Mid-term survivorship of Mini-keel™ versus Standard keel in total knee replacements: Differences in the rate of revision for aseptic loosening

C. Kajetanek*, B. Bouyer, M. Ollivier, P. Boisrenoult, N. Pujol, P. Beaufils

Service de chirurgie orthopédique, hôpital André-Mignot, centre hospitalier Versailles, 177, rue de Versailles, 78157 Le Chesnay, France

ARTICLE INFO

Article history:
Received 7 November 2015
Accepted 2 May 2016

Keywords:
Aseptic loosening
Total knee arthroplasty
MIS tibial component
Modular tibial component
Mini-keel

ABSTRACT

Introduction: To reduce the size of the surgical incision, modular mini-keel tibial components have been developed with or without extensions for the Nexgen™ MIS Tibial Component. Although a smaller component could theoretically result in defective fixation, this has never been evaluated in a large comparative series. Thus, we performed the following case control study to: (1) evaluate intermediate-term survival of a modular “mini-keel” tibial component compared to a reference standard keel component from the same line of products (Nexgen LPS-Flex Tibial Component, Zimmer); (2) to identify any eventual associated factors if the frequency of loosening was increased.

Hypothesis: The rate of revision for aseptic tibial loosening is comparable for both components.

Materials and methods: This comparative, retrospective, single center series of 459 consecutive total knee arthroplasties (TKA) was performed between 2007 and 2010: with 212 modular “mini-keel” (MK) tibial components and 247 “standard” (S) components. Survival, rate of revision for aseptic tibial loosening and identification of a radiolucent line were analyzed at the final follow-up.

Results: After a median follow-up of 5 years, the rate of revision for tibial aseptic loosening was significantly higher in the MK group with 12 cases (5.7%) and 4 cases in the S group (1.6%) (P=0.036). The use of the MK component appears to be a prognostic factor for surgical revision (hazard ratio = 3.86 (1.23–11.88), P=0.02) but not for the development of a radiolucent line (HR = 1.75 (0.9–3.4), P=0.097). The mean delay before revision was 36 months (8–64) in the MK group and 15.2 months (8–22) in the S group (P=0.006). Individual factors, such as gender, body mass index (BMI) and pre- or postoperative alignment were not prognostic factors for revision or radiolucent lines.

Conclusion: The modular "mini-keel" tibial component was associated with a greater risk of revision for tibial component loosening.

Level of evidence: Case control study, III.

© 2016 Elsevier Masson SAS. All rights reserved.

1. Introduction

Total knee arthroscopy (TKA) is a reliable and reproducible procedure with an estimated rate of survival of more than 90% after 15 years of follow-up [1–6]. The main causes of failure are septic or mechanical and may be due to the surgical procedure (malposition, defective fixation or ligament imbalance) or the implant itself (design, metal alloy, quality of the polyethylene) [7,8]. Aseptic loosening is the main cause of mechanical failure and occurs with a mean of 7 years after TKA [9,10]. Good initial fixation of the tibial component is essential for stable long-term fixation [9]. At present, a tibial component with a cemented stem seems to provide the best biomechanical results [11–14].

The reduced field of view with the minimally invasive subvastus approach [15–20] has led to the design of new systems with modular keels to facilitate implant insertion. In particular, with this surgical approach, the tibial cut must be performed and the implant must be inserted without fibio-femoral dislocation. Thus, a modular “mini-keel” tibial component (Nexgen MIS Tibial Component; Zimmer Inc., Warsaw, IN, USA) was developed to meet these needs, allowing placement of a stem extension after positioning the tibial component [21]. Although the size limitations of the keel and the modular design could affect tibial fixation strength, this has not been precisely evaluated.

Thus, we performed a case control study with the following goals:
• to evaluate the rate of loosening and survival with this component compared to the standard tibial component from the same line of products (Nexgen LPS-Flex Tibial Component; Zimmer Inc., Warsaw, IN, USA);
• to define any possible associated factors if the frequency of loosening was increased.

Our hypothesis was that the rate of revision for loosening would be similar for both tibial components.

2. Materials and methods

2.1. Patients

This comparative, retrospective, single center series with multiple surgeons was performed in 439 consecutive patients who received 489 TKA in our department between 2007 and 2010. All of the patients who received a cemented Nexgen LPS-Flex (Zimmer Warsaw, USA) TKA for primary or post-traumatic osteoarthritis as well as osteonecrosis of the knee were included. Patients operated for sequellae for septic arthritis were excluded.

2.2. Surgical technique

The procedure was identical in both groups with no tourniquet and control by the Navitrack™-Orthosoft navigation system. A medial trans-quadriceps parapatellar approach was used except in case of irreducible valgus of > 5° where an anterolateral approach was used.

The femoral component was the same in both groups: a high flex postero-stabilized implant (NexGen LPS-Flex, Zimmer Warsaw). Only the tibial component was different between the two groups: there were 223 “mini-keel” components (MK group) and 266 standard components (S group). The choice of implant was based on the material that was available in the operating room.

Tibial components were composed of a titanium alloy (Tivanium™), without surface treatment, and contained a fixed tibial tray with postero-stabilized polyethylene. The “standard” component was a monoblock design, including a 36 to 47 mm stem, depending on the sizes. The “mini-keel” tibial component included 2 modular parts: the plate, which included a 17 or 19 mm thick tray and the modular keel, which was always screwed into the plate before being cemented into the tibial bone in our series. The keel was tightened with a dynamometric key provided with the instrumentation (torque 95 lbs/43 kg). This extension stem was available in 3 sizes: 45, 75 and 100 mm. The use of a keel/extension stem was decided by the surgeon depending on the severity of the initial deformity, the quality of the bone and the BMI of the patient.

The tibial component-bone surface contact differed depending on the component: for average size, 41 cm² with the mini-keel component without an extension (58 cm² with a 45 mm keel) and 44 cm² with a standard component (Fig. 1). The final components were cemented in one stage with high viscosity Palacos™ bone cement (Heraeus, Hanau, Germany), including the keel. The cancellous femoral and tibial surfaces were
washed under pressure with saline solution then dried. The cement for the tibial component was applied under the base plate with a cement mantle around the tibial keel, then, the piece was impacted. The patella was resurfaced in all cases.

2.3. Methods of assessment

Patient follow-up included clinical and radiographic controls at 6 weeks, 3 months, 6 months, 1 year then 2 years. The main evaluation criterion was the rate of surgical revision for aseptic loosening of the tibial component. Secondary evaluation criteria were:

- analysis of the rate of survival of each system at the final follow-up;
- development of radiological signs of tibial loosening including the presence of a progressive radiolucent line of >2 mm, signs of osteolysis or component tilting (Fig. 2). Radiolucent zones were evaluated using the criteria by Ewald et al. [22] (Fig. 3). Radiological results were assessed independently by 2 surgeons (CK, MO). If the analysis was different, the two surgeons reached an agreement.

Age, gender, etiology, BMI and pre- and postoperative alignment were determined. Alignment of the lower limbs was calculated

---

**Fig. 3.** Mapping of radiolucent zones according to Ewald et al. [22].

**Fig. 4.** Flowchart (pre- and postoperative alignment: -: varus; +: valgus; BMI: body mass index, FU: follow-up).
on preoperative weight-bearing goniometry and 3 months after surgery in all patients. The minimum follow-up was one year. Patients who had not been seen within this time were called in for a clinical and radiological evaluation. A consultation was not possible in 103 patients. These patients were contacted by telephone for a clinical evaluation only. They were asked whether any complications had developed, in particular whether surgical revision had been necessary. Thirty patients were lost to follow-up in the first postoperative year (6%), including 5 deaths and they were not included in the final analysis (Fig. 4).

2.4. Statistical analysis

The distribution was normal according to the Shapiro–Wilk test. The comparison between groups was performed by the Chi² test for binary variables and the Student t-test for continuous variables. Survival analysis was performed with a non-parametric Cox model to study main and secondary evaluation criteria. A hazards ratio (HR) was calculated for each parameter. A correlation between radiolucent lines and surgical revision was looked for with the Pearson test. \( P < 0.05 \) was considered to be significant.

3. Results

Survival and clinical data were obtained in 459 knees, 212 in the “mini-keel” group and 247 in the standard group (Fig. 4). Median follow-up was 5 years (MK group: 4.95 years; S group: 5.1 years). Radiological analysis was performed in 356 knees, 174 in the MK group (82%) and 182 in the S group (73.7%). The groups were comparable for age, etiology, gender, BMI and pre- and postoperative alignment (Table 1). In the MK group, a 45 mm keel was used in 203 knees, a 70 mm keel in 6 patients and no keel was used in 3 patients (Table 2). Twelve patients (5.7%) in the MK group required revision for asptic tibial loosening and 4 in the S group (1.6%) \( (P = 0.036) \) (Table 3). A unipolar tibial revision was performed in all cases. In the MK group, 10/12 revised components had a 45 mm stem, one had a 70 mm stem and one device did not have an extension.

The use of an MK component appeared to be a risk factor for revision for asptic loosening \( \text{HR: 3.86 (1.23–11.88), } P = 0.02 \) (Table 4). Age, gender, BMI and pre- and postoperative alignment did not seem to influence this risk. The delay before revision was longer in the MK group (38 months vs. 15.2; \( P = 0.006 \)). At the final follow-up, surgical revision had been performed in 22 knees in 22 patients after a mean 30.4 months, 15 in the MK group (7%) and 7 in the S group (2.8%) \( (P = 0.057) \) (Fig. 5).

A radiolucent line was found in 22 cases (10.8%) in the MK group and 16 cases (6.5%) in the S group. Like age, gender, BMI and pre- and postoperative alignment, there was no significant difference in the distribution of clinical and radiological data (Table 2).

Table 1

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mini-keel</th>
<th>Standard</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>( n )</td>
<td>212</td>
<td>247</td>
<td>–</td>
</tr>
<tr>
<td>Age (years)</td>
<td>73.2 (47.4–88.5)</td>
<td>73.1 (42.7–89.4)</td>
<td>0.9</td>
</tr>
<tr>
<td>Primary osteoarthritis of the knee</td>
<td>206 (97.2%)</td>
<td>233 (94.3%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Female gender</td>
<td>165 (77.8%)</td>
<td>175 (70.9%)</td>
<td>0.09</td>
</tr>
<tr>
<td>Right side</td>
<td>112 (52.8%)</td>
<td>131 (53%)</td>
<td>0.9</td>
</tr>
<tr>
<td>BMI</td>
<td>28.73 (18.7–47.6)</td>
<td>28.9 (18–43.6)</td>
<td>0.71</td>
</tr>
<tr>
<td>Preoperative alignment</td>
<td>–2.62 (–20/+22)</td>
<td>–3.78 (–25/+24.8)</td>
<td>0.15</td>
</tr>
<tr>
<td>Postoperative alignment</td>
<td>–0.73 (–8/+8)</td>
<td>0.72 (–9/+9)</td>
<td>0.9</td>
</tr>
<tr>
<td>Median follow-up (months)</td>
<td>59.4 (12.4–93.7)</td>
<td>61.3 (13.6–101.9)</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Table 2

<table>
<thead>
<tr>
<th>Type of Mini-keel by size</th>
<th>Without keel</th>
<th>45 mm</th>
<th>70 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>( n )</td>
<td>3</td>
<td>203</td>
<td>6</td>
</tr>
<tr>
<td>Age (years)</td>
<td>63.2 (56–72.7)</td>
<td>73.2 (47.4–88.5)</td>
<td>72.8 (62.7–84.3)</td>
</tr>
<tr>
<td>Primary osteoarthritis</td>
<td>3 (100%)</td>
<td>195 (96%)</td>
<td>6 (100%)</td>
</tr>
<tr>
<td>Female gender</td>
<td>3 (100%)</td>
<td>161 (79.3%)</td>
<td>1 (16.7%)</td>
</tr>
<tr>
<td>Right side</td>
<td>3 (100%)</td>
<td>106 (52.2%)</td>
<td>3 (50%)</td>
</tr>
<tr>
<td>BMI</td>
<td>28.2 (23.5–32)</td>
<td>28.5 (18.7–47.6)</td>
<td>35.9 (24.4–43.6)</td>
</tr>
<tr>
<td>Preoperative alignment</td>
<td>2.9 (1.8/3.9)</td>
<td>–2.6 (–20/+22)</td>
<td>–6.6 (–2/+11)</td>
</tr>
<tr>
<td>Postoperative alignment</td>
<td>–1.3 (–5.5/+1.4)</td>
<td>–0.7 (–8/+8)</td>
<td>–1.3 (–6.5/+1.6)</td>
</tr>
<tr>
<td>Median follow-up (months)</td>
<td>71.3 (51.7–81.9)</td>
<td>55.7 (12.4–93.1)</td>
<td>55.3 (39.6–72.9)</td>
</tr>
<tr>
<td>Revision for aseptic loosening</td>
<td>1 (33.3%)</td>
<td>10 (4.9%)</td>
<td>1 (16.7%)</td>
</tr>
<tr>
<td>Radiolucent line</td>
<td>1 (33.3%)</td>
<td>19 (9.3%)</td>
<td>2 (33.3%)</td>
</tr>
</tbody>
</table>

Table 3

<table>
<thead>
<tr>
<th>Causes of surgical revision</th>
<th>Mini-keel</th>
<th>Standard</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aseptic loosening</td>
<td>12 (5.7%)</td>
<td>4 (1.6%)</td>
<td>0.036</td>
</tr>
<tr>
<td>Infection</td>
<td>1 (19 months)</td>
<td>2 (22 months)</td>
<td>–</td>
</tr>
<tr>
<td>Fracture</td>
<td>1 (84 months)</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Instability</td>
<td>1 (1 month)</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Unusual pain</td>
<td>0</td>
<td>1 (12 months)</td>
<td>–</td>
</tr>
<tr>
<td>Total</td>
<td>15 (7%)</td>
<td>7 (2.8%)</td>
<td>0.057</td>
</tr>
</tbody>
</table>

The use of an MK component appeared to be a risk factor for revision for aseptic loosening \( \text{HR: 3.86 (1.23–11.88), } P = 0.02 \) (Table 4). Age, gender, BMI and pre- and postoperative alignment did not seem to influence this risk. The delay before revision was longer in the MK group (38 months vs. 15.2; \( P = 0.006 \)). At the final follow-up, surgical revision had been performed in 22 knees in 22 patients after a mean 30.4 months, 15 in the MK group (7%) and 7 in the S group (2.8%) \( (P = 0.057) \) (Fig. 5).

A radiolucent line was found in 22 cases (10.8%) in the MK group and 16 cases (6.5%) in the S group. Like age, gender, BMI and pre- and postoperative alignment, there was no significant difference in the distribution of clinical and radiological data (Table 2).

Fig. 5. Survival curve of the 2 prostheses: the rate of surgical revision was equivalent in both groups up to 40 months and significantly increased in the MK group after this date.
postoperative alignment, the type of component did not seem to be a risk factor for the development of a radiolucent line [HR = 1.75 (0.9–3.4), P = 0.097] (Table 5). Radiolucent lines developed after approximately 24 months in both groups (P = 0.15). Zones of radiological loosening were mainly posterior and lateral in both groups (Fig. 6). There was a positive correlation between the presence of a radiolucent line and surgical revision in each group (r²MK = +0.6 and r² = +0.35).

4. Discussion

The goal of this study was to evaluate the rate of surgical revision and radiological loosening of the tibial component in a posterior-stabilized TKA with a fixed base plate according to the type of tibial fixation used (“Mini-Keel” versus standard). The MK component appeared to be a risk factor for revision due to aseptic loosening [HR: 3.86 (1.23–11.88), P = 0.02] with a significantly higher rate of revision at the final follow-up (5.7% versus 1.6%, P = 0.036). Thus, the initial hypothesis was not confirmed in this series.

This case control study has several limitations.

The decision to perform surgical revision was subjective, based on the patient’s symptoms, X-ray interpretation and the surgeon’s experience.

The retrospective design of this study; however, only 30/489 patients were lost to follow-up (6%). Moreover, there was no risk of a memory bias in this study because of the presence of independent judgment criteria (surgical revision) and of the systematic preoperative collection of variables.
The choice of the prosthesis was decided by the availability of components in the operating room and not by randomization. Nevertheless, the groups were comparable for the basic study variables.

There was a positive correlation in each group between the presence of a radiolucent line and the risk of surgical revision ($\rho = 0.86$ and $R^2 = 0.35$) but the MK component did not seem to be a prognostic factor for the development of radiolucent lines ($HR = 1.75 (0.5–3.4)$, $P = 0.097$). The short-term rate of revision, which generally is due to infection, technical failure or defective fixation [23,24], was similar in both groups. Nevertheless, revisions after 40 months were only observed in the MK group, with a 7% final rate of revision in the MK group at 5 years, compared to 2.8% in the standard group (Figs. 4 and 5). This was usually associated with aseptic tibial loosening, which is the main cause of TKA failure [2,23,25,26].

The “Mini-keel” design involves an additional interface between the plate and the keel, which could be a source of loosening. Tightening of the keel could also be an explanation, but this was systematically done before cementing and inserting the component. Cementing was performed in one stage in both groups. Despite a supposedly better fixation with separate cementing (tibia then femur) [24], the 5-year survival of the standard cemented tibial component in our study was comparable to results in New Zealand, Australian and Swedish registers [27–29] and was not found to be a source of error in the data analysis (2.7%, 2.5% and 3.3% respectively compared to 2.8% in our series). Also the surgical approach could not have influenced the results because the same approach was used in both groups.

Several teams have reported different results with short-keel tibial components [30–32], with the goal of limiting the bone loss associated with tibial preparation. Three studies have specifically investigated the “mini-keel” tibial component. The series by Benazzo et Rossi [21] in 200 knees reported a tibial radiolucent line in 11.5% of cases with only 3 cases of surgical revision. However, the follow-up of that study was 3 years, the delay after which we identified nearly 60% of the revisions in our series. In the study by Yoo et al. [33], the rate of radiological loosening was 13% after a minimum of 5 years of follow-up and the rate of revision was less than 1%. However, the percentage of lost to follow-up was nearly 50%. The study by Foran et al. [34] reported the results of 529 TKA with the cemented minimally invasive “mini-keel” tibial component with no extension stem. Revision was performed in eight patients (1.5%) after a mean 17 months for aseptic tibial loosening. At the outset, these authors did not recommend using this prosthesis without a keel.

5. Conclusion

In our experience the mid-term results of the MIS, Mini-Keel tibial component presents a rate of revision for loosening that is statistically higher than the standard Nexgen LPS-Flex prosthesis with a fixed plate and standard keel. All other variables in the study were similar. This study could not identify the cause of this failure, but a biomechanical assessment of the design and primary fixation of this system would be interesting to determine the reason for these failures.

Disclosure of interest

P. Boisrenoult, P. Beauflis and N. Pujol are occasional educational consultants for Zimmer and Smith and nephew. C. Kajetanek, B. Boyer, M. Ollivier declare that they have no competing interest.

References


