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ORIGINAL ARTICLE

Poor results of the Optetrak™ cemented posterior stabilized knee prosthesis after a mean 25-month follow-up: Analysis of 110 prostheses

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Summary
Introduction: The introduction of a new knee arthroplasty model, even if it differs from a validated implant by only a few details, should be followed by rigorous assessment. The Optetrak™ cemented posterior stabilized knee prosthesis evolved from the Insall prosthesis with a smaller tibial keel associated with a higher tibial cam and increased femorotibial congruency as well as a more posterior-stabilized trochlea.
Hypothesis: We hypothesized that this implant with only minor modifications to the Insall prosthesis would provide as favorable results as the Insall prosthesis.
Materials and methods: A continuous series of 110 prostheses (106 patients) implanted between 2005 and 2007 was retrospectively analyzed with a mean follow-up of 25 months (range, 12—42 months) by an independent observer. The follow-up was based on the IKS score and the radiological assessment was conducted by three senior surgeons.
Results: The mean IKS score was 83.7 (range, 13—100) points at the last follow-up, the mean function score was 82.6 (range, 30—100 points), and mean flexion was 120° (range, 80—140°). Seventeen patients (15%) were disappointed or dissatisfied, 25 knees (22%) were painful, requiring regular painkillers. The prostheses had a satisfactory mechanical axis, with a mean HKA angle of 177.4 $\pm$ 4°, but 25 prostheses (22%) presented rims evolving toward tibial implant loosening, and 24 (21%) developed signs of patellofemoral conflict. With follow-up less than 5 years, nine cases were revised for tibial loosening, three for patellofemoral instability, and one for patellofemoral pain. The cases of tibial loosening were particular because they occurred at the cement—tibial-implant interface. The cumulated survival rate at 36 months was 80.97 $\pm$ 9.1% and 76.74 $\pm$ 12% at 45 months.

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Discussion: This tibial implant with a small keel does not resist the stresses applied by posterior stabilization, with notably a higher level of stress than the Insall prosthesis from which it was derived. In cases of centering defect, the design of the trochlea can lead to impingement between the edges of the patella and the prominent edges of the prosthetic trochlea. We have suspended implantation of this prosthesis and continue to monitor the progression of patients having received these implants.
Level of evidence: Level IV, retrospective study.
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Introduction

The results of a total knee arthroplasty (TKA) depend to a large extent on the implantation technique, but also on mechanical factors related to implant design and material [1]. A new knee prosthesis should be introduced following a rigorous procedure, even if the new prosthesis differs from the reference prosthesis by only a few details that may seem trivial, because a minimal change can produce unfavorable consequences [2,3]. The Optetrak™ cemented posterior stabilized knee prosthesis (Exactech, Gainesville, FL, USA) was launched on the market in 1995. It was presented as a successor to the Total Condylar prosthesis [4] and the Insall-Burstein posterostablized prosthesis of the Insall-Burstein II (IBII) type [5]. Compared to the latter, the Optetrak™ proposed several innovations to the tibial insert and the design of the femoral trochlea. These modifications aimed to reduce the localized stresses on the tibial polyethylene insert, to improve patellar tracking, to provide flexion greater than 120° while remaining stable in the sagittal and frontal planes, and to increase resistance to tibial subluxation.

We report the radiological and clinical results of a series of implantations of this prosthesis. We hypothesized that this implant would allow us to obtain results that were at least as favorable as the Insall-Burstein prosthesis from which it was derived.

Patients and methods

Implant

The Optetrak™ (Exactech, Gainsville, FL, USA) included a cemented femoral implant in chromium-cobalt alloy (Co-Cr-Mo) that was anatomic and asymmetrical. The trochlear groove was deep and oblique upward and outward (7°) to facilitate patellar tracking and centering (Fig. 1). The femoral condyles presented a symmetrical curve radius. In the frontal plane, the ratio of the radius curves of the condyle and the corresponding tibial surface was high (0.96) so as to ensure a high level of congruency and to limit polyethylene wear. The surface coating between the tibial surface and the bone was identical for the fixed-bearing and mobile-bearing tibial trays, with a microbead porosity. Two keel models were proposed: a classical rectangular or a smaller keel, shorter, round, and with wings. Only the second model was used in this series (Fig. 1). A mobile-bearing tibial tray was used in 94 cases (85%) and a fixed-bearing tray in
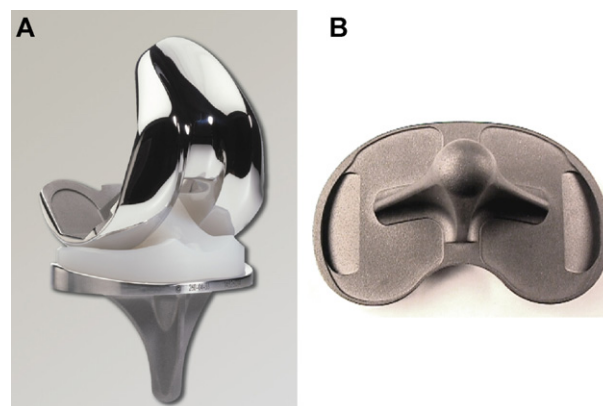
Figure 1 Optetrak™ cemented posterior stabilized knee prosthesis. A. Anterior view of the fixed-bearing tray model; the trochlear groove is ultracongruent. B. Inferior view of the tibial tray showing the cement pockets and the winged keel.

16 cases (15%). In the RBK (rotating bearing knee) mobile-bearing tibial tray, the tibial component was in a Cr-Co alloy. The polyethylene component could turn around the axis of the proximal surface of the tibial tray, which was colinear with the plug axis. The tibial surface of this mobile-bearing tray was adapted to the geometry of the polyethylene, with a wave-shaped design so that the tibial polyethylene thickness remained constant with the joint surface. The tibial tray with fixed-bearing polyethylene was made of titanium alloy.

The posterior stabilization tibial cam curved forward to reduce stresses, but it was higher than on the reference IBII implant so as to increase resistance to subluxation. This posterior stabilization mechanism provided 145° of flexion with no risk of posterior contact between the femoral component and the tibial polyethylene. The polyethylene thickness of the tibial tray was 9 mm in 47 cases (42%), 11 mm in 46 cases (41%), and 13 mm in 17 cases (15%).

The patella was a symmetrical and spherical dome with a slightly concave slope matching the shape of the prosthetic trochlea with a choice of four patellar implant sizes. All operations were performed under vertical laminar airflow and all the implants were cemented with gentamycin-impregnated Palacos™ (Schering Plough, Herouville Saint Clair, France). We modified nothing in our technique compared to the IBII implants that we had used before. Consequently, for patients with normal mechanical alignment or those with a varus deformity, we used a parapatellar approach in 19 cases (17%) and a mid-vastus approach in 80 cases (73%) [6,7], whereas the Keblish-type

lateral approach was used for the 11 cases of genu valgum [8].

Patients

This retrospective continuous multioperator study included 111 patients (115 knees) operated between March 2005 and October 2007 in two orthopaedic units at the Lille University Hospital. In more than half of the cases, the intervention was led by a senior surgeon specialized in this surgery.

The mean follow-up was 25 months (range, 12—42 months). The review was carried out by an observer (CET) who was not one of the operators. At follow-up, one patient had died (with one prosthesis) and four had been lost to follow-up (four prostheses); they were removed from the analysis of the functional results but were included for the survival analysis. Three patients who refused to come to the follow-up visit took part in a telephone interview, which confirmed that clinical manifestations had not reoccurred. A total of 106 patients (110 knees) were seen at follow-up.

The mean age at surgery was 69.7 ± 8.4 years (range, 40—87 years), the series comprised 24 males (24%) and 82 females (76%), and they had a mean body mass index (BMI) of 29.8 ± 5.2. One hundred and four knees (95%) were operated for primary or secondary osteoarthritis, three knees (2.5%) for inflammatory rheumatism, and three knees (2.5%) for aseptic condylar osteonecrosis. Eighty knees (82%) had never been operated, 20 (18%) had undergone one intervention (osteotomy, meniscectomy, tibial tuberosity translation). Seventy-seven patients (70%) had single-joint involvement, 29 (26%) had bilateral involvement, and four (3.6%) had multiple joint involvement.

Evaluation method

The evaluation used the IKS [9] and KOOS [10] scores. The radiographic analysis used the IKS criteria [11] based on a radiographic work-up including anteroposterior and lateral images with load, a 30° patellofemoral flexion angle, and stress valgus and varus images using the Telos stress device. Femorotibial HKA alignment was measured on standing AP long-leg films. The patella position was analyzed on the patellofemoral view at 30°. A medial tilt was retained when the α angle (defined as the tangent to the patellar cut and by the tangent to the prosthetic trochlea) was greater than 5°. Patellar translation was calculated using the method described by Keblish et al. [12]: the patellar congruency index compared to the trochlear groove was expressed as a percentage. Abnormal patellofemoral contact was sought between the patella bone surface and the edge of the femoral component. Finally, the thickness of the patella, the Blackburne and Peel index [13], and the height of the joint space were assessed. The AP femoral component, identified by the tangent line from the distal part of the prosthetic condyle, was aligned if it was perpendicular to the femur's mechanical axis (within $\pm 2°$) and laterally was aligned (within $\pm 2°$), or if not, it was considered a flexion or recurvatum deformity. The tibial component, materialized by the metallic baseplate, had to be perpendicular in the AP view to the tibia's mechanical axis (within $\pm 2°$); if not, it was considered varus or valgus. On the lateral image,

the tibial component had to have a slope between 3 and 7° compared to the posterior tibial cortex [14].

The tibial and femoral radiolucent lines were interpreted following the IKS criteria. Tibial loosening, suspected with knee mobilization, was confirmed by the presence of evolving radiolucent lines, possibly associated with the existence of a space and implant movement. If substantial loosening was suspected, a bone scan with technetium injection was performed to look for localized hyperfixation in the suspicious areas. Abnormal contact associated with patellofemoral pain was retained as a complication. The radiographic measurements were evaluated by a single observer (CET), but all radiographic anomalies were confirmed by a second reading by three senior surgeons who were not operators.

Statistical analysis

The qualitative variables were compared with the chi-square test and the F-test. The quantitative variables were compared using the Student t-test and the Kruskal—Wallis test for comparison of small groups. In all the comparisons, the $p < 0.05$ significance threshold was retained. The various analyses were performed using SAS Version 9.1 software. A Kaplan—Meier survival analysis was performed with changing the tibial component as the failure criterion.

Results

Clinical results

The mean IKS knee score increased from 37.7 points (range, 5—80 points) to 83.7 points (range, 13—100) (Table 1). Mean mobility increased from 109° (range, 40—130°) to 120° (range, 80—140°), mean preoperative flexion deformity decreased from 5° (range, 0—35°) to 1.2° (range, 0—20°). The mean IKS function score increased from 46.3 points (range, 5—80 points) to 82.6 points (range, 30—100) (Table 1). Twenty patients (18%) presented patellofemoral pain associated with radiological patellofemoral impingement, 27 patients (24%) presented consistent pain, correlated with the knee and function scores. The clinical results were not influenced by the approach or the preoperative deformity. A total of 94 patients (85%) were satisfied and 16 patients (15%) dissatisfied.

Radiographic results at follow-up

At follow-up, 70 knees (65%) had a normal HKA angle between 177° and 183°, 34 knees (32%) showed varus greater than 3°, and six knees (5%) valgus greater than 3°. Twenty knees (18.7%) had varus greater than 5° and two knees (1.6%) valgus greater than 5°.

The AP femoral component was perpendicular (within $\pm 2°$) to the mechanical axis of the femur in 77 cases (70%), varus in 18 cases (16%), and valgus in 15 cases (14%). In the lateral view, the femoral component was aligned (within $\pm 2°$) in 68 cases (61%), with a flexion

Table 1 Preoperative and follow-up data.

	Preoperative	At follow-up
	Mean ± standard deviation	Mean ± standard deviation
Number of knees	110	
Arthrosis/arthritis	104/3	
Knee score (IKS)	37.7 ± 17.3 (5—80)	83.7 ± 14.3. (13—100)
Function score (IKS)	46.3 ± 15.3 (5—80)	82.6 ± 17 (30—100)
Pain score (KOOS)	8.3 ± 7.7	43 ± 12.2. (5—50)
Mobility (°)	109 ± 13.5 (40—130)	120 ± 12.4. (80—140)
Flexion deformity (°)	−5.6 ± 7.5 (0—35)	−1.2 ± 3. (0—20)
Frontal laxity <5 mm (%)	46	87
Sagittal laxity <5 mm (%)	86	95
HKA angle (°)	174.6 ± 5.9 (162—190)	177.4 ± 4.2. (163—187)
Varus (n)	66	34
Mean HKA angle	171.8 ± 2.2	175.3 ± 3.1
Normal HKA	32	70
Mean HKA angle	178.8 ± 1.1	179.1 ± 2.1
Valgus (n)	12	6
Mean HKA angle	186.2 ± 3.5	184.2 ± 2.7

IKS: International Knee Society; KOOS: Knee Injury and Osteoarthritis Outcome Score; HKA: angle between mechanical axes of the femur and the tibia.

deformity in 20 cases (19%) and a recurvatum deformity in 22 cases (20%).

The tibial component, shown by the metallic tray, was frontally perpendicular to the tibia's mechanical axis (within ± 2°) in 82 cases (75%), varus in 23 cases (21%), and valgus in five cases (4%). From a lateral perspective, the slope of the tibial component compared to the posterior tibial cortex was between 3 and 7° in 55 cases (50%), less than 3° in 38 cases (35%), and greater than 7° in 17 cases (15%).

Tibial radiolucent lines were observed on the AP images in 43 cases (38%) and judged to be progressive in 27 cases (24%). Twenty-five tibial trays (22%) were deemed loosened on the X-rays: eight fixed-bearing trays out of 16 (50%) and 17 mobile-bearing trays out of 96 implanted (18%) (the fixed-bearing trays loosened more frequently; $p = 0.008$, F test). For these loosened tibial implants, the pain score and satisfaction were significantly lower ($p < 0.05$). On the other hand, neither the HKA angle nor the beta angle influenced the loosening rate (Table 2).

The preoperative position of the patella on the patellofemoral images at 30° of flexion was considered to be aligned in 82 cases (74%) and laterally subluxated in 28 cases (26%). At follow-up, patellar tilt was 0 ± 3.4° (−20 to 18°), between −5 and 5° in 69% of the cases, and the patellar cutting angle was 0.3 ± 3.3° (−9 to 10°), between −5 and 5° in 88% of the cases. Pathological patellofemoral contact was present in 24 cases (21%). In these cases, patellar pain, the satisfaction index, and the knee score were significantly altered ($p < 0.05$). The HKS angle and patellar tilt were also significantly different ($p < 0.05$) for these cases of pathological patellar contact (Table 3). The postoperative Blackburne and Peel index was 0.58 ± 0.2 (range, 0.2—1.47), with six cases (5%) of patella baja. The mean length of the patellar tendon was 39 mm (range, 12—62 mm), correlated with final flexion ($p < 0.05$).

Postoperative complications

Five patients experienced thromboembolic complications: four phlebitis and one pulmonary embolism. Four early revisions were required for one case of hematoma and three deep infections. For the latter, in two cases *débridement-lavage* associated with prolonged antibiotic therapy after identification of the bacterium sufficed, but the last case required changing the prosthesis in two interventions. All these infections were healed at the last follow-up with no incidence on function.

Early loosening and patellofemoral pain

Thirteen revisions were performed to change prosthetic components, for either resistant patellofemoral pain (four knees) or early aseptic loosening of the tibial component (nine knees) (Fig. 2). On the Technetium 99m bone scan, pathological linear focal hyperfixation was found in the nine latter cases. Intraoperatively, when mobility in the cement—prosthesis interface was found, the removal of the tibial component was generally uneventful, but tibial components with tibial stem extension were used for the revision prosthesis (Fig. 3). Finally, at the end of this analysis, 10 patients remained with pain and presented worrisome radiological and clinical signs indicating loosening or patellofemoral impingement.

Survival analysis

With the endpoint of tibial component replacement, the cumulated Kaplan-Meier survival rate was 89 ± 4% at 25 months, 80.97 ± 9.1% at 36 months, and only 76.74 ± 12% at the follow-up at 45 months. We had 14 failures, 13 of which were caused by the prosthesis (nine cases of aseptic

Table 2 Comparison of clinical and radiological results of implants considered to be loosened.

	Loosened tibial implants (n = 25)	Non-loosened tibial implants (n = 85)	p
Clinical data			
BMI	30.4 ± 4.6 (20—50)	30.9 ± 4.1 (20—51)	NS
Pain (/50)	n = 25	43.2 ± 12.2 (21—50)	<0.05
KOOS pain score, satisfied	19/100 ± 20	11.5/100 ± 15	0.02
Percent disappointed or dissatisfied (%)	28%	16%	0.01
IKS knee score	84.3 ± 17.9	85.1 ± 14.1	NS
IKS function score	83.2 ± 18.3	83.6 ± 17.8	NS
Radiological data			
Type of tray			
Mobile-bearing (MBP)	18% (n = 17)	82% (n = 77)	0.009 for FBP
Fixed-bearing (FBP)	50% (n = 8)	50% (n = 8)	
HKA	177.4 ± 4.2	177.6 ± 4.4	NS
Alpha	95.6 ± 2.5	95.5 ± 2.4	NS
Beta	88.1 ± 2.7	88.4 ± 2.8	NS
Mean Ahlbäck stage	3.4	3.4	NS

BMI: body mass index; IKS: International Knee Society; KOOS: Knee Injury and Osteoarthritis Outcome Score; HKA: angle between mechanical axes of the femur and the tibia; alpha: angle between the anatomical axis of the femur and the tangent to the condyles; beta: angle between the anatomical axis of the tibia and the tangent to the tibial trays; NS: non-significant difference.

tibial loosening and four painful patellofemoral impingement) (Fig. 4) and one infection mentioned above that resulted in changing the component in two interventions.

Discussion

We chose this cemented posterior stabilized prosthesis with no second thoughts because it was a new version of a validated model (the IBII prosthesis) that presented theoretical advantages: improved patellar tracking, reduction of the risk of femorotibial dislocation through an increase in the height of the posterostabilization polyethylene peg, a smaller keel allowing resection of less bone, the possibility of a rotational tray, and reduction of polyethylene wear through better distribution of the stresses [15]. Our hypothesis was not confirmed because this prosthesis gave less satisfactory results than the reference IB II implant [4,5]. Two types of complications appeared in the short term and seem to be related to the modifications in the newer model: early tibial loosening at the tibial tray—cement interface and abnormal painful patellar contact on a highly restricted trochlea.

Table 3 Clinical and radiological results of the patellofemoral images considered pathological.

	PFI 30° flexion, pathological (n = 24)	PFI 30° flexion, normal (n = 86)	p
	Mean ± standard deviation, range	Mean ± standard deviation, range	
Patellar pain	43%	22%	0.018
Climbs stairs	42.6 ± 7.5	44.1 ± 7.8	NS
% disappointed or dissatisfied	29%	12%	0.05
Knee score	80 ± 14.8	91 ± 15.2	0.019
Function score	83 ± 17.7	85.1 ± 17.9	NS
HKS	8 ± 1.1	7 ± 0.9	0.018
HKA	176.1 ± 3.5	177.5 ± 3.2	NS
Patellar tilt	1.2 ± 0.56	1.1 ± 0.51	0.04
Alpha	95.2 ± 2.6	95.8 ± 2.8	NS
Patellar thickness	2.1 ± 0.11	2.2 ± 0.13	NS
Blackburne and Peel index of	0.57 ± 0.06	0.59 ± 0.05	NS
patellar congruency	106.2 ± 17.4	105.7 ± 17.1	NS
Cutting angle	0.4 ± 3.9	0.3 ± 3.6	NS
Joint space height	18 ± 5.4	18 ± 5.3	NS

HKA: angle between mechanical axes of the femur and the tibia.
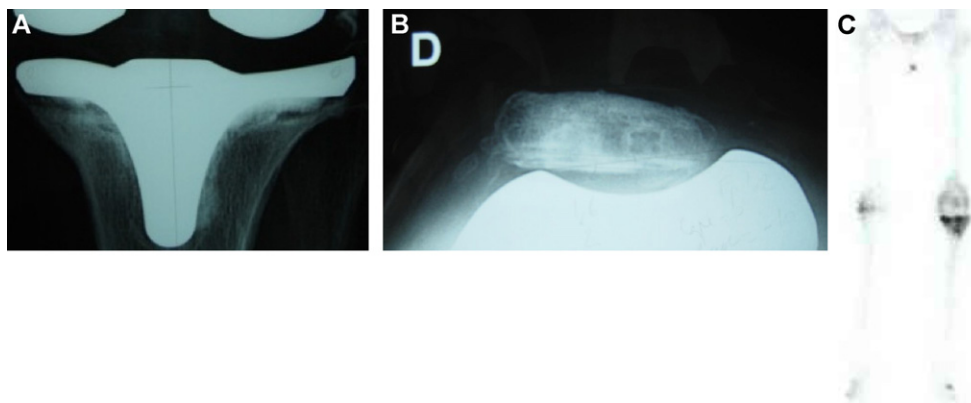
Figure 2   Complications. A. Loosening of the tibial implant. B. Patellofemoral impingement. C. Scintigraphic aspect of tibial loosening.
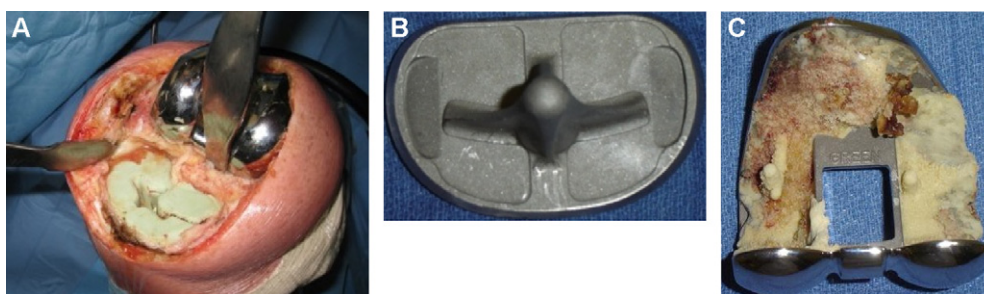
Figure 3   Loosening of tibial component of Optetrak™ tibial prosthesis. A. Surgical view showing that loosening was particular because the tibial component was separated from the cement remaining entirely on the bone. B. The tibial tray has no cement, in contrast to 3C with the femoral component.

Our revision rate with this implant is much higher than what has been reported by other teams with the same prosthesis [16,17] and is much higher than the rate observed in our team with other validated implants, even though patient management has remained unchanged compared to the knee prostheses used before [18,19]. The fixation mode (keel geometry) and the high level of stress (high congruency) may play a role in the occurrence of these margins and tibial loosening: 1) the architecture of the round, small tibial keel with a small surface compared to the classical rectangular keel does not prevent local micromotion according to

Stern et al. [20]. The rectangular tibial keel model used with this implant by other authors has given better medium-term results [16,17]. Although loosening preferentially affected the fixed-bearing trays, they also affected mobile-bearing trays with a high frequency (17.7%). The latter have an original wave structure to maintain a constant polyethylene thickness, which could increase stresses and thus promote tibial component loosening [21]. 2) The contact between the femoral cam and the tibial plug should take place in a very low area located so that low tibial tilting force is generated in the sagittal plane. For the Optetrak™ implant, the
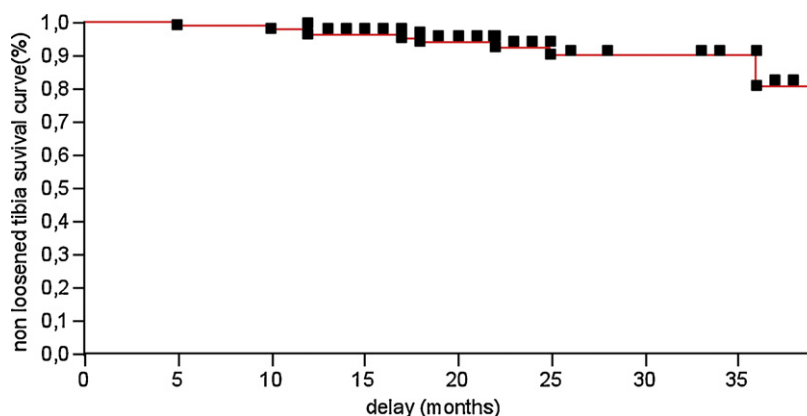
Figure 4   Cumulated survival curve if failure is defined as tibial loosening.

intercondyloid eminence has a greater height than on the IBII so as to increase resistance to subluxation. This increase in contact could create greater stress on the tibial sealing, causing failure of the implant—cement fixation. Bartel et al. [21,22] showed that ultra-congruency reduced wear but increased the stresses at the bone—implant interface. In the Optetrak™ prosthesis assembly, the combination of a fine keel and a hypercongruent tibial polyethylene insert can contribute to explaining the early loosening caused by an increase in stresses on the tibial plateau.

The microbead coating of the tibial implant was intended to facilitate grip between the tibial plateau and the cement, but the particular type of loosening at the cement—prosthesis interface with nearly nonexistent cement adherence has raised doubts in this area. For the same reason, the role played by the lateral pockets under the tibial tray, designed to improve tibial cementing hold, remain unconvincing.

Factors not related to the prosthesis such as cementing quality and bone quality could also explain our cases of failure [23], yet our surgical technique had not evolved compared to the original Insall implant (IB II implant and its successors), which, at the same follow-up time, had not led to this type of problem [20,21]. Cementing was done with a tourniquet in place: after pulsed lavage and drying, the bone cement was placed in the paste phase according to the recommendations [23,24], with keel and tray cementing as recommended by Rodriguez et al. [25]. Peters et al. [26] emphasize the need for the cement to penetrate at least 3 mm, whereas Hoffmann et al. [27] and Smith et al. [28] note that the preoperative bone quality may play a role in the appearance of radiolucent lines, related to defective injection of the cement into sclerotic bone.

Our population did not differ from the reference series reported in the literature in terms of etiology (87% osteoarthritis, 3.7% rheumatoid arthritis) age, weight, and sex (67.7 years, 76% female). In addition, our postoperative results for the IKS knee and function scores as well as the radiographic positioning of the implants differed little from previous reports [29—36]. However, our subjective clinical results are some of the most disappointing of all the series encountered (15% of the patients dissatisfied), including a high number of surgical revisions for tibial loosening or patellofemoral pain. In their meta-analyses of more than 5000 prostheses, Gioe et al. [37,38] observed 98.1% survival at 4 years for metal-back prostheses and 99% for monobloc polyethylene tibial trays. Kilgus et al. [39] considered that a 4.5% revision rate for porous coated anatomic (PCA) prostheses is a catastrophic result, but this is nonetheless lower than our series with 11.8% before 4 years of follow-up. We believe that these failures stem more from intrinsic factors related to a defective geometry leading to excessive stresses on the tibial tray whose keel is too small and/or to patellofemoral pain related to an overly constrained trochlea. This impression is confirmed by an abnormally high rate of radiolucent lines (38%) on the tibia for such a short follow-up period. Robinson [18] observed 42% radiolucent lines on the tibia with the Optetrak™ but with a mean follow-up of 5 years. Conversely, in their series of IBII implants, O'Rourke et al. [2] and Lachiewicz et al. [40] reported a lower rate of tibial radiolucent lines: 4 and 16%, respectively. The Optetrak™ femoral component

is in cobalt-chromium-molybdenum alloy, like the IBII with its already well-known advantages [40] such as a lower induced inflammatory reaction [41] and good wear resistance [39]. Anderson et al. [42] did not observe differences in results between the IB II PS and the Optetrak™ prostheses, but these authors used a regular rectangular keel that could withstand the additional stresses with the Optetrak™ implant.

We also observed 20 cases (18%) of pain related to an anomaly in the patellar tracking, which is three to five times greater than the rate reported with the IBII prosthesis [5,30,40] and the derived HLS prosthesis [41]. The particularity of the Optetrak™ is its deep trochlea with its prominent edges, which turned out to be detrimental in cases of an even minimal patellar centering defect. The patellar tracking problems were observed in 24 cases (21%) and in 20 cases patellofemoral pain was also present, underscoring that this highly constraining trochlea was very unforgiving of the least tracking anomaly. Even if the Optetrak™ prosthesis tibial fixation problems can be reduced with a larger keel, the patellofemoral problems are not solved, which severely limits the use of this prosthesis in our opinion. These patellofemoral problems as well as the tibial fixation problems had already been reported in the Australian registry, a reminder of the value of consulting the national registries before choosing a new implant [43].

Conclusion

The small size of the tibial keel does not seem to resist the stresses applied by the ultracongruent shape of the posterior stabilization of this implant and the increase in intercondyloid eminence height. In cases of defective patellar centering, the trochlea design can lead to impingement with the prominent edges. This series is a reminder that introducing a new knee prosthesis model requires systematic assessment to screen for any unforeseen effects of even seemingly minimal modifications. Close monitoring of this model is warranted.

Disclosure of interest

GP and HM are occasional consultants in education and research for Zimmer, HM is an occasional consultant for Tornier. CET and CM declare no conflicts of interest.

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