The Unispacer™ unicompartmental knee implant: Its outcomes in medial compartment knee osteoarthritis

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Introduction: A new concept has been recently developed for use in the treatment of isolated medial tibiofemoral osteoarthritis: the Unispacer™ implant. This mobile interpositional, self-centering implant replicates the meniscal shape. This mini-invasive device does not require bone cuts or component fixation. The implant trajectory is guided by the medial condyle.

Hypothesis: The Unispacer™ knee implant enhances knee function in the treatment of isolated tibiofemoral osteoarthritis graded 2 and 3 according to Ahlbäck radiographic evaluation scale.

Material and methods: This prospective study involved 17 Unispacer™ knee systems implanted in 16 patients between April 2003 and March 2009 within the frame of a clinical research project (CRP). Patients were clinically (IKS score) and radiographically evaluated during a mean follow-up period of 40 months.

Results: Nine patients (10 implants) had a IKS score > 160. The mean overall knee score at reassessment, including failures, increased from 51 points preoperatively to 78 points postoperatively. The mean overall Knee Society Function score increased from 55 preoperatively to 75/100 postoperatively. The reported complication rate was 35% (pain or implant instability). One-third of the failures were not technique- or implant-related but rather induced by the use of an inappropriate width in the frontal plane.

Discussion: Good results regarding pain relief and function are reported when using a mobile implant with no peripheral overhang which could be responsible for medial capsuloligamentous impingement. The Unispacer™ has three theoretical advantages: no bone resection, no implant fixation, no polyethylene wear debris. On the basis of its uncertain clinical results and high revision rate (six cases out of 17), we do not recommend this system despite the expected improvements on this range of implants.

Level of evidence: Level III, prospective study.

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Introduction

The operative treatment of isolated medial tibiofemoral osteoarthritis in patients aged under 60 is controversial.
Results and failures of the Unispacer™ knee implant for osteoarthritis of the knee

Material and methods

Patients

From April 2003 to March 2009, 17 Unispacer™ arthroplasties were performed by the same surgeon in 16 patients (11 females and five males) for the treatment of isolated medial compartment osteoarthritis of the knee. The mean age at surgery was 58 years (40–72). The mean Body Mass Index (BMI) was 32.5.

The inclusion criteria were: stage 2 or 3 tibiofemoral osteoarthritis according to the Ahlbäck radiographic evaluation scale without exceeding 8° of wear varus, epiphyseal varus lower than 5°, intact anterior cruciate ligament. An asymptomatic remodelling of the patellofemoral joint was tolerated. Exclusion criteria were: tear of the anterior or posterior cruciate ligament, flexum deformity, previous history of total medial meniscectomy, symptomatic patellofemoral osteoarthritis, lateral tibiofemoral osteoarthritis, femoral condyle necrosis. Patients overweight was not considered an exclusion criterion.

A partial medial meniscectomy had been performed in nine knees at a mean 8-year before index surgery. Two opening wedge valgus tibial osteotomies had been carried out. Six knees had not history of previous surgery prior to the Unispacer™ implantation.

Pain was the main complaint: from mild to severe, persistent despite proper traditional treatment plans. Mean flexion was 110°.

Unispacer™ overview

The Unispacer™ is available in six sizes (38, 42, 46, 50, 54 and 58 mm) featuring four thicknesses (2, 3, 4, 5 mm) and one single width for each implant length. Twenty-four implants are thus available to be implanted in right knees and 24 in left knees.

The femoral articulating surface is cup-shaped (concave) and replicates the anatomy of a tibial plateau with intact meniscus, thus capturing the femoral condyle while it simultaneously glides and rolls back. The tibial surface of the Unispacer is slightly convex, thus matching the surface of the medial tibial plateau. The conforming design of the Unispacer™ has a major role in its intrinsic stability.

Restoration of the height of the medial joint line allows retensioning of the medial collateral ligament. During flexion and extension movements of the knee, the implant moves freely within the joint. It realizes a dual movement of anteroposterior translation and rotation. This displacement is guided by the femoral condyle and the peripheral wall of the meniscus which should be present since it medially stabilizes the medial periphery of the implant. During extension, the implant translates anteriorly from the tibial plateau and moves in external rotation. During knee flexion, the implant progressively moves backwards on the tibial plateau and displaces through posterior translation and internal rotation at full flexion of the knee (Fig. 2). Rotation movements are underlined by the roll back of the anterior horn occurring during extension and posterior horn occurring during flexion.

Surgical technique

It was univocal. The patient was placed in the supine position with the knee flexed to 90°. Diagnostic arthroscopy was systematically performed to confirm the patient had the proper indications for the procedure. A partial meniscectomy was performed with preservation of the meniscal wall. However, the posterior portion was fully resected to allow backward movement of the implant during knee flexion.

A short medial parapatellar arthrotomy was made to allow for the resection of the remaining anterior horn of the medial meniscus. A notchplasty called “tween - plasty” was carried out to host the anterior horn of the implant at the level of the superomedial aspect of the lateral condyle dur-
ing knee extension. The exact location of the notchplasty was determined according to the position of the anterior horn of the trial implant during knee extension. This stage of the procedure is essential to allow external rotation and full extension of the implant, thus avoiding any abutment of the anterior horn of the implant against this critical zone. The femoral and tibial articular surfaces were then prepared to facilitate movements of the Unispacer™ and osteophytes were removed.

The anteroposterior length of the medial tibial plateau was measured to determine the implant size. Trial implants were clinically assessed and a true intraoperative fluoroscopic view confirmed the ideal length. Fluoroscopic control in the coronal plane was used to avoid any thickness over-correction which could induce a nutcracker effect on the lateral compartment. Stability and mobility of the trial implant were assessed in both flexion/extension (Fig. 3) and varus/valgus of the knee.

The appropriately sized Unispacer™ implant was inserted with the knee in flexion so as to clear the condylar surface. The upper surface of the implant was held against the femoral condyle while its inferior face was left uncovered. Then, the knee was put into extension. The medial tibial plateau could thus host the inferior aspect of the implant.
Results and failures of the Unispacer™ knee implant for osteoarthritis of the knee

**Method**

Patients were pre- and postoperatively evaluated using the International Knee Society scores (IKS) [10]. Sixteen patients were reviewed. For patients who underwent revision, the postoperative IKS scores were calculated before the second surgery.

A visual analog scale was used to rate pain.

The preoperative radiographic evaluation included anteroposterior and lateral radiographs of the knee in weight-bearing or non-weight-bearing conditions, a schuss view of the knee in 30° of flexion, a valgus stress view, a goniometric measurement of the knee under unipodal weight-bearing conditions, a patellar tracking measurement at 45° and a MRI. The Ahlbäck radiographic evaluation scale was used to grade the severity of the medial compartment arthritis [11].

The clinical results were graded as excellent (IKS score over 180), good (range, 160 to 180), fair (range, 140 to 160) and poor (lower than 140). We used a patient subjective satisfaction index made of four items: very satisfied, satisfied, dissatisfied and very dissatisfied. The visual analog scale was used to assess pain intensity.

The postoperative radiographic evaluation included a goniometric assessment under unipodal weight-bearing conditions, a series of lateral views (in full extension, at 45° and 90° of knee flexion and in full flexion) to assess sagittal mobility (Fig. 2), a forced valgus view to assess the height of the lateral compartment, an anteroposterior view to detect any medial overhang.

**Results**

**Clinical results**

The mean follow-up period is 40 months (8—77).

Results are reported in Table 1.

The mean overall knee score increased from 51 points preoperatively to 78 points at revision. In seven patients, scores were over or equal to 45 (no pain or mild occasional pain). The mean overall range of flexion was essentially unchanged. In patients who did not undergo revision surgery, the mean range of flexion was 125°.

The mean overall knee function score increased from 55 to 75/100 at revision. Six patients demonstrated an unlimited walking perimeter.

The overall IKS score at revision was 153. Nine patients reported good and excellent results with scores exceeding 160.

Six patients were rated as very satisfied, four were satisfied, four were dissatisfied and two were very dissatisfied. The female patient who underwent bilateral knee surgery was very satisfied (patient 6).

**Radiographic results**

Radiographic results are reported in Table 2.

The mean overall range of motion of the sagittal track was 16 mm ± 9. The mean range of motion in patients with good and excellent results was 19.5 mm and was 11.3 mm in those who reported fair and poor results. The most mobile was the implant in the sagittal plane (Fig. 2), better were the results, excepted in one case (patient 12) (persistent pain despite a 120° knee flexion).

**Postoperative complications**

Two female patients had dislocation episodes more than 3 years after surgery (Fig. 4). One female patient underwent revision to a TKA, the other one underwent implant reduction through manipulations under general anaesthesia reporting a satisfactory clinical and functional result (overall
Table 1  Pre- and postoperative IKS and EVA scores.

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<tr>
<th>Patients</th>
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<th>Pre-operative Flexion</th>
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<th>Pre-operative IKS F</th>
<th>Total preoperative IKS</th>
<th>Post-operative Pain</th>
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<th>Pre-/post-operative VAS</th>
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<td>153</td>
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Flexion is expressed in degrees.
IKS K: knee score; IKS F: function score; VAS: visual analogic scale.
Revision procedures considered as failures

Six conversions (35%) were necessary (five for persistent pain and one for implant dislocation). Regarding the five revisions cases for pain, two patients complained of medial pain due to the implant overhang (Fig. 5). This complication was directly attributed to the single width available for each length of implant. They reported a normal range of motion.

Five patients underwent revision, with no difficulty, in our department. At last follow-up, these five patients had an IKS score superior to 170.

Discussion

According to Hallock and Fell [4], the Unispacer\textsuperscript{TM} and its minimally-invasive insertion have three advantages: no bone cuts, no implant fixation, no polyethylene. Hallock emphasizes three key points which should be explained to the patient prior to the surgery. The first one is pain. Pain will

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure4}
\caption{Intra-articular implant dislocation (left knee).}
\end{figure}
not be completely relieved but should be reduced by about 80%. The Unispacer™ implant is a compromise between bone preservation and pain reduction. The second point to underline is rehabilitation with a maximum benefit achieved only after a 3- to 6-month follow-up period. Finally, he considers this solution as an alternative to total knee arthroplasty, thus allowing revision surgery to be performed using the standard techniques on an intact knee.

Only four studies [4,12–14] with a very short follow-up period have already been published (Table 3). Our series has the longest mean follow-up period (40 months). In Hallock and Fell study [4], 66 implants (63 patients) over the initially managed 71 knees remained in place at 1 postoperative year. The results, according to the reported IKS scores, are good since the mean knee score is 78 and the mean function score is 72. Sisto and Mitchell [12] do not report such favorable results. After a mean duration of follow-up of 26 months, they report a 28% rate of good results (score exceeding 80 points), 40% of fair results (score ranging from 79 to 70) and 32% of poor results (lower than 70) according to the IKS scores. Six of the 12 poor results (32%) were associated with anterior dislocation of the implant. Bailie’s series [13] mainly focuses on revision rate and pain intensity. The mean postoperative pain score is three points (range, 0 to 11.5 points).

The overall revision rate reported by Hallock and Fell [4] is 21% at 1 year. Ten knees (14%) had an exchange of the Unispacer™ implant because of either persistent pain or dislocation. Five knees (7%) were revised to a total knee arthroplasty.

In Sisto and Mitchell’s study [12], all 12 knees with a poor result (six of which with anterior dislocation) were revised to a total knee arthroplasty (32% of the knees). Twenty-five implants (68%) remained in place at a mean of 28 months. A 44% revision rate is reported in the series of Bailie [13] (eight patients). Two revised knees were managed with a larger Unispacer™ implant after dislocation. Three knees were revised to an unicompartmental prosthesis and three other knees were revised to a total knee arthroplasty. Friedman [14] reported a revision rate of 34%.

In our series, patients still having their Unispacer™ implant in place (10 patients with 11 implants) have a postoperative pain rated 1.8/10 on the visual analogic scale (VAS). The mean value of the whole population is 3.8 postoperatively and 7.4 preoperatively, that is a decrease of 48%. This decrease in pain is less significant than that reported by Hallock.

In six patients, the implant was revised to either a unicompartmental knee implant or a total knee replacement. The implant was revised because of a persistent disabling pain in three patients, associated, in two cases, with a restricted implant mobility, because of isolated medial pain in two cases and implant dislocation in one patient. Regarding pain due to a restricted implant mobility, no bone notch or increased chondral wear could be observed at explantation. Sisto and Mitchell [12] focus on the mechanisms of failure. In their series, six implants became wedged despite the fact that all the implants could rotate properly at the time of surgery. The occurrence of adherences could prevent proper implant mobility and induce pain. In our series, isolated medial pain could be attributed to an impingement with the deep fibers of the medial collateral ligament due to an excessive width of the implant. In fact, when the size of the implant is

<table>
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<tr>
<td>Pre-/postoperative IKS function</td>
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</tr>
<tr>
<td>Pre-/postoperative VAS</td>
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<td>Revision rate %</td>
<td>21</td>
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<td>Mean follow-up in month</td>
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Figure 5  Major medial overhang (right knee).
increased to achieve a good anteroposterior coverage of the tibial plateau, as advocated by Hallock to avoid dislocation, the width of the implant is inevitably increased in the frontal plane. Medial overhangs on the medial collateral ligament are thus reported (Fig. 5). This mechanism of failure, twice reported in our series, has not been described in other Unispacer™ series. This concern could be resolved by adding supplemental width options for each implant length.

Conclusion

On the basis of the significant failure rate reported in our series as in the four other series published in the literature, the interest of the Unispacer™ implant may be controversial in the treatment of isolated medial compartment degenerative arthritis of the knee. Due to the high revision rate observed in the short term, greater caution should be taken when selecting the proper indications of this implant. Despite possible and easy revision surgery, this procedure might increase the infection risk inherent to any iterative surgery. The role of this implant, if any, should be further defined. On the basis of this experience, we cannot currently recommend the use of the Unispacer™ implant despite the attractive specifications of such concept. At most, we could take advantage of a more comprehensive range of implant widths, thus reducing the risk of medial impingement.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References