Aesculap Orthopaedics
Clinical Evidence for OrthoPilot® THA Navigation
## Clinical Evidence for OrthoPilot® THA Navigation

<table>
<thead>
<tr>
<th>Content</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rationale</td>
<td>3</td>
</tr>
<tr>
<td><strong>Clinical Evidence</strong></td>
<td>4</td>
</tr>
<tr>
<td>1) Basic Information</td>
<td>4</td>
</tr>
<tr>
<td>2) Literature Overview</td>
<td>6</td>
</tr>
<tr>
<td>3) Leg Length</td>
<td>7</td>
</tr>
<tr>
<td>4) Learning Curve</td>
<td>8</td>
</tr>
<tr>
<td>5) Clinical and Functional Outcome</td>
<td>8</td>
</tr>
<tr>
<td>6) Meta-Analyses</td>
<td>9</td>
</tr>
<tr>
<td>7) Other Endpoints</td>
<td>9</td>
</tr>
<tr>
<td><strong>Key Messages</strong></td>
<td>16</td>
</tr>
<tr>
<td><strong>Abstracts</strong></td>
<td>18</td>
</tr>
<tr>
<td><strong>References</strong></td>
<td>26</td>
</tr>
</tbody>
</table>
Rationale

Total hip and knee arthroplasty belong to the most frequent orthopedic interventions. The number of joint reconstructions is steadily increasing and joint replacement is indicated in more and more younger patients. For these patients functional results and long-term stability is essential, revision surgery has to be avoided as long as possible to keep up quality of life. It has been proven in a number of studies that the alignment of prosthesis components within a certain range reduces the number of early component loosening in total knee arthroplasty (TKA) as well as in total hip arthroplasty (THA). With manual techniques 80 % of implants are inserted within this safe zone in TKA according Jeffery (1) and in only 25 % of cups in THA according to Lewinnek (2).

To achieve reproducible results and thus, to improve precision, navigation systems have been introduced in the late 1990s into clinical practice. As a result of reduced malalignment it was assumed, to improve functional outcome in conventional open as well as minimal-invasive surgical techniques. Thus, these systems aim to ensure maximum possible longevity of the implant components.

From the beginning, when in 1994 first experiments on kinematic navigation started at the University of Grenoble, OrthoPilot® was designed as CT-free, kinematic navigation system for orthopedic surgery. All necessary bony, patient individual landmarks are palpated intraoperatively. In addition, the center of hip, knee and ankle joint can be determined through kinematic movements.

After the success of orthopedic navigation in total knee arthroplasty, an application for the navigation of hip cups has been developed. The navigation applications for stem navigation followed.

The OrthoPilot® THA software enables the surgeon to restore the function of the hip joint in respect to stability and a high range of motion. The intra-op assessment of the three-dimensional cup orientation is difficult in the freehand technique, navigation helps to insert the cup in the correct angles. Furthermore a correct leg length and offset can be achieved. An increased longevity of the implants can be obtained by inserting the cup within the `safe zone` according to Lewinnek (2) and by positioning the stem in relation to the cup orientation.

The cup application of the OrthoPilot® navigation system has been used since 2001 and was completed with the stem application in 2005 (3). Both are standard procedures in the meantime.

OrthoPilot® is an advanced and frequently used kinematic navigation system: A pioneer from the early beginning.
Clinical Evidence

All orthopedic navigation applications have the aim to reach the best possible placement of the implant components with the help of anatomic landmarks.

1) Basic Information

As soon as 1978 Lewinnek et al. (2) have assumed that there is a safe zone for cup positioning in THA as well as for knee positioning in TKA. The authors studied a population of 300 cases and found a correlation between deviation from the average angles of anteversion as well as inclination and dislocation of the implant. They found that inclination of 40°±10° and anteversion of 15°±10° proved as appropriate limits. The three-dimensional intra-operative positioning of the angles is difficult, thus the ranges are relatively wide. The authors conclude that only 1.5 % of the patients have an event of dislocation if the cup is implanted within the safe zones compared to 6.1 % of dislocation if the safe zone was not met. The majority of publications on computer aided hip replacement refer to the safe zone defined by Lewinnek (2).

A literature research on the EMBASE Database has been performed on February the 2nd, 2012 (Table 1) with a combination of terms to find relevant publications of clinical studies on computer-assisted surgery with the Aesculap navigation system OrthoPilot®. Meta-Analyses and Systematic Reviews on the subject of computer-assisted Total Hip Arthroplasty not within in the results, were added. After review of titles and abstracts some publications had to be excluded due to irrelevant endpoints (Figure 1).
<table>
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<td>#11</td>
<td>aesculap:df,ab,ti</td>
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<td>#10</td>
<td>#9 AND ('clinical trial'/exp OR 'clinical trial' OR 'controlled clinical trial'/exp OR 'controlled clinical trial' OR 'controlled study'/exp OR 'controlled study' OR 'meta analysis'/exp OR 'meta analysis' OR 'randomized controlled trial'/exp OR 'randomized controlled trial')</td>
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<td>#3</td>
<td>Navigation</td>
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<td>#2</td>
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<tr>
<td>#1</td>
<td>'computer assisted' AND surger*</td>
<td>245320</td>
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Table 1: Search Strategy Computer Assisted Surgery + THA
2) Literature Overview

16 publications were found with the searching strategy described above (Table 1). Studies were excluded that used CAS (computer assisted surgery) but only describe the techniques without reporting clinical results (n=3) or that described other measurements within computer assisted implantation of THA e.g. palpation methods (n=1).

Accuracy of implantation is the key issue for navigation of hip cups and stems, therefore 9 of the remaining 12 publications focus on inclination and anteversion angles of navigated cups which is the clear majority of the studies. Anyway, the studies are not perfectly well comparable as the control varies in the studies: only in three studies navigated cups are compared to conventionally implanted cups (4-6).

The precision of navigated THA implantation has been studied by Honl et al. (7) in 2006: the authors evaluated the precision of cup orientation during implantation ‘in-vitro’ using different navigation systems and compared it to the manual technique. 90 identical specimen of an acetabulum were manufactured. Three surgeons performed five interventions with five different navigation systems and five manual implantations. Afterwards the authors measured the precision of the alignment of the inserted cups. They concluded that the implantation method did influence the surgeries’ results for both, inclination and anteversion, significantly.

By the use of any of the five navigation systems the variation of anteversion and inclination was significantly lower compared to the manual technique.

This study was not within the results of the literature research as it is rather an ‘in-vitro’ examination than a clinical study.
Five studies in the results of the literature research evaluate the reliability of the navigated angles by comparing the anteversion and inclination achieved intraoperatively to postoperative radiographs or CT-scans, respectively (3;8-11). The authors’ conclusions vary: Jenny et al. are convinced that using a navigation system improves accuracy: they achieved 87 % and 79 % of the inclination and anteversion angles within the safe zone according to Lewinnek (9), respectively. In two studies the use of navigation for THA is called ‘encouraging’ and ‘the validity of the navigation system confirmed’ (3;10); in two cases with special operative techniques (minimally invasive and ‘flip technique’, respectively) the use of navigation system is called ‘unreliable’ (8;11).

The use of navigation for patients with higher risks such as obesity or severe dysplasia is evaluated in one study (12), showing that the error in anteversion is significantly increasing in obese patients, the error in inclination is not significantly different compared with ‘normal’ cases. No significant differences were reported for cases with severe dysplasia, neither in anteversion nor inclination.

There is a tendency for more accurate cup orientation with THA-navigation, but for the reason of the wide ranges and difficult measurements the differences to conventional implantation is not as obvious as for TKA.

3) Leg Length

Only two publications deal with the subject of leg length discrepancy, having stem navigation as a focus (13;14). In another study leg length is reported additionally to cup orientation (3). Leg length discrepancy is an issue with hip replacement and it is assumed that with the use of a navigation system less discrepancy and/or better correction of the leg length is achieved. Nishio et al. show in their study that a new generation of OrthoPilot® stem navigation provides better results concerning leg length than the previous one, showing the evolution of the system (14). Confalonieri et al. have shown that computer assisted surgery has an influence on the selection of implant components. The authors observed a greater variability in the femoral necks used to ensure an optimized functional result. In this study they describe the advantages of the combination of a modular hip replacement system with navigation to achieve correct limb length and femoral offset (13).
Clinical Evidence

4) Learning Curve

One study focuses on the learning curve in the use of navigated THA (15), the inclination and anteversion of the navigated cups measured by OrthoPilot® intraoperatively and measured on radiographs postoperatively for the first 30 cases of a surgeon are compared to another 30 cases of the same surgeon, operated later. The study shows that the difference between intraoperative and postoperative orientation differs significantly within the first 30 cases. After the learning curve there is no statistically significant difference between intra- and postoperative angles, the postoperative cup-orientation corresponds to the measures of the navigation system. Thorey et al. (15) give five popular reasons for surgeons not to use computer navigation in THA, besides the financial and technical effort to have a navigation system available and the assumed prolongation of operative time, it is the need for a learning curve and the belief that conventional implanted cups are adequately positioned.

The authors did not evaluate the accuracy of the implantation, but only the mean and standard deviations. On the box plot in their publication, it is obvious that
- inclination angles measured by OrthoPilot® are within a much narrower range than radiographically measured – for CAS-beginners as well as for CAS-experienced surgeons. This might be due to the fact that measurement of inclination on standard radiographs is rather imprecise.
- anteversion angles, contrarily, show a narrower box and shorter whiskers for radiographic analysis in both the beginners and the experienced group. It could be assumed, that anteversion is easier to achieve without navigation system, but is not influenced negatively by it.

5) Clinical and Functional Outcome

Within the results of the literature research no studies were found that reported on functional or clinical results. In none of the studies a score was evaluated.
6) Meta-Analyses

Two meta-analyses are available on the topic of navigation in THA. These two haven’t been found with the search strategy as it is limited to studies with ‘Aesculap’ or ‘OrthoPilot’ mentioned.

Gandhi (16) identified three existing publications of randomized controlled trials, covering 250 cases, and summarized them in a meta-analyses in 2008. One of the studies compared manual and imageless navigated cases, one compared manual and CT-based navigated cases and one study compared all three techniques. For the meta-analysis all navigated cases were included in one ‘navigation’ group regardless of imageless and CT-based navigation and compared with manually operated cases. The authors found outliers according to Lewinnek (2) in cup positioning in approximately 10% in the navigation group and about 40% in the conventional group. The limitation of the review is addressed by the authors, as a very small number of studies and no longterm follow-up being included. Therefore no conclusion on the clinical effect and the subsequent cost-reduction of necessary reoperations in the long term can be drawn from these data. The authors conclude that there is a further need for well-designed RCTs with survival rates, longterm follow-up, quality of life- and cost-analysis.

Another meta-analysis has been published in 2009 by Beckmann (17) including 5 RCTs – the three reported by Gandhi (16) and two additional RCTs, increasing the number of patients observed to 400. Corresponding to the results in total knee arthroplasty and to the former meta-analysis it was found that the risk of cup positioning outside the defined safe zone is significantly decreased by 37% in the navigation group.

The conclusion of the two Meta-Analyses, reporting on the same clinical trials is, that a more precise alignment can be achieved with a navigation system and that there is no difference in precision between image-based and imageless navigation systems.

7) Other Endpoints

OP-Duration

Only a few of the publications that we retrieved in the literature research report also the surgery time, concluding that operation is more time consuming with navigation, but the additional time is justified by the better results in alignment. The extension of OP-duration is minimized to an acceptable amount after the surgeon learned to handle the navigation system. The additional time needed for the first navigated hip procedures (30 cases) of $13.2 \pm 5.2$ minutes is decreased to $4.8 \pm 3.8$ minutes afterwards (15).
# Clinical Evidence

<table>
<thead>
<tr>
<th>No.</th>
<th>Titel</th>
<th>Year</th>
<th>Author</th>
<th>Aim of Study</th>
<th>Study Control N°of Cases</th>
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</thead>
<tbody>
<tr>
<td>8</td>
<td>Reliability of cup position in navigated THA in the lateral decubitus position using the ‘flip technique’</td>
<td>2011</td>
<td>Carcangiu A</td>
<td>Reliability of imageless navigation in acetabular positioning employing data acquisition in the supine position and surgery in the lateral position (‘flip technique’)</td>
<td>CAS [N=24]</td>
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<tr>
<td>14</td>
<td>Adjustment of leg length using imageless navigation THA software without a femoral tracker</td>
<td>2011</td>
<td>Nishio S</td>
<td>In this study, the accuracy and reliability of this newly developed system were evaluated in 50 consecutive primary THAs implanted using the OrthoPilot® THAplus and compared with the results of another 50 patients who underwent primary THAs using the previous software not equipped with the leg length adjustment system</td>
<td>THAplus CAS [N=50]</td>
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<td>THA CAS [N=50]</td>
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<td>12</td>
<td>Decreased accuracy of acetabular cup placement for imageless navigation in obese patients</td>
<td>2010</td>
<td>Tsukada S</td>
<td>The aims of this study were to calculate placement precision of imageless navigation for THA in the supine position and to evaluate placement precision in obese patients and in patients with acetabular dysplasia</td>
<td>Obese [N=15 joints]</td>
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<td></td>
<td>Non-Obese [N=54 joints]</td>
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<td>Dysplasia [N=56 joints]</td>
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<td></td>
<td></td>
<td></td>
<td>Non-Dysplasia [N=13 joints]</td>
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<tr>
<td>15</td>
<td>Cup positioning in primary total hip arthroplasty using an imageless navigation device: is there a learning curve?</td>
<td>2009</td>
<td>Thorey F</td>
<td>Analysis of the learning curve of imageless computer navigation in THA regarding the intraoperative cup positioning achieved by CAS compared with postoperative results as seen on radiograph study</td>
<td>Learning Period [N=30]</td>
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<td>After Learning Period</td>
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<td>[N=30]</td>
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<td>Outcome</td>
<td>Study Type</td>
<td>Duration of Follow-Up</td>
<td>Statistical Relevance</td>
<td>Author's Conclusion</td>
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<tr>
<td>Inclination + anteversion (comparison: intraop vs. CT postop)</td>
<td>case-series</td>
<td>3 months</td>
<td>Inclination: 41.5° SD 9.61° OrthoPilot® 44.2° SD 5.83° CT (p &gt; 0.05) Anteversion: 9.5° SD 4.01° OrthoPilot® 14.4° SD 6.42° CT (p = 0.04)</td>
<td>‘Acquisition of parameters in the supine position with surgery performed in the lateral decubitus position creates unreliable data concerning cup anteversion using an imageless navigation system, and therefore the ‘flip technique’ cannot be recommended’</td>
<td></td>
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<tr>
<td>Leg Length in two generations of navigation systems</td>
<td>case-control study with retrospective control</td>
<td>postop</td>
<td>postop: absolute: 2.0 mm [0;5] THAplus 6.2 mm [0;20] THA p &lt; 0.05 Average: 0.9 mm [-5;+5] THAplus 2.9 mm [-13;20] THA ±5 mm Discrepancy: 100 % THAplus 48 % THA; no statistical values given, only stated: significant difference with absolute leg length discrepancy</td>
<td>‘Comparison of the surgical results as compared with the control group performed with the conventional navigation system showed the advantage of this system over the previous one.’</td>
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<tr>
<td>Inclination + anteversion (obese vs. non-obese and dysplasia vs. non-dysplasia)</td>
<td>retrospective analysis of consecutive series</td>
<td>postop</td>
<td>Inclination error: 2.7°±2.3° obese 2.3°±1.6° non-obese p = 0.75 2.1°±2.4° dysplasia 2.4°±2.4° non-dysplasia p = 0.58 Anteversion error: 4.8°±2.5° obese 3.2°±2.6° non-obese p = 0.01 3.9°±3.3° dysplasia 3.5°±3.2° non-dysplasia p = 0.66</td>
<td>‘Imageless navigation can be performed with an error of 3°–4° at the anterior pelvic plane. However, the accuracy of cup anteversion was found to decrease in obese patients.’</td>
<td></td>
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<tr>
<td>Inclination + anteversion (learning vs. experienced)</td>
<td>case-control study</td>
<td>postop</td>
<td>Inclination: 43.7°±4.2° learning intraop 47.3°±6.5° learning postop p &lt; 0.05 46.5°±3.7° experienced intraop 48.7°±6.6° experienced postop p = 0.12 Anteversion: 15.1°±5.7° learning intraop 20.9°±3.1° learning postop p &lt; 0.05 18.6°±9.7° experienced intraop 20.8°±5.8° experienced postop p = 0.31</td>
<td>‘Imageless navigation is a dependable and accurate method of cup positioning during THA... ..., accuracy of cup placement and length of operating room time were affected by the surgeons experience using the system.’</td>
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<tr>
<td>No.</td>
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<td>Year</td>
<td>Author</td>
<td>Aim of Study</td>
<td>Study Control N° of Cases</td>
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<td>(9)</td>
<td>Navigated non-image-based positioning of the acetabulum during total hip replacement</td>
<td>2009</td>
<td>Jenny J-Y</td>
<td>We tested the hypothesis that the non-image-based navigation system used in our department was able to measure accurately the 3D positioning of the acetabular cup of a THR and to increase the accuracy of its implantation during THR</td>
<td>CAS [N=48]</td>
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<td>(13)</td>
<td>Leg length discrepancy, dislocation rate, and offset in total hip replacement using a short modular stem: navigation vs. conventional freehand</td>
<td>2008</td>
<td>Confalonieri N</td>
<td>We hypothesized that computer-assisted THA achieves a better joint reconstruction with effective control over leg length discrepancy</td>
<td>CAS [N=22] CON [N=22]</td>
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<td>(10)</td>
<td>Assessment of accuracy of acetabular cup orientation in CT-free navigated total hip arthroplasty</td>
<td>2008</td>
<td>Fukunishi S</td>
<td>Intraoperative cup orientation as presented by the OrthoPilot® navigation system was compared with the value obtained through postoperative radiological assessment</td>
<td>CAS [N=27]</td>
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<td>(4)</td>
<td>Navigation of short-stem implants</td>
<td>2006</td>
<td>Lazovic D</td>
<td>Primary stability, ease of minimal invasive implantation, and restoration of the biomechanics were evaluated</td>
<td>CAS [N=28] CON [N=27]</td>
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<td>Outcome</td>
<td>Study Type</td>
<td>Duration of Follow-Up</td>
<td>Statistical Relevance</td>
<td>Author's Conclusion</td>
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</table>
| Inclination and anteversion (OrthoPilot® vs. CT) + rate within safe zone | consecutive series    | postop                | Inclination: 42°±4° [35;49] CAS 44°±5° [30;57] CT 42 of 48 cases (87 %) within safe zone  
Anteversion (Flexion): 15°±3° [6;22] CAS 19°±7° [2;32] CT 38 of 48 cases (79 %) within safe zone | 'The non-image-based system used in our department allowed us to define more accurately the intra-operative positioning of the acetabular cup of THR in comparison to the computed tomography reference measurement. Inclination measurements were more accurate than anteversion measurements. A high percentage of cups were implanted in the safe zone defined prior to the study.' |
| Surgical time, leg length discrepancy                                  | matched, control pairs retrospective | CAS: 10.8 months CON: 11.6 months | Surgical time: 102.5 min ±12.2 min CAS 87.7 min ±11.7 min CON p = 0.0001  
Leg length discrepancy: 4.1 mm ±1.7 mm CAS 7.9 mm ±2.8 mm CON p > 0.0001 | '...show that using CAS in THA with modular short stem femoral components can enhance the ability to correct limb length discrepancy and to restore the original femoral offset.' |
| Inclination + anteversion (navigation system vs. radiographs)          | consecutive series    | postop                | Inclination: 43.5°±2.17° [39.9;46.6] CAS 44.9°±3.3° [38.1;55.0] radiograph 26 of 27 (96 %) within ±5°  
Anteversion: 11.1°±5.6° [0;17.8] CAS 13.5°±5.9° [5.1;21.6] radiograph 26 of 27 (96 %) within ±5° | 'A good agreement between the intraoperative values presented by the navigation system and those in the postoperative CT evaluation was observed, and the validity of this navigation system was confirmed.' |
| Inclination + anteversion (CAS vs. CON)                                | case-series           | 6 months              | Inclination: 45.3° CAS 45.0° CON  
Anteversion: 16.8° CAS 19.7° CON | 'In this experience, navigated short stem prosthesis offered good intraoperative handling and good preliminary results.' |
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<th>Study Control N’of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>(11)</td>
<td>Our experience with an image guided navigation system for accurate alignment in total hip replacement by minimally invasive posterolateral surgery</td>
<td>2006</td>
<td>Stipcak V</td>
<td>The aim of the study was to compare a radiographic position of the acetabular component with a position guided by the navigation system in final acetabular cup alignment</td>
<td>CAS [N=15]</td>
</tr>
<tr>
<td>(5)</td>
<td>Optimization of cup positioning in THA – Comparison between conventional mechanical instrumentation and computer-assisted implanted cups by using the OrthoPilot® navigation system</td>
<td>2005</td>
<td>Ottersbach A</td>
<td>The goal of the study is to determine the accuracy of free-hand and computer assisted cup replacement</td>
<td>CAS [N=50] CON [N=50]</td>
</tr>
<tr>
<td>(3)</td>
<td>OrthoPilot® total hip arthroplasty workflow and surgery</td>
<td>2005</td>
<td>Kiefer H</td>
<td>To analyze the workflow and navigation principles of the OrthoPilot® THA ..., a consecutive series of 60 patients was used to compare the navigated intraoperative data and postoperative measurements of stem and cup position</td>
<td>CAS [N=54]</td>
</tr>
<tr>
<td>(6)</td>
<td>Implantation of a non-cemented acetabulum with the use of a navigation system</td>
<td>2004</td>
<td>Stipcak V</td>
<td>To compare, on the basis of clinical and radiographic findings, the results of non-cemented acetabulum implantation involving the use of a CT-free navigation system with those of implantation without its use</td>
<td>CAS [N=25] CON [N=25]</td>
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Table 2: Tabular View of Publications
<table>
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<tr>
<th>Outcome</th>
<th>Study Type</th>
<th>Duration of Follow-Up</th>
<th>Statistical Relevance</th>
<th>Author's Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclination + anteversion (navigation system vs. radiographs)</td>
<td>case-series</td>
<td>postop</td>
<td>Inclination: 41.8° [35;51] CAS radiograph 27.8° [22;35] CAS navigation system Anteversion: 19.8° [5;32] CAS radiograph 24.3° [17;28] CAS navigation system</td>
<td>‘Because the data recorded by the system used in our study were not accurate, we do not consider the OrthoPilot® navigation system to be an effective aid in minimally invasive posterolateral surgery.’</td>
</tr>
<tr>
<td>Inclination + anteversion (CAS vs. CON) absolute and rate</td>
<td>randomized controlled trial</td>
<td>postop</td>
<td>Inclination: 40.1°±5.0° CAS 40.3°±7.4° CON Anteversion: 16.3°±2.8° CAS 16.0°±6.9° CON Inclination rate: 92 % CAS vs. 68 % CON Anteversion rate: 100 % CAS 78 % CON</td>
<td>‘In Conclusion a higher precision of Cup Positioning is assumed for CT-based as well as kinematic navigation systems.’</td>
</tr>
<tr>
<td>Inclination + anteversion (only CAS) navigation system vs. radiographs</td>
<td>consecutive case-series</td>
<td>discharge</td>
<td>Inclination 42.5°±7.5° AND Anteversion 12.5°±7.5°: 91 %; Safe Zone acc. to Lewinnek: 96.3 %; leg length discrepancy: 46 (85 %) within ±5 mm</td>
<td>‘...the results encourage the authors to continue to use this technology for THA.’</td>
</tr>
<tr>
<td>Inclination + anteversion (CAS vs. CON)</td>
<td>randomized controlled trial</td>
<td>postop</td>
<td>Inclination: 43.0° [32;55] CAS 50.6° [38;62] CON Difference of inclination p &lt; 0.05 Anteversion: 10.4° [8;16] CAS 9.4° [3;18] Accuracy of anteversion p &lt; 0.05</td>
<td>‘A comparison of the groups showed that the computer-assisted navigation system used in implantation resulted in an optimal position of the acetabular component’</td>
</tr>
</tbody>
</table>
Key Messages

- Computer assisted surgery is a reliable tool for optimization of cup placement in THA. (15, 17, 18)

- The number of outliers of cup alignment can be significantly reduced by using OrthoPilot® imageless hip navigation. With computer navigation the number of outliers beyond the so-called 'safe-zone' is reduced. (5, 16, 17)

- Intraoperative measurements of cup position with the OrthoPilot® are well correlated to measurements in postoperative CT scans. (10)

- The ability to correct limb length discrepancy and to restore the original femoral offset is enhanced by OrthoPilot® computer assisted surgery (with short stem femoral components). (13, 19)
Carcangiu A, D’Arrigo C, Topa D, Alonzo R, Speranza A, de Sanctis S, Ferretti A.

Reliability of cup position in navigated THA in the lateral decubitus position using the ‘flip technique’.

Hip Int. 2011 Nov-Dec;21(6):700-5.

Malpositioning of the acetabular component in total hip arthroplasty (THA) increases the risk of dislocation, reduces the range of motion and may contribute to bearing surface wear. During computer assisted navigation, the anterior pelvic plane is registered intraoperatively by percutaneous palpation, but this may be unreliable. The aim of our study was to evaluate the reliability of imageless navigation in acetabular positioning employing data acquisition in the supine position and surgery in the lateral position (‘flip technique’). We report 24 patients affected by primary osteoarthritis undergoing THA in which implants were placed with a conventional free-hand technique using the acetabular transverse ligament for cup orientation. For imageless navigation we used OrthoPilot®-Aesculap software. All patients had a postoperative computed tomography (CT) scan at three months, using previously validated dedicated software for cup orientation. Data collected using navigation software were compared with CT measurements. The mean acetabular inclination and anteversion recorded intraoperatively using navigation software were 41 (degrees) 5’ (SD: 9.61) and 9 (degrees) 5’ (SD: 4.01) respectively. The mean inclination and anteversion calculated post-operatively by the CT based image software were 44 (degrees) 2’ (SD 5.83) and 14 (degrees) 4’ (SD 6.42) respectively. There was a statistically significant difference between the anteversion values (p = 0.04). Therefore, the acquisition of parameters in the supine position with surgery performed in the lateral decubitus position creates unreliable data concerning cup anteversion using an imageless navigation system, and therefore the ‘flip technique’ cannot be recommended. (copyright) 2011 Wichtig Editore.
Nishio S, Fukunishi S, Fukui T, Fujihara Y, Yoshiya S.

Adjustment of leg length using imageless navigation THA software without a femoral tracker.


**BACKGROUND:** Adjustment of leg length discrepancy is an important factor influencing the outcome of total hip arthroplasty (THA). However, leg length discrepancy after THA has been reported to be associated with inferior clinical outcome in previous studies. A new version of the imageless navigation software ‘OrthoPilot® THAplus’ has been developed to assess the leg length adjustment and offset value. The clear advantage of this system is the elimination of the need for femoral pin insertion, which is associated with potential complications and additional surgical invasion.

**METHODS:** In this study, the accuracy of this newly developed system was evaluated in 50 consecutive hips implanted with primary THA. The operative results of these 50 patients were compared with those of another 50 consecutive primary THA patients operated on with the previous navigation system that was not equipped with the leg length adjustment system.

**RESULTS:** After surgery, the average leg length discrepancy in the THAplus group was 0.9 mm (range -5 to 5 mm), while the corresponding value in the other group with the older software was 2.9 mm (range -13 to 20 mm), showing a significant difference.

**CONCLUSION:** The accuracy and reproducibility of new software added to the imageless THA navigation system in achieving equalization of leg length were assessed. Comparison of the surgical results as compared with the control group performed with the conventional navigation system showed the advantage of this system over the previous system. (copyright) The Japanese Orthopaedic Association 2011.

Tsukada S, Wakui M.

Decreased accuracy of acetabular cup placement for imageless navigation in obese patients.


**BACKGROUND:** Optimal acetabular cup position is an important determinant of the success of total hip arthroplasty (THA), and navigation systems have been developed and applied to improve placement precision. However, the registration method touching bony landmarks through soft tissues may decrease the accuracy in obese cases and in patients with acetabular dysplasia.

**METHODS:** Placement accuracy in 69 joints in which THA was performed with imageless navigation was calculated by comparing the placement angle in the anterior pelvic plane and the placement angle in the X-ray table plane with the patient in the supine position. We defined the difference between the placement angle in the anterior pelvic plane and the angle displayed on the navigation screen as the error and the difference between the placement angle in the plane of the X-ray table and the target angle of acetabular component position as the difference in target angle. Patients were divided into obese (BMI ≥ 25) and nonobese (BMI < 25) groups and into acetabular dysplasia and nondysplasia groups.

**RESULTS:** The mean (plus or minus) SD navigation errors for all cases were 2.4 (degrees) (plus or minus) 2.0 (degrees) for inclination and 3.7 (degrees) (plus or minus) 2.3 (degrees) for anteversion. The mean difference in target angle for all cases was 2.8 (degrees) (plus or minus) 2.5 (degrees) for inclination and 4.2 (degrees) (plus or minus) 3.0 (degrees) for anteversion. The error in anteversion was significantly higher in the obese group (4.8 (degrees) (plus or minus) 2.5 (degrees)) than in the nonobese group (3.2 (degrees) (plus or minus) 2.6 (degrees)) (p = 0.01). No significant difference was observed between the acetabular dysplasia and nondysplasia groups.

**CONCLUSION:** Imageless navigation can be performed with an error of approximately 3 (degrees) at the anterior pelvic plane. However, accuracy was found to decrease in obese cases. (copyright) 2010 The Japanese Orthopaedic Association.
Cup positioning in primary total hip arthroplasty using an imageless navigation device: is there a learning curve?


In this study, the success of cup positioning in total hip arthroplasty (THA) using an imageless navigation system was analyzed (1) during the learning period and (2) after the learning period for using the navigation system. Sixty THAs were performed in which threaded cups were placed with use of a computer-assisted navigation device (B. Braun Aesculap, Tuttlingen, Germany). Half of the procedures (30), group A, were done by the same surgeons under the learning curve for using the navigation system; the other half (30), group B, were done by surgeons who were no longer considered under the learning curve. Intraoperative acetabular component parameters (inclination, anteversion) for both groups were compared with postoperative radiographic alignment values. In group A, significant differences were seen between intraoperative and postoperative cup orientation. In group B, no significant differences were seen between intraoperative and postoperative cup orientation. Additionally, the percentage of outliers decreased in group B. Operating and anesthesia times significantly decreased with the surgeon’s experience in imageless cup navigation. There was an individual increase of precision during the learning curve for all surgeons. Imageless navigation is a dependable and accurate method of cup positioning during THA. However, accuracy of cup placement and length of operating room time were affected by surgeons’ experience using the system. Imageless navigation may lead to a reduction in the length of the learning curve for surgeons beginning to perform THAs, improvement in the surgeon’s ability to perform this procedure safely, and minimization of outliers. (copyright) 2009, SLACK Incorporated.
Jenny JY, Boeri C, Dosch JC, Uscau M, Ciobanu E.

Navigated non-image-based positioning of the acetabulum during total hip replacement.


We tested the hypothesis that the non-image-based navigation system used in our department was able to measure accurately the 3D positioning of the acetabular cup of a total hip replacement (THR) and to increase the accuracy of its implantation during THR. We studied 50 consecutive navigated implantations of a THR and compared the intra-operative measurement of the cup by the navigation system to the post-operative measurement by computed tomography (CT) scan. The mean difference between the navigated and CT scan measurements for cup inclination was 2 (degrees). The mean difference between the navigated and CT-scan measurements for cup flexion was 4 (degrees). These differences were significant but considered to be clinically irrelevant in most cases. A total of 73 % of the cases were within the safe zone defined prior to the study. The non-image-based system used allows a precise orientation of the cup during THR. (copyright) 2007 Springer-Verlag.

Confalonieri N, Manzotti A, Montironi F, Pullen C.

Leg length discrepancy, dislocation rate, and offset in total hip replacement using a short modular stem: navigation vs conventional freehand.

*Orthopedics. 2008 Oct;31(10 Suppl 1).*

We present a match-paired study between computer-assisted and freehand techniques using a short modular femoral stem (Metha®; B. Braun Aesculap, Tuttingen, Germany) in total hip replacement (THR). Surgical time, clinical outcome, dislocation rate, limb length, and offset in 44 patients with ideal indication for this more conservative implant were assessed. Despite both longer surgical time and similar early outcomes, the results showed how computer-assisted techniques allow easier management of limb length discrepancy and offset restoring. We believe that navigated short modular stems are safe for less invasive THR.
Fukunishi S, Fukui T, Imamura F, Nishio S.

Assessment of accuracy of acetabular cup orientation in CT-free navigated total hip arthroplasty.

Orthopedics. 2008 Oct;31(10).

We have used the OrthoPilot® (Aesculap AG, Tuttingen, Germany) computed tomography (CT)-free navigation system to ensure accurate and reproducible acetabular cup orientation. In this system, cup orientation is assessed with respect to bony configuration as determined by palpation of the anatomical landmarks (the bilateral anterosuperior iliac spines and the upper margin of the pubic symphysis). In this study, intraoperative cup orientation as presented by the OrthoPilot® navigation system was compared with the value obtained through postoperative radiological assessment using CT Digital Imaging and Communications in Medicine (DICOM) data and Medical Imaging, Analysis, and Visualization (MIPAV; National Institutes of Health, US Department of Health and Human Services, Bethesda, Maryland). Intra- and postoperative results obtained from 27 consecutive navigated total hip arthroplasties (THAs) were analyzed. For cup positioning, the desired inclination and anteversion angles were set within the ‘safe zone’ proposed by Lewinnek. In the intraoperative evaluation, the mean inclination angle as determined by the navigation system was 43.5 degrees ±2.17 degrees (range, 39.9 degrees to 46.6 degrees) after the final implantation. In contrast, the mean inclination angle determined by postoperative calculation using MIPAV was 44.9 ±3.3 degrees (range, 38.1 degrees to 55.0 degrees). A discrepancy of > 5 degrees was observed in only 1 hip. For the anteversion, the mean intra- and postoperative values were 11.1 degrees ±5.6 degrees (range, 0 degrees to 17.8 degrees) and 13.5 degrees ±5.9 degrees (range, 5.1 degrees to 21.6 degrees), respectively. Again, a discrepancy of > 5 degrees was observed in 1 case. Mean differences between the intra- and postoperative values were 1.9 degrees ±1.9 degrees and 2.6 degrees ±1.6 degrees for inclination and anteversion, respectively. A good agreement between the intraoperative values presented by the navigation system and those in the postoperative CT evaluation was observed, and the validity of this navigation system was confirmed.
**Lazovic D, Zigan R.**

*Navigation of short-stem implants.*


Short-stem prostheses with modular necks were implanted using a modified Watson-Jones approach in 55 cases from November 2004 to May 2006. Twenty-eight cases were navigated using the OrthoPilot® navigation system (B. Braun Aesculap, Tuttlingen, Germany). Primary stability, ease of minimal invasive implantation, and restoration of the biomechanics were evaluated. Short-term result showed a good functional outcome and a low complication rate without any dislocations. Apart from cup navigation, the navigation system helps to restore biomechanics in terms of center of rotation, leg length, and offset by advising surgeons on the modular neck offering best fit and predicting the safe range of motion (ROM) reliably.

**Stipcak V, Hart R, Kucera B.**

*Our experience with an image guided navigation system for accurate alignment in total hip replacement by minimally invasive posterolateral surgery.*


**PURPOSE OF THE STUDY:** The aim of the study was to compare a radiographic position of the acetabular component with a position guided by the navigation system in final acetabular cup alignment.

**MATERIAL:** Between May and October 2005, 15 patients underwent implantation of a cementless acetabular component from the posterolateral minimally invasive approach with the use of kinematic navigation.

**METHODS:** The final acetabular cup alignment was determined from the data saved in the navigation system. The radiographic measurement of acetabular cup inclination was made from an anteroposterior projection of both hips on one image, and anteversion was determined by the Ackland method.

**RESULTS:** The average values for inclination and anteversion shown on radiographs were 41.8 degrees (range, 35-51) and 19.8 degrees (range, 5-32), respectively. The average values of cup alignment recorded at implantation by the navigation system were 27.6 degrees (range, 22-35) for inclination and 24.3 degrees (range, 17-28) for anteversion.

**DISCUSSION:** The acetabular cup alignment is considered optimal when inclination is 45 degrees and anteverision 15 degrees. This is more difficult to achieve in minimally invasive surgery due to a limited view of the operating field. This disadvantage can be overcome by using various navigation systems the function of which depends on the accuracy of recorded data.

**CONCLUSION:** Because the data recorded by the system used in our study were not accurate, we do not consider the OrthoPilot® navigation system to be an effective aid in minimally invasive posterolateral surgery.
Optimization of cup positioning in THA – Comparison between conventional mechanical instrumentation and computer-assisted implanted cups by using the OrthoPilot® navigation system.

*AIM:* The goal of the current study was to determine the accuracy of free-hand and computer-assisted cup replacement.

*MATERIAL AND METHODS:* We analysed the cup positions after 50 conventional instrumented THAs and compared them with the positions of 50 navigated cups. The operations were done between October 2002 and November 2004. To determine the accuracy of the cup position, the author developed a special measurement tool. With the help of the method it was ensured that the radiograph central beam reached the pelvis in a horizontal position. The central beam was focused directly on the head. We calculated the anteversion and the inclination.

*RESULTS:* The variability of the cup position was significantly higher in the free-hand implanted group. The standard deviation for antetorsion in the navigation group was 5.0 and for inclination angles 2.8. In the conventionally implanted group the standard deviation was 7.4 for inclination and 6.9 for antetorsion. In particular, the anteversion cannot be exactly calculated without a navigation tool since the individual position of the patient’s pelvis cannot be assessed by the surgeon without aids. Clinical long-term studies for the clarification of a higher stand-time of the computer-navigated cups are still necessary. (copyright) Georg Thieme Verlag KG Stuttgart.
Kiefer H, Othman A.

OrthoPilot® total hip arthroplasty workflow and surgery.


To analyze the workflow and navigation principles of the OrthoPilot® total hip arthroplasty (THA) Version 2.0 (B. Braun Aesculap, Tuttingen, Germany), a consecutive series of 60 patients was used to compare the navigated intraoperative data and postoperative measurements of stem and cup position. Within the safe zone, 96.3 % of 54 acetabular cups were positioned. The rotational accuracy of femoral instruments was 65 degrees in 41 THAs. The femoral offset was medialized by 6.05 mm in 76 % and lateraled by 2.1 mm in 14 %. The data for leg length and range of motion from 60 THAs and the navigated data were similar. Thus, the first clinical validation of the workflow of the OrthoPilot® THA Version 2.0 is encouraging.

Stipcak V, Stoklas J, Hart R, Janecek M.

Implantation of a non-cemented acetabulum with the use of a navigation system.


PURPOSE OF THE STUDY: To compare, on the basis of clinical and radiographic findings, the results of non-cemented acetabulum implantation involving the use of a CT-free navigation system with those of implantation without its use.

MATERIAL: A total of 50 patients undergoing implantation of a non-cemented acetabulum in the period from April 2002 to September 2003 were evaluated. Twenty-five patients operated on without the navigation system were included in group 1 on a random basis and 25 patients treated with the use of the system constituted group 2.

METHODS: Both groups were evaluated on the basis of clinical and X-ray findings. The radiographic measurement of acetabular inclination was based on anteroposterior projection of both hips made on films equal in size. Anteversion of the acetabulum was assessed according to the Ackland system. The Merle d’Aubigne and Postel scores were used for clinical evaluation. The results were compared statistically.

RESULTS: In group 1, the average inclination was 50.6 degrees (range, 38-62) and the average anteversion was 9.4 degrees (range, 3-18). In group 2, the values were 43.0 degrees (32-55) and 10.4 degrees (8-16) for the average inclination and anteversion, respectively. The difference in acetabular inclination between the two groups was statistically significant. When accuracy was evaluated, the difference in acetabular anteversion was statistically significant.

DISCUSSION: The achievement of an optimal position of the acetabular component is one of the important factors for good, long-term outcomes of hip replacement. The optimal position that, as suggested by many authors, involves an inclination of 45 (plus or minus) 10 degrees and an anteversion of 15 (plus or minus) 10 degrees provides sufficient stability, low wear and a satisfactory range of motion in the hip joint. The results close to these values were achieved in the patients included in group 2.

CONCLUSIONS: A comparison of the groups showed that the computer-assisted navigation system used in implantation resulted in an optimal position of the acetabular component.


