Aseptic loosening is one of the most common reasons for total knee arthroplasty (TKA) revision. The main cause of aseptic loosening is increased polyethylene wear that arises due to off-center implant load. Navigation systems first entered clinical use at the end of the 1990s. The development stemmed from the desire to reconstruct a neutral mechanical femorotibial angle (mTFA) to prevent off-center loading of the polyethylene. This was based on the findings from a number of papers that the risk for aseptic loosening drops if the axis deviation is no greater than 3° to the neutral axis.

In the years following the introduction of computer-assisted navigation, studies showed that procedures involving navigation significantly reduce the risk of malalignment. Meta-analyses came to the same result. In additional meta-analysis, Rebal et al were also able to demonstrate the clinical superiority of navigation over the short term. Although an initial study has been conducted on the clinical relevance over a longer period after 10 years, the findings have not yet been confirmed.

The current authors’ hypothesis was that, after a period of 10 years following implantation, a navigated TKA would be found to have a significantly higher survival rate than a conventional implanted TKA.
Materials and Methods

Approval was obtained from the regional ethics committee (reg. no.: 1115/09/111). All of the TKAs performed by 3 primary surgeons in 1999 using the Aesculap Search prostheses (Tuttlingen, Germany) were included in the study. From the middle of 1999, with the introduction of the OrthoPilot (Aesculap) kinematic navigation system, all remaining TKAs were implanted with navigation. All patients were invited to the 10-year follow-up. In the group that underwent the conventional procedure, there were 113 TKAs, and in the navigated group, there were 104 TKAs (217 TKAs in total of 213 patients).

Of the patients originally included in the study, 100 were no longer able to take part. Seventy-two patients (73 prostheses) were already deceased, and 28 patients were unable to participate on account of serious concomitant diseases or for personal reasons. Of these 28 patients, none had undergone revision of their primary TKA at the time contact was made, there were no current radiographs available, and all refused a radiograph examination in the vicinity of their home.

Of the remaining 113 patients, 19 patients (12 conventional and 7 navigated) had undergone revision surgery for any reason. As a result, the current authors were able to follow up on 96 TKAs (46 conventional and 50 navigated in 94 patients) after 10 years.

Operating Technique

The standard procedure was conducted with a tourniquet, a standard parapatellar approach, and the tibia first technique. The navigated procedure was performed using a similar technique to that described by Magin.14

Radiographic Evaluation

If the patients were unable to supply current radiographs, radiographs were taken in a single-leg stance and a lateral view of the operated knee for the purposes of follow-up. All of the radiographs were evaluated for signs of loosening in accordance with the criteria of the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring Systems.15 The implantation geometry was measured in accordance with Moreland et al.16 Mahaluxmivala et al.6 and Haaker et al.17

Clinical Evaluation

The Hospital for Special Surgery (HSS) Score, the Knee Society Score (KSS), and the 36-item Short Form Health Survey (SF-36) were collected. In addition, the sociodemographic background of the patients was determined, their height and weight at the time of follow-up were measured, and the current range of motion of the knee joint was ascertained. Joint instabilities were determined on a semi-quantitative basis.

Statistical Evaluation

If the data collected from both groups were normally distributed and the variances homogeneous, the t-test for independent samples was used. Normal distribution was verified using the Shapiro-Wilk test and homogeneity using the Levene test. If the null hypothesis “normal data distribution” had to be rejected, the current authors used the Mann-Whitney U test for nonparametric independent samples in the current authors’ study. The current authors used the chi-square test to compare variations in the frequency of a characteristic.

The significance level was set at $P \leq 0.05$ for the primary endpoint, and $P \leq 0.01$ for all secondary endpoints.

Results

There were no significant differences in gender distribution, body mass index (BMI) at the time of surgery, or the size distribution of the prosthesis components used. The only significant differences were in the age of the patients and the surgery time required (Table 1). In the radiographic evaluation, there were no significant differences either in the average value of the determined mTFA. The mTFA was only found to be within the reference range of ±3° ($P = 0.43$) in 58% of the prostheses from the conventional TKAs and 78% from the navigated TKAs (Figure 1). At follow-up, a significant increase in the varus axis deviation was found in the conventional group.

There were 19 revisions, 8 of which were due to aseptic loosening (7 in the conventional group, 1 in the navigated group) (Table 2). This equates to an 87% survival rate for conventionally implanted prostheses after 10 years and 98% for prostheses implanted using computer-assisted navigation (Figure 2). This is a statistically significant difference ($P = 0.03$).

After conclusion of the follow-up examinations, 17% of the conventional and 9.8% of the navigated TKAs

Table 1

<table>
<thead>
<tr>
<th>Overview of Measured Data</th>
<th>Conventional</th>
<th>Navigated</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender distribution, female: male, No.</td>
<td>85:28</td>
<td>85:19</td>
<td>.24</td>
</tr>
<tr>
<td>BMI, mean±SD, kg/m²</td>
<td>32.3±5.2</td>
<td>30.8±4.7</td>
<td>.021</td>
</tr>
<tr>
<td>Age at time of operation, mean±SD, y</td>
<td>68.6±7</td>
<td>73.9±8.9</td>
<td>.00001</td>
</tr>
<tr>
<td>Surgery time, mean±SD, min</td>
<td>85±20</td>
<td>107±28</td>
<td>.0001</td>
</tr>
<tr>
<td>mTFA postoperation, mean±SD, deg</td>
<td>0.6±4.2</td>
<td>0.5±3</td>
<td>.9</td>
</tr>
<tr>
<td>mTFA in reference range ±3° around neutral axis postoperation</td>
<td>58%</td>
<td>78%</td>
<td>.043</td>
</tr>
<tr>
<td>mTFA at follow-up, mean±SD, deg</td>
<td>4.7±5.7</td>
<td>2±4.4</td>
<td>.01</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index; mTFA, mechanical femorotibial angle.
were found to have undergone aseptic loosening. All of the TKAs subject to aseptic loosening presented with mTFA outside the reference range of ±3° by 0°. Of these prostheses classified as loose, 75% from the conventional group and 80% from the navigated group had a varus axis deviation.

There were no statistically significant differences in the HSS score and KSS score (Table 3). In the SF-36, there was also no significant difference between the groups or compared with the average population of individuals older than 70 in Germany (Table 4).

**DISCUSSION**

Over the past few decades, TKA loosening has remained an unresolved problem. Particularly problematic is the high revision rate of 8.5% in patients younger than 65 that is quoted in the Swedish Knee Arthroplasty Register, as compared with a revision rate of 2% in patients older than 65.18

Most of the studies, with a few isolated exceptions,19,20 concur that significantly improved TKA longevity is related to an accurately aligned mTFA.3-5

On the basis of these summarized results, the current authors can see that the aseptic revision rate for TKAs in the navigated group after 10 years was significantly lower than that for the conventional group. This study also found evidence of loosening of the prostheses after follow-up in almost twice as many patients in the conventional group than in the navigated group.

When you look at the mTFA of the patients found to have loosening of the prosthesis, it is apparent that all had a postoperative mTFA that was outside of the reference range of ±3° around the neutral axis. Since a higher loosening rate was also found in the conventional group, this group accordingly also had a statistically relevant lower rate of optimally implanted prostheses than the navigated group (58% compared with 78%).

It has to be considered that in the navigated group, all patients were included in the study despite an initial learning curve when starting with the OrthoPilot navigation system. Consequently, the findings of this study confirm the current authors’ hypothesis that TKA procedures involving computer-assisted navigation achieve a significantly higher survival rate.7-9
The current authors’ research showed that, to date, only 1 other study has been published on the subject of the loosening rate of conventional vs navigated TKAs that included a horizon of more than 10 years.13 The Kim study13 reported no significant difference in the survival rate, whether implanted conventionally or with navigation. From a comparison of the survival rates, it is apparent that the revision rates in both groups were very low (0.8% for conventional and 1.2% for navigated), also in respect of the comparative study itself. Two different types of prostheses were involved in the comparison (cruciate-retaining mobile, posterior-stabilized fix). Each patient underwent a conventional and a navigated TKA. However, it is not possible to determine how many of the respective prostheses were included in the 2 groups.

A study focusing on a similar time period as the present study (8 years),21 published a statistically insignificant failure rate of 18.9% for conventionally implanted prostheses and 5.6% for navigation-assisted prostheses. The study of Molfetta and Caldo,22 which covered a 5-year period, similarly showed no significant difference in the aseptic loosening rate associated with conventional and navigated TKAs. This must, however, be qualified by mentioning that the above study defined as an exclusion criterion a preoperative varus axis deviation of more than 15°.

In the current authors’ study, the results for the navigated group were also similarly promising, with no signs of loosening in a total of 90.2% of the prostheses. However, the conventional group within the current authors’ study was found to have a higher loosening rate than that reported in the studies of Kim13 and Molfetta and Caldo.22 The study by Ewald et al15 published a total TKA failure rate of 6.5% after 10 years. The majority of the revisions were attributable to the design of the femoral prosthesis plate, which caused an increased loosening rate of the retropatellar replacement and thus a requirement for revision. The study by Emmerson et al16 reported a primary TKA survival rate of 95% after 10 years, and 87% after 13 years. The percentage of conventionally implanted prostheses in the current authors’ study showing no signs of loosening was comparatively lower, whereas in the navigated group, the percentage of intact TKAs was higher.

Wright et al25 reported a significantly lower aseptic loosening rate after 10 years of just 2.8% in patients who had received the conventional procedure. This could be explained by the lower average BMI of the patients included in the study (BMI of 27.2) compared with that of the current authors’ study (BMI >31).

In summary, the group of patients in the current authors’ study who underwent a navigated TKA had lower loosening rates after 10 years than reported by the long-term studies involving patients treated using the conventional procedure.

The results of the current authors’ study must, however, be qualified by mentioning that despite a relatively high number of patients included in both groups initially, the current authors’ study had a relatively high lost to follow-up rate.

Unlike more recent versions of the OrthoPilot navigation system, the software version used in this study, version 2.1, was unable to measure ligament tension in flexion and extension. The rotation of the femoral prosthesis was generally positioned in 3° lateral rotation in relation to the dorsal condyle axis. However, the current authors know today that the variability of that angle is very high.26

### Table 3

<table>
<thead>
<tr>
<th>HSS Score and KSS Evaluation</th>
<th>Conventional, Mean±SD</th>
<th>Navigated, Mean±SD</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSS score</td>
<td>82.1±11.6</td>
<td>82.6±9.5</td>
<td>.84</td>
</tr>
<tr>
<td>KSS</td>
<td>135.6±29.3</td>
<td>141.3±36.8</td>
<td>.19</td>
</tr>
</tbody>
</table>

**Abbreviations:** HSS, Hospital for Special Surgery; KSS, Knee Society Score.

### Table 4

<table>
<thead>
<tr>
<th>SF-36 Evaluation</th>
<th>Conventional (Mean±SD)</th>
<th>Navigated (Mean±SD)</th>
<th>P Value</th>
<th>Average Population &gt;70 (Mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>48.3±25.8</td>
<td>43.3±20.3</td>
<td>.43</td>
<td>58.59±27.44</td>
</tr>
<tr>
<td>Physical role</td>
<td>57.7±47.0</td>
<td>61.7±45.1</td>
<td>.71</td>
<td>62.16±40.80</td>
</tr>
<tr>
<td>Pain</td>
<td>61.1±22.7</td>
<td>66.2±27.8</td>
<td>.41</td>
<td>64.20±28.13</td>
</tr>
<tr>
<td>General health perception</td>
<td>57.6±20.7</td>
<td>57.6±20.5</td>
<td>.98</td>
<td>55.30±20.96</td>
</tr>
<tr>
<td>Vitality</td>
<td>46.0±20.0</td>
<td>49.3±21.1</td>
<td>.45</td>
<td>53.91±21.39</td>
</tr>
<tr>
<td>Social function</td>
<td>90.2±20.2</td>
<td>91.5±15.9</td>
<td>.98</td>
<td>83.94±21.27</td>
</tr>
<tr>
<td>Emotional role</td>
<td>69.8±44.7</td>
<td>68.1±45.6</td>
<td>.91</td>
<td>83.04±33.72</td>
</tr>
<tr>
<td>Mental health</td>
<td>65.7±16.5</td>
<td>69.2±20.7</td>
<td>.22</td>
<td>71.41±17.21</td>
</tr>
<tr>
<td>Physical health summary score</td>
<td>42.70</td>
<td>41.80</td>
<td>-</td>
<td>39.90</td>
</tr>
<tr>
<td>Mental health summary score</td>
<td>50.31</td>
<td>51.69</td>
<td>-</td>
<td>52.39</td>
</tr>
</tbody>
</table>

**Abbreviation:** SF-36, 36-item Short Form Health Survey.
The literature uses a range of different scores to evaluate the results achieved—particularly the functional results—and patient satisfaction. In this study, the current authors used the most commonly used scores for TKA, the HSS Score and the KS Score derived from this. Both of these scores were developed specifically for patients who have undergone TKA.27,28

The current authors’ study found that quality of life in respect to the physical health summary score was higher than the average German population both in the conventional and navigated groups.29 The current authors’ results contradict those of Rissanen et al,30 Jerosch and Floren,31 and Núñez et al,32 whose studies report a lower quality of life compared with the average population following a TKA.

In reference to the subcategory “Pain,” patients who underwent the navigated procedure showed a lower pain level than the average population. Compared with the results reported by Jerosch and Floren,31 which covered a shorter follow-up interval, and those of Wright et al,25 with a follow-up period of a similar length, the pain levels of both of the groups in the current authors’ study were significantly lower.

In summary, the patients included in the current authors’ follow-up reported a higher quality of life than the average German population of the same age.

In conclusion, it can be stated that, in the first 10 years, navigation offers a significantly lower revision rate and a significantly higher number of optimally positioned TKAs compared with the conventional procedure. Patients whose TKA is performed using computer-assisted navigation appear to experience less pain than patients who undergo the conventional procedure. This indicates a clinically significant advantage of the navigation technique compared with the conventional procedure.

References