Original article

AKILE™ total ankle arthroplasty: Clinical and CT scan analysis of periprosthetic cysts

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ABSTRACT

Introduction: Despite good clinical results following total ankle replacement (TAR), the development of large periprosthetic cysts (>400 mm²) in the medium-term is a source of concern.

Objective: The primary objective of this study was to detect any large periprosthetic cysts in a cohort of AKILE™ patients using radiographs and CT scans, and then to compare these findings to published ones.

Material and methods: A total of 127 TAR procedures were performed between June 1995 and January 2012. We retrospectively evaluated 68 cases with the newest AKILE™ implant design that had a minimum follow-up of 36 months. The average follow-up was 31 ± 13 months; eight patients were lost to follow-up. The outcomes consisted of analyzing radiographs (AP and lateral weight bearing views, Meary view and lateral views of flexion/extension) and helical CT scans, performing clinical evaluations (range of motion, AOFAS score, Foot Function Index, pain levels) and determining the survivorship of TAR implants.

Results: TAR survival at 5 years was 79% for in situ implants and 62% for revision-free implants. The AOFAS score improved from 33.7 ± 14.7 to 77.1 ± 15.1 (out of 100) and the pain sub-score was 30.2 ± 9.7 (out of 40) at the last follow-up. The average ankle range of motion was 32.3 ± 12.7° on the radiographs. CT scan revealed Type A cysts (<400 mm²) under the talar implant in 52% of cases and in the tibia in 50% of cases; these cysts were smaller than 100 mm² in 80% of cases and had no effect on the implants. No periprosthetic cysts larger than 400 mm² in size were identified.

Discussion: The medium-term functional results and survivorship are comparable to those reported for other TAR designs. The incidence of cysts was low overall and there were no large-diameter cysts, which should improve long-term survival. The implant’s design and materials likely played a role in preserving the periprosthetic bone stock. The AKILE™ TAR has distinctive features related to the low rate of large periprosthetic cysts in the medium-term.

Level of evidence: IV (retrospective case series).

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1. Introduction

The functional benefits of mobile-bearing total ankle replacement (TAR) implants in the medium-term are significant [1,2]. But periprosthetic osteolysis and cysts in the medium and long-term are a source of concern and temper the excellent short-term results [3]. In some studies, the rate of radiolucent lines and cysts has reached 75%, with large cysts compromising implant stability [4–6]. The primary objective of the current study was to analyze the radiographic results in a cohort of existing AKILE™ TAR by looking for the presence of bone cysts and evaluating their size on CT scans. The secondary objective was to determine the clinical results and compare them to published results. Only patients who had undergone TAR with the newest AKILE™ implant design were reviewed.

2. Material and methods

2.1. Study design

This was a retrospective study of the AKILE™ TAR procedures performed by the surgeon designers (DC and OL, Bordeaux University Hospital) between June 1995 and January 2012. The inclusion criteria consisted of primary, post-traumatic or inflammatory ankle arthritis as graded by Morrey and Wiedemann [7], which had failed conservative treatment and had at least 10° range of motion with no equinus deformity. Exclusion criteria consisted of greater than 10°...
misalignment of the hindfoot, insufficient bone stock, significant risk to the skin, morbid obesity and poor peripheral vascularization. Although 127 TAR procedures were carried out during that time period, the clinical and radiology analyses were performed on only the patients who received the newest implant design and had at least 36 months of follow-up.

2.2. Patient series

The cohort consisted of 68 cases in 66 patients (41 men, 25 women) having an average age of \(57 \pm 12.2\) years (range 26–77) at implantation; nine patients were lost to follow-up (LTF) and one had died before the last follow-up (Fig. 1). The average follow-up was \(81 \pm 33.3\) months. The arthroscopy etiology was traumatic in 40 cases, primary in 11 cases and inflammatory in 17. Ten ankles were Grade 1, 34 were Grade 2 and 24 were Grade 3 based on the Morrey and Wiedeman classification (Grade 0: normal ankle, Grade 1: small osteophytes and minimal joint narrowing, Grade 2: moderate osteophytes and moderate joint narrowing, Grade 3: significant narrowing with joint deformation or fusion) [7]. The TAR procedure was performed on the left ankle in 35 cases (51.5%) and the right ankle in 33 cases (48.5%). The implant’s modular design allowed the surgeon to determine if a tibial keel and/or cement were needed on a case by case basis (Fig. 2).

2.3. Implant and surgical technique

The newest AKILE™ prosthesis is a third-generation, spherical trochlear resurfacing implant with a high-molecular weight polyethylene (PE) mobile-bearing. It is made up of three components: a spherical tibial component, a trochlear-shaped talar component and a dual-curve PE insert (Fig. 3). The tibial and talar components are made of ultra-strong high nitrogen stainless steel (ISO 5832-9). The surfaces in contact with the PE are coated with a diamond-like carbon material (Carbioceram™). This coating reduces the coefficient of friction of the metal surfaces and helps minimize PE debris [8–10]. An anterior approach was used in all cases and an additional tibial bone flap was used in cases where a tibial keel was implanted. Cementing of the implants was optional; one surgeon (DC) cemented all the talar components while the other surgeon (OL) did not. A locking tibial keel was added in cases where the surgeon’s intra-operative assessment of bone quality led to doubts about the hold of the tibial component.

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The following additional procedures were performed: 18 percutaneous pie-crust lengthening of the Achilles tendon, 9 subtalar fusion and 2 varus osteotomy of the calcaneus (carried out 3 weeks before the TAR). Weight bearing was not allowed during the first 4 weeks after surgery so as to maximize bone integration of the alumina surfaces; rehabilitation was initiated afterwards.

2.4. Outcome measures

2.4.1. Radiological

Weight bearing radiographs (A/P, lateral, Méary view) were performed before the surgery and at every follow-up visit. Dynamic weight bearing radiographs in maximum ankle flexion and extension were performed before the surgery and at the last follow-up visit to evaluate the joint’s range of motion. Helical CT scan was performed in all patients at the last follow-up visit. All of these images were reviewed by two independent evaluators (ET, JL).

2.4.1.1. Implant positioning. Implant positioning was evaluated through the following criteria: alpha angle between horizontal axis of tibial component and tibial axis (normal value of 90° ± 5), beta angle between the sagittal axis of the tibial component and the tibial axis (normal value of 86° ± 5) and gamma angle between the axis of the talar component and the ground (normal value of 0 ± 5). The tibial axis was defined as a line passing through the centre of the tibial shaft and the centre of the ankle mortise (Fig. 4).

2.4.1.2. Bone-implant interface. Analysis of abnormal bone appearance was performed according to the 10-zone joint map and protocol described by Besse et al. [4] (Fig. 5). The appearance was defined as either normal (N: 0 mm), with radiolucent lines (L: 0–2 mm), or the presence of cystic lesions with size measured in mm: A (3–5 mm), B (5–10 mm), C (10–20 mm), D (20–30 mm), and E (more than 30 mm). Five additional areas were defined and analyzed on the CT scans; the volume of any cysts was measured in mm² (maximum area on the sagittal or coronal plane) using OSIRIX™ software. These measurements were used to classify the cysts into three groups: A (0–200 mm²), B (200–400 mm²), C (more than 400 mm²) [11]. Group A was divided in four sub-groups to refine the analysis of small cysts (Fig. 6).

2.4.2. Clinical and functional

Follow-up visits were scheduled for 1, 6 and 12 months post-surgery and then annually. Functional and clinical outcome measures (AOFAS score, joint range of motion and Foot Function Index [FFI]) were taken before the surgery and at the last follow-up [12,13]. Any postoperative complications were classified according to Glazebrook et al. [14]. Any re-operations on the ankle were noted.

2.5. Data analysis

Statistical analysis was performed using Student’s or Welch’s test for paired samples to compare pre- and postoperative data; the chi-squared test was used to determine if a relationship existed between variables. Kaplan-Meier survival curves were calculated by defining full revision (or removal) of the implant and a new surgical procedure as the end point for all patients. To determine if there was a learning effect, another set of survival curves was calculated with non-revised implants (new surgical procedure as end point) by comparing the first 30 TAR procedures in the initial 127 patient cohort with the last 30 TAR procedures having at least 3 years of postoperative follow-up. A threshold of P < 0.05 was used to determine statistical significance in all of the tests. The statistical analysis was performed with the XLstat software (Addinsoft, Paris, France).

3. Results

At the last follow-up, 51 of the 68 TAR implants were still in place (in situ). The 5-year survivorship was 79.4% [71.9–87.0] for in situ TAR implants and 62% [52.9–71.2] for non-revised implants (Fig. 7). The 3-year revision-free survival was 56.7% [38.9–74.4] for the first 30 cases and 77.4% [62.7–92.1] for the last 30 cases (Fig. 8).
3.1. **Complications**

Intra-operative and postoperative complications (Table 1) were classified according to a modified Glazebrook classification. Two groups were added: idiopathic residual pain as a high-grade complication and implant impingement (mainly in the grooves) as a medium-grade complication. Thirteen cases had to be revised with an arthrodesis procedure; all had fused at the last follow-up and the average AOFAS score had improved from 45.4 [17–49] to 65.6 [25–69]. Of the five arthrodesis procedures performed because of idiopathic pain, only three patients experienced complete pain relief after the fusion.

3.2. **Clinical and functional outcomes**

The functional outcomes (AOFAS Hindfoot and Ankle Scale) improved from an average of 33.7 ± 14.7 [7–77] before the surgery for all implants to 77.1 ± 15.1 [25–98] at the last follow-up for the 51 in situ implants. For these 51 implants, the average FFI score was 101.2 ± 36.2 (out of 209) [40–179] and the average AOFAS pain score was 30.2 ± 9.7 (out of 40) [0–40]. In 13 of these 51 cases, the pain score was less than 30.

Average range of motion before the surgery was 23.6° ± 9.7° [10°–60°] including 4.9° ± 4.2° [0°–35°] of dorsiflexion. After the surgery, the range of motion was 29.7° ± 11.6° [15°–60°] including 5.6° ± 5.8° [0°–20°] of dorsiflexion (P > 0.05).

3.3. **Radiological outcomes**

Plain radiographs were taken in all the patients during the follow-up period.

Djian’s quadrilateral was measured on the Méary views. The average valgus deformity was 3.7° ± 3.2° [−5° to 10°] before the surgery and 3.5° ± 3.0° [−5° to 10°] at the last follow-up. The ankle range of motion at the last follow-up was 32.3° ± 12.8° [10° to 60°] (Fig. 9). The location of cysts was defined using the Besse zones (Table 2) and their volume and quantity were measured (Table 3) [4].
CT scans were performed in 42 implants (97.7% of in situ implants) at the last follow-up [Fig. 1] to more specifically analyze the bone-implant interface. Ten of the CT scans had no signs of osteolysis; 28 (67%) had Type A images (<200 mm²). Only four (9%) had a signs of Type B osteolysis (200–400 mm²); these were associated in 50% of cases to another Type A image. This osteolysis was located at the cemented tibial component in three cases. The talar implant showed no signs of migration; the cysts identified were 208, 346 and 244 mm² in size, respectively, in CT scans performed at 47.2, 56.2 and 92.5 months, respectively [Fig. 10]. The CT scan analysis is summarized in Table 4.

Since Type A cysts were most common (93% of all cysts found), sub-groups were created (Table 5). In 80% of cases, these cysts were smaller than 100 mm² [Fig. 11]. The risk of cysts appearing under the talar component was significantly greater for cemented implants or when the talar component was improperly positioned (P<0.05). There was no statistical relationship between the risk of cysts appearing and the presence of a tibial keel (P=0.79).

### Table 1
<table>
<thead>
<tr>
<th>Complications based on a modified Glazebrook classification.</th>
<th>n=</th>
<th>Secondary surgery Needed</th>
<th>Fusion Needed</th>
<th>Average time elapsed (months) between TAR and secondary procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High-grade complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aseptic loosening</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>40.5 [11.3–81.9]</td>
</tr>
<tr>
<td>Deep infection</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>n&lt;5</td>
</tr>
<tr>
<td>Implant failure (bearing dislocation)</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>n&lt;5</td>
</tr>
<tr>
<td>Idiopathic pain</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>43.5 [25.1–64.1]</td>
</tr>
<tr>
<td><strong>Medium-grade complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant subsidence</td>
<td>6</td>
<td>6</td>
<td>0</td>
<td>40.2 [18.9–98.9]</td>
</tr>
<tr>
<td>Postoperative fracture</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>X</td>
</tr>
<tr>
<td>Technical error</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>X</td>
</tr>
<tr>
<td>Impingement</td>
<td>15</td>
<td>15</td>
<td>0</td>
<td>22.5 [6.7–56]</td>
</tr>
<tr>
<td><strong>Low-grade complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-operative fracture</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>X</td>
</tr>
<tr>
<td>Delayed wound healing</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>X</td>
</tr>
</tbody>
</table>

TAR: total ankle replacement.
Table 2
Location of cysts on the radiographs.

<table>
<thead>
<tr>
<th>Location of cysts</th>
<th>1 year A (%)</th>
<th>1 year B (%)</th>
<th>1 year C (%)</th>
<th>2 years A (%)</th>
<th>2 years B (%)</th>
<th>2 years C (%)</th>
<th>5 years A (%)</th>
<th>5 years B (%)</th>
<th>5 years C (%)</th>
<th>7 years A (%)</th>
<th>7 years B (%)</th>
<th>7 years C (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tibial component</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2.6</td>
<td>0</td>
<td>0</td>
<td>2.8</td>
<td>0</td>
<td>0</td>
<td>7.4</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Zone 2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Zone 3</td>
<td>0</td>
<td>0</td>
<td>1.8</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Zone 7</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2.2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Talar component</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Zone 8</td>
<td>0</td>
<td>0</td>
<td>1.8</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Zone 9</td>
<td>0</td>
<td>0</td>
<td>3.6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2.8</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 3
Characteristics of bone-implant interface based on radiographs.

<table>
<thead>
<tr>
<th>Bone-implant</th>
<th>Talus</th>
<th>Tibial</th>
<th>Talus</th>
<th>Tibial</th>
<th>Talus</th>
<th>Tibial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 year</td>
<td>2 years</td>
<td>5 years</td>
<td>7 years</td>
<td>1 year</td>
<td>2 years</td>
</tr>
<tr>
<td>Normal</td>
<td>53 (96%)</td>
<td>39 (100%)</td>
<td>34 (97%)</td>
<td>27</td>
<td>48 (87%)</td>
<td>34 (87%)</td>
</tr>
<tr>
<td>RLL (≤ 2 mm)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6 (11%)</td>
<td>4 (10%)</td>
</tr>
<tr>
<td>Small cyst Type A cyst (3–5 mm)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Medium cyst Type B cyst (&gt; 5 mm to 1 cm)</td>
<td>0</td>
<td>0</td>
<td>1 (3%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Large cyst Type C cyst (1–2 cm)</td>
<td>2 (4%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (2%)</td>
<td>1 (3%)</td>
</tr>
<tr>
<td>Massive cyst Type D &amp; E cyst (&gt; 2 cm)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

RLL: radiolucent lines.
Fig. 10. Example of CT scan after 8 years showing a talar cyst greater than 200 mm² in size on a cemented implant.

4. Discussion

This study demonstrates that CT scans are better than radiographs at detecting bone cysts. Cysts were found near 50% of tibial components (all type A) and 57% of talar components (93% type A). Limitations of this study revolve around its retrospective design and the number of patients lost to follow-up, although most of the cases in this study (97.7% of in situ implants) were evaluated by CT scan.

4.1. Clinical and functional outcomes

The medium-term clinical and functional results in the current study are similar to the ones for other mobile-bearing TAR implants, which had between 70% and 98% survivorship at 3–6 years [15–17]. The significant increase in the AOFAS score and the survival curves are similar to those of studies not involving the implant designers and to results of national registers [18,19]. The outcomes in the current study were all evaluated by independent raters who had not been involved in the surgery or implant design.

Table 4
Characteristics of bone-implant interface based on CT scans (42 scans/44 TAR).

<table>
<thead>
<tr>
<th>Number &amp; size of cysts</th>
<th>Location</th>
<th>Talus: head</th>
<th>Talus: body</th>
<th>Tibia med</th>
<th>Tibia lat</th>
<th>Fibula</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (&lt;200 mm²)</td>
<td>1 or 2</td>
<td>8</td>
<td>16</td>
<td>15</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>&gt;2</td>
<td>6</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B (200–400 mm²)</td>
<td>1 or 2</td>
<td>1</td>
<td>2</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C (&gt;400 mm²)</td>
<td>1 or 2</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;2</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Table 5
Distribution of Type A cysts found on CT scans.

<table>
<thead>
<tr>
<th>Location</th>
<th>Volume</th>
<th>0–50 mm²</th>
<th>50–100 mm²</th>
<th>100–150 mm²</th>
<th>150–200 mm²</th>
<th>Total A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talus: head</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Talus: body</td>
<td>6</td>
<td>15</td>
<td>1</td>
<td></td>
<td></td>
<td>22</td>
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<tr>
<td>Tibia med</td>
<td>2</td>
<td>9</td>
<td>3</td>
<td>2</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Tibia lat</td>
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<td>1</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Fibula</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td></td>
<td></td>
<td>7</td>
</tr>
</tbody>
</table>

Fig. 11. Type A cyst that is smaller than 100 mm².
The main cause of revision was impingement at the malleolar grooves, which we added to the Glazebrook’s list of medium-grade complications [14,20]. The current study confirms the learning effect with this implant, as there were fewer revisions in the surgeons’ later cases [21]. The presence of idiopathic pain was also added to the list of high-grade complications.

4.2. Radiological outcomes

The appearance of cysts and osteolysis around TAR implants in the medium and long-term has contributed to CT scanning being an optimal imaging modality for following TAR implants. Mapping of the periprosthetic areas is now routine [11,22]. One of this study’s strengths lies in the large number of postoperative CT scans that were performed. Our results confirm the findings of other teams that such an analysis is best at evaluating and quantifying any cystic osteolysis, which is underestimated by radiographs [4,23,24]. The three cases with a cyst larger than 200 mm² occurred in cemented talus implants. Our findings indicate that the risk of osteolysis is significantly larger with cemented implants. We have since stopped cementing TAR implants, unless the bone quality is so low that the surgeon believes the implants will have poor primary stability. The vast majority of the cysts identified in the current study were smaller than 200 mm²; 80% were smaller than 100 mm² and were found under the talus component or on the medial side of the tibia.

Although we cannot explain why there were no large cysts, we suspect that the AKILE™ implant’s design and composition likely had an effect, suggesting a potential advantage associated with Carboceram™. Unlike other TAR models which are made of cobalt-chrome, the AKILE™ implant is manufactured from high nitrogen stainless steel and coated with Carboceram™. The hardness of this diamond-like carbon reduces the friction coefficient and production of polyethylene or metal wear debris that causes osteolysis [25,26]. Cobalt-chrome particles seem to be the most toxic for osteoblasts and fibroblasts [27,28]. Titanium is typically used in implants because it is fully biocompatible, non-allergic and resists corrosion, but its lack of hardness triggers the release of micro-particles. A large amount of titanium and cobalt-chrome particles have been observed in periprosthetic tissues [29,30]. These interfere with osteoblast function and stimulate osteolysis [31–33]. In the AKILE™ implant, the bone-implant interface consists of alumina instead of hydroxyapatite and porous titanium. The alumina coating interferes less with homeostasis because it is biologically inert and provides good bone integration [34–36].

5. Conclusion

The AKILE™ implant is unique in its design (spherical tibial implant, dual-curvature mobile-bearing), composition (stainless steel implants with a Carboceram™ ceramic coating) and fixation through an alumina coating. The combination of these features has led to clinical outcomes that are similar to other TAR implants. However, fewer and smaller periprosthetic cysts were found in the medium-term, which should improve stability in the long-term. At this point, we are not able to isolate which of these factors is the most important. Implementation of a national TAR registry would be very valuable because only long-term follow-up of large cohorts has the ability to bring together multiple factors and to answer some of the questions surrounding total ankle arthroplasty.

Disclosure of interest


JL-H, ET, VD declare that they have no conflicts of interest concerning this article.

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