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A prospective osseointegration retrieval analysis of second generation cementless shells

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1. Introduction

First-generation cementless prostheses had a number of design flaws including thin polyethylene liners, poor locking mechanisms and sharp edges at screw holes resulting in the generation of polyethylene debris from both the bearing surface and from back-side wear. The Duraloc® acetabular shell (Depuy Synthes, Warsaw, IN., U.S.A.) was first introduced in 1980 and became a widely used cementless cup system.[1] The Duraloc® was a second generation, porous coated, metal-backed, subhemispherical press-fit implant. Titanium sintered beading (Porocoat®) bonded to the implant surface gave a mean pore size of 250 µm. The Pinnacle® acetabular component from the same manufacturer, is the current hemi-spherical evolution of Duraloc®and retains the same porous coating. Gription® (more porous) and Duofix® (hydroxyapatite coated) options are also available as surface coatings for the Pinnacle® cup. Biomechanical studies have demonstrated no difference in primary stability/micromotion between the Duraloc® and Pinnacle®[2] while retrieval studies have shown excellent osseointegration with both designs.[3]

Early polyethylenes used in acetabular components demonstrated poor wear characteristics with correspondingly high periarticular osteolysis and aseptic loosening.[1,4,5] Highly cross-linked polyethylene (XLPE) was introduced in 2001. Retrieval and radiostereometric analysis studies have demonstrated better wear results compared with ultra-high molecular weight polyethylene (UHMWPE).[6–10]

The conventional non-crosslinked Enduron® (DePuy Synthes) UHMWPE liner coupled with the Duraloc® shell has demonstrated unacceptably high wear rates in published studies.[11,12] The modular Enduron® liner was manufactured by ram extrusion process and was gas plasma sterilised prior to implantation. In the late 1990's, an irradiated and heat-treated polyethylene liner (Marathon™, DePuy Synthes) was introduced, showing higher crosslinking with elimination of free radicals.[13,14] The Duraloc® and Pinnacle® shells have demonstrated substantially reduced wear and osteolyis when combined with this crosslinked polyethelyne liner.[15–17] Poor performance of the Enduron® liner has been highlighted by increased wear rates when compared with other conventional UHMWPE liners.[12]

Other studies have demonstrated that aseptic femoral component loosening is often the cause of revision in retrieved Duraloc® components[18–20] and this reflects our experience. Large numbers of Duraloc® shells were implanted at our institution between 1990 and 2008.As a department, we routinely perform a shell revision to

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a large head or dual-mobility compatible cup to optimise stability. Under these circumstances we have noticed good osseointegration regardless of surrounding osteolysis. It is our experience that Duraloc® Porocoat® shells osseointegrate well but are associated with excessive polyethylene wear and femoral osteolysis. The aim of this study was to quantify the degree of osseointegration of the Duraloc® Porocoat® surface by area and location on all shells retrieved over a 15 month period.

2. Methods

2.1. Patients and retrieved shells

All explanted Duraloc® Porocoat® shells that were retrieved during revision hip surgery between December 2018 and February 2020 were assessed for osseointegration. Data pertaining to primary and revision joint replacement are recorded prospectively at our institution by independent assessors as part of a national joint registry. This includes patient demographic detail, years since index surgery, reason for index surgery, reason for revision surgery and pre and post-revision Oxford Hip Score. Index surgical notes and implant detail were available in all reported cases of implant retrieval. Institutional review board ethical approval was granted for this study.

2.2. Surgical retrieval

Revision surgery was performed via a posterior approach by fellowship trained arthroplasty surgeons. Patients were placed in the lateral decubitus position with regional anaesthesia and chemoprophylaxis. Tranexamic acid was used both intravenously and topically. Cemented and cementless femoral stems were first explanted via an endofemoral or transfemoral approach as necessary. Attention was next turned to the acetabular component. Prior to explant osteotome use, the surgeon referenced ASIS, PSIS, pubic symphysis and superior obturator foramen intraoperatively. Quadrants were identified from a line drawn from the ASIS to the centre of the acetabular component, and a line perpendicular to this - again passing through the centre of the cup [Fig. 1]. Grooves were etched on the acetabular components using a high speed burr marking the trajectories of both lines. A further groove was etched to denote the superior apex of the shell. The acetabular component was then removed using Explant Acetabular Cup Removal System® (Zimmer, Warsaw, IN, U.S.A). Because the Duraloc shell is sub-hemispherical, care was taken to use an explant blade smaller than the shell diameter to avoid excessive bone loss. Upon shell removal, the remaining acetabulum was assessed and graded according to Paprosky.[21] The acetabulum was reconstructed using a multi-hole revision system with or without augments (Tritanium™, Stryker Orthopaedics, Mahwah, NJ, U.S.A). Dual mobility (MDM, Stryker) or 36 mm HXLPE liners (X3, Stryker) were used in all cases to optimise stability postoperatively. Femoral reconstruction followed with a modular (Restoration Modular™,Stryker) or tapered fluted monoblock (Redapt®,Smith and Nephew, Memphis, TN, U.S.A) stem. Patients were permitted to weight bear as tolerated immediately postoperatively.

Following retrieval, the shells were irrigated with 1L 0.9% normal saline using pulse lavage, with subsequent dehydration through immersion in 40% ethanol solution for 30 min. Following this, the shell was dried in air for an hour. At 4 h post dehydration, clinical photographs were recorded with a Canon IXUS 185 digital camera at a 1 m height above the shell. Digital images with a pixel density of 35.05 MP/cm^2 were imported to Image J2 analysis software [Fig. 2] (U. S. National Institutes of Health, Bethesda, Maryland, USA) on a Macbook Pro (Apple Inc) to map the extent of bony ingrowth across the porous surface. The image of the shell was divided along the superoinferior and anteroposterior axis with reference to the intraoperative burr etching. The quadrants of the shell were named according to *in vivo* position as described by Meldrum et al.[22]

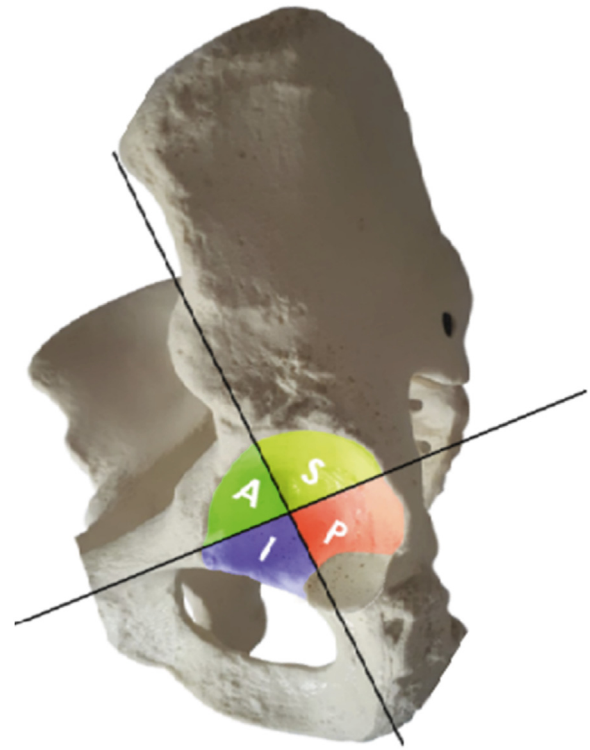

Fig. 1. Superior (S),Inferior (I), Anterior (A), and Posterior (P) quadrants identified from a line drawn from the Anterior Superior Iliac Spine (ASIS) through the centre of the acetabulum, with a second line drawn perpendicular to this, again passing through the centre of the acetabulum.

2.3. Retrieval analysis

The Fiji/TWS plugin of ImageJ2 (U. S. National Institutes of Health, Bethesda, Maryland, USA) was initially used for segmentation of the images - producing binary pixel classification to exclude the background surrounding the acetabular component as well as the central metallic plug of the Duraloc® shell. This process identified the surface area available for osseointegration. Through the 'Find Edges' function, a Sobel edge detector was used to sharply demarcate the boundary between the image background and the components edges. Subsequent Trainable Weka Segmentation (TWS) was used to train the classifier manually to identify Porocoat® and bone in each image as a whole, and in each quadrant. Pixel quantification was then used to determine percentage bony ingrowth in the specimen as a whole, and per quadrant [Fig. 3].

2.4. Radiographic assessment

All radiographs pertaining to the study population were available for analysis. Preoperative radiographs were calibrated with a 254 mm templating ball placed between the legs at the same level as the greater trochanter.

To assess acetabular component osseointegration, each radiograph was independently reviewed by two blinded senior orthopaedic residents using the criteria suggestive of osseointegration as described by Moore and Engh.[23] Namely, the[1] absence of

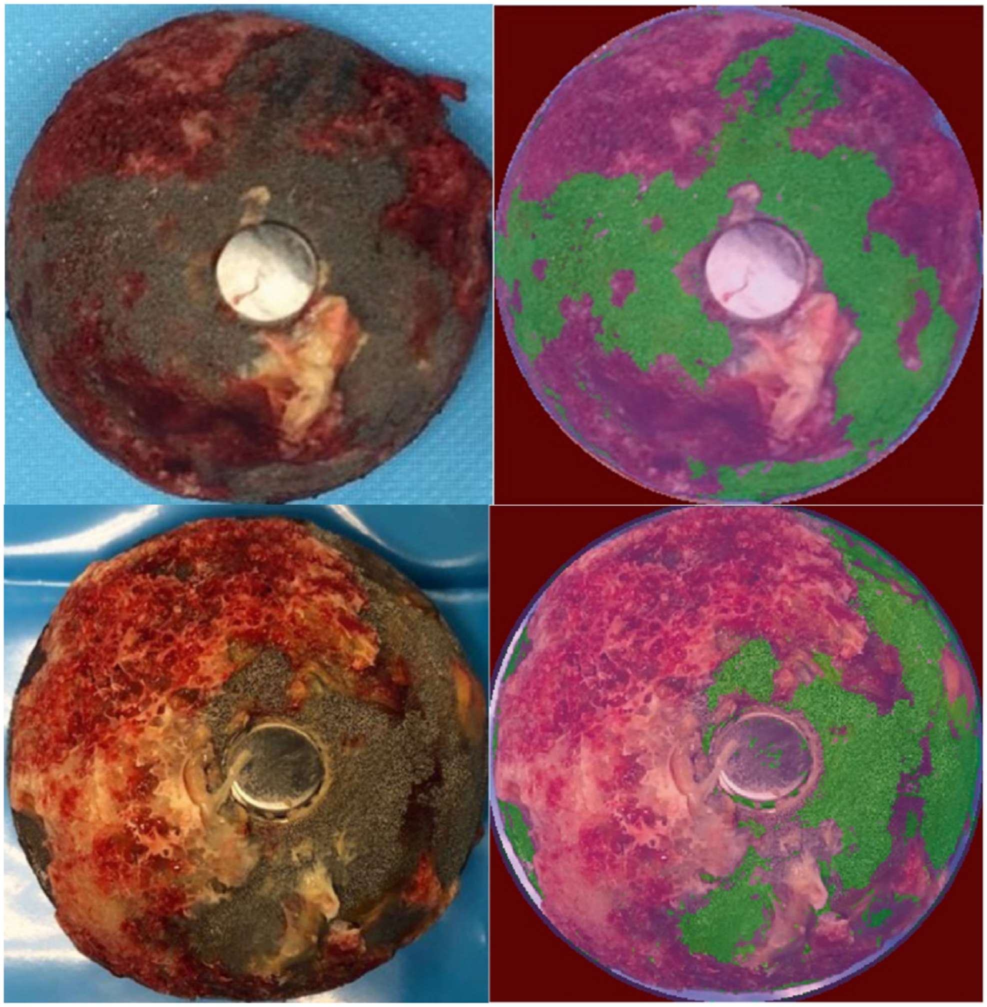

Fig. 2. Retrieved acetabular components and subsequent segmentation with ImageJ2 software.

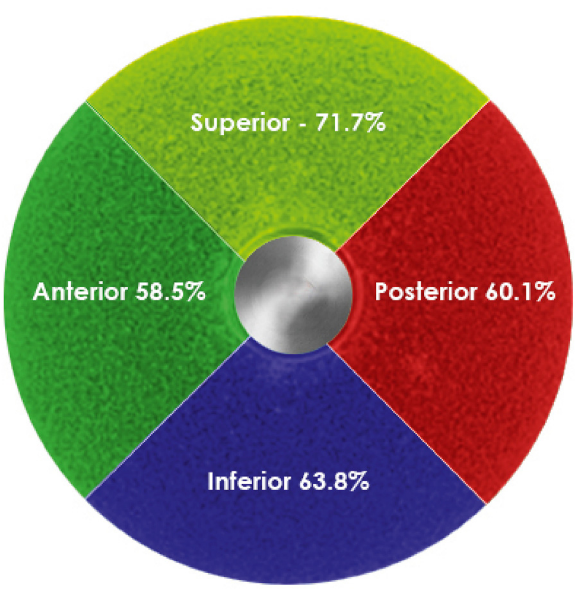

Fig. 3. Mean values for osseointegration per quadrant for the whole cohort of retrieved shells.

radiolucent lines >2 mm[2]; presence of a superolateral buttress[3]; presence of medial stress-shielding[4]; presence of radial trabeculae; and[5] presence of an inferomedial buttress. In the original paper, 97% of retrieved acetabular components with 3 or more signs present on radiographs were found to be well integrated at surgery, while 83% with two or less signs were found to be loose - as such, we categorised our cohort into these two groups.

2.5. Statistical analysis

The Shapiro-Wilk test in conjunction with visual QQ plots, boxplots and histograms were used to assess the distribution of our data. Student's T Test was used to analyse normally distributed continuous variables and non-parametric Mann-Whitney test was used for the continuous variables that did not have a normal distribution. Mann-Whitney was also employed when comparing normal data with non-normal data. Fisher's exact test was used for categorical variables because of low numbers per category (<5). Linear regression was used to determine a correlation between two continuous variables. Inter-observer reliability was determined with Cohen's kappa test. Significance was set at $p \leq 0.05$. Normally distributed data is presented as a mean (SD), while non-parametric data is presented using the mean(median, IQR), where IQR is the interquartile range. Analysis was performed using SPSS Version 25 (IBM Corp., Armonk, NY, USA).

3. Results

3.1. Patients

Twenty Duraloc® Porocoat® shells were retrieved from 20 patients; 14 males and 6 females with a mean age of 72.60 (±6.69) years [Table 1]. This represents all retrieved Duraloc Porocoat® shells during the identified time period. The indication for primary THR in all cases was osteoarthritis. Average implantation time was 14.85 (±1.89) years with revision performed for femoral aseptic loosening (n = 15), instability (n = 3) and femoral periprosthetic fracture (n = 2) [Fig. 4].

3.2. Initial radiographic assessment

Mean cup inclination angle was 47.10 ± 9.71°. Of the 20 shells, 18 met 3 or more radiographic criteria for osseointegration and 2 shells met 2 criteria. The 2 independent observers demonstrated substantial to almost perfect agreement in 3 individual Engh criteria (identification of medial stress shielding, trabeculae and inferomedial buttress) and also exhibited perfect agreement in recognizing shells with 3 or more criteria present (kappa = 1, $p < 0.001$) [Table 2].

3.3. Shell retrieval data

All acetabular components retrieved were Duraloc® 100 series. No shells were grossly loose and all were subjectively well fixed. No rim fractures were recorded.The mode of acetabular component size was 52 mm. Ten degree lipped Enduron liners were used in all cases with small diameter CoCr heads (22 mm [n = 6]; 28 mm [n = 14]). All polyethylene liners demonstrated eccentric wear [Fig. 5].

The average bony ingrowth calculated from retrieved components was 63.5% ± 20.1. In 9 cases (45%) the superior weightbearing quadrant demonstrated the most ingrowth. Of the remaining 11 shells, the dominant quadrant was anterior in 5 (25%), posterior in 4 (20%) and inferior in 2 (10%) [Fig. 6].

Mean superior quadrant ingrowth was 71.7% (SD 22.5). Mean posterior quadrant ingrowth was 60.1% (SD 21.9). Mean anterior quadrant ingrowth was 58.5% (SD 26.7). Mean inferior quadrant ingrowth was 63.8% (median 74.1, IQR = 40.1–85.4). The percentage of bony ingrowth in the superior, anterior and posterior quadrants had a quasi-normal distribution, whereas the inferior quadrant had a non-parametric, bimodal distribution.

Table 1
Demographic, Clinical and Radiographic data.

Number Of Patients	20
Mean Age (Years)	72.6 (SD 6.69)
Male: Female	14 : 6
Right: Left	11 : 9
Surgeon (FR: TM)	12 : 8
Indication For Revision	
Femoral aseptic loosening	15
Instability	3
Fracture	2
Mean Implantation Period (Years)	14.85 (SD 1.89)
Mean Cup Size	52 (SD 3.37, Mode 52)
Mean Abduction Angle (Degrees)	47.10 (SD 9.71)
Paprosky Grade	
Grade 1	9
Grade 2A	10
Grade 2B	2
Mean Preop OHS	22 (SD 6.9)
Mean Postop OHS	42 (SD 6.5)
Mean Preop EQ-5D-5L	0.38 (SD 0.13)
Mean Postop EQ-5D-5L	0.78 (SD 0.15)

3.4. Correlation between radiographic and retrieval results

Both observers were in complete agreement (kappa = 1) for total Engh score, so for clarity, we will present both their observations as one. There was no difference in total bony ingrowth between the patients that had an Engh score >3 (mean 62.9%) and the ones with a score of less than 2 (64.0%), with p = 0.92, two-tailed. No significant differences were found between Engh scores greater than 3 and the scores less than 2 with regards to quadrant ingrowth (Table 3) (see Table 4).

A subgroup analysis of the cups fulfilling at least 3 Engh criteria was performed. An intraoperative Paprosky Grade 1 was significantly associated with a higher Engh score of 4–5. A Paprosky Grade 2A was significantly associated with a lower Engh score of 3 (p = 0.05). No correlation was found between Paprosky Grade 2B and the Engh score (p = 1). No differences were found between a lower Engh score of 3 and a higher score of 4–5 with regards to total bony ingrowth (p = 0.14), superior quadrant ingrowth (p = 0.17), anterior quadrant ingrowth (p = 0.25), posterior quadrant ingrowth (p = 0.27) and inferior quadrant ingrowth (p = 0.15).

Of the individual Engh criteria, for Observer 1, only the radiographic presence of an inferomedial buttress was associated with less bony ingrowth in the anterior quadrant when compared to the absence of the buttress (47% vs 69%, p = 0.05). Conversely, for Observer 2, only the absence of translucent lines was associated with a higher total ingrowth (73% vs 50%, p = 0.006), superior quadrant ingrowth (82% vs 58%, p = 0.01), anterior quadrant ingrowth (69% vs 45%), and inferior quadrant ingrowth (77% vs 47%, p = 0.01) when compared with the cups that had radiolucent lines on Xrays.

There was no difference between a more vertical inclination (>= 43.5°) with regards to total bony ingrowth (p = 0.49), superior quadrant ingrowth (p = 0.77), anterior quadrant ingrowth (p = 0.76), posterior quadrant ingrowth (p = 0.25) and inferior quadrant ingrowth (p = 0.36).

4. Discussion

The most important finding of this study is that the porous coating applied to the Duraloc® Porocoat® shell demonstrates excellent osseointegration even in the setting of high polyethylene wear. There are reports of high medium-term Duraloc® shell revision rates.[24,25] This is not our experience and we report mean 63.5% total bony ingrowth of the implant surface area. Our retrieval analysis correlates with Norwegian and Australian registry data that report good 10 yr survival at 94 and 96%, respectively.[26,27] In our series, the indication for revision was femoral related or instability. Cup revision was performed to facilitate dual mobility systems or large diameter heads, to mitigate against instability risk rather than for aseptic loosening.[28–30]

Our findings show that the polyethylene liner is responsible for revision of this THA combination. The Enduron® UHMWPE polyethylene paired with the Duraloc® has been implicated in failures of this couple. A 10 year double-blinded RCT of 122 patients demonstrated significantly reduced wear rates (0.03 mm/yr vs 0.27 mm/yr), osteolysis (8% v 38%) and implant survival (2 v 10 revisions for aseptic loosening) of acetabular components paired with cross-linked Marathon liners versus Enduron® liners.[16] Studies have also shown inferior results of the Enduron® liner when compared to other non-crosslinked polyethylene liners such as the Trilogy liner (Zimmer, City, State). Yan et al. published a higher incidence of osteolysis in the Enduron® cohort (33.3% v 12%

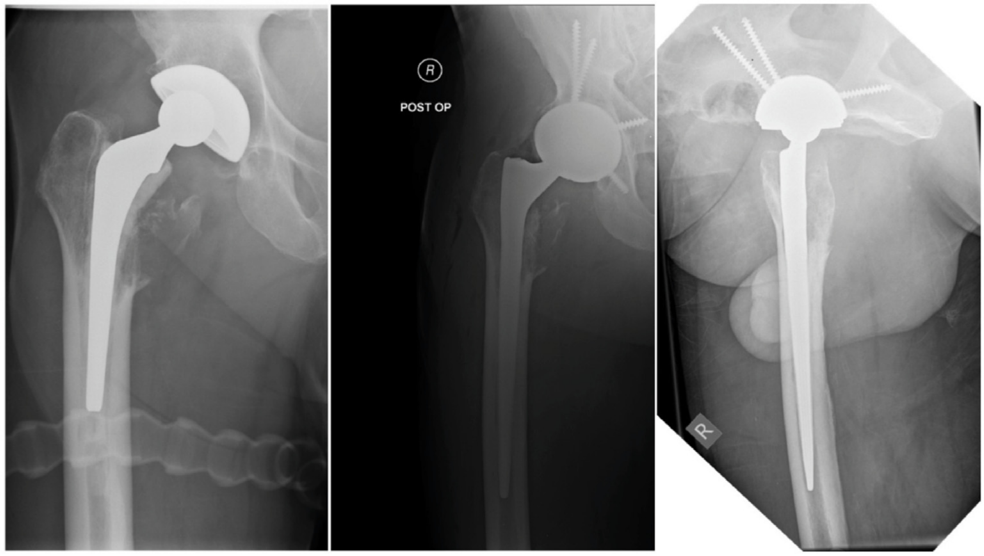

Fig. 4. Revision for femoral aseptic loosening to a monoblock stem with screw-augmented revision acetabular cup and dual mobility system.

Table 2
Implant characteristics.

Femoral Stem	
Force Closed (Charnley)	17
Taper Slip (Exeter)	2
Modular (Broach plasma)	1
Head Size	
22.225 mm	6
28 mm	14

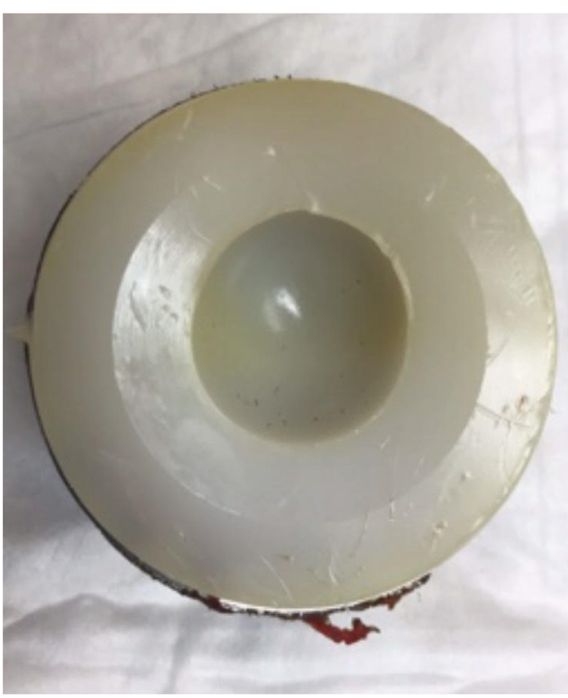

Fig. 5. Retrieved polyethylene liner demonstrating eccentric wear.

$p < 0.05$) and higher linear wear rates (0.20 mm/yr v 0.09 mm/yr, $p < 0.01$). In this study scanning electron microscopy suggested that the smaller, more bioactive polyethylene particles produced by the Enduron® liner explain its high failure rates, with 82% of polyethylene debris particles <1 μm, and 50% < 0.5 μm.[12] Correspondingly, Jialaing et al. linked the degree of bony lysis to the degree of Enduron polyethylene linear wear which approached up to 0.39 mm/yr.[25]All retrieved shells in our series had a dome-hole screw and there were no shell screws. Although back-side wear may have occurred with the polyethylene liners used in our series, significant acetabular osteolysis was likely avoided by no screws and a reduced total potential joint space.

Engh et al.[23] identified a high positive predictive value for the presence of bone ingrowth with each individual radiographic sign (92–96%). We found good correlation between pre-operative radiographic signs and acetabular defects at revision surgery but poorer correlation between pre-operative radiographic signs and osseointegration of retrieved shells: Engh scores of 4 and above correlated with Paprosky scores of 1, while an Engh score of 3 correlated with Paprosky 2A defects. In their paper, 97% of shells with 3–5 criteria present were osseointegrated compared with 67% surface bony ingrowth in our 18 patients meeting the same criteria. This difference may be attributable to the definition of osseointegration: The authors retrospectively gathered data from operative reports and defined shells as ingrown, fibrous stable, or loose. We prospectively gathered data and assessed the shells as grossly stable or not upon exposure and subsequently analysed the porous surface for bone. Notwithstanding this we found correlation between osseointegration and the presence of three or more radiographic indices.

Initial press fit of uncemented cups is a prerequisite for osseointegration and secondary stability of acetabular components and most bony ingrowth occurs within 6 weeks to 3 months of implantation. Load distribution is concentrated in the superior aspect of the acetabulum, buttressed by the ilium. Second highest load transfer occurs postero-inferiorly at the ischial facet with the third highest experienced anteriorly near the pubis.[31] Local forces can be grouped into an iliac, an ischial, and a pubic group contributing 55%, 25%, and 20% to the total hip joint force. While pure pole contact would not occur in a subhemispherical cup, the magnitude and location of these local forces are reflected in our measurements of osseointegration; with the most ingrowth recorded in the superior quadrant. To our knowledge, ours is the first study to demonstrate this correlation, and implies that early

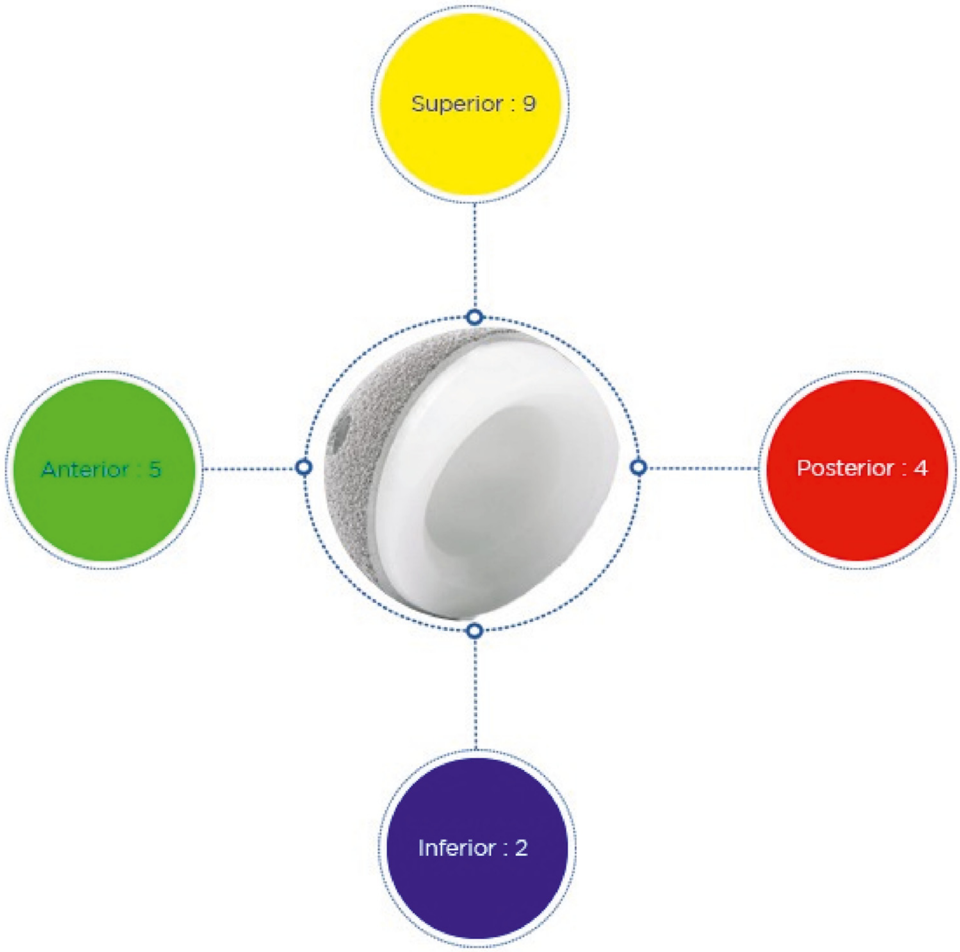

Fig. 6. Representation of the cohort's dominant quadrants of osseointegration.

Table 3
Interobserver reliability for Engh criteria.

	Cohen's Kappa coefficient	p value
Absence of radiolucent lines	0.22 (fair agreement)	0.37
Presence of superolateral buttress	0.02 (no agreement)	1
Presence of medial stress shielding	0.79 (substantial agreement)	0.00[a]
Presence of radial trabeculae	0.64 (substantial agreement)	0.10
Presence of inferomedial buttress	0.90 (perfect agreement)	0.00[a]
Total score (out of 5)	1.00 (perfect agreement)	0.00[a]

[a] Marks a statistically significant result.

loading forces can dictate the extent and location of osseointegration on acetabular components.

Our study may draw two criticisms: Firstly, how we defined osseointegration and secondly, the non-cross-sectional analysis of the retrieved shells. The shell investigated in this study integrates biologically via ingrowth of acetabular bone around sintered titanium beads. We extrapolated that bone remaining proud of the shell surface represented biological ingrowth deep to the surface and therefore osseointegration. Sectioning of the shell with subsequent electron microscopy would have accurately determined porous ingrowth of these shells. We do not have the resources at our institution to investigate the shells in this manner.

5. Conclusion

In an era of increasing demand for joint arthroplasty and the ever-present quest for efficiency and cost-containment, the

Table 4
Engh score correlations with bony ingrowth.

	Engh score >3	Engh score ≤ 2	p value	U value	Z value
Total bony ingrowth (%)	62.9 (20.7)	64 (19.5)	0.94		
Superior quadrant ingrowth (%)	72.5 (23.7)	63.9 (20.9)	0.62		
Anterior quadrant ingrowth (%)	58.2 (28.3)	61.2 (24.8)	0.88		
Posterior quadrant ingrowth (%)	61.6 (22.8)	46.1 (19.2)	0.37		
Inferior quadrant ingrowth (%)	61.6 (63.3; 39.1–83.4)	83.4 (83.4; 73–83.4)	0.31	10.0	−1.008

Normal distributed data is presented as mean (SD).
Non-parametric data is presented as mean(median, IQR).

implantation of reliable devices is important. Although the original polyethylene coupled with the Duraloc® Porocoat® implant demonstrated unacceptably high rates of wear, we have shown that the shell osseointegrates well. Innovation should be a considered process rather than unbridled and early surface coating technology should not be discarded for newer, perhaps more expensive materials. We conclude that continued use of the porous surface used in the manufacturing of this particular shell may result in stable implant-bone interfaces.

Ethical approval

Granted by local ethics committee 411-317.

CRediT authorship contribution statement

M. Curtin: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Roles, Writing – original draft, Writing – review & editing. **E. Pomeroy:** Conceptualization, Methodology, Project administration, Writing – review & editing. **M. Grigoras:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Roles, Writing – original draft, Writing – review & editing. **T. Murphy:** Conceptualization, Methodology, Project administration, Supervision, Writing – review & editing. **Fiachra E. Rowan:** Conceptualization, Methodology, Project administration, Supervision, Writing – review & editing.

Declaration of competing interest

Fiachra E Rowan declares that he is a paid consultant for Depuy Synthes. The remaining authors declare that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

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