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RESEARCH

Analysis of the Attune tibial tray backside

A COMPARATIVE RETRIEVAL STUDY

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Objectives

The Attune total knee arthroplasty (TKA) has been used in over 600 000 patients worldwide. Registry data show good clinical outcome; however, concerns over the cement-tibial interface have been reported. We used retrieval analysis to give further insight into this controversial topic.

Methods

We examined 12 titanium (Ti) PFC Sigma implants, eight cobalt-chromium (CoCr) PFC Sigma implants, eight cobalt-chromium PFC Sigma rotating platform (RP) implants, and 11 Attune implants. We used a peer-reviewed digital imaging method to quantify the amount of cement attached to the backside of each tibial tray. We then measured: 1) the size of tibial tray thickness, tray projections, peripheral lips, and undercuts; and 2) surface roughness (Ra) on the backside and keel of the trays. Statistical analyses were performed to investigate differences between the two designs.

Results

There was no evidence of cement attachment on any of the 11 Attune trays examined. There were significant differences between Ti and CoCr PFC Sigma implants and Attune designs ($p < 0.05$); however, there was no significant difference between CoCr PFC Sigma RP and Attune designs ($p > 0.05$). There were significant differences in the design features between the investigated designs ($p < 0.05$).

Conclusion

The majority of the earliest PFC Sigma designs showed evidence of cement, while all of the retrieved Attune trays and the majority of the RP PFC trays in this study had no cement attached. This may be attributable to the design differences of these implants, in particular in relation to the cement pockets. Our results may help explain a controversial aspect related to cement attachment in a recently introduced TKA design.

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Keywords: Total knee arthroplasty, Implant-cement interface, Retrieval analysis

Article focus

- Assessment and comparison of cement adhesion to tibial trays of total knee arthroplasties (TKAs).

Key messages

- None of the Attune implants showed evidence of cement adhesion, in contrast with the other designs.
- There are significant differences in the design features between the latest and older designs.

Strengths and limitations

- This is the first retrieval study examining Attune tibial components and comparing them with retrieval findings from another knee design.
- The sample number is a limitation.

Introduction

Total knee arthroplasty (TKA) is one of the most common orthopaedic procedures performed worldwide. Over the coming decades, the number of TKAs is projected to

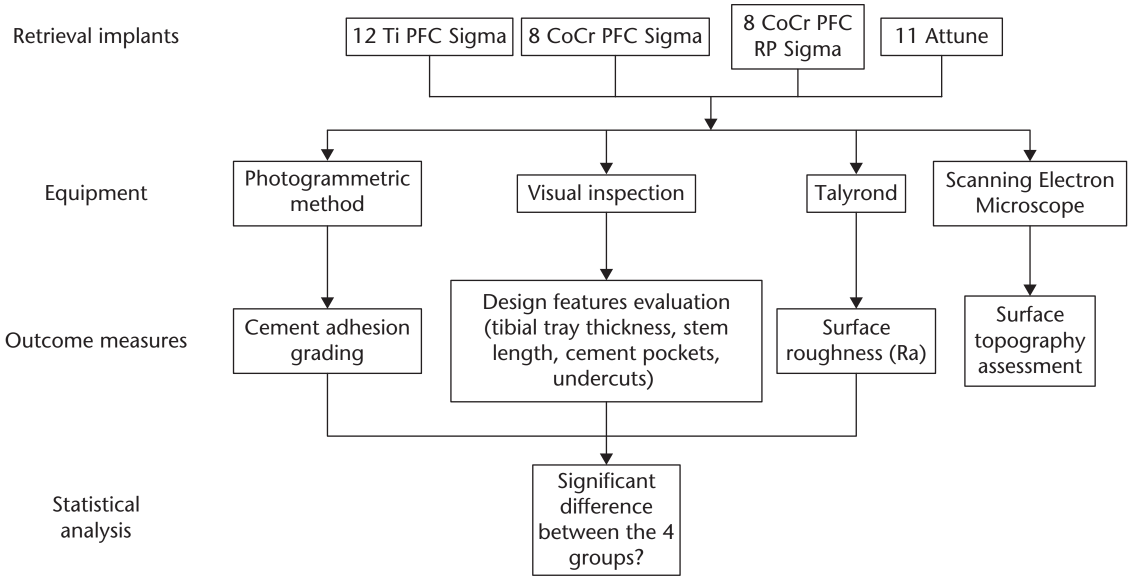

Fig. 1

Flowchart showing the methods used and outcome measures assessed in the four different tibial trays investigated. Ti, titanium; CoCr, cobalt-chromium; RP, rotating platform.

increase.[1,2] In addition, international joint registry data show an increase in the number of TKA revisions.[1-3]

Aseptic loosening in both cemented and cementless TKAs remains a common reason for early revision, accounting for a third of failures.[1-6] Retrieval studies have shown that osteoclastic-mediated bone resorption stimulated by polyethylene wear particles is one of the causes of aseptic loosening.[7] Another explanation is stress shielding, which is significantly influenced by tibial tray material and design,[8-11] stem length, and geometry.[12,13] There is also evidence that aseptic tibial loosening may be caused by debonding of the tibial implant-cement interface as a result of cement type (high viscosity) and application methods.[14-16]

Recently, early aseptic failures at the implant-cement interface in the Attune TKA system (DePuy, Warsaw, Indiana) were reported in a retrospective study without a control group;[17] the authors found a high rate of early aseptic tibial loosening. The study was based on data from the Manufacturer and User Facility Device Experience (MAUDE) database,[18] which is of limited use because it is a self-reported manufacturer database. In contrast, the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) reported low rates of aseptic loosening for the same TKA design, with excellent survivorship rates in comparison with other TKA designs,[1,19] In a series of 9559 implanted Attune TKA (up to January 2017), only two cases of tibial loosening were reported. The overall aseptic loosening rate was 0.05%. In addition, for the Australian Joint Registry (AOANJRR), which included 4831 Attune TKA by 2016, the estimated cumulative revision rate was 0.5% for the cruciate-retaining (CR) TKA and 0.4% for the posterior-stabilized (PS) TKA at one year. In a recent study, the Attune implant was found to give more satisfactory results, in terms of injury risk to the tibial cortex, than its predecessors.[20] This subject therefore remains controversial.

We aimed to investigate the *in vivo* performance of the Attune knee arthroplasty by reporting evidence from retrieval analysis. Our primary objective was to compare the amount of cement adhesion between the Attune and three other knee designs from the same manufacturer. Secondly, we compared the design and surface features of the implants analyzed.

Materials and Methods

Figure 1 shows a flowchart of the retrieval study design.

Implant and patient demographics. Institutional approval was obtained (reference 07/Q0401/25) and patients gave informed consent for participation in the study. Our retrieval centre has received more than 200 TKA implants since 2015. Of these, 39 were selected for this comparative study, all produced by a single manufacturer (DePuy). They consisted of two basic designs: PFC (n = 28) and Attune (n = 11). The PFC implants included three different design iterations: titanium (Ti) PFC Sigma (n = 12) and cobalt-chromium (CoCr) PFC Sigma (n = 8), both with fixed bearings; and PFC Sigma rotating platform (RP) (n = 8) made of CoCr. The Attune implants had either fixed (n = 7) or rotating (n = 4) bearing inlays, with the same tray backside design made of CoCr.

Our cohort was revised by five different, experienced, high-volume surgeons (PA, JL, AE, MTH). After the revision, the implants are put in secure packaging and shipped to us immediately, in order to preserve their condition. Implants were received from 29 female and ten male patients, with a median age of 66 years (interquartile range (IQR) 58 to 74), and a median time to revision

Table I. Implant and patient demographics

Case number	Gender	Age, yrs	Time to revision, mths	Reasons for revision	Design	Revision surgeon
1	Male	69	15	Aseptic loosening	Ti PFC Sigma (DePuy)	Surgeon 1
2	Female	53	45	Malposition	Ti PFC Sigma	Surgeon 1
3	Female	78	148	Instability	Ti PFC Sigma	Surgeon 2
4	Male	88	118	Infection	Ti PFC Sigma	Surgeon 2
5	Female	63	61	Aseptic loosening	Ti PFC Sigma	Surgeon 1
6	Female	49	17	Instability	Ti PFC Sigma	Surgeon 1
7	Female	67	13	Patella maltracking	Ti PFC Sigma	Surgeon 1
8	Female	55	169	Instability	Ti PFC Sigma	Surgeon 1
9	Female	62	66	Patella maltracking	Ti PFC Sigma	Surgeon 1
10	Male	69	115	Instability	Ti PFC Sigma	Surgeon 2
11	Female	76	237	Osteolysis	Ti PFC Sigma	Surgeon 2
12	Female	76	105	Instability	Ti PFC Sigma	Surgeon 2
13	Female	51	36	Stiffness	CoCr PFC Sigma (DePuy)	Surgeon 2
14	Female	68	17	Oversized components	CoCr PFC Sigma	Surgeon 2
15	Female	73	18	Malposition	CoCr PFC Sigma	Surgeon 2
16	Female	57	58	Instability	CoCr PFC Sigma	Surgeon 2
17	Female	61	10	Instability	CoCr PFC Sigma	Surgeon 1
16	Female	64	42	Infection	CoCr PFC Sigma	Surgeon 2
19	Female	50	39	Instability	CoCr PFC Sigma	Surgeon 2
20	Female	81	10	Malposition	CoCr PFC Sigma	Surgeon 2
21	Male	66	53	Malposition	CoCr PFC Sigma RP (DePuy)	Surgeon 1
22	Male	76	27	Infection	CoCr PFC Sigma RP	Surgeon 3
23	Female	46	20	Pain	CoCr PFC Sigma RP	Surgeon 1
24	Female	62	60	Instability	CoCr PFC Sigma RP	Surgeon 1
25	Female	72	19	Stiffness	CoCr PFC Sigma RP	Surgeon 1
26	Female	73	11	Instability	CoCr PFC Sigma RP	Surgeon 1
27	Male	57	105	Instability	CoCr PFC Sigma RP	Surgeon 2
28	Male	71	174	Instability	CoCr PFC Sigma RP	Surgeon 2
29	Female	78	5	Instability	Attune (DePuy)	Surgeon 1
30	Female	64	22	Instability	Attune	Surgeon 1
31	Female	62	24	Instability	Attune	Surgeon 1
32	Male	46	56	Aseptic loosening	Attune	Surgeon 4
33	Female	78	15	Instability	Attune	Surgeon 1
34	Female	85	13	PCL rupture	Attune	Surgeon 1
35	Female	65	21	Malposition	Attune	Surgeon 1
36	Male	56	12	Instability	Attune	Surgeon 1
37	Male	74	8	Instability	Attune	Surgeon 1
38	Female	67	5	Malposition	Attune	Surgeon 1
39	Female	N/A	N/A	Malposition	Attune	Surgeon 5

Ti, titanium; CoCr, cobalt-chromium; RP, rotating platform; N/A, not available

of 26 months (IQR 15 to 61). The reasons for revision were instability (n = 18), malposition (n = 7), infection (n = 3), aseptic loosening (n = 3), patellar maltracking (n = 2), stiffness (n = 2), pain (n = 1), osteolysis (n = 1), posterior cruciate ligament (PCL) rupture (n = 1), and oversized components (n = 1).

Table I summarizes the TKA specifications and patient demographics for each case.

Sample preparation. All tibial components were decontaminated using 10% formaldehyde solution (Solmedia Ltd, Shrewsbury, United Kingdom), followed by rinsing with water. The tibial tray backside and stem surfaces were prepared by using methylated spirit 99% (Solmedia Ltd) to gently remove biomaterial without affecting cement adhesion.

Grading of tibial tray backside cement adhesion. A published photogrammetric method[21,22] was used to grade the amount of cement attached to the tibial tray backside. High-resolution images of the tibial tray backside were captured using an EOS 5D Mark II camera (Canon Inc., Tokyo, Japan) (Fig. 2). The images were analyzed using public domain software (ImageJ 1.4.3.6.7, Broken Symmetry Software). First, the area covered by cement was measured and subsequently divided by the total backside area, in order to obtain the percentage of the area of interest.

Design features assessment. The geometry and dimensions of the tibial trays, tray projections (stem and/or fins), peripheral lips, and undercuts were measured using digital callipers (Digimatic Absolute AOS; Mitutoyo, Kawasaki, Japan) and compared between the four different designs. Figure 3 shows the design features that were analyzed.

Surface roughness measurement. A contact profilometer Talyrond 365 (Taylor Hobson Ltd, Leicester, United Kingdom) was used to measure surface roughness (Ra)

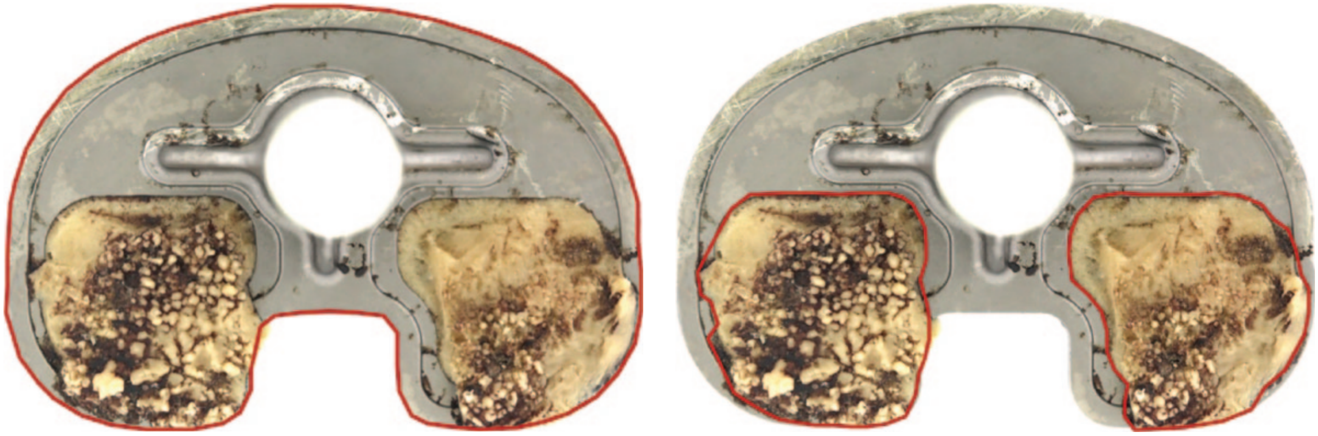

Fig. 2a

Fig. 2b

Example of sample analyzed using the photogrammetric method.[20,21] a) Total tibial tray backside surface contours highlighted in red. b) Amount of surface covered by cement highlighted in red.

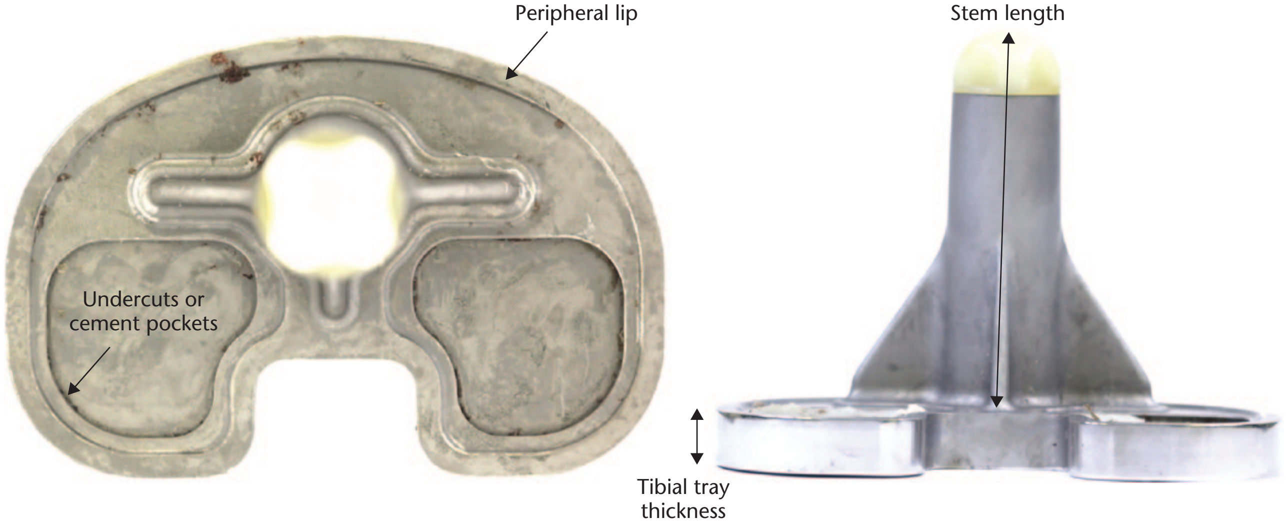

Fig. 3

Design features analyzed by visual inspection: undercuts or cement pockets, peripheral lips,[23] tibial tray thickness, and stem length.

on the backside of the tibial tray. Surface roughness is defined as the mean average of the absolute values of the surface height deviations measured from the mean plane. The implant was positioned on the spindle, and measurements were taken using a 5 µm contact stylus. Six vertical traces were acquired on both the backside and stem of tibial trays, for a total of 12 traces for each implant. Measurements were performed while avoiding areas surface-damaged by scratches made during the revision surgery.

Surface topography assessment. A scanning electron microscope ((SEM) Jeol JSM5500; Jeol Ltd, Tokyo, Japan) was used to assess the surface topography of the backside of the trays. Images with a magnitude of ×300 were taken in different areas of the tibial tray backsides. Grain quality and dimensions were compared between the four different designs.

Statistical analysis. Data were analyzed using Prism 7 (GraphPad Software Inc., La Jolla, California). We compared the four groups for the following outcome measures: 1) cement adhesion; 2) tray thickness; 3) tray projections; 4) tray undercuts; 5) tray lips; and 6) roughness using analysis of variance (ANOVA) tests (ordinary one-way ANOVA and Kruskal–Wallis). A $p < 0.05$ was considered significant throughout.

Results

Grading of tibial tray backside cement adhesion. The percentage of tibial tray backside covered by cement was highly variable (Fig. 4). The majority of Ti PFC Sigma (n = 12) showed evidence of cement adhesion with a % area median of 49% (IQR 31% to 57%); all CoCr PFC Sigma implants (n = 8) had cement adhesion, with a median value of 23% (IQR 8% to 41%). In PFC Sigma RP implants,

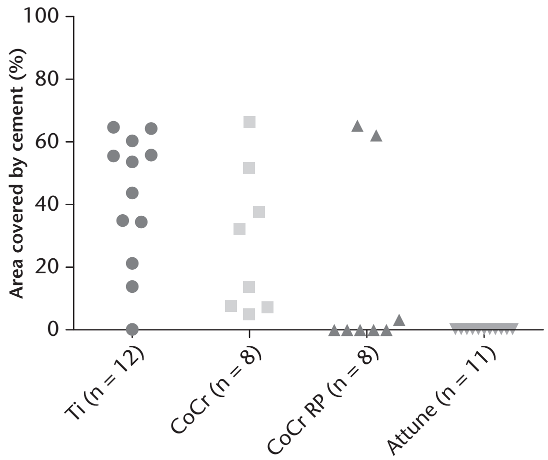

Fig. 4

Graph showing the percentage of area covered by cement in the four designs analyzed. The difference between the Attune and the old PFC Sigma designs (titanium (Ti) and cobalt-chromium (CoCr)) was significant ($p < 0.05$). RP, rotating platform.

three out of eight cases showed cement attached to the tibial tray, with a median value of 0% (IQR 0% to 18%). None of the Attune implants showed evidence of cement attachment.

There was no significant difference in the percentage of area covered by cement between the three PFC designs ($p > 0.05$). There were significant differences between Ti and CoCr PFC Sigma implants and Attune designs ($p < 0.05$) but there was no significant difference between CoCr PFC RP and Attune designs ($p > 0.05$). Figure 5 shows images of all of the components examined.

Only between the Ti PFC Sigma and Attune designs was there a significant difference in the time to revision ($p = 0.015$); the median values were 86 and 17 months, respectively.

Visual inspection. Visual inspection revealed substantial differences between the Attune and PFC designs (Fig. 6).

Attune implants had the thinnest tray dimensions (median = 4.08 mm), followed by the PFC Sigma RP (median = 4.88 mm), and both the Ti and CoCr PFC Sigma designs (median = 6.36 mm and 6.39 mm, respectively). The difference between the two PFC Sigma and the two latest designs was significant, as was the difference between PFC Sigma RP and Attune designs ($p < 0.05$).

Considering tibial tray projections, Ti and CoCr PFC Sigma showed a straight, linear, and central stem, with three orthogonal fins, polyethylene tips, and median lengths of 46.00 mm and 48.00 mm, respectively. PFC Sigma RP and Attune designs showed a thicker, central, tapered stem, entirely made of metal, with two diagonal fins and median lengths of 39.00 mm and 37.00 mm, respectively. The difference in length between the two PFC Sigma and the two latest designs was significant ($p < 0.05$).

Titanium and CoCr PFC Sigma presented undercuts, with similar shape and geometry and with a median depth of 0.89 mm ($p = 0.4390$). Regarding the peripheral lips, the Ti and CoCr PFC trays showed a median depth of 0.29 mm, while PFC Sigma RP and Attune designs showed median values of 0.66 mm and 0.61 mm, respectively; this difference was significant ($p < 0.0001$). Figure 7 shows in detail the cement pockets and lips.

Table II summarizes the measurements taken, showing median and range values.

Roughness measurement. Talyrond 365 measurements revealed that CoCr PFC Sigma presented the lowest value of tibial tray surface roughness, with a median value of 0.38 μm (Ra), followed by Ti PFC Sigma, Attune and PFC Sigma RP, with median values of 0.68 μm, 1.24 μm, and 1.96 μm, respectively. The same trend was also observed in the stem roughness but with higher values; Table III shows these results, displaying median values and IQRs. Figure 8 shows both tibial tray and stem surface roughness in the four different designs. The difference in both tibial tray and stem surface roughness between the four designs was significant ($p < 0.0001$).

Scanning electron microscopy. Images from SEM analysis were concordant with the surface roughness results from the Talyrond (Fig. 9): CoCr and Ti PFC Sigma designs showed a similar surface topography, with smaller grain dimension when compared with PFC Sigma RP and Attune, which, instead, presented a more irregular surface topography and a rougher microstructure.

Discussion

Our retrieval study is the first to examine Attune knee components and compare them with retrieval findings from another knee design. Our most important finding was a significant difference in the area of cement adhesion to the tibial tray backside of the Attune when compared with the oldest PFC Sigma designs; notably, none of the Attunes in our cohort showed cement attachment. This may be attributable to the differences in design features between the implants.

Interestingly, cement was mainly found on the Ti and CoCr PFC Sigma designs, attached to the undercuts. These findings are in agreement with previous studies.[23,24] In a retrieval post-mortem study, Gebert de Uhlenbrock et al[23] reported that all four different LCS (DePuy) tibial trays, whose design and material were similar to PFC Sigma RP and Attune ones, failed for debonding at the cement-implant interface during a pull-out force test, in contrast with the bone-cement interface failure of the Ti PFC Sigma with cement pockets. Schlegel et al[24] suggested that cement pockets allow the creation of a thicker cement layer, although the benefits of a thicker layer are still controversial. However, they also stated that this design feature does not alter or enforce bone-cement penetration, considered to be advantageous for an optimal fixation.[25] The LCS and PFC Sigma RP are clinically very successful designs. In our study, the majority of PFC

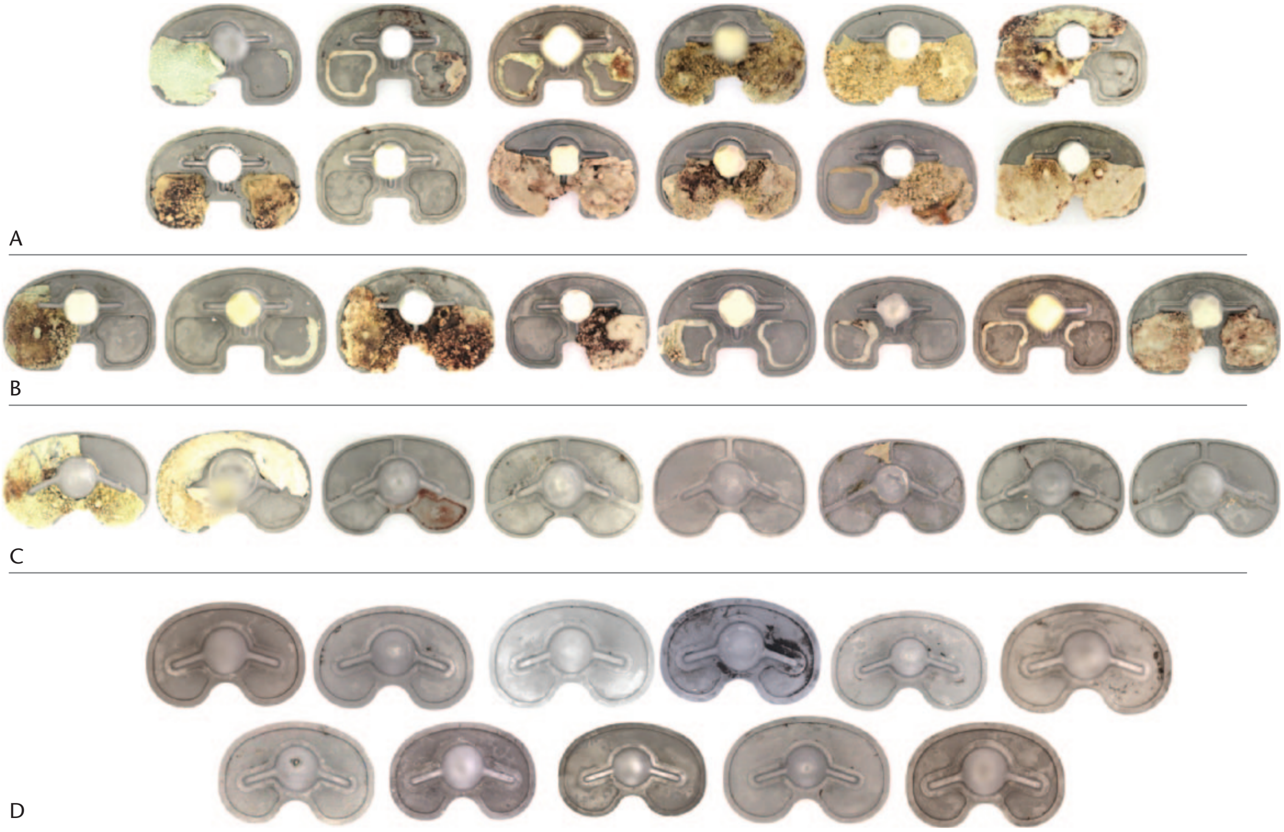

Fig. 5

Picture showing the entire cohort, divided by design: a) titanium (Ti) PFC Sigma; b) cobalt-chromium (CoCr) PFC Sigma; c) CoCr rotating platform (RP) PFC Sigma; d) Attune.

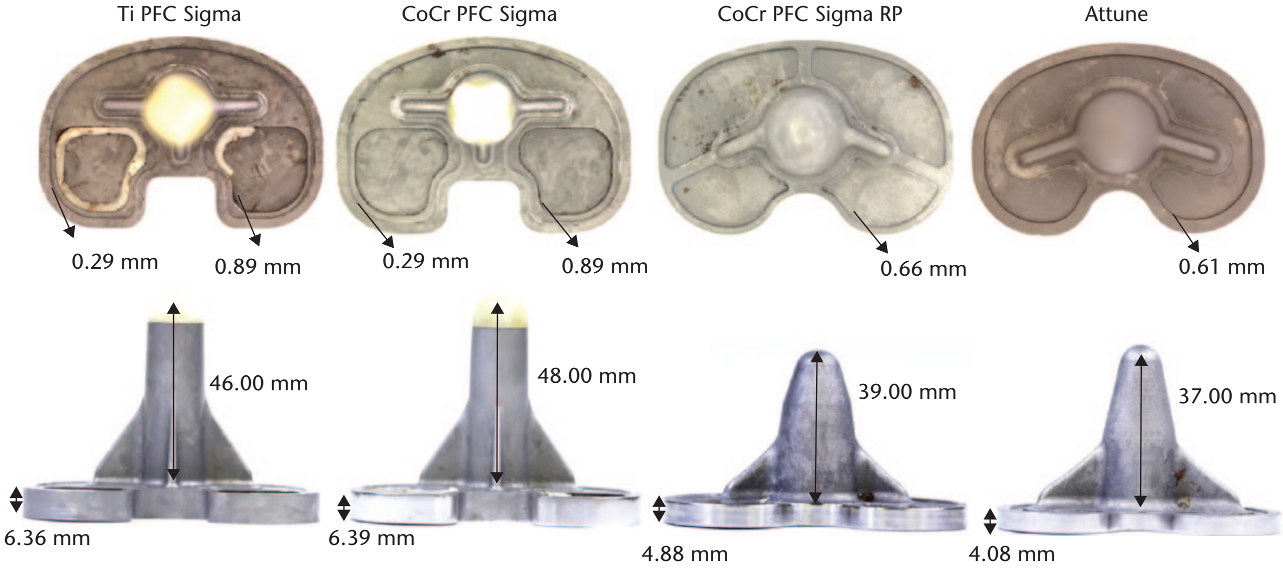

Fig. 6

Median values from visual inspection of the design features analyzed, divided by design. Ti, titanium; CoCr, cobalt-chromium; RP, rotating platform.

Sigma RP showed no evidence of cement attachment. The impact of these retrieval findings on clinical performance, therefore, is not clear at this stage.

The present study highlights significant differences in backside surface and stem roughness between the different tibial tray designs investigated ($p < 0.0001$). It is

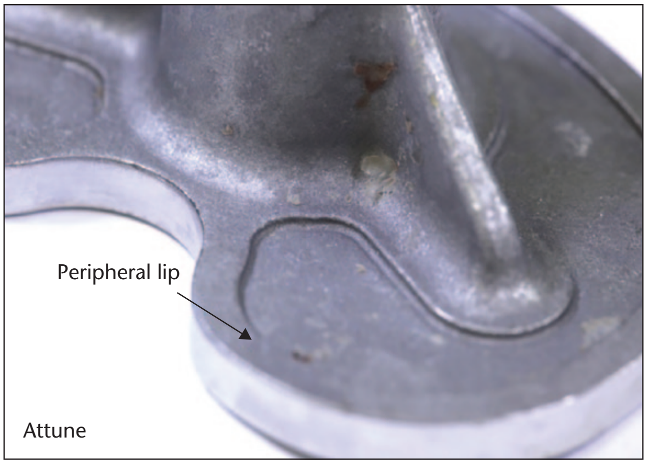

Fig. 7a

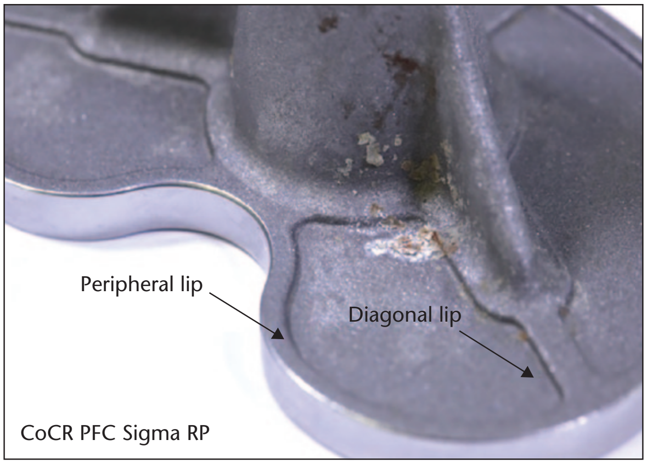

Fig. 7b

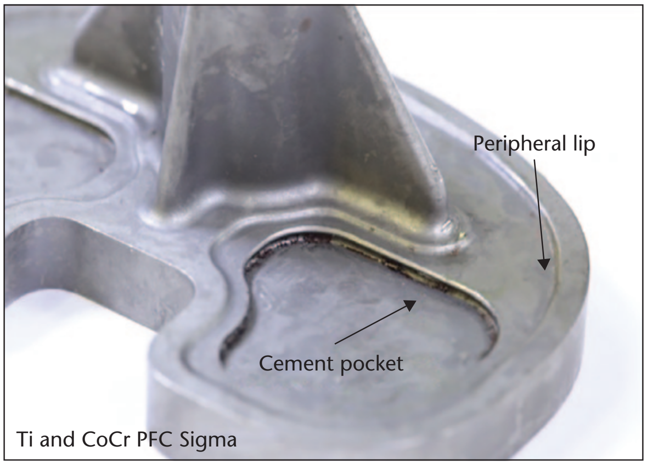

Fig. 7c

Detailed examples of lips and undercuts found in our cohort. a) Attune shows only one peripheral lip; b) cobalt-chromium (CoCr) PFC Sigma rotating platform (RP) has peripheral and diagonal lips; c) titanium (Ti) and CoCr PFC designs presented a peripheral lip and two cement pockets.

Table II. Median and interquartile range (IQR) values of tibial tray thickness, stem length, cement pocket depth, and lips

Design	Tibial tray thickness, mm	Stem length, mm	Cement pockets, mm	Lips, mm
Ti PFC Sigma	6.36 (6.30 to 6.47)	46.00 (45.79 to 49.78)	0.89 (0.85 to 0.96)	0.29 (0.25 to 0.30)
CoCr PFC Sigma	6.39 (6.34 to 6.43)	48.00 (45.86 to 50.68)	0.89 (0.88 to 0.96)	0.29 (0.25 to 0.30)
CoCr PFC Sigma RP	4.88 (4.86 to 4.88)	39.00 (37.17 to 39.25)	N/A	0.66 (0.65 to 0.67)
Attune	4.08 (4.05 to 4.12)	37.00 (36.20 to 40.00)	N/A	0.61 (0.58 to 0.64)

Ti, titanium; CoCr, cobalt-chromium; RP, rotating platform; N/A, not applicable

Table III. Median and interquartile range (IQR) values of both the tibial tray backside and stem roughness

Tibial tray design	Tibial tray backside roughness, µm	Stem roughness, µm
Ti PFC Sigma	0.68 (0.57 to 0.74)	0.85 (0.79 to 0.93)
CoCr PFC Sigma	0.38 (0.30 to 0.42)	0.60 (0.52 to 0.62)
PFC Sigma RP	1.96 (1.84 to 2.23)	2.26 (2.11 to 2.71)
Attune	1.24 (1.21 to 1.40)	1.29 (1.15 to 1.59)

Ti, titanium; CoCr, cobalt-chromium; RP, rotating platform

interesting to notice that implant designs with the lowest surface roughness, such as Ti and CoCr PFC Sigma designs, showed no significant difference in cement adhesion when compared with CoCr PFC Sigma RP, which showed the highest surface roughness. On the other hand, there was a significant difference in cement

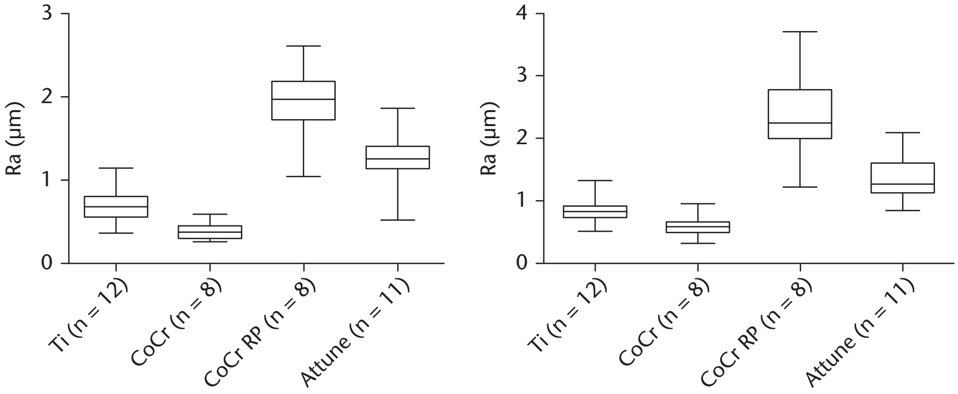

Fig. 8a

Fig. 8b

Graphs showing both the a) tibial tray roughness and b) stem surface roughness (Ra) in the four designs analyzed. In both cases, the difference between all designs was significant ($p < 0.05$). Ti, titanium; CoCr, cobalt-chromium; RP, rotating platform.

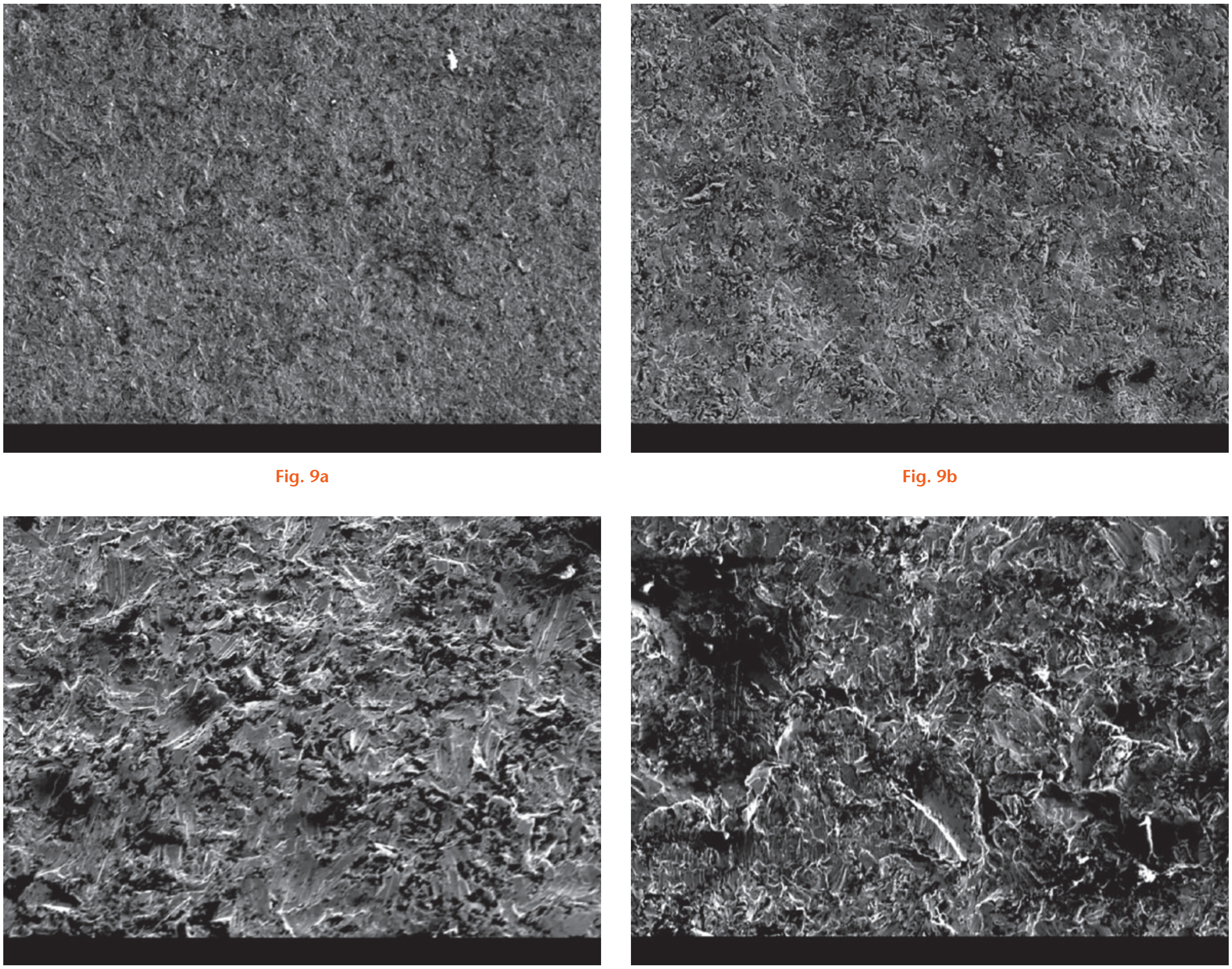

Fig. 9a

Fig. 9b

Fig. 9c

Fig. 9d

Images from SEM analysis at 10 kV and ×300 magnification, showing the surface topography of a) cobalt-chromium (CoCr) PFC Sigma, b) titanium (Ti) PFC Sigma, c) Attune, d) CoCr PFC Sigma rotating platform (RP). It is possible to notice the increase in the surface irregularity.

adhesion when compared with the Attune (Ra median value = 1.22 µm). In an *in vitro* test, Pittman et al[10] found that, in general, metal-cement interface strength increases with increasing surface roughness. Additionally, they found that samples made of titanium attained stronger bonds with cement when compared with cobalt-chromium ones. In contrast, we found no significant difference in the amount of surface covered by cement between Ti and CoCr PFC Sigma designs. This discrepancy may be due to the nature of this *in vitro* study. Moreover, Pittman et al[10] performed their tests on 60 cylindrical samples, conditions that do not take into consideration the implant design, which clearly has a fundamental role in cement adhesion.

Our study has limitations, similar to all retrieval studies. Our sample size was small; however, this was the first study of its kind for the Attune and these data can be used for sample size calculations in future studies. Further analyses, including a larger number of retrievals of a single design, are required in order to further investigate the possible association between every single feature design and cement adhesion. In order to address the controversial debate on the early-loosening cases reported for the Attune design, we chose its predecessors as the closest comparison group. Although this may facilitate the comparison, future studies should consider comparison with designs from other manufacturers.

The surface roughness evaluation was performed only on retrieved tibial trays. It may be possible that these measurements have been affected by wear due to micromotion at the implant-cement interface or the implant removal itself. Thus, future analysis should also include unused tibial tray implants, in order to estimate the roughness changes after *in vivo* performance.

Lastly, we focused only on features strictly related to the implant design, without investigating other factors such as cement type and cementing techinique. Nonetheless, it is interesting to note that PALACOS bone cement (Zimmer Biomet, Warsaw, Indiana) was used in the majority of the Attune implants (n = 9/11) and almost half of the PFC Sigma implants (n = 13/28), and the cementing procedure was standardized for all these cases, involving a double cementation (both the implant and bone sides), as reported by the operating surgeons. Other studies[14,15] suggested high-viscosity cement associated with early loosening of the tibial tray; however, in both case series the tibial tray designs investigated (Biomet Vanguard (Zimmer Biomet), PFC Sigma RP (DePuy) and Smith & Nephew Genesis (Smith & Nephew, Memphis, Tennessee) showed an absence of cement pockets, as with the Attune design, and therefore may be an example of a design problem rather than a cement problem.

We acknowledge that the surgical implantation technique may affect the cement adhesion; however, the Attune implant procedures were performed by nine different high-volume surgeons. We also acknowledge that the technique of removal may influence the amount of cement left on the tibial component: in our study, one surgeon (MTH) used an oscillating saw and chisels during the tibial tray removal which could explain the absence of cement adhesion from the majority of the Attune implants (n = 9/11). However, almost half (n = 13/28) of the PFC Sigma designs were retrieved by the same surgeon with the same technique; it is possible to say that the same removal technique gave the same results in terms of cement adhesion.

Future analysis is required in order to better address the role of both the design and cement features in order to understand fully the phenomenon of debonding at the implant-cement interface observed in a previous study.[17]

In conclusion, this is the first retrieval study to investigate cement adhesion on the tibial trays of the Attune knee design, and to compare findings with other contemporary designs, following evidence of early aseptic tibial loosening reported in a previous study. Comparison with retrieval results from three other designs from the same manufacturer suggested that the absence of cement attached may be related to the absence of separate cement pockets, as seen in the first PFC Sigma designs.

Our results may help to explain a controversial aspect related to cement attachment in a recently introduced TKA design. Future analysis is required to better address the role of both the design and cement features in order to understand fully this controversial aspect and possibly contribute to an improvement in implant design.

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