Analysis of Attune Polyethylene: A Retrieval Study

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Abstract

Background With the introduction of the Attune Knee System (DePuy) in March 2013 a new polyethylene formulation incorporating anti-oxidants was used. Although several in vitro studies have demonstrated the positive effects of antioxidants on UHMWPE, no retrieval study has looked at polyethylene damage of this system yet. It was the aim of this study to investigate the in vivo performance of this new design, by comparing it with its predecessors in retrieval analysis.

Methods Twenty-four PFC (18 fixed bearing and 6 rotating platform designs) and 17 Attune (8 fixed bearing and 9 rotating platform designs) implants were retrieved. For retrieval analysis a macroscopic analysis of polyethylene components, using a peer-reviewed damage grading method was used. Medio-lateral polyethylene thickness difference was measured with a peer-reviewed micro-CT based method. The roughness of metal components was measured. All findings were compared between the two designs.

Results Attune tibial inserts with fixed bearings showed significantly higher hood scores on the backside surface when compared with their PFC counterparts (p=0.0150), no other significant differences were found in the polyethylene damage of all the other surfaces analysed, in the surface roughness of metal components and in medio-lateral linear deformations.

Conclusion A significant difference between PFC and Attune fixed bearing designs were found in terms of backside surface damage: multiple changes in material and design features could lead to a potential decrease of implant performance. Our results may help to understand how the new Attune Knee System performs in vivo.

Key words: Total knee arthroplasty; Polyethylene; Retrieval analysis; Polyethylene surface damage; Polyethylene linear deformation.

Introduction

In March 2013 the DePuy Attune^{TM} Knee System was introduced in the market: this new design was developed in order to improve patients' outcome, by increasing motion and stability. Since its introduction, national registries reported promising early clinical results [1,2].

This innovative design includes several changes in all the three components, such as gradually reducing femoral radius, an innovative lock-mechanism on the tibial base, and a new polyethylene formulation [3].

In particular, tibial inserts were made of AOX^{TM} polyethylene and incorporating the COVERNOX^{TM} antioxidant [4]: the introduction of hindered phenols in ultrahigh molecular weight polyethylene (UHMWPE) is speculated to address oxidation stability and degradation of long term mechanical properties [5,6], overcoming limitations given by post-irradiation thermal treatments, such as annealing or re-melting methods [7,8].

Several in vitro studies testing different total knee arthroplasty (TKA) designs [9–12], and the Attune design in particular [13,14], demonstrated the positive effects of antioxidants on UHMWPE in terms of mantainance of the mechanical properties, as well as oxidation and wear resistance. However, only one comparative study on retrieved Attune TKAs has been conducted [15]: in this study, anti-oxidant showed to prevent in vivo oxidation more effectively than remelted highly-crosslinked polyethylene; no other material property was investigated, a part from tensile toughness.

The aim of this retrieval study was to assess the polyethylene wear performance of the Attune TKA system. To achieve this, we (1) performed macroscopic analysis of polyethylene components, using a peer-reviewed damage grading method, (2) measured medio-lateral polyethylene thickness difference, with a peer-reviewed micro-CT based method, (3) measured roughness of metal components and (4) compared findings with the PFC.

Materials

Retrieval Cohort

Institutional approval was obtained and patients gave informed consent for participation in the study (07/Q0401/25).

This study examined all Attune (n=17) and PFC (n=24) TKA implants consecutively received at our centre since 2015; all are produced by a single manufacturer (DePuy Synthes, Warsaw, IN, USA).

The PFC implants consisted of three different design iterations: titanium (Ti) PFC Sigma (n=12) and cobalt chromium (Co-Cr) PFC Sigma (n=6), both with the same fixed bearing design, and PFC Sigma Rotating Platform (RP) (n=6) made of Co-Cr. The tibial inserts were made of Gamma Vacuum Foil (GVF, n=20) and Cross-linked (X-LK, n=4) polyethylene. These implants were retrieved from 18 female and 6 male patients, with a median (range) age of 67 (46-88) years. The median (range) time to revision was 45 (10-237) months and the main reason for revision was instability (n=10).

The Attune implants had either fixed bearing (n=8) or rotating platform (n=9) inlays, all made of Co-Cr; all the tibial inserts were made of AOX^{TM} polyethylene, incorporating the COVERNOX^{TM} antioxidant (PBHP or pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]). These implants were retrieved from 14 female and 3 male patients, with a median (range) age of 70 (46-84) years old. The main reason for revision was instability (n=8) and the median (range) time to revision was 21 (8-56) months; this was statistically shorter than for the PFCs (p=0.0101).

Table 1 summarises the TKA specifications and patient demographics for each case.

Figure 1 shows the three PFC design iterations and Attune implants.

Sample preparation

All tibial components were decontaminated using 10% formaldehyde solution (Solmedia Ltd., UK), followed by rinsing with water.

Methods

Figure 2 describes the study design.

Surface damage in polyethylene tibial inserts (Hood score)

All the polyethylene tibial inserts were visually investigated and the surface damage on both articulating and backside surfaces was assessed by using the Hood Score [16]. This grading system consists of dividing both the articulating and backside surfaces into 10 sections and grading each of them according to the presence and severity of seven modes of surface damage (surface deformation, pitting, embedded debris, scratching, burnishing, abrasion and delamination). The surface division is shown in Figure 3.

The maximum damage grade possible is 21 for a single section (grade 3 for each of the seven damage modes) and 210 for the entire surface (grade 3 for each of the seven damage modes for each of the 10 sections).

Articulating and backside surface scores were assessed, as well as the overall score as sum of the previous two.

Scores were normalized to the time to revision and median values for each design iteration were calculated.

Unpaired t-tests were performed in order to assess significant differences between the two designs.

Linear deformation in polyethylene tibial inserts (micro-CT)

For a subgroup of 20 TKAs (10 PFC and 10 Attune implants), information from pre-revision clinical 3D-CT images about implant position in the coronal plane were provided: no significant differences in femoral, tibial or tibio-femoral angles were found among the two groups ($p>0.05$); this result made the subgroup suitable for a comparison of polyethylene deformation.

Differences in thickness between medial and lateral compartments were investigated using a peer reviewed method, based on micro-Computed Tomography (micro-CT) [17].

All the polyethylene tibial inserts were scanned using a micro-CT scanner (XTH 225, Nikon Metrology NV), with an X-ray tube voltage of 80 kV and a current of 300 µA. Scans were reconstructed at the full 45-µm isotropic resolution.

Image segmentation was performed by using Simpleware ScanIP (Simpleware ScanIP, software version 7.0, Exeter, UK); the resulted geometry was saved in stereolithography (STL) file format.

Subsequently, all the 3D models were analysed with Geomagic Control X (Geomagic Inc, Morrisville, NC, USA): each segmented image was imported as measured data, and a plane was created and placed parallel to the backside surface to serve as reference data. A 3D comparison between measured and reference data was then performed and a colour map representing relative distances generated. In order to establish the most deformed compartment, the thinnest point in both the medial and lateral compartments was identified and the difference in thickness between them computed. This deformation was considered as a combination of wear and creep: no distinction between these two contributes was made in the present study.

All the measurements were normalized by the time to revision and median values for each design iteration were calculated.

Unpaired t-tests (Mann-Whitney) were performed in order to assess significant differences among the two designs.

Articulating surface roughness of metal components (profilometer)

In order to measure the articulating surface roughness (Ra) of metal components, a contact profilometer Talyrond 365 (Taylor Hobson, Leicester, UK) with a 5μm-probe was used. Surface roughness (Ra) is defined as the average of the absolute values of the surface height deviations measured from the mean plane.

Each metal component was position on the spindle and three vertical traces (length=10 mm; number of points=10,000) were acquired on the articulating surface, avoiding areas damaged by scratches created during the revision surgery, Figure 4.

All the measurements were normalized by the time to revision and median values for each design iteration were calculated.

Unpaired t-tests were performed in order to assess significant differences among the two designs.

Results

Surface damage in polyethylene tibial inserts (Hood score)

Visual investigation revealed the most common types of polyethylene surface damage were scratching, pitting and burnishing. The median overall hood score (range) for the entire cohort was 47 (12-128), while the median (range) values for articular and backside surfaces were 37 (10-64) and 8 (0-64), respectively. The majority of the tibial inserts (n=20) showed higher hood scores on the medial side, whilst 29% (n=12) had higher hood score on the lateral side. Only 22% (n=9) showed the same hood score on both sides.

The median (range) overall hood scores for PFC and Attune implants were 47 (12-87) and 48 (20-127), respectively.

There was no significant difference in the overall and articulating surface damage (p=0.0935 and p=0.1284, respectively) between PFC and Attune implants with fixed bearings. There was a significant difference in the backside damage (p=0.0150): Attune polyethylene inserts showed significantly higher hood scores, Figure 5.

Comparing PFC and Attune implants with rotating platform, statistical analysis (Mann-Whitney) revealed that there was no significant difference in the overall, articulating or backside surface damage (p=0.5858, p=0.2625 and p=0.9317, respectively), Figure 6.

Linear deformation in polyethylene tibial inserts (micro-CT)

Micro-CT analysis revealed that 60% of the tibial inserts showed higher deformation on the medial compartment, with a thickness difference median (range) value of 0.042 mm (0.005-0.320 mm); whilst the remain had higher deformation on the lateral compartment, with a thickness difference median (range) value of 0.061 mm (0.005-0.145 mm).

The median value (range) of thickness difference for PFC and Attune implants were 0.042 mm (0.005 mm - 0.32 mm) and 0.055 mm (0.005 mm - 0.145 mm), respectively.

Statistical analysis (Mann-Whitney) on the normalized measurements revealed that there was no significant difference in the thickness difference among the designs (fixed bearing, p=0.7791; rotating platform, p=0.7000), Figure 7.

Articulating surface roughness of tibial components (profilometer)

Results from the contact profilometer revealed that PFC femoral implants showed a median surface roughness value of 0.0400 μm, whilst Attune implants had a median value of 0.0424 μm.

Regarding tibial components, CoCr PFC RP tibial tray showed the smoother surface (median Ra = 0.1144 μm), followed by Attune with fixed bearing (median Ra = 0.1368 μm), CoCr PFC (median Ra = 0.1883 μm) and Attune with rotating platform (median Ra = 0.2932 μm). The Ti PFC had the rougher surface (median Ra = 0.5590 μm).

Analysing the normalized roughness values (Mann-Whitney), no significant differences were found in surface roughness of the metal components between PFC and Attune (femoral components: $p=0.0842$; fixed bearing tibial tray: $p>0.9999$; rotating platform tibial tray: $p=0.0873$), Figure 8.

Discussion

This is the first retrieval study comparing surface damage and linear deformation between Attune tibial inserts, incorporating anti-oxidant (AOX^{TM}), and the control group of PFC polyethylene components (GVF and X-LK).

Our results revealed that Attune tibial inserts performance is similar to their PFC counterparts in terms of surface damage and linear deformation. Although tibial inserts incorporating anti-oxidants showed significantly higher hood scores on the backside surface when compared with PFC implants with fixed bearings ($p=0.0150$), no other significant differences were found in the polyethylene damage of all the other surfaces analysed and in medio-lateral linear deformations.

Ultrahigh molecular weight polyethylene (UHMWPE) has been used in orthopaedic replacements since its first introduction in the 1960s, remaining the gold standard for bearing surfaces [18]. UHMWPE *in vivo* performance is strictly related to its wear, oxidation and fatigue resistance [19]. It has been proven that cross-linking gamma radiations initiate the formations of free radicals [20–23], very reactive molecules able to trigger the oxidation process in combination with oxygen. Oxidation leads to polyethylene delamination and embrittlement with reduction in material properties and performance [24], especially in total knee arthroplasty (TKA), due to its complex geometry leading to large contact stresses and shear forces [5,25]. Post-irradiation thermal treatments, such as annealing or re-melting methods, were designed in order to reduce or eliminate free radicals, improving oxidation resistance; however, these processes demonstrated to affect UHMWPE mechanical properties [7,8].

More recently, an alternative method to stabilize irradiated UHMWPE was developed: incorporation of anti-oxidants, such as hindered phenols (vitamin E and pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]), in the second generation of polyethylene is speculated to address oxidation stability and degradation of long term mechanical properties [5,6].

Different studies conducting accelerate aging and knee simulator tests reported the superior performance of anti-oxidant doped polyethylene in terms of wear resistance, oxidation resistance and stability of material properties when compared with conventional polyethylene [9–12,26]. In a previous in vitro study Micheli et al. reported that after 5 million cycles both vitamin-E doped and conventional polyethylene tibial inserts, with fixed bearing designs, showed similar evidence of scratching and burnishing on both condylar and backside surfaces [26]. In a more recent study, Grupp et al. confirmed these findings, highlighting that conventional polyethylene tibial inserts showed also evidence of delamination, differently from the vitamin-E doped polyethylene tibial inserts [12]. Our findings agreed with these studies: scratching, pitting and burnishing were the most common types of surface damage reported and, in the majority of the cases, no significant differences were found among anti-oxidant and conventional polyethylene. However, we found that polyethylene tibial inserts incorporating anti-oxidant showed higher backside surface damage in fixed bearing implants: this result could be also influenced by changes in other design features.

Our results from micro-CT analysis revealed that, in similar condition of coronal alignment and, thus, of loading distribution in the frontal plane, there was no significant difference in the medio-lateral asymmetrical deformation between PFC and Attune polyethylene. This deformation takes in account of both wear and creep contributions and it is only a relative measurement: future retrieval studies are required in order to assess the absolute linear deformation from the original unworn geometry and, possibly, quantify wear.

The introduction of cobalt chromium in the design of tibial trays allowed orthopaedic manufacturers to create highly polished surfaces and consequently reduced backside wear. In a retrieval study Berry et al. found that fixed bearing inserts in polished CoCr trays wear less than their counterparts in rough Ti trays [27]. However, Rao et al. [28] reported no significant difference between the nineteen titanium tibial components and the ten cobalt-chromium tibial components with regard to the backside polyethylene damage score, in agreement with our results. The significant difference found between Attune and PFC implants with regards to the backside surface damage in fixed designs seems to be linked to design difference instead of being material-related: in fact, no significant difference was found in the surface roughness of the tibial trays that could explain this result. Moreover, the fixed bearing lock-mechanism designs are very different. As stated by the manufacturer [29], the “i2 Locking Mechanism” of the PFC implants covers the entire polyethylene perimeter and provides little room of movement between polyethylene and tibial tray, minimizing the rotational micromotion and potential backside polyethylene wear. Differently, the Attune “Logiclock Mechanism” has three-point locking features that holds the tibial insert in place, leaving the lateral sides open

[30]: this could facilitate material ingress that could explain the increased surface damage on the polyethylene backside.

Our study has a considerable number of limitations. First, our sample size was small and the time to revision was very low; however, it is important to highlight that the Attune design has been introduced in the market very recently. Further analyses including a larger number of retrievals are required in order to better investigate the possible association between every single feature design and polyethylene performance.

Secondly, the Hood score is a semi-quantitative score used to assess surface damage, which was recently proved to be only a moderate predictor of material volume loss [31]. However, the significant higher surface damage found in the backside of the Attune fixed design should be monitored.

Conclusions

Although previous studies revealed that Attune anti-oxidant polyethylene showed superior oxidation and wear resistance when compared to its conventional counterparts, we found a significant difference between PFC and Attune fixed bearing designs in terms of backside surface damage: multiple changes in material and design features could lead to a potential decrease of implant performance.

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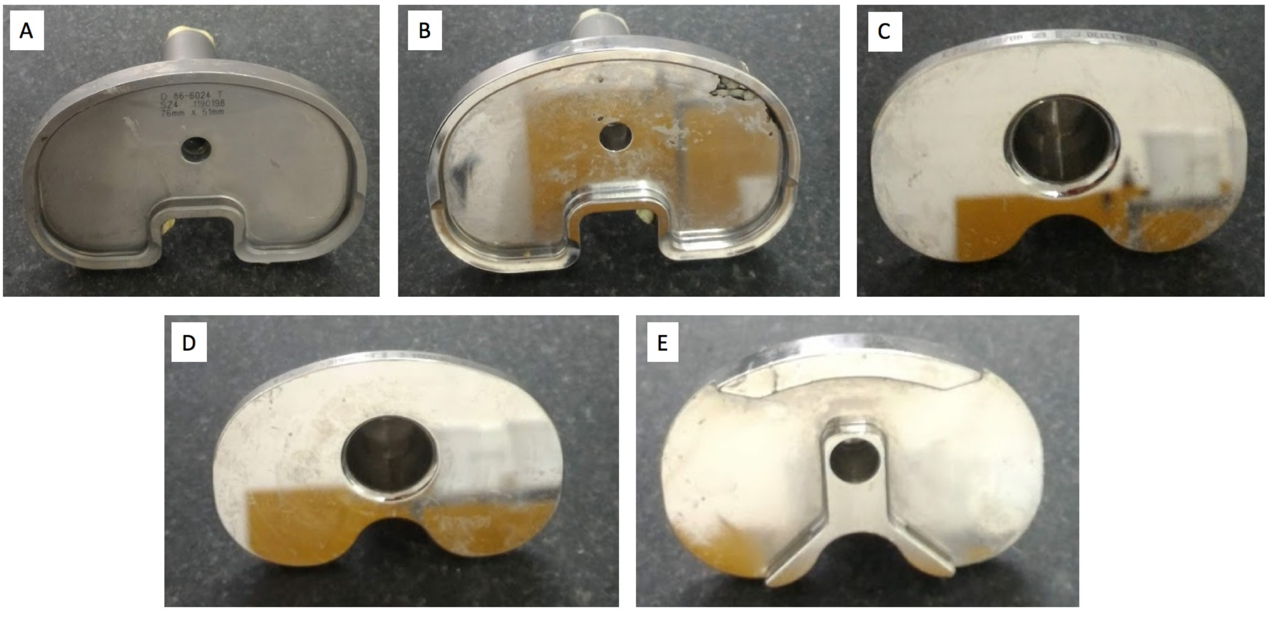

Figure 1: Examples of 2 designs and relative iterations involved in the study: (A) Ti PFC fixed bearing, (B) CoCr PFC fixed bearing, (C) CoCr PFC RP, (D) Attune fixed bearing, (E) Attune rotating bearing.

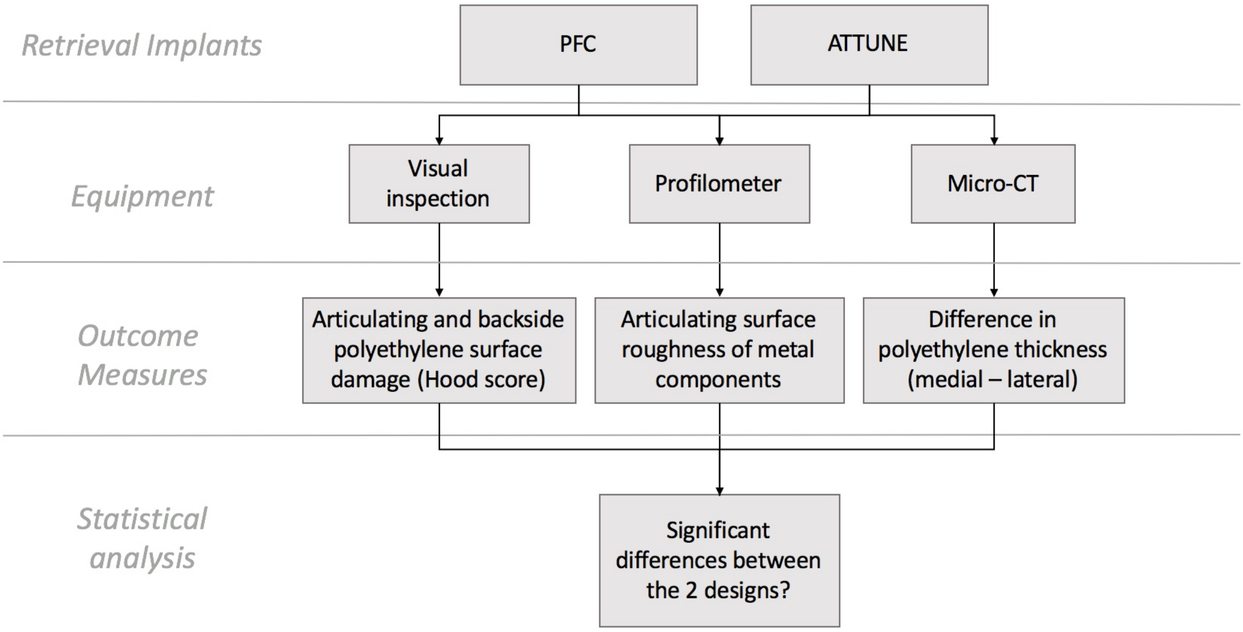

Figure 2: Flow chart showing the study design.

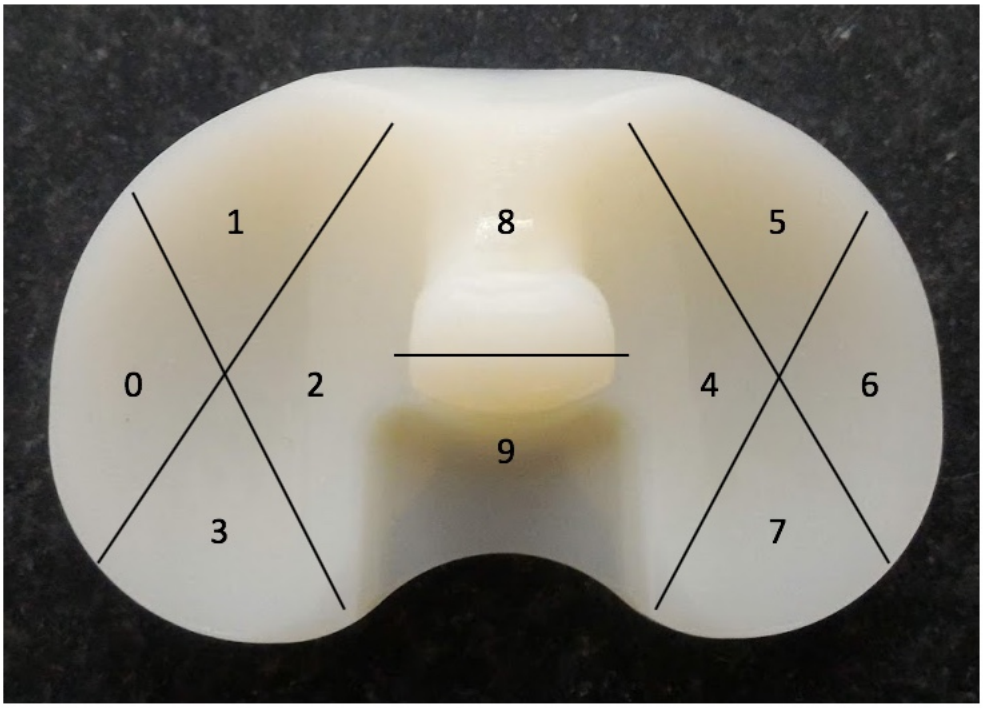

Figure 3: Surface division according to the Hood score.

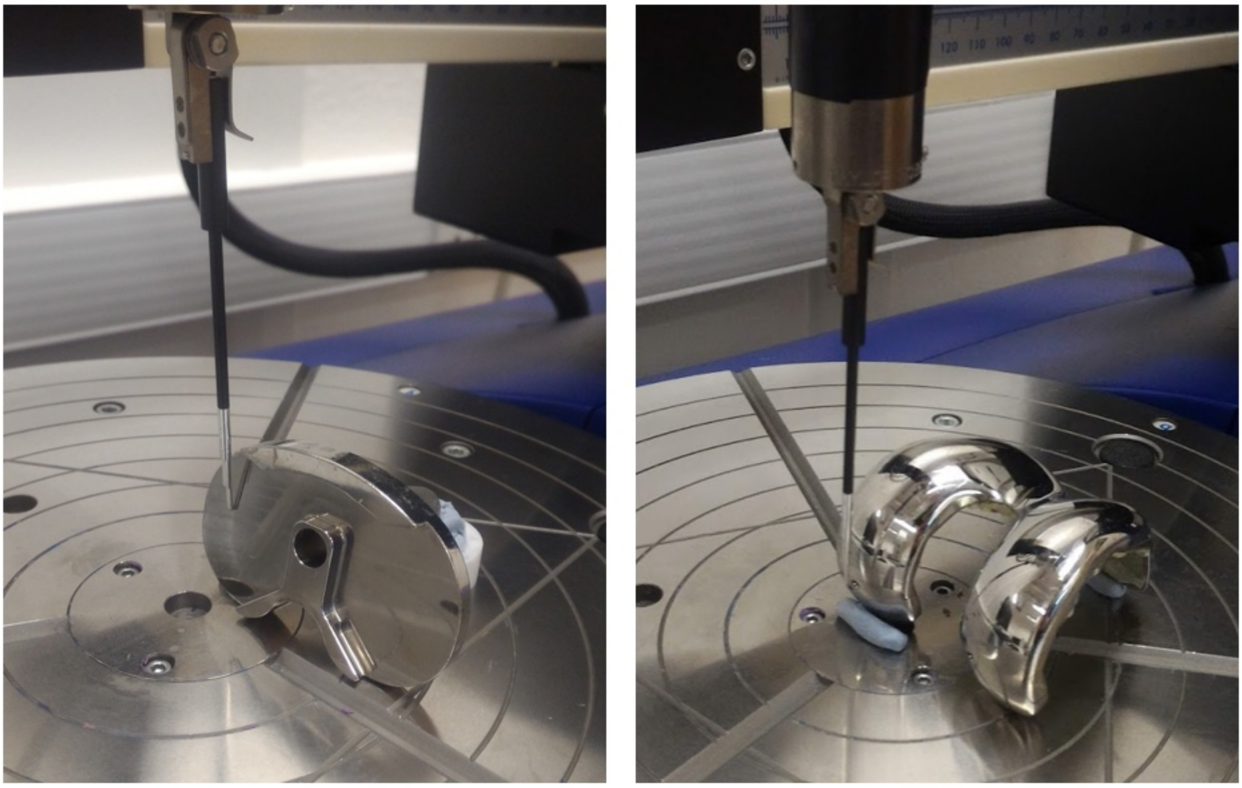

Figure 4: Example of surface roughness analysis performed by using a contact profilometer.

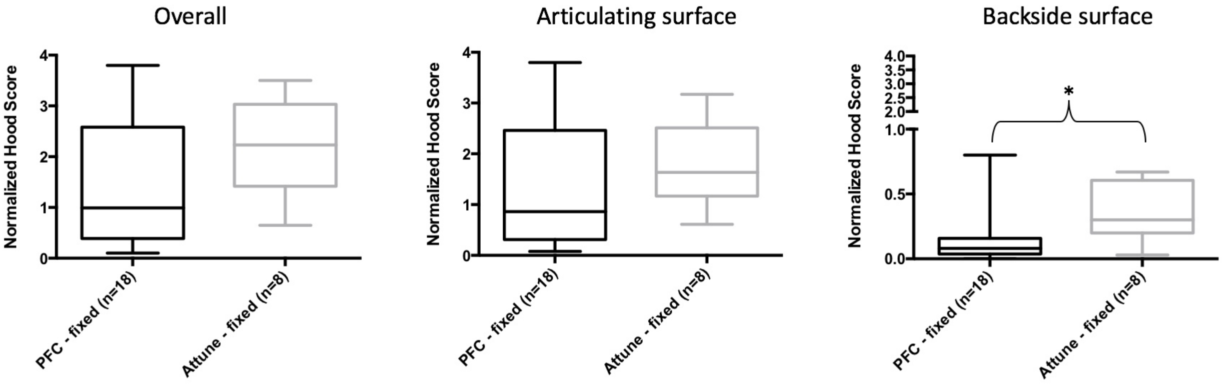

Figure 5: Graphs showing the comparison of overall, articulating and backside surface normalized Hood score between PFC and Attune implants with fixed bearings.

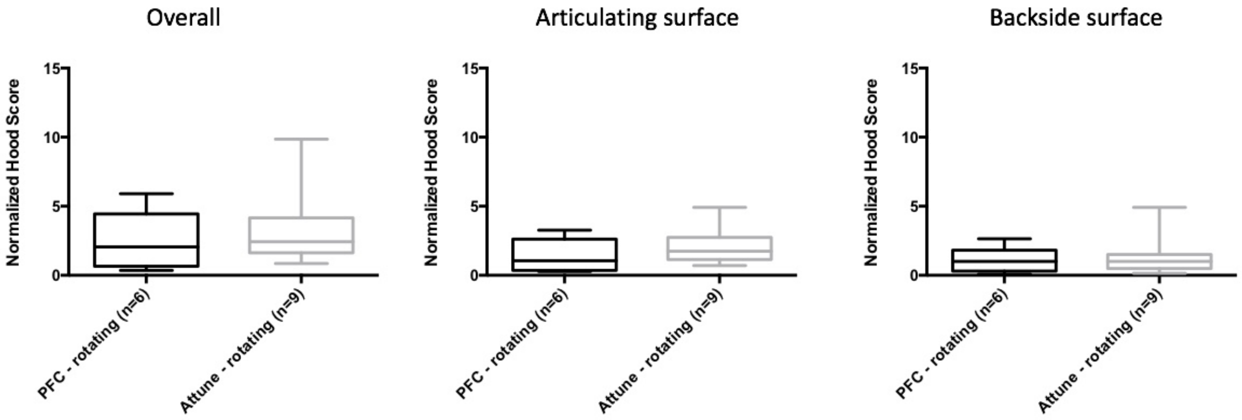

Figure 6: Graphs showing the comparison of overall, articulating and backside surface normalized Hood score between PFC and Attune implants with rotating bearings.

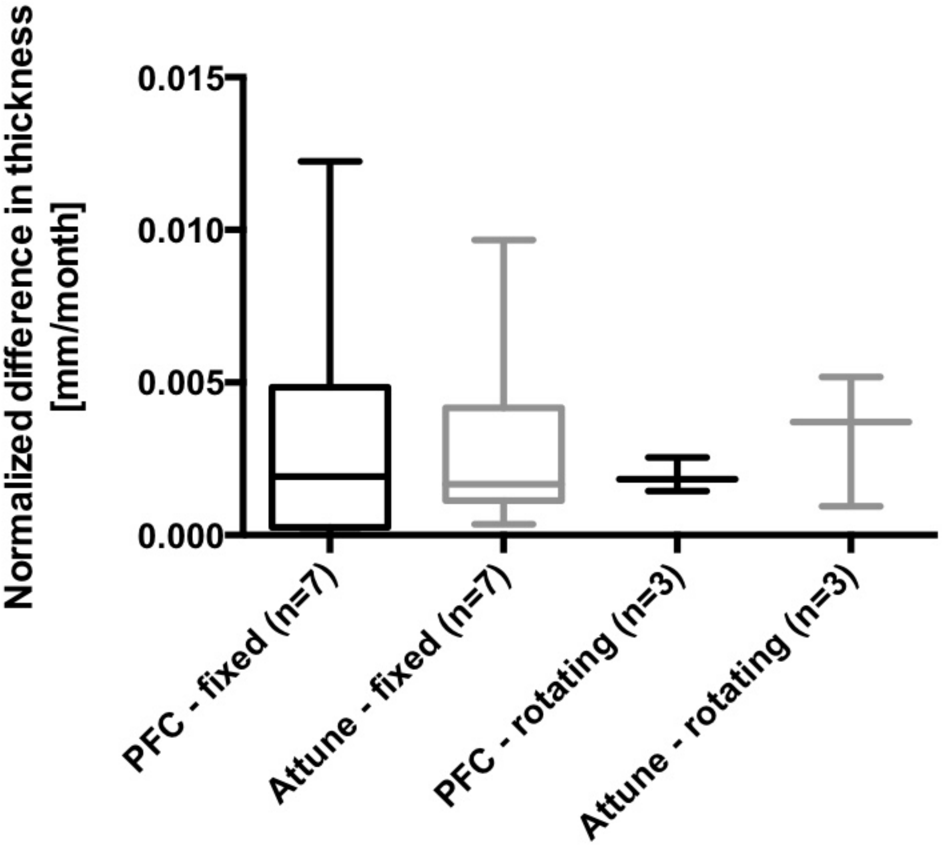

Figure 7: Graphs showing the comparison of medio-lateral difference in thickness between PFC and Attune implants.

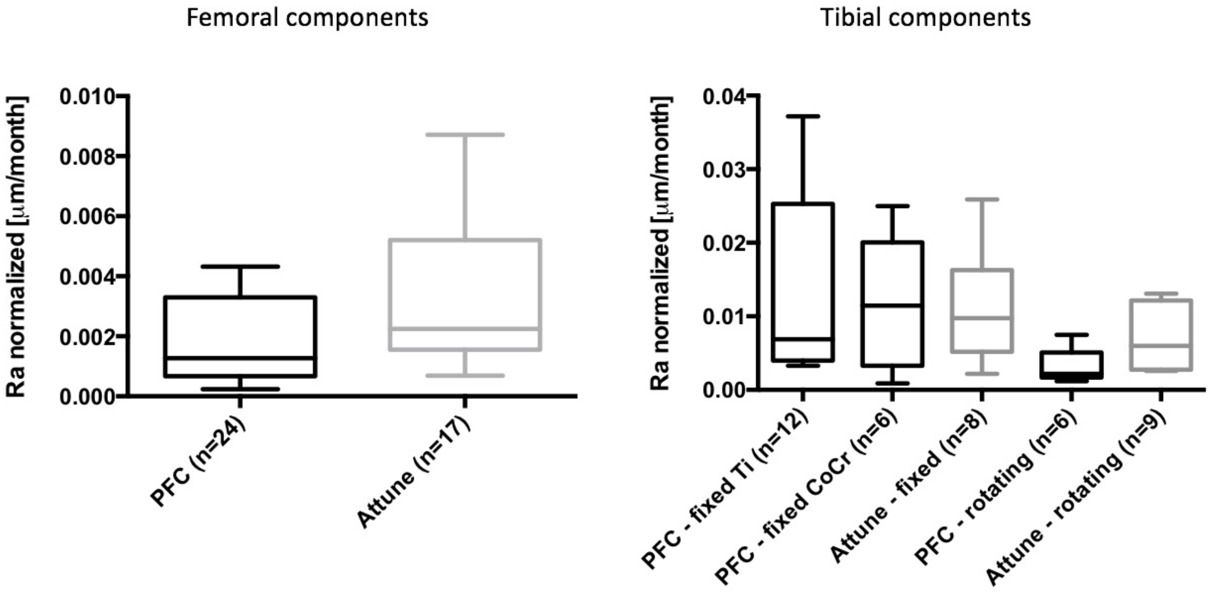

Figure 8: Graph showing the comparison of articulating surface roughness of femoral and tibial components between PFC and Attune implants.

Case number	*Gender*	*Age [years]*	*Time to revision [months]*	*Reasons for revision*	*Design*
1	M	69	15	Aseptic loosening	Ti PFC
2	F	53	45	Malposition	Ti PFC
3	F	78	154	Instability	Ti PFC
4	M	88	118	Infection	Ti PFC
5	F	63	61	Aseptic loosening	Ti PFC
6	F	49	17	Instability	Ti PFC
7	F	67	13	Patella maltracking	Ti PFC
8	F	55	169	Instability	Ti PFC
9	F	62	66	Patella maltracking	Ti PFC
10	M	69	115	Instability	Ti PFC
11	F	76	237	Osteolysis	Ti PFC

12	F	76	105	Instability	Ti PFC
13	F	51	26	Stiffness	Co-Cr PFC
14	F	68	17	Oversized components	Co-Cr PFC
15	F	61	10	Instability	Co-Cr PFC
16	F	64	45	Infection	Co-Cr PFC
17	F	50	39	Instability	Co-Cr PFC
18	F	81	10	Malposition	Co-Cr PFC
19	M	66	53	Malposition	Co-Cr PFC RP
20	F	46	20	Pain	Co-Cr PFC RP
21	F	72	31	Stiffness	Co-Cr PFC RP
22	F	73	11	Instability	Co-Cr PFC RP
23	M	57	115	Instability	Co-Cr PFC RP
24	M	71	174	Instability	Co-Cr PFC RP
25	F	68	15	Instability	Attune
26	F	70	21	Malposition	Attune
27	F	78	13	Instability	Attune
28	F	64	22	Instability	Attune
29	F	62	24	Instability	Attune
30	M	46	56	Aseptic loosening	Attune
31	F	70	21	Malposition	Attune
32	F	79	21	Pain	Attune
33	M	56	12	Instability	Attune
34	M	74	8	Instability	Attune
35	F	67	35	Malposition	Attune
36	F	73	16	Movement restriction	Attune
37	F	58	31	Instability	Attune
38	F	77	15	Instability	Attune
39	F	84	11	PCL rapture	Attune
40	F	72	23	Fracture (tibial bone)	Attune
41	F	58	13	Tibial loosening	Attune