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Mobile-Bearing Total Knee Prosthesis

A 5- to 9-Year Follow-Up of the First 110 Consecutive Arthroplasties

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Abstract: This study regards the total articulating cementless knee. This is a mobile-bearing knee, the tibial component of which consists of 2 parts: a highly conforming polyethylene insert freely rotating on a metal tray. Our case study relating to the implant of the first 110 knees operated on consecutively from 1991 to 1995 is reported, with an average follow-up of 6.3 years (range, 5–9 years). The average preoperative Knee Society Score was 78 points, and the average postoperative score was 156 points. The complications specifically related to the prosthetic components and which required revision surgery were 4: 2 cases of instability, 1 aseptic loosening of the tibial tray, and 1 traumatic dislocation of the tibial insert. A further 3 patients underwent reoperation for causes not strictly related to the implant: 2 because of intractable patellar pain and 1 because of periprosthetic ossifications that limited flexion. All of the complications were observed in patients operated on during the first 3 years of our experience, thus suggesting a definite learning curve with this prosthesis. No evidence of progressive radiographic periprosthetic osteolysis was recorded, and no relevant polyethylene wear was observed over time. Kaplan-Meier survival curves show the probability of survival to be 93.7% with revision surgery for any reason as an endpoint, and 96.3% with revision surgery for a mechanical reason as an endpoint. Certainty that mobile-bearing total knees are able to assure a longer life of the implant than the conventional models would require an evaluation of results over 15 to 20 years. However, in the meantime, these good preliminary results at least justify continuing the use of this type of prosthesis, which still awaits confirmation of the, as-yet-theoretical, advantage compared with fixed-bearing total knees. **Key words:** arthroplasty, knee, mobile bearing, wear, follow-up studies.

Although this is not a new concept, mobile-bearing knees have been the most challenging breakthrough in knee arthroplasty over the years. Though conventional prostheses have shown a high success rate even after 15 or 20 years [1,2], there is still a significant rate of failures caused by the loosening of the prosthetic components and by polyethylene wear, which is reported to exceed those described in hip prostheses [3]. To solve these problems, constrained knee prostheses were introduced, followed by the low-conforming, and then by the partially conforming, prostheses, all aiming at solving the well-known wear-conformity dilemma. This dilemma regards the impossibility of

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using high-conforming articulating surfaces, which are preferable from the point of view of the polyethylene wear, because of the risk of generating excessive stresses at the bone-implant interface. On the other hand, low-conformity articulating surfaces lead to high wear of polyethylene even if they reduce the stress at the interface [4]. The subsequent, partially conforming prostheses have not succeeded in maintaining the stresses on the polyethylene lower than the compressive yield strength of the plastics [5]. Allowing movement between the 2 tibial components, mobile-bearing knees seem to finally provide designers with the solution of the wear-conformity problem, significantly reducing both the stress at the bone-implant interface and, thanks to the high conformity of the polyethylene tibial insert, the polyethylene wear.

With the aim of preserving the attractive features of meniscal bearing, but avoiding some disadvantages reported in the literature with the use of such designs [3,6,7], the total articulating cementless knee (TACK) was developed during the late 1980s.

The purpose of this study is to report our midterm clinical experience with the mobile-bearing TACK. To our knowledge, this is the first study performed on the clinical results achieved with this type of knee arthroplasty.

Materials and Methods

The present study observes clinical evolution of TACK total knee prostheses implanted at our Institution. TACK (Waldemar Link GmbH & Co, Hamburg, Germany) is a resurfacing knee arthroplasty. The implant consists of 3 components, with the option of a fourth component (patella). The metal components are made of a cobalt-chrome-molybdenum alloy. The femoral component is highly congruent and anatomically shaped, with left and right versions. The nonarticulating surfaces of tibia and femur are textured to encourage bone ingrowth, with or without hydroxyapatite ceramic coating. A version to be cemented is also available. The tibial part has 2 components. A metal tray with a conical stem is implanted on the bone, and a high-conforming ultrahigh-molecular-weight (UHMW) polyethylene bearing sits in the tray. Polyethylene is sterilized by ionizing radiation (gamma rays, 27 ± 2 KGray). The components are shaped to allow free rotation to occur between the polyethylene and the metal (Fig. 1). Both tibial components have a posterior recess to accept the posterior cruciate ligament in case of its retention.

Fig. 1. The components of the TACK, including a femoral component, a mobile-bearing polyethylene tibial insert, and a tibial baseplate.

From February 12, 1991, to December 23, 1995, the TACK prosthesis was implanted in 117 consecutive patients, for a total of 125 knees (8 patients had both knees operated on). At the moment of review, 102 patients were available for clinical evaluation (5 were deceased, and 10 could not be traced), for a total of 110 knees. The minimum follow-up was 5 years, and the maximum was 9 years (average, 6.3 years).

The patients included 48 men and 54 women, with an average age of 71.6 years (range, 50–83 years). The average height of the patients was 166 cm (range, 148–186 cm), and the average weight was 73 kg (range, 49–98 kg).

Preoperative pathologic conditions included osteoarthritis (104 knees [94.5%]), either primary (100 knees) or posttraumatic (4 knees), and rheumatoid arthritis (6 knees [5.5%]). Eighteen knees (16.5%) had undergone prior proximal tibial valgus osteotomy as treatment for their osteoarthritis.

Preoperative alignment of the limb was varus in 77% of cases, valgus in 9%, and neutral in 14%. The average varus angulation (with respect to the mechanical axis of the limb) was 6° (range, 1°–25°); the average valgus angulation was 12° (range, 7°–30°). Most knees (73 cases) had a flexion contracture ranging from 1° to 30° (average, 7°). The average range of motion was 98° (range, 0°–135°).

Preoperatively, all patients were assessed by 1 observer using the Knee Society Score [8]. Preoperative evaluation included standard anteroposterior, lateral, and patellar skyline views in addition to long-leg radiographs taken with the patient standing. Patellar congruency was measured on the skyline views using the method described by Keblish et al. [9].

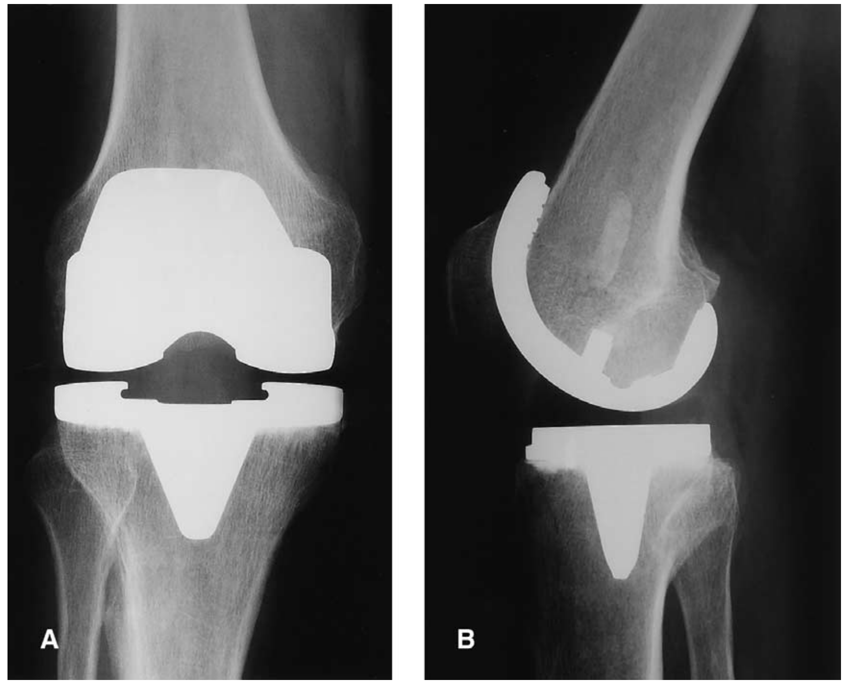

Fig. 2. Postoperative (A) anteroposterior and (B) lateral radiographs at 5 years.

After surgery, patients were assessed clinically by the same independent observer and radiographically at 3 months, 6 months, and then at yearly intervals (Fig. 2A and 2B). The radiographic evaluation consisted in assessment of alignment of the limb, implant fixation, patellar tracking, and evidence of polyethylene wear.

Antibiotic prophylaxis consisted in Cefazolin (2 g intravenously) administered 30 minutes before surgery and after the first 12 and 24 postoperative hours. All patients received Enoxaparin (4,000 UI/d) as prophylaxis for deep venous thrombosis.

All surgeries were performed by the same surgeon (V.S.). An anterior midline approach was always performed, followed by a medial arthrotomy and lateral luxation of the patella.

In 40 cases (36.5%), the femoral and tibial components were uncemented; in 59 cases (53.5%), only the tibial component was cemente; and in 11 cases (10%), both components were cemented.

The patellar component was never implanted. A patelloplasty, including circumferential rim cautery for partial denervation, osteophyte removal, and downsizing or contouring to original anatomy, usually was performed. When required, a lateral release was performed to establish a normal patellar tracking.

The posterior cruciate ligament was always retained. In case of lack of extension or when the tibial component had a tendency to lift anteriorly during flexion, resection of posterior femoral osteophytes and detachment of posterior capsule were performed, followed, when required, by a partial release of the posterior cruciate ligament. No other significant soft-tissue release was usually performed.

Kaplan-Meier survival estimates using the endpoint of revision for any reason and the endpoint of revision for a mechanical reason were calculated. A mechanical reason indicates problems, inducing revision, strictly related to the prosthetic components. Data were analyzed using the 95% confidence interval (CI).

Results

The average preoperative clinical score was 33 points (range, 10–70; SD = 12.8), and the average preoperative functional score was 45 points (range, 12–75; SD = 12.6), for a total of 78 points. The average postoperative clinical score was 82 points (range, 59–100; SD = 8.1), and the average postoperative functional score was 74 points (range, 40–100; SD = 9.5), for a total of 156 points. The average preoperative flexion was 98° (range, 45°–135°, SD = 18.1); the average postoperative flexion was 108° (range, 0°–135°; SD = 29.7). Complete extension was observed in most patients, but 8 knees (7.3%) had a postoperative flexion deformity

Table 1. Revision Surgeries Performed After TACK Arthroplasty

Indication for Revision Surgery (n)	Procedure (n)
Instability (2)	Exchange (2)
Aseptic loosening (1)	Exchange (1)
Patellar pain (2)	Proximal realignment (1); patellar resurfacing (1)
Polyethylene dislocation (1)	Surgical reduction and extensor knee mechanism reconstruction
Periprosthetic ossifications (1)	Ossification removal

(average, 5°; range, 2°–10°; SD = 2.5). The postoperative limb alignment (with respect to the mechanical axis of the limb) was neutral in 74 cases (68%), varus in 34 cases (31%), and valgus in 2 cases (1%).

Seven cases required reoperation (Table 1), although only 4 were caused by problems strictly related to the prosthetic components. Three patients (2.7%) had the prosthesis exchanged: 2 cases because of instability and 1 case because of aseptic loosening of the tibial tray.

A dislocation of the polyethylene tibial insert occurred in 1 case. After a useless attempt of noninvasive reduction, the patient underwent reoperation with relocation of the polyethylene and reconstruction of the interrupted extensor knee apparatus. At 7 years, the Knee Society total score (functional + clinical) was 98 points.

A persistent patellar pain was present in 6 patients (5.5%). Four cases recorded a good improvement with conservative treatment; 2 cases remained unchanged. One of these 2 cases showed a lateral patellar subluxation and was treated by surgery with a proximal realignment according to Insall. At 7 years, the Knee Society total score was 128 points. The second case showed a properly aligned patella; therefore, an all-polyethylene patellar component was implanted. At 5 years, the Knee Society total score was 119 points. The last case, which required reoperation, was the case of a patient with large anterior femoral periprosthetic ossifications limiting the flexion beyond 70°. At 8 years, the Knee Society total score was 154 points.

The radiographic study showed no progressive radiolucency around any of the 2 metallic components. No evidence of any asymmetrical wear of the tibial insert was observed.

Patellar tracking was reported to be correct in 87 knees (79.1%) and lateralized in 23 (20.9%), but most of these cases were asymptomatic as for patellar pain. Kaplan-Meier survival analysis showed that the probability of survival of the implant was 93.6% (95% CI, 88.%–98.%) with revision surgery for any reason as an endpoint (Fig. 3A). With revision surgery owing to mechanical reason as an endpoint, the probability of survival rose to 96.3 % (95% CI, 92.8%–99.9%) (Fig. 3B).

Discussion

Since Buechel and Pappas introduced the principle of mobile bearing in total knee prostheses in the 1980s to address the problems of loosening and wear, the interest in this type of knee arthroplasty

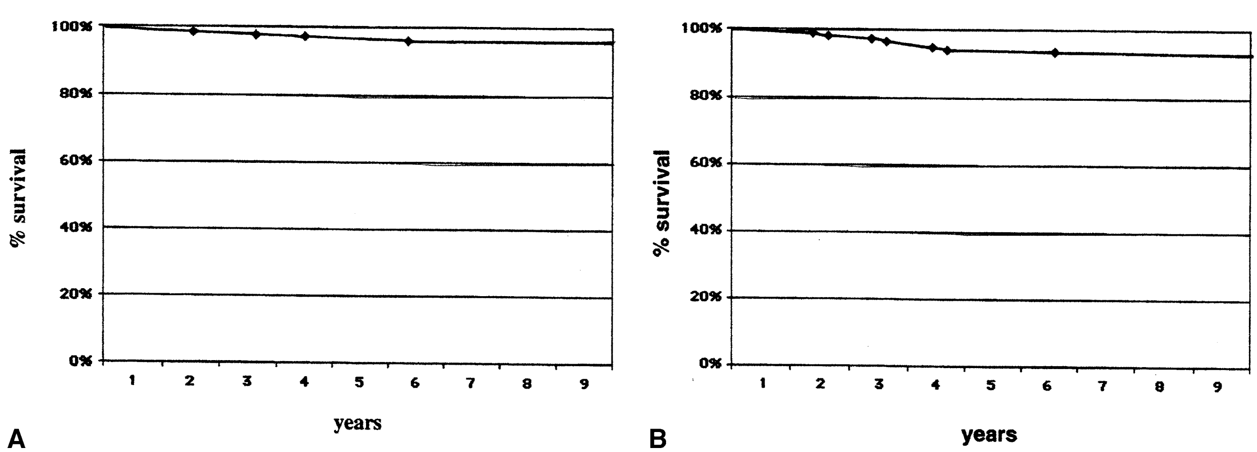

Fig. 3. Kaplan-Meier survival analysis of the TACK arthroplasty at a mean follow-up of 6.3 years. (A) Probability of survival with revision surgery for mechanical reason as an endpoint. (B) Probability of survival with revision surgery for every reason as an endpoint.

has been growing. In fact, the mobile bearing seems to provide considerable theoretical advantages compared with conventional prosthetic knee models. Theoretically, the stresses at the bone-implant interface should be considerably reduced or even cleared by the movement of the polyethylene tibial component on the tibial tray.

The relative displacement between both tibial components should allow a load sharing with the periarticular soft tissues that, for this reason, may gradually strengthen, in a fashion similar to that of the normal knee. Soft tissues, unlike inert prostheses, have the capacity to respond and remodel to challenges of the expanding activities performed as the pain-free knee is rehabilitated. Simultaneously, the partial load sharing with the soft tissues reduces the joint loads and may contribute to the reduction of prosthetic wear. Moreover, the high conformity of the polyethylene insert seems to assure a low wear rate of polyethylene [10,11] and good stability [12].

The rotational mobility of the polyethylene insert should allow a further advantage consisting of the automatic correction of small errors of rotational alignment of the tibial metal component [10].

These theoretical advantages appear to allow a surgical treatment option with greater confidence, even in relatively young patients affected by severe knee osteoarthritis. Thus far, this segment of the population remained virtually excluded from surgical indications for a total knee arthroplasty, considering poorer results obtained in comparison with those obtained on elderly patients and the concerns about implant-life duration.

The TACK has all of the features—and, consequently, all of the potential advantages—of mobile-bearing knees. It is provided with unrestricted axial rotation, but it does not allow for the anteroposterior translation movement existing in other types of mobile-bearing knees. However, in light of published fluoroscopic studies [13], this aspect does not seem to be a restriction [13,14], but rather an advantage. In fact, in our opinion, it provides a better kinematic behavior by cancelling or minimizing the paradox effect of the anterior femoral sliding in flexion, detected in the mobile-bearing knees that allow the anteroposterior translation of the polyethylene tibial insert. [13,14]. The paradox effect of the anterior femoral translation in flexion involves at least 2 negative results: a potential increase in delamination wear of polyethylene and a restriction of flexion.

The anteroposterior and medial-lateral stability of the TACK is very high, as proven by laboratory biomechanical tests [12]. The data obtained allow for consideration of the TACK as a constrained model with regard to drawer and varus-valgus displacements, while rotation is unrestricted.

The high conformity on the coronal plane, if not able to reduce the femoral condylar lift-off, should at least minimize the adverse effects of such a mechanism on polyethylene. In mobile-bearing designs with high coronal conformity, Stiehl et al. [15] observed that peak stresses remain below the yield strength of polyethylene even in the presence of femoral condylar lift-off.

The tibial cut has a backward slope of 10° which mimics the angle of the normal tibial plateau. The posterior tilting may have 2 positive effects: it may reduce the amount of anteroposterior shear forces and may allow a thinner tibial cut.

Considering the relatively recent proliferation of the use of mobile-bearing knees, there are few clinical trials published on this subject, and none on TACK arthroplasty.

By reviewing the results of our case study, we can state that they favorably compare with data reported by other authors. Buechel and Pappas [16] observed 95.1% good or excellent results in cemented cases and 98.2% good or excellent results in uncemented cases with the LCS system. Furthermore, Sorrells had excellent results with the uncemented rotating platform in a series of 665 consecutive cases. The survival rate was 94.7% at 11 years [17].

Jordan et al. [7] also reported the results with the LCS system. The Kaplan-Meier survival rate was 94.6% at 8 years with revision surgery for a mechanical reason as an endpoint. Meniscal-bearing dislocation occurred in 1.1% of cases, and bearing breakage occurred in 1.5% of cases.

The complications related to the bearing insert are reported to be 0.7% with meniscal bearing and 3.2% using a rotating platform [3,6,16]. More recent data, however, appear to contradict such a high rate of complications related to polyethylene inserts.

The outcome of Rotaglide total knee arthroplasty was reported by Polyzoides et al. [18]. The short-term results (average, 3.1 years) are good or excellent in 95% of cases, and no platform bearing dislocation was observed.

Kaper et al. [19] published their results with the Self Aligning I total knee arthroplasty and reported 91.7% probability of survival with revision surgery for any reason as an endpoint, and 98.8% for revision surgery because of polyethylene wear as an endpoint after an average follow-up of 5.6 years. No cases of bearing dislocation or breakage were seen.

Callaghan et al. [20] reported excellent results with a cemented rotating platform knee that was similar to the index implant. The 9- to 12-year follow-up is one of the longest studies in the literature of a mobile-bearing knee. None required a reoperation, and none had a dislocation of the mobile bearing.

Finally, in the last clinical survey published by Buechel et al. [21], the rate of complication relative to meniscal bearing decreased to an overall 1.2%.

In the current series of 110 cases, only 1 (0.9%) bearing dislocation occurred, but it seems to be an exceptional, posttraumatic event linked to a series of peculiar and not easily replicable causes, and it would be likely to occur with any kind of mobile-bearing knee. In fact, the dislocation occurred during the night, 5 days after surgery: the patient had psychological and movement disorders, and fell from her bed when she tried to get up with no knee brace and without the nurse's help. During revision surgery, the suture of the extensor apparatus was found fully torn off, and this, very likely together with a hyperflexion mechanism of the knee, allowed the polyethylene insert to rotate 90°. Such a mechanism is impossible with an intact extensor apparatus.

The 2 cases of instability we observed occurred 24 and 28 months, respectively, after surgery. In both cases, they were elderly women (73- and 78-year-olds, respectively) with normal body size. In the second case, which originally showed an intense medial osteoarthritis with a severe varus deformity and medial femoral subluxation, we could identify a 3° varus positioning of the tibial component. The flexion valgus-stress maneuver revealed a gross laxity and a discernible "clunk," likely the result of a deficiency of the medial collateral ligament, which occurred gradually. In fact, both patients had been fine for at least 2 years after surgery. Both patients underwent revision surgery, during which the implant was replaced with a semiconstrained prosthesis. In both cases, the components were firmly fixed. In the case of the 78-year-old patient, posteromedial polyethylene wear was observed, whereas in the other patient, the polyethylene appeared almost intact.

The only instance of aseptic loosening in our case study occurred in a 75-year-old man of 173-cm height and 82-kg weight. Four years after surgery, at the radiographic control, we observed the subsidence of the cemented tibial component and tilting to a varus position. By retrospectively examining the case, the patient had never recovered the full extension of his knee, and he showed a flexion contracture of about 10° degrees, although his flexion was very good (125°). Upon revision, the posterior cruciate ligament looked very tight, and this may have generated eccentric loads in flexion on the tibial tray, causing its loosening. On the contrary, the femoral component was perfectly stable.

Thus, in at least 2 of 4 cases with mechanical problems, the cause of the prosthetic failure may be ascribed to a surgical technique error: a varus malalignment in 1 case and an inadequate soft-tissue balance in the other case. In this regard, it is interesting to observe that all cases that we revised had the first surgery in the preliminary 3 years of our experience, thus suggesting the existence of a learning curve with this knee system.

Consistent patellar pain was observed in 6 cases (5.5%). Four of these obtained good results with conservative treatment (physiotherapy). No improvement was achieved in the other 2 cases. In 1 of these cases, there was evident lateralization of the patella, which then was treated surgically by proximal realignment according to Insall. In the second case, the patella looked properly aligned; therefore, the all-polyethylene patellar component was implanted. In both cases, the result is generally fair, although there is still moderate pain in going up and down the stairs, which reduces the final score of both patients by about 20 points.

As for the case with periprosthetic ossifications, we believe that the cause of failure has been overly aggressive and overly early rehabilitation treatment. The removal of calcifications through a small lateral incision in the thigh, occurring 5 months after implanting the prosthesis, did not cause any special trouble, and the patient easily recovered adequate flexion.

An understandable concern with mobile-bearing knees, especially those with a rotating platform, is whether the polyethylene insert keeps its mobility over time. In our experience, in all cases submitted to revision surgery, the tibial polyethylene insert had maintained its ability to rotate, and we did not observe any sign of growth of soft tissues hindering such movement.

The decision to cement the tibial tray in a high number of cases may seem apparently in conflict with the theoretical considerations about the reduction of the stresses at the bone-implant interface. In reality, different reasons influenced this decision. First, we considered bone quality. All tibial components in patients older than age 75 were cemented. The second reason, concerning few cases, was the result of some slight irregularities of the cutting surface that made us fear a possible tilting of the component.

However, regardless of age and of the proper resection of the bone, both components were cemented in patients affected by rheumatoid arthritis (6 cases) and in the presence of osteoporotic bone (5 cases).

Of the 3 cases that went through revision surgery with replacement of the prosthesis, 2 had the tibial component cemented. Our data obviously are too limited to assume a different behavior of the cemented and uncemented knees in terms of interface stability.

We did not observe any significant difference between the cases with maintained posterior cruciate ligament and those in which the posterior cruciate ligament was not intact, thus proving the good anteroposterior stability of this prosthesis. However, we always tried to retain the posterior cruciate ligament, at least partially, whenever this was possible, also considering other factors like the role of the posterior cruciate ligament as an anteroposterior primary constrain and as a medial-lateral secondary constrain [22]. Moreover, a better proprioceptive function of the replaced knees is described when this ligament is retained [23,24]. It also is easier to maintain the level of the joint line that, in case of ligament removal, tends to rise.

The good stability in varus-valgus movements detected during laboratory tests is not enough, in our opinion, to recommend the use of this knee in case of deficiency of 1 or both collateral ligaments—even in light of our experience with 2 cases of instability occurring after surgery.

In conclusion, the preliminary results of this mobile-bearing knee case study are good at a 6-year follow-up and, in our opinion, further justify the use of this prosthesis and the extension of the indications even to relatively young, active patients. A longer follow-up obviously is necessary to make a more precise statement about this knee arthroplasty system, but our preliminary results at least do not contradict the theoretical advantages of mobile bearing in terms of polyethylene wear and stability of components.

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