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Pre-clinical studies to validate the MITCH PCR^{TM} Cup: a flexible and anatomically shaped acetabular component with novel bearing characteristics

Ahmed M. H. Latif · Aude Mehats · Martyn Elcocks · Neil Rushton · Richard E. Field · Eric Jones

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Abstract A previous clinical study was undertaken to evaluate the safety and efficacy of an anatomically shaped, flexible acetabular cup. Clinical results achieved were satisfactory, although some deficiencies in the model were identified. Design changes to the original model have been implemented to improve both initial stability and long term biological fixation. This was achieved through modifications made to both the anchoring mechanism and by the application of an appropriate backing surface layer promoting bone on-growth. In addition, changes to the articulation couple have also been introduced to improve implant durability and bearing performance, utilising a carbon fibre reinforced polyetheretherketone—alumina couple. Simulated loading, in both models, was performed using Finite Element Analysis. Mechanical and tribological tests were also performed to ensure the robustness of the new optimised design. Bio-compatibility of the articulation couple was demonstrated using an animal model. Implantation of the device has been extensively tested and re-validated in vitro to achieve a favourable polar contact between cup and femoral head and establish a reproducible operative technique. This preliminary work is undertaken prior to commencing a post market surveillance study of the CE marked implant.

A. M. H. Latif (✉)
Clinical Fellow in Orthopaedics, South West London Elective Orthopaedic Centre, Dorking Road, Surrey, London KT18 7EG, UK
e-mail: ahmedlatif@doctors.org.uk

A. Mehats
Stryker Orthopaedics, 203 Boulevard de la Grande Delle, Herouville-Saint-Clair, France

M. Elcocks
Stryker SA, Cite-Centre, Grand Rue 90, 1820 Montreux, Vaud, Switzerland

N. Rushton
University of Cambridge, Box 180, Addenbrooke's Hospital Foundation Trust, Cambridge CB2 0QQ, UK

R. E. Field
South West London Elective Orthopaedic Centre, Dorking Road, Surrey, London KT18 7EG, UK

E. Jones
Stryker Orthopaedics, Raheen Business Park, Limerick, Ireland

1 Introduction

An anatomic, flexible, horseshoe-shaped acetabular component was designed to replace the damaged articular cartilage and the surface layers of the underlying subchondral bone. The implant is intended to load the horseshoe weight-bearing segment of the acetabular socket, which is covered normally with articular cartilage. The shape and flexibility of the horseshoe cup allows it to fuse and flex in concert with adjacent bone. A number of other acetabular implants, designed to deform with surrounding bone, have been previously subjected to clinical evaluation. Encouragingly excellent short and medium term results have been reported [1, 2, 3].

The Cambridge Cup provided the first clinical experience of an anatomically shaped flexible acetabular implant [4, 5]. Despite good clinical results, a number of potential design enhancements have since been identified. Pre-clinical validation of these changes has been undertaken as a precursor to the introduction of an evolutionary new component.

The analysis of retrieved Cambridge Cups [6] has demonstrated progressive loss of HA coating and has also raised questions over the suitability of an uncoated carbon composite as a surface for long-term osseo-integration. To

address this concern, a two-layer outer surface has been developed (Fig. 1a) that comprises an outer HA coating (nominal thickness 100 μ) and an under layer of plasma sprayed CP-Ti (nominal thickness 90 μ).

Since the original study of the Cambridge Cup, clinical evaluation of 30% carbon fibre reinforced polyetheretherketone (CFRPEEK) has been undertaken in a separate study [7]. This work has confirmed that CFRPEEK is suitable as an acetabular bearing, when coupled with a ceramic femoral head. Substitution of the 30% carbon fibre reinforced polybutyleneterephthalate (CFRPBT) (used to fabricate the outer layer of the Cambridge Cup) with CFRPEEK has rendered the inner polyethylene layer of the Cambridge Cup unnecessary (Fig. 1b). Thus, the new component is thinner than the original Cambridge Cup and the internal interface between materials of differing chemical properties has been removed.

The third design change incorporated into the new component is the substitution of six polar spikes with two parallel fins. This change was undertaken because fracture of the spikes was observed, on some occasions, during component implantation. Finally, the terminal dowel holes were removed as this secondary fixation mechanism had not been utilised in a proportion of the original Cambridge Cup patients and it was recognised that this mode of fixation was unnecessary. The new implant (MITCH PCR^{TM} Cup) has been made in size range from 44 to 66 mm OD in 2 mm increments, articulating with a femoral head component, of an appropriate material, in sizes 38 mm to 60 mm in 2 mm increments. Figures 2a, b highlight the major differences between the Cambridge Cup and the MITCH PCR^{TM} Cup.

2 Materials and methods

2.1 FEA

A three-dimensional finite element model was generated, based on a cadaver pelvis of a 45-year-old female donor, to study the peri-prosthetic stress and strain patterns in the bone adjacent to the Cambridge and MITCH PCR^{TM} Cups. The FEA models were validated using previously reported, in-vitro and computational results [8, 9, 10, 11]. A peak joint reaction force of 3KN was applied for all models simulating a maximum joint force during the stance phase of gait [12]. Forces from 22 muscles were also taken into account [12, 13].

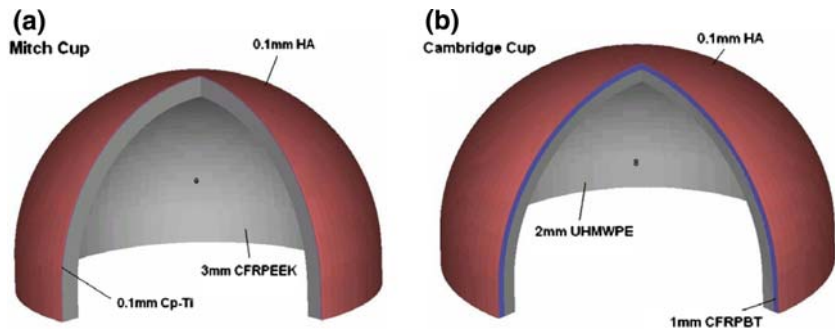

Fig. 1 This shows cut section through old Cambridge Cup and new MITCH PCR^{TM} Cup to demonstrate differing constructs: (**a**) Depicts the construct of the MITCH PCR^{TM} Cup (**b**) Depicts the construct of the Cambridge Cup component, in which there is no bonding between the bearing layer and support layer

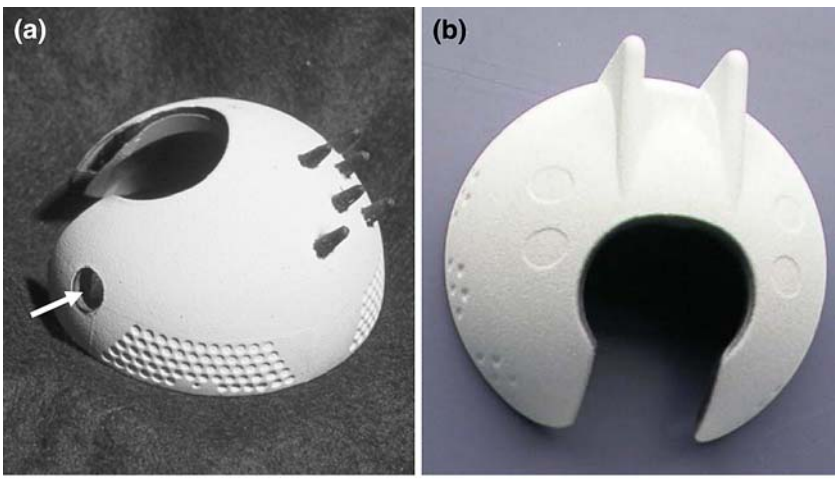

Fig. 2 Showing the outer surface of the two cups. Demonstrating; (**a**) The change from spikes to fins (**b**) The loss of dowel holes (arrow)

2.2 Component fabrication

Medical grade PEEK (Victrex 151G) was compounded with milled graphitic carbon fibres (Amoco VMX12) using a twin extrusion process to produce a composite moulding compound containing 30% by weight of carbon fibre (no processing aids were used). The components and test plaques were then injection moulded from this material using a reciprocating screw-type machine. The cups were subsequently machined to a high tolerance to form a unique internal bearing geometry and were tested to establish mechanical properties.

2.3 Tribology properties of the ceramic PEEK bearing

Wear studies were carried out using a hip joint wear simulator [14] with five articulating wear stations and a sixth loaded soak control station, mounted in the anatomical position. The femoral components oscillated with approximate sinusoidal motion (period 1s) through + 30° to −15° in the flexion/extension plane, whilst the acetabular components were oscillated through ± 5° to give internal/external rotation. A simplified loading cycle was applied pneumatically, for which the maximum and minimum loads were set at 2,800 N and 250 N respectively. The lubricant used was 30% stabilised calf serum, with test being carried out at room temperature. Gravimetric analysis was used to estimate the wear rate, and the study was allowed to run for 25 million cycles.

2.4 Biocompatibility tests

Biological conformance to ISO 10993 was confirmed. Additional tests were carried out using CFRPEEK particles. One study was based on rat model in which the CFRPEEK samples were injected into a prepared pouch. The rats were sacrificed at intervals up to 10 days. Cellular response was assessed by monitoring the pouch thickness, and localisation of macrophages was assessed by immunohistochemistry using ED 1 antigen. The inflammatory marker of vascular proliferation was assessed using ICAM 1(intracellular adhesion molecule). Polyethylene particles were used for comparison. In the second study, tissue samples were collected from surgical procedures for the revision of ABGII CFRPEEK acetabular liners implanted as part of a clinical study [7]. Histological analysis was performed to determine the nature of the particles and check for indication of a biological response to the composite particles.

2.5 Mechanical

2.5.1 Clearance validation

Compression of the cup in the acetabulum during implantation can result in a reduction of the internal diameter of the cup. The clearance of the femoral head in the cup depends on the design clearance between the femoral head and cup as well as the diameter of the reamed acetabulum. Tests were designed to measure all manufactured tolerances in the cup fabrication and the reaming process to establish the minimum clearance that was required to ensure polar contact was achieved. Increase in clearance was achieved by altering the internal geometry of the cup by effectively relieving the "arms" of the cup, with the prepared cavity in the fixture being machined to required diameters. The nature of contact was established by using friction data and wear tracks.

2.5.2 Fatigue tests

Representative cups from the range (48 mm and 58 mm outer diameter) were selected for the fatigue studies. Samples were mounted in a test fixture and pre-stressed by closing the gap between the side arms by 0.4 mm. A compressive load of 175 N was applied to the cup causing side arms to flex inwards by a further 0.3 mm per side. The test was run at 25 Hz for 10 million cycles. At the end of the study the samples were examined to determine if damage had been caused to either the coatings or to the body of the cups.

2.6 Stability

2.6.1 Frictional torque stability

Rotational stability of the cup was determined by measuring the frictional torque developed between the femoral head and cup. The test was carried out using the Durham Friction Simulator [15] set in the hip mode, using carboxymethylcellulose of various viscosities as lubricants. Testing was performed until failure occurred.

2.6.2 Spikes versus fins

Spike fixation was used to stabilise the earlier Cambridge Cup design and proved to be a weakness. The six spikes were replaced by two fins, in order to achieve superior anti-rotational stability. Mechanical testing of the fins was carried out by applying a direct load perpendicular to the

axis of the fins, at a constant rate, until fracture occurred. For comparison, testing of the spikes of the Cambridge Cup was also performed.

2.6.3 *Cup stability over a focal bone deficiency*

A series of friction tests were conducted on two cups using a 60.5 mm inside diameter holder. A 5 mm diameter hole was drilled in the cup holder just underneath the load bearing part of the cup to simulate the presence of a cyst in the acetabulum. The diameter of this hole was increased to 10, 15 and 20 mm to simulate conditions of different potential sizes of cysts and the friction tests were repeated. A wear test (one million cycles) was then performed on five previously unworn cups (plus one soak control), using a void diameter of 20 mm in the holder. Friction tests were performed after wear testing (using a 20 mm diameter hole only).

2.7 Coating validation

The acetabular cup is coated with a titanium sub-coating to provide a good biological surface for osteoblast activity when the hydroxyapatite (HA) top coating resorbs. One hundred and twenty cups were grit blasted and coated with Ti/HA, and then analysed. Micro-sections were prepared and viewed microscopically (ASTM F1854) to determine the Ti thickness, HA thickness, the percentage of porosity, and the quality of the coating on the fins. The bond strength of both coatings was also assessed (ASTM F 1147) and the surface roughness of the Ti layer and the Ti/HA layer was determined with a perthometer (EN ISO 3274, 4287 and 4288).

2.8 Cadaver studies

2.8.1 *Reaming validation*

The accuracy and reproducibility of acetabular reaming was validated by performing two series of cadaver studies. An alginate imprint of each acetabular cavity was taken before and after reaming. Thin plaster models were moulded from the imprints within 6 h to reproduce the acetabular cavity. These were scanned with a laser sensor (METRIS, Leuven, Belgium) mounted onto a co-ordinate measuring machine (Mitutoyo Corporation, Kawasaki, Japan). The point coordinates recorded were converted into an Initial Graphics Exchange Specification (IGES) file, and the dimension and centre of the cavities measured. The size of the simulated cavities were sequentially increased or decreased to look at sites of contact that bone will make with the un-deformed cup. The reamed cavity was measured before and after cup implantation.

2.8.2 *Clearance validation*

Using the method described in the reaming validation, a sphere resembling the exact outer diameter of the finishing reamer was constructed and super-imposed on the IGES file for each cup. The 3D perspective was viewed to identify the points of contact with bone and determine the effect of cavity size on the deformation of the implanted cup.

3 Results

3.1 FEA

Peri-acetabular stress and strain patterns of the MITCH PCR™ Cup were very similar to those of the Cambridge Cup (Fig. 3). Furthermore, deformation of the MITCH PCR™ Cup closely resembles that of the natural hip. The peak bearing stresses for the MITCH PCR™ Cup did not exceed the tensile or yield strength for 30% CFR-PEEK [16].

3.2 Material properties

The important mechanical properties of the CFRPEEK have been determined and are recorded in Table 1. In order

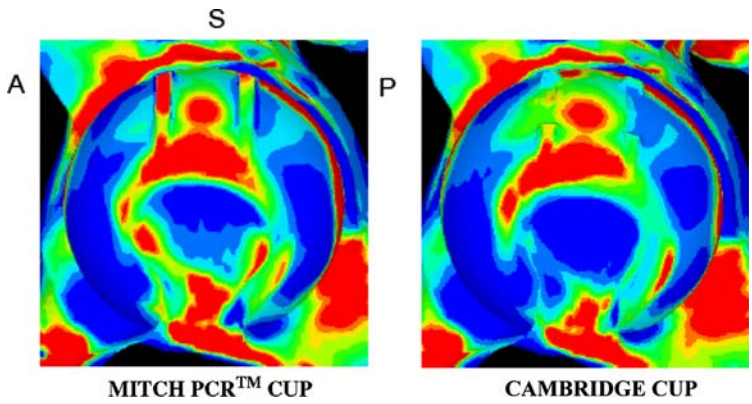

Fig. 3 Showing minimum principal stresses in the periacetabular bone region (lateral view) for MITCH PCR™ (left) and Cambridge (right) Cup models. [A: anterior; P: posterior; S: superior]

Table 1 Mechanical properties of CFRPEEK

Mechanical property	Units	Result	Victrex data
Tensile strength	MPa	125	225
Elongation at break	%	1.2	2
Young's modulus	GPa	12	13
Flexural modulus	GPa	8	19.2

to improve the wear properties it has been necessary to reduce the length of the carbon fibres and change their nature. This has resulted in an acceptable reduction of the mechanical strength of the composite, compared with the commercially available CFRPEEK composites [17].

3.3 Tribology properties ceramic PEEK bearing

Figure 4 shows the volume loss versus the number of cycles in the wear simulator for prostheses 1 to 5. These results show volumetric component wear corrected relative to the control joint (no. 6). During the first 1.6 million cycles, an overall weight gain was observed owing to absorption of the lubricant and protein deposition. Estimated wear levels were calculated by regression analysis and were seen to increase subsequently. The lowest wear rate was observed for cups 3 and 5, with final recorded wear volume losses of 15.87 mm^3 and 20.12 mm^3 respectively after 25 million cycles. This compares with 28.19 mm^3 for cup 1, 28.40 mm^3 for cup 2 and 23.90 mm^3 for cup 4. The mean wear rate for all five articulating cups was 23.3 mm^3 or 0.932 mm^3 per million cycles.

3.4 Biocompatibility tests

3.4.1 Rat-pouch model

After one day, both polyethylene and CFRPEEK particles had accumulated in discrete regions. This was apparent at one, three and ten days. None of the pouches produced large amounts of exudate. Analysis of histological sections, using a visual scoring system, showed that pouches challenged with polyethylene particles appeared to be more inflamed than control pouches or those challenged with CFRPEEK particles. Using this scoring system, inflammation in the pouches challenged with CFRPEEK particles was greater than in the control pouches. Measurement of the thickness of the layers of the upper pouch showed no significant differences between all three treatments. ED1 staining showed an infiltration by macrophages in all three treatments, but there was no noticeable difference between the different treatments. ICAM1 staining was increased in pouches challenged with particles compared with the control pouches. However, there was no difference between pouches challenged with CFRPEEK and polyethylene particles. Based on these results, there appears to be little difference between polyethylene and CFRPEEK particles.

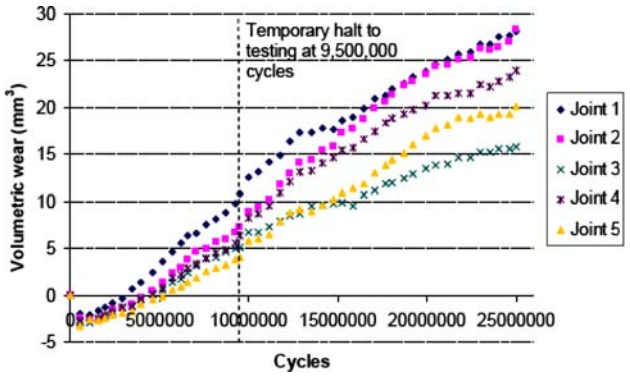

Fig. 4 Wear data for a 25 million cycle simulated study on the 54-mm (ID) MITCH PCR^{TM} Cup. Normalised with the soak sample (not shown)

3.4.2 Tissue analysis from revised composite cup

Synovial tissue samples were taken from the posterior, anterior, and neck regions of the hip joint of a patient undergoing femoral revision surgery following a periprosthetic fracture. At surgery, the synovium was seen to be grey/black but there was no evidence of synovial hypertrophy. The biopsies were examined histologically. They consisted of connective tissue of varying density, which at some locations was clearly structured in sheets. Between the sheets of connective tissue, darker material was present (Fig. 5a). It appeared that numerous dark stained particles were engulfed by mononuclear or multinuclear macrophages High magnification showed two types of particles; rod like particle that were intense black and smaller granular particles (Fig. 5b). There were no necrotic areas and the tissue was well vascularised with numerous small vessels. No accumulations of lymphocytes or polymorphonuclear leucocytes were found around the blood vessels. Locally, larger numbers of dilated vessels were present, but also at these locations there was no inflammatory reaction.

3.5 Mechanical

3.5.1 Clearance validation

The results from the acetabular reaming study revealed sufficient variation in the diameters of the cavity, so that both the bearing clearance and the component fixation could be compromised (Table 2). The dimension of the

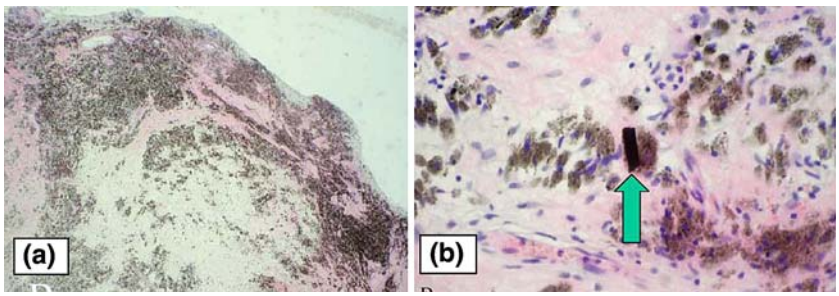

Fig. 5 A & B Sections of retrieved tissue treated with H & E stain and magnification of 200×. Figure **a** shows the presence of some dark staining of the connective tissue whilst Fig. **b** shows a detached carbon fibre 10 μ in diameter. No inflammatory response is evident

Table 2 Reamed acetabula and interference data

	Reamed acetabulum		CUP outer diameter			Interference	
Test	Average radius	Diameter	Nominal	Min cup OD	Max cup OD	Min	Max
20	28.05	56.1	56	56.34	56.78	0.24	0.68
21	25.86	51.72	52	52.34	52.78	0.62	1.06
22	25.5	51	52	52.34	52.78	1.34	1.78

reamed cavity may result in compressing (sample 20) or relieving (sample 22) the cup. The friction factor did not increase to significant levels until there was no clearance between the cup and the head (Fig. 6), at which point the contact between the head and ball changed from polar to radial.

3.5.2 Fatigue tests

All cups completed 10 million cycles without any apparent damage. However, in one of the cups some cracking was observed after 3.4 million cycles because of a failure in the holding fixture, which initiated the failure in the cup.

3.6 Stability

3.6.1 Frictional torque stability

The results are presented as a Stribeck plot, (friction factor versus the Sommerfield number) and are displayed in (Fig. 6). Stability was tested at full contact (no clearance) where the friction factor was high (0.6)

Using the formula:

$$F = \frac{T}{Lr}$$

Where

F = friction factor
T = frictional torque

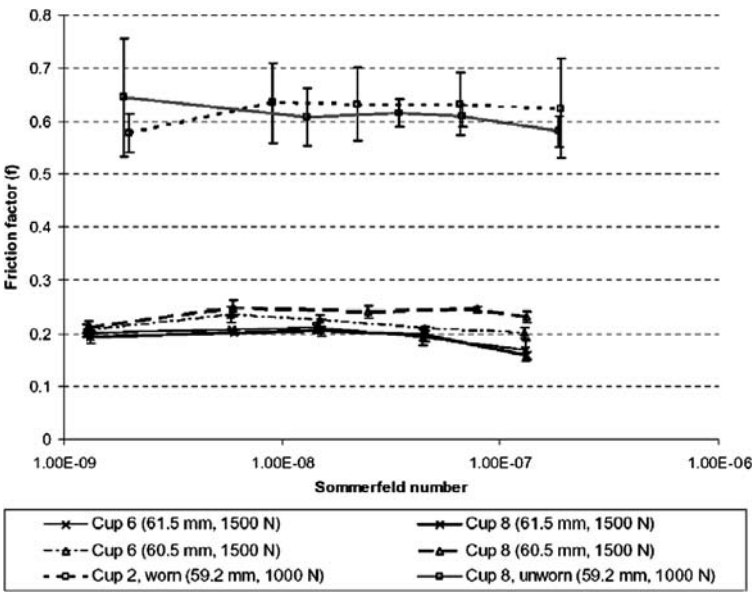

Fig. 6 Stribeck plot comparing friction data for cups with and without clearance. Upper lines with a high friction factor (0.6), cups with no clearance. Lower lines have a smaller friction factor (0.2), cups with a clearance of 0.25–0.75 mm

L = applied load (1000 N)
r = radius of femoral head (54 mm)

The frictional torque at this condition for the 54 mm diameter head can be calculated as 32.4 Nm. No breakage to the fins was recorded at this high torque level.

3.6.2 *Spikes versus fins*

Mechanical loading of the fins gave individual strength values of 405 ± 65 N, in comparison to the values of 35 N obtained for the corresponding loading value for the spikes of the Cambridge Cup. This corresponds to an overall strength of at least 680 N for the two fins compared with a value of 210 N for the 6 spikes. The values obtained show a significant increase in the strength for anti-rotational resistance.

3.6.3 *Cup stability over a focal defect*

There was little variation in friction as the size of the defect was increased (Table 3). The friction factor at a physiological viscosity (0.012 Pas) produced a mean value of 0.22 (SD 0.024) for a 5 mm hole, 0.23 (SD 0.020) for a 10 mm hole, 0.20 (SD 0.020) for a 15 mm hole and 0.20 (SD 0.027) for a 20 mm hole, with little data scatter. The differences in friction the values between the 5 mm hole and both the 10 mm ($P = 0.440$) and 15 mm ($P = 0.212$) holes were not statistically significant. However, the reduction in friction on increasing the whole size from 5 mm to 20 mm was significant ($P = 0.013$). The reduction in friction was not seen in cup 8, and, and therefore no overall trend can be inferred. Gravimetric estimation of wear was inconclusive as the protein deposited on to the HA coating was impossible to remove. However, there was an increase in the average post wear friction factor from 0.23 to 0.27.

Table 3 Data presenting the determined friction factors (mean value) for cyst size for two of the tested cups

Cup	Cyst simulation (mm)	Mean	Standard deviation
6	5	0.22	0.024
	10	0.23	0.020
	15	0.20	0.020
	20	0.20	0.027
8	5	0.24	0.011
	10	0.25	0.013
	15	0.25	0.009
	20	0.24	0.017

Table 4 Properties of titanium and hydroxyapatite coatings for 54-mm outer diameter MITCH PCR^{TM} Cup

Property	Cup recorded values	Cup specification
Ti layer thickness (μm)	82.8 ± 10	90 ± 30
HA layer thickness (μm)	101.6 ± 8	100 ± 40
Ti adherence (Mpa)	33.7 (average)	>20
Ti/HA adherence (Mpa)	13.8 (average)	>5
Ra roughness Ti/HA (μm)	14.4	7–20
Rz roughness Ti/HA (μm)	89.5	150

3.7 Coating validation

The specification and results from the coating characterisation for the 54-mm outer diameter cup are shown in the Table 4. Average values for other sizes of cup are different, but fall within the general specification also tabulated. Testing also confirm that the properties are independent of machine parameter settings. The repeatability of the process was validated to confirm that the cups were not overheated during continuous spraying.

3.8 Cadaver studies

3.8.1 *Reaming validation and clearance validation*

In the first study, it was found that the achieved reamed diameter was variable and in some cases unacceptable interferences, as large as 1 mm, were produced resulting in annular contact between head and cup. Peaks along the surface of bone can interfere with seating and are not desirable. In the second study, cadaver acetabulae were reamed with conventional and finishing reamers with improved manufacturing tolerances (+0/−0.2 mm). These results are presented in Fig. 7 depicting the quality of the bone surface.

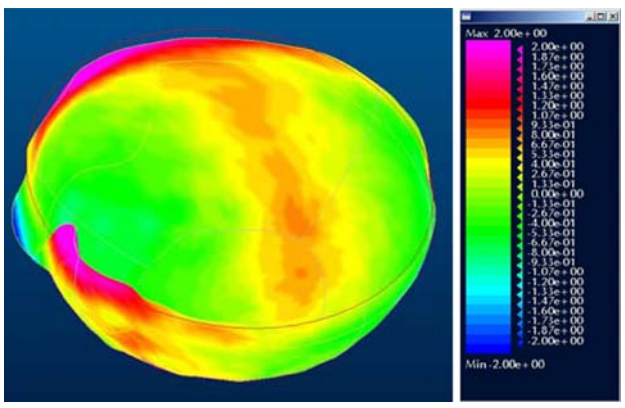

Fig. 7 A graphic representation showing the smoothness of the bone after preparation with a finishing reamer. The graph is colour coded to indicate surface roughness

4 Discussion

The Cambridge Cup study demonstrated the merits of a flexible, anatomical acetabular component articulating against a large diameter head. The purpose of this study has been to validate modifications to the original design, prior to a further clinical study.

The main modification has involved a change in the material used for the acetabular cup. In the modified cup a single material provides both structural integrity and excellent bearing characteristics when articulated against alumina. The results of the FEA study confirmed that the MITCH PCR^{TM} Cup transfers load to the acetabulum in a manner that is similar to the Cambridge Cup. Thus it may be expected that the bone response to the new component should be similar to that observed with the Cambridge Cup [5].

A further important aspect is the biological response to the CFRPEEK, particularly in the particulate form. The results from the rat-pouch model show that the response is similar to that of polyethylene when challenged at the same dose rate. The thickening of the fibrous tissue is similar in both cases, and the immuno-histochemistry showed similar macrophage infiltration. Even though similar dose rates were used in this study, the wear study has shown that the volume of wear particles was an order of magnitude less with CFRPEEK/alumina ($\sim$0.94 mm^{-3}/Mcy) than UHMWPE/alumina (17 mm^3/Mcy) [18]. The articular couple of CFRPEEK with alumina eliminates both UHMWPE wear particles and the metal ions. The earlier clinical study on a 28 mm CFRPEEK liner [7] has also provided some important information on the biological response, showing that wear particles do not give rise to a serious inflammatory response.

The integrity of the prosthesis-bone construct is important to long-term function. In the Cambridge Cup study, fibrous tissue replaced bone in cases where the HA had resorbed after 8 years [6]. This limitation has been corrected in the new design by the inclusion of a sub-coat of pure titanium. The tests show that both coats are mechanically well integrated and of sufficient roughness to encourage and maintain bone attachment [19].

Mechanical testing of the fin anti-rotational feature has shown it to be significantly stronger than the spikes used in the Cambridge Cup. Frictional torque studies have demonstrated that the resistance offered by this mechanism to loosening. Fracture of the fins or loosening of the cup was not seen even at the high frictional torques applied.

In order for this cup design to be successful, a fine balance needs to be maintained between the amount of press-fit of the cup in the prepared cavity and clearance of the femoral head in the cup at the bearing interface. Tolerance and reaming study results show that this balance can be achieved using a proprietary finishing reamer to obtain an accurately prepared, hemispherical cavity with the correct clearance maintaining polar contact of the head in the cup. The finishing reamer also eliminates the presence of bony ridges, that may be left by conventional reamers, which may compress the cup when situated on the side of the cavity and affect the seating when on the floor of the acetabulum. Simulated wear studies carried out to 25 million cycles show a near linear wear rate of 0.94 mm^{-3}/Mcy, The presence of a simulated cyst, up to 20 mm diameter, had little impact in the functioning of the cup.

Our data indicates that the MITCH PCR^{TM} Cup design will provide the benefits previously seen with the Cambridge Cup and improved long-term component wear and stability. Clinical evaluation of the CE marked prosthesis is ongoing.

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