Software and instrument improvements reduced significantly navigation acquisition time in computer assisted TKA: A cadaveric study

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Software and instrument improvements reduced significantly navigation acquisition time in computer assisted TKA: A cadaveric study

Frank Lampe¹,², Carlos J. Marques*¹ and Jörg Lützner³

Abstract: Purpose: Computer navigation in total knee arthroplasty (TKA) has proven to significantly reduce the number of outliers in prosthesis positioning and to improve mechanical leg alignment. Despite these advantages the acceptance of navigation technologies is still low among orthopaedic surgeons. The time required for navigation might be a reason for the low acceptance. Objective: The aim was to test whether software and instrument improvements made in an established navigation system could lead to a significant navigation acquisition time reduction. Materials and methods: An improved and the current version of the TKA navigation software were used to perform surgery trials on a human cadaveric specimen by two experienced orthopedic surgeons. Results: A significant effect of the "procedure" (navigation software version) on the navigation time (p < 0.001) was found, whereas the difference between surgeons was not significant (p = 0.2). There was no significant interaction between surgeon and navigation software version (p = 0.5). The improved version led to a significant navigation acquisition time reduction of 28%. Conclusions: Software and instrument improvements led to a statistically significant navigation acquisition time reduction. The achieved navigation acquisition time decrease was independent from surgeon. Specific instrument and software

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PUBLIC INTEREST STATEMENT
With the use of computer assisted surgery (CAS) in orthopedics, surgeons can achieve better prosthesis and leg alignment results in TKA. A good prosthesis alignment is related to longer survival rates since it decreases wear and aseptic loosening. Despite scientific evidence on the advantages of orthopedic CAS, the acceptance of this technology is still low within the surgeons’ community. One of the reasons for the low acceptance may be related with the assumption that CAS increases the total surgical time. In the present study the effects of software and instrument improvements of an established image free CAS system on total navigation time were investigated. The workflow changes through the new software version and a new instrument led to a significant reduction of the time needed for navigation during surgery. The achieved navigation time reduction was independent from the surgeon.
improvements in established navigation systems may significantly decrease the surgery time segments where navigation takes place. However, the total navigation acquisition time is low in comparison to the total surgery time.

**Subjects:** Computer Science; Engineering & Technology; Biomedical Engineering; Medicine, Dentistry, Nursing & Allied Health

**Keywords:** computer assisted surgery; total knee replacement; operative time; navigation acquisition time

### 1. Introduction

Correct implant position and mechanical leg alignment have been advocated to influence the survival rates by decreasing wear and aseptic loosening in total knee arthroplasty (TKA) (Jasper, Jones, Mollins, Pohar, & Beaupre, 2016; Khan, Osman, Green, & Haddad, 2016; Mason, Fehring, Estok, Banel, & Fahrbach, 2007; Ritter, Faris, Keating, & Meding, 1994). Computer navigation and robotic systems were introduced to improve the accuracy of prosthesis positioning and mechanical leg alignment in joint replacement procedures. Several meta-analyses have shown that computer assisted TKA achieves significantly better component position and mechanical leg alignment outcomes in comparison with traditional TKA (Alcelik et al., 2016; Hetaimish et al., 2012; Moskal, Capps, Mann, & Scanelli, 2014; Rebal et al., 2014). The question whether better prosthesis position and leg alignment achievements would result in better clinical outcomes remained unanswered during a long time period (Venkatesan, Mahadevan, & Ashford, 2013). Two recent meta-analyses have shown that with computer assisted TKA the short term clinical outcomes (WOMAC and KSS) were also superior in comparison with traditional TKA (Moskal et al., 2014; Rebal et al., 2014).

Another advantage of computer assisted TKA is the possibility to quantitatively assess soft-tissue balance. This was a subjective matter in traditional TKA, since it depended on the experience and subjective evaluation of the surgeon. Soft-tissue balance issues have been linked to complications after TKA, like persistent pain (Aveline et al., 2014), instability and stiffness (Le, Goodman, Maloney, & Huddleston, 2014). In a study by Guske et al. the patients with quantifiably balanced soft-tissues achieved significant clinical gains sooner than unbalanced patients (Gustke, Golladay, Roche, Elson, & Anderson, 2014). These results were confirmed by another recent study (Lampe, Marques, Fiedler, Sufi-Siavach, & Matziolis, 2016).

Despite the evidence on the advantages of computer assisted surgery in TKA, the acceptance of these technologies is still low among the surgeon’s community. The reasons may be related with the high acquisition costs, the additional costs per use, the need of additional equipment in the operation room and the increased surgical time (Cerha, Kirschner, Güntner, & Lutzner, 2009).

The surgery time was proven to be significant increased with the use of computer assisted navigation systems in comparison with traditional techniques (Alcelik et al., 2016). In times where the management of the surgery rooms is of great economic importance, a significant longer surgery time might be the main barrier to implement the use of navigation systems in orthopedic surgery.

The OrthoPilot® (Aesculap AG, Tuttlingen, Germany) is an image free computer navigation system. With the release of the TKA software application version 6.0 the supplier aims to increase the general ease of use and to decrease the time required for navigation by means of software and instrument improvements.

The aim of the present study was to compare the required navigation acquisition time between the current OrthoPilot® TKA version 4.4 and the new version 6.0 (prototype). The following question was to be answered: do the software and instrument improvements in the 6.0 version lead to a significant navigation acquisition time reduction?
2. Materials and methods

This is a cadaveric study performed at the Anatomical Institute of the Ludwig-Maximilian-University in Munich, Germany. The right knee of a human specimen was used for the purpose of the study. The written consent to serve for scientific purposes was given pre-mortem by the subject.

Two senior surgeons (FL and JL) experienced with the navigation system performed the surgery trials. Previously to the test-trials each surgeon performed one “warm-up” trial to familiarize with the new instrument and the new software workflow. Thereafter, each surgeon performed 12 trials (n = 6 with the current version 4.4, and n = 6 with the improved version 6.0). The performance sequences (surgeon A vs. surgeon B and software version 4.4 vs. 6.0) were randomized.

2.1. Procedures

The right knee of a human specimen was prepared. The tibia plateau was resected and replaced through a removable tibia component. This was made in order to increase the reproducibility of the surgery trials. The femur condyles remained unresected. The resection of the femur condyles would implicate the use of one cadaveric specimen per surgery trial. Since this would introduce another source of variability, the authors decided to use the same cadaver through all surgery trials.

The environmental conditions were reproduced as in the surgery room. Each surgeon was assisted by two persons. The time needed for navigation data acquisition was recorded by an observer and retrospectively subdivided in three time intervals: the first time segment began with the palpation of the anatomical points and finished with the record of the mechanical alignment of the leg; the second time segment started after the record of the mechanical leg alignment and finished after the alignment of the tibia cutting jig; the third time segment began with the tibia-checkplate to monitor the tibia resection cuts and finished with the palpation step “optimize anterior cortex” (Figure 1).

For the present purpose the first and third time segments were of relevance, since the software and instrument developments in the improved version 6.0 most aimed to influence these two surgery phases.

The tibia-first technique was used (Becker, Malzdorf, Stärke, Randolf, & Lohmann, 2012). This technique has the advantage, that final soft-tissue balance can be predicted before femoral bone cuts (Matsumoto et al., 2012). As mentioned above, the preparation of the knee and the resection of the tibia plateau were made previously and were not included in the time-assessment. The reason for this methodological decision was based on the fact that both software versions remained unchanged concerning the steps for tibia plateau resection. Additionally, the resection of the tibia plateau is also the surgery step with the greatest influence on the surgeon’s learning curve. That is, a time reduction during the second time segment depends mainly on the surgeon’s experience and not on variations of the navigation software.
Prior to the surgery trials, each surgeon performed two reference trials using each of the systems respectively. During the reference trials the focus was set on the accuracy of palpation. In reference to these, a beforehand accuracy corridor of 12 mm was set for the palpation of each of the anatomical points during the surgery trials. Trials with two or more points measured outside the 12 mm accuracy corridor were eliminated. This methodological decision was taken to avoid a decrease in accuracy in favor of shorter navigation acquisition times while palpating the anatomical points during the time assessments.

Furthermore, the following agreements were made previously: (1) each surgeon had to respect the “all green” principle (all notes on the OrthoPilot display had to be green before the surgeon stepped further); (2) for the palpation of the medial and lateral posterior condyles the knee should be in deep flexion.

2.2. Materials
Two different OrthoPilot® TKA navigation software versions were used, the current version 4.4 and the improved version 6.0 (prototype). The navigation system is based on intra-operatively acquired data. An infrared camera tracks infrared-reflecting marker spheres, which have been previously fixed on the femoral and tibia bones, on a hand-held pointer or on the multifunctional instrument (depending on the version as shown in Figure 1), and on the cutting blocks (Clemens & Miehlke, 2005). The optical tracking system used by OrthoPilot is the hybrid Polaris Spectra® (Northern Digital Inc., Waterloo, Ontario, Canada). According to the supplier, the accuracy of the system is 0.25 mm RMS when applying the pyramid measurement volume method (Polaris Optical Tracking Systems Web Page: Northern Digital Incorporation, 2015; Wiles, Thompson, & Frantz, 2004). The reliability of leg alignment when using this system, as well as the reliability of the navigation guided gap technique were tested in the past in experimental settings (Han, Nha, Yoon, Lee, & Chae, 2008; Hauschild et al., 2009). Detailed information on the surgical procedure and workflow when using the OrthoPilot system were published previously (Lampe & Hille, 2004).

The version 6.0 differs from the current version in the following points: (1) The workflow (software) is new and easier to follow (i.e. the surgeon doesn’t has to change the instruments so often to perform the required steps); (2) A multifunctional instrument (MuFu) was developed, which embodies the function of three different instruments and a footswitch in the current 4.4 version, thus saving time by avoiding the persistent change of instruments (Figure 2a); (3) the acquisition of the hip joint center follows a new movement pattern, therefore it is easier in the improved version; (4) The navigation on the display (workflow) as well as the palpation of the anatomical landmarks can be performed with the use of the click-button on the MuFu instrument. In the current version this was made with a footswitch (Figure 2b).

The same surgical instruments were used with both navigation systems.
2.3. Statistical analysis
Sample size calculation was performed previously based on the results of a similar pilot-study with the use of the nQuery software version 7.0 (Statistical Solutions Ltd., Cork, Ireland). For a two-sample T-test with a two-sided significance level of 0.05 and a power of 0.8 a number of at least 10 surgery trials per group (version 4.4 vs. version 6.0) was calculated. Twelve surgery trials per group were aimed to account for possible failed trials.

A bi-variate linear regression model with “surgeon” and “procedure” (OrthoPilot version) as dichotomous co-variates was used to assess their possible effects on navigation acquisition time. The interaction between “surgeon” and “procedure” was also tested for significance in order to verify, whether the effects of “procedure” on navigation acquisition time were surgeon-specific.

The level 0.05 was accepted as the criterion for statistical significance.

All statistical tests were carried out with the SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

3. Results
From the 24 surgery trials performed by both surgeons one was rejected due to values found outside the accuracy corridor of 12 mm. This trial was repeated. The data of 24 surgery trials were pooled for analyses. Since the null-hypotheses of normal distribution of the data was not rejected, mean and standard deviation (SD) values are used to describe the sample.

As mentioned above, the total navigation acquisition time was subdivided into three time intervals (Figure 1). The mean ± SD values for “time segments 1&3” and “total time” are presented in Table 1.

The results of the bi-variate linear regression model revealed a significant effect of the “procedure” (OrthoPilot software version) on the navigation acquisition time intervals 1&3 ($p < 0.001$), whereas the difference between surgeons was not significant ($p = 0.2$). There was no significant
interaction between surgeon and OrthoPilot version \((p = 0.5)\), meaning that the effects of “procedure” on navigation acquisition time were similar for both surgeons (Figure 3). On average the improved version 6.0 led to a navigation acquisition time reduction of 28\% (mean Diff. = 47 s; 95\% CI: [30; 64]).

4. Discussion
Significant lower number of outliers in prosthesis alignment (Hetaimish et al., 2012), significant better mechanical leg alignment (Rebal et al., 2014) and quantifiable soft-tissue balance (Gustke et al., 2014), are some of the benefits of computer assisted TKA. Despite these advantages the acceptance of this technology remains low among the orthopedic surgeon’s community (Davey, Craven, Meenan, Martin, & Crowe, 2011). One barrier against the widespread use of computer navigation might be the increased surgery time when using such devices. In a web-based survey carried out to study how computer assisted orthopedic surgery (CAOS) for TKA is being used in everyday orthopedic centers, the potential for improving the prosthesis alignment was the most strongly cited reason for using a navigation system (Friederich & Verdonk, 2008). On the other hand, the potential for increasing

| Procedure       | Surgeon | n  | Time segments 1&3 | Total time   |
|-----------------|---------|----|-------------------|--------------|
| OrthoPilot TKA 4.4 | A       | 6  | 169 ± 22          | 189 ± 24     |
|                 | B       | 6  | 163 ± 26          | 180 ± 26     |
|                 | Total   | 12 | 166 ± 23          | 185 ± 25     |
| OrthoPilot TKA 6.0 | A       | 6  | 128 ± 28          | 150 ± 32     |
|                 | B       | 6  | 110 ± 13          | 135 ± 19     |
|                 | Total   | 12 | 119 ± 23          | 143 ± 26     |

Note: Values (total time in s) are mean ± SD.

Figure 3. Mean “navigation acquisition time 1&3” with 95\% CI of the mean by surgeon and OrthoPilot software version (Circle = OrthoPilot current version 4.4; Triangle = OrthoPilot improved version 6.0).
operation times and the risk of infections were the most cited reasons for not using a navigation system. The same authors reported that the half of the surveyed surgeons believed that navigation systems were a real innovation, however heavy usage (≥51% of the cases) was only reported by 33.1% of them.

The aim of the present study was to test, whether software and instrument improvements carried out in an established navigation system would influence the navigation acquisition time. In the experimental setting only the navigation acquisition time was used for analysis. The surgery time, which is normally the time frame between skin incision until wound closure, was not assessed for methodological reasons. This is not considered by the authors as study limitation, since the aim of the study was to investigate the influence of the navigation software version on the navigation acquisition time. For organizational reasons only two surgeons performed the test trials. Both surgeons were high volume TKA surgeons and regular users of the OrthoPilot® TKA version 4.4. Each surgeon performed 6 test-trials with each of the systems. The low number of surgeons (two) and the high number of repetitions (6 with each system version) can be seen as a study limitation. Extending the number of surgeons and their levels of experience in using the navigation systems could have led to different results.

The factors that affect total surgery time in TKA are manifold. In a recent study by Maruthapper et al., the surgeon’s surgical experience ($p < 0.001$), the trainee surgical experience ($p < 0.05$), the cumulative team operative experience ($p < 0.0001$) and the team familiarity ($p < 0.0001$) were associated with significant reductions in total surgery time. The authors reported that the expected reduction in surgery time after 25 years of practice was 51 min (Maruthappu et al., 2016).

As shown in Table 1, the navigation acquisition time is short in comparison with the total surgery time in TKA. Going from the assumption that on average an experienced surgeon performs a complication free primary TKA in $60 \pm 15$ min, the gains reported in this study, achieved through software and instrument improvements, seem to be only small. However, the reduction of additional time, which is necessary for the navigation system only, might help to increase the acceptance of computer assisted navigation systems among surgeons. Furthermore, a simple software workflow, which can be used intuitively, may reduce barriers for the use of CAOS. Nevertheless, the additional surgery time evoked by CAOS should always be seen in relation to its proven benefits.

Future studies on this issue, comparing total surgery time in TKA with and without the use of computer navigation systems, should consider the acquisition of partial times. This would enable a quantifiable assessment of the time needed for navigation in relation to the total surgery time. When planning such studies it should also be provided that the surgeons, who perform the surgeries with computer assisted navigation systems, are heavy users of the system in their everyday clinical practice.

5. Conclusions
Software and instrument improvements led to a statistically significant navigation acquisition time reduction. The achieved 28% navigation acquisition time decrease was independent from the factor surgeon.

Specific instrument and software improvements in established navigation systems may significantly decrease the surgery time segments where navigation takes place. The total navigation acquisition time is low in comparison with the total surgery time.

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Competing Interests
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