of the leg (N = 39643).

Multivariate analysis of variance (general linear model) was used to compare the association of displacement and deflection and the independent variables of type of fixation, leg, position of the leg, and the site of fixation. In addition a post hoc Dunnett-T3 analysis was performed to test pairwise differences between groups as necessary (Levene test, p < 0.05). Statistical analysis was carried out using SPSS, version 11.0. All tests were two-tailed, with the level of significance set at p < 0.05. The results were expressed as means and standard deviations.
Results
The means and standard deviations of the six different pins showed marked movement of the A3 pin and the standard screw P. Least movement was seen with the K-wires and the A4 pins (Table I).

The six types of fixation differed in terms of displacement and deflection. The K-wires displaced the least. Differences between the K-wires and the A3, A4, and S3 pins and the P screw were highly significant (p = 0.001), and differences between the K-wires and the S4 pin were significant (p = 0.005). Regarding deflection, the K-wires showed the most favourable values, while the differences between the K wires and the A3, S3, S4 pins and the P screw were highly significant (p = 0.001) (Table II).

The highest deflection for all the varieties of fixation occurred in the figure-four position (Fig. 4), with the exception of the A3 pin, which showed equally high movements in all positions. The A3 pins broke twice during the measurements.

Table I. Means and standard deviations of displacement (mm) and deflection (°)

<table>
<thead>
<tr>
<th>Fixation type</th>
<th>Displacement (mm) Mean</th>
<th>Number</th>
<th>SD</th>
<th>Deflection (°) Mean</th>
<th>Number</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>A3</td>
<td>2.9</td>
<td>6622</td>
<td>2.7</td>
<td>5.4</td>
<td>6622</td>
<td>9.1</td>
</tr>
<tr>
<td>A4</td>
<td>2.6</td>
<td>6551</td>
<td>2.4</td>
<td>1.3</td>
<td>6551</td>
<td>1.5</td>
</tr>
<tr>
<td>K</td>
<td>2.3</td>
<td>6590</td>
<td>2.6</td>
<td>1.3</td>
<td>6590</td>
<td>1.4</td>
</tr>
<tr>
<td>P</td>
<td>3.2</td>
<td>6601</td>
<td>4.3</td>
<td>2.8</td>
<td>6601</td>
<td>9.8</td>
</tr>
<tr>
<td>S3</td>
<td>2.5</td>
<td>6626</td>
<td>2.6</td>
<td>1.9</td>
<td>6626</td>
<td>3.0</td>
</tr>
<tr>
<td>S4</td>
<td>2.4</td>
<td>6653</td>
<td>2.6</td>
<td>2.6</td>
<td>6653</td>
<td>5.9</td>
</tr>
<tr>
<td>Total</td>
<td>2.7</td>
<td>39643</td>
<td>3.0</td>
<td>2.4</td>
<td>39643</td>
<td>6.3</td>
</tr>
</tbody>
</table>

Table II. Pairwise differences between the K-wires and the other types of fixation using the Dunnett-T3 test

<table>
<thead>
<tr>
<th>Displacement</th>
<th>Mean difference (I to J)</th>
<th>Standard error</th>
<th>Significance</th>
<th>95% Confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>A3</td>
<td>-0.6568154(*)</td>
<td>0.046249</td>
<td>0.000</td>
<td>-0.7915502 -0.5220806</td>
</tr>
<tr>
<td>A4</td>
<td>-0.2859301(*)</td>
<td>0.044008</td>
<td>0.000</td>
<td>-0.4141839 -0.1576763</td>
</tr>
<tr>
<td>K</td>
<td>-0.9585644(*)</td>
<td>0.062328</td>
<td>0.000</td>
<td>-1.1409412 -0.7761876</td>
</tr>
<tr>
<td>P</td>
<td>-0.2633884(*)</td>
<td>0.046078</td>
<td>0.000</td>
<td>-0.3976236 -0.1291532</td>
</tr>
<tr>
<td>S3</td>
<td>-1.596329(*)</td>
<td>0.046033</td>
<td>0.005</td>
<td>-2.2937281 -0.0255377</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deflection</th>
<th>Mean difference (I to J)</th>
<th>Standard error</th>
<th>Significance</th>
<th>95% Confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>A3</td>
<td>-3.2410775(*)</td>
<td>0.112915</td>
<td>0.001</td>
<td>-3.5721232 -2.9100318</td>
</tr>
<tr>
<td>A4</td>
<td>-0.0316927</td>
<td>0.025310</td>
<td>0.971</td>
<td>-0.1054365 0.042051</td>
</tr>
<tr>
<td>K</td>
<td>-1.5722088(*)</td>
<td>0.122189</td>
<td>0.000</td>
<td>-1.9304287 -1.2139888</td>
</tr>
<tr>
<td>P</td>
<td>-0.6354805(*)</td>
<td>0.041462</td>
<td>0.001</td>
<td>-0.7570334 -0.5139275</td>
</tr>
<tr>
<td>S3</td>
<td>-1.3655943(*)</td>
<td>0.074180</td>
<td>0.001</td>
<td>-1.5831361 -1.1480525</td>
</tr>
<tr>
<td>S4</td>
<td>-0.8354805(*)</td>
<td>0.041462</td>
<td>0.001</td>
<td>-0.7570334 -0.5139275</td>
</tr>
</tbody>
</table>

* indicates statistical significance

Fig. 3
Set up for stiffness experiments loading a two-pin anchor axially and radially.
The stiffness values of the anchors are presented as a magnitude relative to the stiffness of the standard anchoring screw (P), with a thread length of 50 mm and a diameter of 4 mm (Table III).

The multivariate analysis of variance showed highly significant effects on fixation type ($p = 0.001$), leg ($p = 0.001$), fixation area ($p = 0.001$) and leg movement ($p = 0.001$). In addition to $p$ values, the partial eta-squared value, expressing the strength of the effect, was computed. With regard to displacement, the effect of the leg and leg movement is stronger than the effect of the pin. Concerning deflection, the effect of the leg is as strong as the effect of the pin. The adjusted R-square shows that 38.3% of the variance of displacement, a dependent variable, and 60.2% of deflection were explained by independent variables in this model. The accuracy of fit of the model was significant at 99% ($p = 0.001$).

**Discussion**

For the navigation of implants in THA, rigid bodies have to be fixed to the bones.\(^1\) Regardless of the localisation principle of the tracking system, the fixation must be stable in order to ensure accurate detection of the position of the bone. For navigation of the acetabular cup, the marker must be attached to the pelvis. The most prominent and easily detectable bony landmark in the pelvis is the anterior superior iliac spine. Attachments here are affected neither by movements of the pelvis nor by muscular tension, as the pelvis usually remains relatively static during THA when the patient is supine.\(^5\,6\)

For navigation of the stem in THA or of the femoral component in TKA, particularly in minimally-invasive approaches, the marker must be placed percutaneously. Depending on the procedure, a variety of locations may be used for femoral markers depending mainly on the planned implant (knee or hip), with which it should not interfere, and on the position of the patient. With the patient in the supine position as for anterolateral approaches to the hip and the knee, straight fixation devices are usually placed...
ventrally in order to render them visible to the camera system. Lateral fixation is advantageous for patients in the lateral decubitus position, as in the posterior approach to the hip. Usually the distal area on the anterior aspect of the femur is given preference. Our study was designed to evaluate different fixation devices and locations. The data show that markers are more stable when fixed laterally than when anterior or medial, regardless of the fixation device used (Fig. 5). Thus, lateral fixation is desirable even when the patient is supine. Depending on the navigation system in use, placing the marker in a lateral position visible to the camera might require some modification to the system.

Rotational stability is essential for a tracking device. In the case of the Stryker bi-cortical screw, protection against rotation is achieved by a claw which engages into the cortex of the bone. Insertion of this screw requires a larger skin incision. All the other devices can be implanted through stab incisions and rotational stability is achieved by coupling two pins with a clamp. We used fresh cadavers to compare the stability of different anchoring options but even in a non-fixed cadaver, the muscle quality is not identical to living tissue. Dead muscles tend to be stiffer and tear more easily which might have produced higher induced forces on the fixation devices from the soft tissues. Thus, this experimental setting depicts the behaviour of marker fixation under maximal strain.

The best site for placement of the markers was the lateral third of the distal femur where all the anchoring systems showed little deflection. This may be because the muscle tension produced by the quadriceps on the ventral side is higher than that by the tensor fascia lata on the lateral side. Muscular tension results in deflection of the anchor, which is less for the mechanically superior two-pin device. The mechanical superiority of two-pin systems could be demonstrated by the stiffness measurements shown in Table I, where the force needed for deflection of any of the two-pin systems was substantially higher than that for the single standard screw.

In the figure-of-four position, which was used for orientation of the stem during broaching and implantation, all fixation options showed the highest deflection. This indicates that the highest forces are produced with the knee in flexion and with the hip in maximal external rotation and simultaneous extension. The deflection of the anchoring pins was much lower in all other positions of the leg. The figure-of-four position is unsuitable for marker fixation. In navigated THA the femur is exposed. The femoral preparation and insertion of the stem are performed under direct navigational assistance, thus obviating the need to hold the leg in the figure-of-four position. The anchoring systems with two connected pins, with the exception of 3 mm Apex pins, proved to be more stable than single screw fixation with a rotational stabiliser and their introduction is less invasive than with the anchoring pin with rotational protection.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References