

■ SHOULDER AND ELBOW

Histological evaluation of two designs of shoulder surface replacement implants

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Aims

To assess the extent of osteointegration in two designs of shoulder resurfacing implants. Bony integration to the Copeland cylindrical central stem design and the Epoca RH conical-crown design were compared.

Patients and Methods

Implants retrieved from six patients in each group were pair-matched. Mean time to revision surgery of Copeland implants was 37 months (standard deviation (SD) 23; 14 to 72) and Epoca RH 38 months (SD 28; 12 to 84). The mean age of patients investigated was 66 years (SD 4; 59 to 71) and 58 years (SD 17; 31 to 73) in the Copeland and Epoca RH groups respectively. None of these implants were revised for loosening.

Results

Increased osteointegration was measured under the cup in the Copeland implant group with limited bone seen in direct contact with the central stem. Bone adjacent to the Epoca RH implants was more uniform.

Conclusion

This difference in the distribution of bone-implant contact and bone formation was attributed to the Epoca implant's conical crown, which is positioned in more dense peripheral bone. The use of a central stem may not be necessary provided there is adequate peripheral fixation within good quality humeral bone.

Take home message: Poor osteointegration of cementless surface replacement shoulder prosthesis may be improved by implant design.

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Osteoarthritis is the most common reason for shoulder replacement surgery and is largely associated with ageing.¹ The shoulder is the third most common joint to undergo arthroplasty and surgery has seen a nearly ten-fold increase in the last 25 years.² The National Joint Registry for England, Wales and Northern Ireland (NJR) reported that a total of 2225 shoulder arthroplasties were performed within a nine month period in 2012. Of the 2225 procedures, 1202 were undertaken for osteoarthritis.³ Cementless surface replacement arthroplasty (CSRA) is increasingly being used to treat shoulder arthritis. Compared to stemmed total shoulder arthroplasties (TSA) these implants are designed to reproduce the individual's anatomy (diameter, radius of curvature, version) while preserving bone stock, making any subsequent revision easier. Good clinical outcomes at short- and mid-term follow-up of the Copeland implant (Biomet

Merck, Swindon, United Kingdom) has been reported.^{4,5} However, a recent clinical study reported a high revision rate where 22% of implants failed by 13 months after surgery and that failure was due to pain with 'overstuffing' of the joint, an un-resurfaced glenoid, or aseptic loosening of the humeral component.⁶ Overstuffing of the joint was stated to occur when the head of an implant protrudes excessively above the greater tuberosity resulting in increased tension on the rotator cuff and lengthening of the gleno-humeral offset.^{7,8} Altered joint reaction forces, component malposition, glenoid wear and insufficient bony support of the implant have been reported as factors that may contribute to aseptic loosening.^{1,9} Using finite element analysis Schmidutz et al¹⁰ reported stress shielding of bone in the sub cupola region adjacent to the Copeland design and predicted bone resorption in this region. Stress shielding is associated with



Fig. 1a



Fig. 1b

Photograph of the two types of shoulder resurfacing implants a) Copeland, and b) Epoca RH.

Table I. Clinical data of 12 pair-matched patients with retrieved Copeland and Epoca RH humeral head resurfacing prostheses

Match pair	Implant type	Age (yrs)	Gender	Duration <i>in vivo</i> (mths)	Side	Reason for replacement	Indication for failure
1	Epoca	69	M	48	Left	OA with significant pain	Pain, restricted ROM
	Copeland	70	F	48	Right	OA	Pain and limited ROM
2	Epoca	65	F	48	Left	OA following an injury and instability	Rotator cuff failure
	Copeland	62	F	48	Left	OA	Pain limited ROM axillary nerve impingement
3	Epoca	73	M	12	Left	Rotator cuff tear	Glenoid erosion
	Copeland	65	F	14	Right	Rotator cuff tear	Glenoid wear and cuff tear
4	Epoca	65	M	12	Right	Cuff tear arthropathy	Instability
	Copeland	64	F	16	Left	Pain and OA	Posterior and inferior glenoid wear
5	Epoca	31	F	24	Right	OA with instability	Persistent pain and instability
	Copeland	73	M	21	Right	Pain and OA	Glenoid wear and massive cuff tear
6	Epoca	44	F	84	Right	Joint instability	Persistent pain and instability
	Copeland	59	M	72	Left	Post fracture	Nerve impingement

OA, osteoarthritis; ROM, range of movement

redistribution of physiological load due to insertion of a stiffer metallic implant.^{11,12} Compared to the Copeland device, the fixation of the Epoca CSRA (Synthes, Oberdorf, Switzerland) is associated with denser peripheral bone and has a conical crown design, which may affect bone ingrowth through stress distribution. In order to investigate whether design was a factor in implant fixation, the aim of this study was to quantify and compare bone-implant contact and bone area adjacent to these two designs. Our hypothesis was that the degree of osteointegration was a consequence of implant design.

Materials and Methods

Implant design and fixation. Both implant designs were manufactured from cobalt chrome with a spherical joint surface and inner surface plasma sprayed with a highly crystalline (> 85%) thin (50 µm) hydroxyapatite coating. The Copeland implant consists of a central grooved and tapered stem, whereas the Epoca RH has no central stem

but instead is stabilised by a hollow cylinder, which is referred to as a conical crown, positioned so that it is embedded within the circumferential trabecular bone of the humeral head (Fig. 1).

Study design. Following ethical approval, 25 Copeland and six Epoca RH cementless resurfacing shoulder implants were retrieved from patients at revision surgery. The patients' clinical records were reviewed and the following information collected: gender, age at the time of revision surgery, reason for primary CSRA, operated side, duration *in vivo* and reason for failure. A total of 12 patients were retrospectively pair-matched (six matched pairs) according to implant time *in vivo*, age and reason for surgery (Table I). Retrieved Copeland implants were obtained from four female and two male patients; and the six Epoca implants were obtained from three male and three female patients.

Histology. On retrieval, all implants with surrounding tissue were immersed in 4% paraformaldehyde solution at room temperature for seven days. Specimens were then pro-

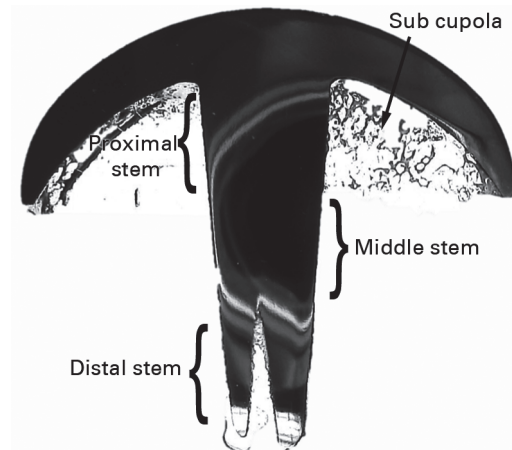


Fig. 2

Photomicrograph of a longitudinal section through a Copeland prosthesis showing the regions where measurements were taken.

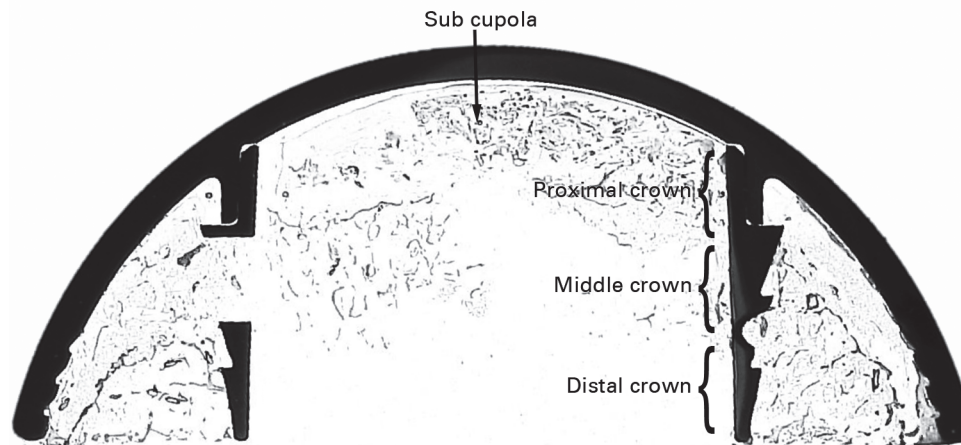


Fig. 3

Photomicrograph of a longitudinal section through an Epoca RH prosthesis showing regions where measurements were taken.

cessed for undecalcified hard tissue histology. Following dehydration in ascending concentrations of alcohol solution and defatting in chloroform, implants were embedded in hard grade acrylic resin (LR White, London Resin Company, Reading, United Kingdom). Longitudinal sections were prepared through the centre of each implant (orientation was unknown) using grinding and polishing techniques (EXAKT, Hamburg, Germany). During analysis, Copeland implants were divided into four regions of interest (ROI); under the shell, the proximal stem, mid-stem and distal stem (Fig. 2). Similar regions adjacent to the conical crown were identified in the Epoca RH implants (Fig. 3). All implants were initially examined using backscattered scanning electron microscopy (BSEM) (JEOL 3500 SEM, Tokyo, Japan). Thin sections (70 to 120 μm) were prepared and samples stained with toluidine blue and paragon, which stained soft tissue and bone respectively. Light microscopy and image analysis techniques (Axiovision 4.5,

Carl Zeiss, Jena, Germany) were used to quantify bone-implant contact and bone area within the ROI adjacent to the implant. Images spanning each implant were captured using a $5\times$ objective lens and the percentage bone-implant contact calculated when the length of surface with direct bone attachment was divided into the total length of surface available for integration. Bone area measurements were calculated when five random areas within each ROI were image captured and 'free-hand' image analysis techniques used to select and quantify the area of bone. Bone-implant contact and bone area were then calculated as a mean from a set of images of each ROI and statistical comparisons were performed. Images were quantified by one assessor.

Statistical analysis. As the numbers were small, a normality test (Shapiro-Wilk) was carried out which showed that the data was non-parametric for regions in each implant group, and parametric when all regions were combined and the

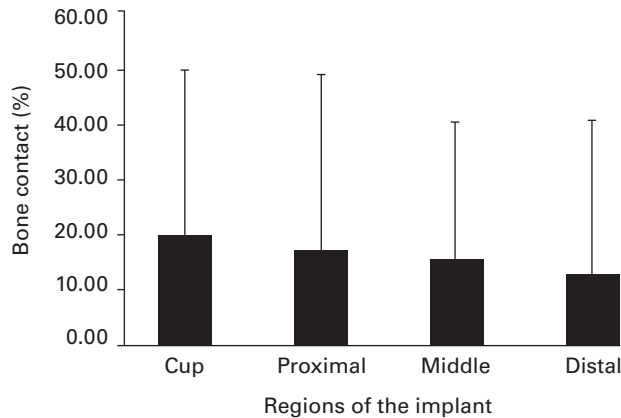


Fig. 4

Graph showing mean percentage of bone contact adjacent to the Copeland prosthesis by region of interest. Error bars indicate standard deviation.

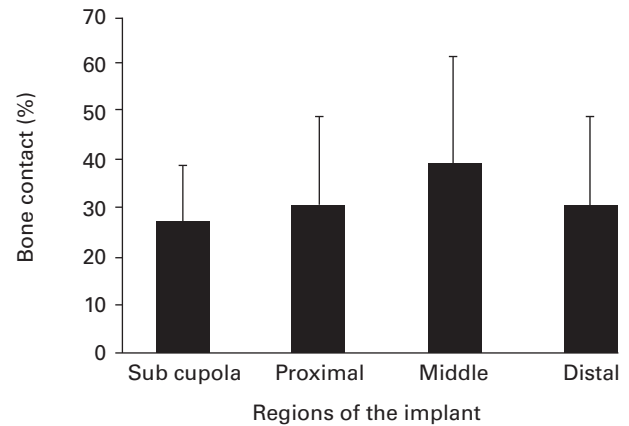


Fig. 5

Graph showing mean percentage of bone contact adjacent to the Epoca RH prosthesis by region of interest. Error bars indicate standard deviation.

two implant types compared. To determine significant differences between regions and implant type a Mann Whitney-U test was used where the data were non-parametric and a *t*-test for parametric data. These tests were done on all retrievals irrespective of time *in vivo* and reasons for failure. Spearman's rank correlation coefficient was used to assess whether there was a correlation between bone-implant contact and bone area, patient age and duration *in vivo*. Statistical significance was assumed for all *p*-values < 0.05. All measurements were reported as a mean with standard deviation (SD).

Results

Scanning electron microscopy. Qualitative examination of the Copeland implants showed that most bone-implant contact was observed in the area immediately beneath the cup. This was followed by the proximal, middle and distal regions of the stem in decreasing order. However, in comparison, bone-implant contact adjacent to Epoca RH implants appeared to be more uniformly distributed over the surface of the implant. In both implant groups, the amount of bone-implant contact seen varied between patients, but in all cases the bone layer present was thin. The trabecular connections and bone stock in the Copeland implants were mainly found in the cup region and was limited around the stem, whereas with the Epoca design it was more evenly distributed in regions connected to both cup and crown region of the implant. Variation was also seen where some patients had greater bone on one side of the cup compared with the opposite side, or one side of the stem compared with the other.

Bone-implant contact - sub-cupola region. Results showed a mean total bone-in-contact (BIC) of 19.92% (SD 29.71; 9.75 to 33.41), in the sub cupola region of Copeland implants and a mean BIC of 26.10% (SD 10.50; 16.35 to 37.24) was measured in the sub-cupola region of Epoca RH

implants. No significant difference between the two groups was found (*p* = 0.38, independent samples *t*-test).

Bone-implant contact - stem. Mean BIC adjacent to Copeland implants in the proximal, 17.63% (SD 31.26; 2.31 to 39.84 *p* = 0.04), mid 15.97% (SD 24.63; 5.08 to 29.34, *p* = 0.04) and distal 13.47 (SD 27.14; 0.00 to 28.61, *p* = 0.001) regions of the stem was significantly decreased when compared with the sub-cupola region (Fig. 4). Significantly increased BIC was measured when the proximal (*p* = 0.01) and mid (*p* = 0.03) regions were compared with the distal region of the stem. No other significant differences were found. A Mann Whitney-U test was used to determine significant differences between regions.

In the Epoca RH group, the results showed no significant differences in the mean BIC when the sub-cupola region 26.10% (SD 10.50; 16.35 to 37.24), was compared with the proximal 31.15% (SD 16.56; 12.43 to 58.97%, *p* = 0.818), mid 39.40% (SD 56.40; 10.00 to 66.40), *p* = 0.485) and distal 30.76% (SD 16.24; 11.64 to 51.91, *p* = 0.937) regions of the conical cylinder (Fig. 5). An independent samples *t*-test was used to examine differences.

When all regions were combined and the two implant types compared, results showed that decreased mean BIC was found adjacent to the Copeland implants 16.84% (SD 10.40; 7.40 to 31.69) when compared with the implants in the Epoca RH group 31.85% (SD 16.43%; 16.97 to 44.58). However, this difference was not significant (*p* = 0.056). An independent sample *t*-test was used to determine significant differences.

Bone area - sub-cupola region. In the sub-cupola region the mean bone area adjacent to the Copeland implant was 0.17 mm² (SD 0.14; 0.03 to 0.42) in contrast to the Epoca RH implants for which the mean bone contact area was 0.26 mm² (SD 0.23; 0.14 to 0.28). However this difference was not statistically significant (*p* = 0.13, independent samples *t*-test).

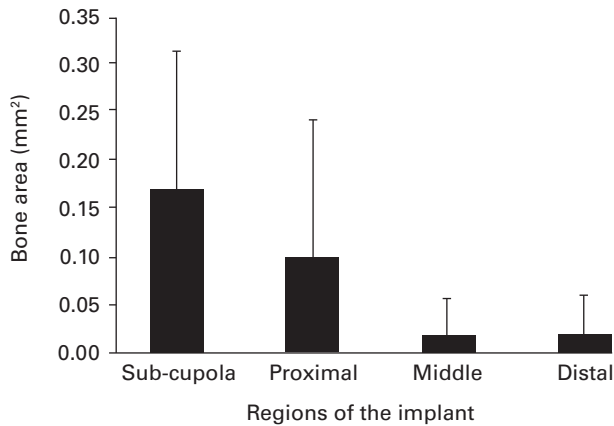


Fig. 6

Graph showing mean bone area adjacent to the Copeland prosthesis by region of interest. Error bars indicate standard deviation.

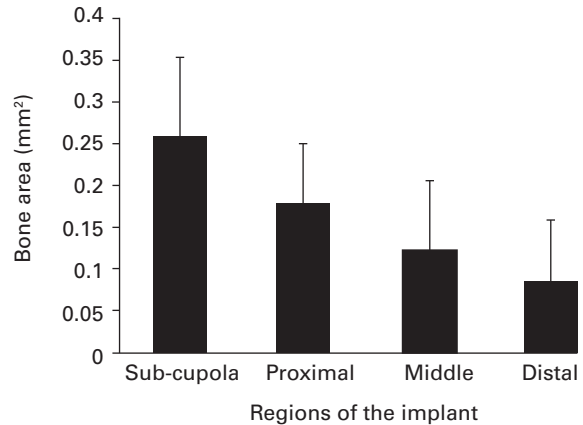


Fig. 7

Graph showing mean bone area adjacent to the Epoca RH prosthesis by region of interest. Error bars indicate standard deviation.

Bone area - stem. In the Copeland group, decreased mean bone area was measured in the proximal (0.10 mm², SD 0.13; 0.01 to 0.35, $p = 0.18$), mid (0.02 mm², SD 0.04; 0.00 to 0.11, $p = 0.041$) and distal (0.02 mm², SD 0.05; 0.00 to 0.12, $p = 0.01$) zones of the stem when compared with bone area measured in the sub-cupola region (Fig. 6). However, no significant differences were found when each of the regions was compared. A Mann Whitney-U test was used to determine significant differences between regions.

In the Epoca RH group, reduced mean bone area was also measured in proximal (0.18 mm², SD 0.07; 0.14 to 0.38 mm, $p = 0.13$), mid (0.12 mm², SD 0.08; 0.02 to 0.24, $p = 0.04$) and distal (0.09 mm², SD 0.04; 0.03 to 0.14, $p = 0.002$) regions adjacent to the conical crown when compared to the sub-cupola region (Fig. 7). Significantly increased bone area was measured in the sub-cupola region when compared with the mid and distal regions of the crown, and also when the proximal region of the crown was compared with the distal region ($p = 0.04$). An independent samples t -test was used to determine significant differences.

When all regions were combined and the two implant types compared, results showed decreased mean bone area adjacent to the Copeland implants (0.08 mm², SD 0.06) compared with that measured adjacent to the Epoca RH implants (0.16 mm², SD 0.12) but this difference was found not statistically significant using a Mann Whitney-U test ($p = 0.065$).

Correlation analysis. In the Copeland group and when the results for all implants and regions were combined, no significant correlation ($r = -0.20$, $p = 0.70$) was found when mean bone-implant contact and mean bone area were analysed. In addition, no correlation ($r = 0.26$, $p = 0.61$) was found when bone area in the sub-cupola region and implant duration *in vivo* were analysed.

In the Epoca RH group, a significant correlation was found between mean bone-implant contact and duration *in vivo*, with a gradual increase in bone-implant contact over

time ($r = 0.833$, $p = 0.020$). When the results for all implants and regions were combined, no significant correlation ($r = 0.31$, $p = 0.54$) was found when mean bone-implant contact and mean bone area were analysed. No significant associations in BIC were found when mean bone-implant contact and age ($r = -0.48$, $p = 0.32$); mean bone area and age ($r = 0.31$, $p = 0.54$); and mean bone area and time *in vivo* ($r = 0.61$, $p = 0.19$) were analysed.

Discussion

The long-term success of joint replacement surgery is dependent on many factors, including successful osteointegration.¹³ Stress shielding in hip resurfacing arthroplasty is due to load transfer by the stem causing non-physiological strain in the bone leading to proximal bone resorption.^{14,15} However, it must be considered that forces acting on the shoulder are different to those in the hip. Bone density in the humeral head is less than that of the femoral head and the orientation of trabeculae is also different.¹⁶ Both qualitative and quantitative analysis of the retrieved implants in our study showed reduced or no bone adjacent to the stem of Copeland prostheses. This may be associated with the size and positioning of the implant stem in the humeral head. The conical crown in Epoca RH implants is positioned in more dense bone, as it is located more peripherally than the central stem of the Copeland device. There is a decrease in bone density in the humeral head from superiorly to inferiorly and from posteriorly to anteriorly.¹⁷ The most superior and medial part of the humeral head was shown to possess the highest bone mass.¹⁸ In addition bone density is greatest at the periphery of the humeral head and becomes less dense centrally. Satioh et al¹⁹ showed the proximal part of the humeral head had the greatest amount of bone mineral, with the humeral neck having only approximately one half of the bone mineral density of the head. Additionally, the cancellous bone of the neck demonstrated only one third of the mechanical strength of the humeral head following indentation testing. We have shown

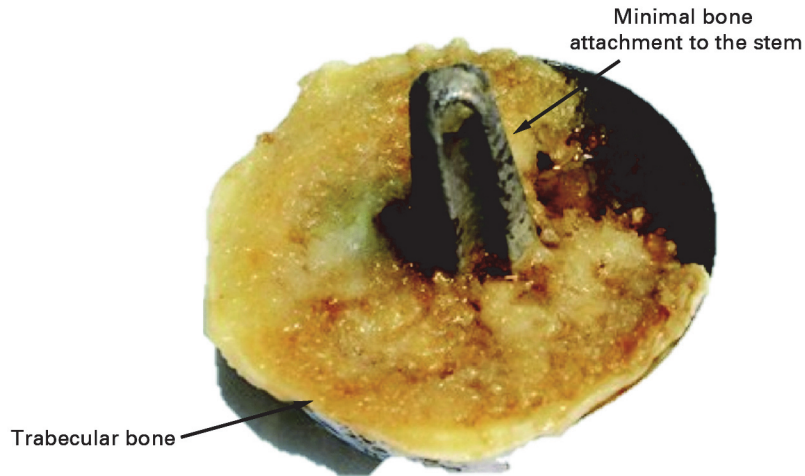


Fig. 8a

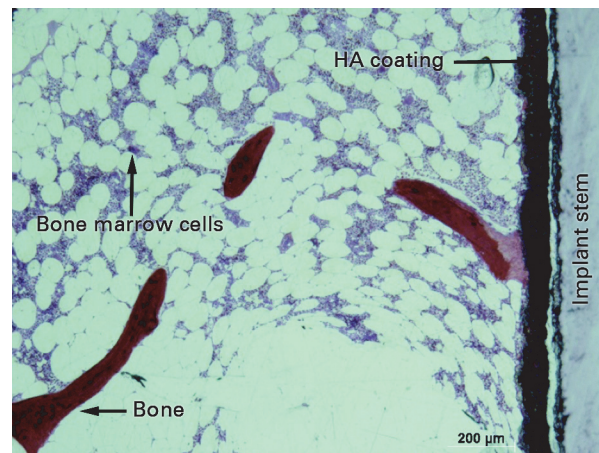


Fig. 8b

a) A photograph of a retrieved Copeland implant (duration *in vivo*, 16 months) following retrieval showing trabecular bone formation within the sub cupola region with no bone adjacent to the stem. b) A photomicrograph showing minimal bone contact to the stem surface.

that the position of the stem in the Copeland and the conical crown in the Epoca RH devices significantly affected the amount and distribution of bone contact and bone formation. Epoca RH implants demonstrated uniform bone growth and bone contact over the entire surface whereas the Copeland implants showed most bone in growth in sub cupola region (Figs 8 and 9).

Our results are in contrast to a recently published Finite Element Analysis (FEA) study on the CRSA by Schmidutz et al¹⁰ in which the predicted increased compressive strain adjacent to the stem led to bone apposition. Three-dimensional FEA models of hip resurfacing arthroplasty also described bone loss and reduced stress under the femoral component due to increased stress around the stem and bone formation.^{15,20-23} Orr et al,²⁴ using two-dimensional finite element models for hip resurfacing, reported that

stress shielding occurred underneath the metal femoral component, resulting in lower bone density in the femoral head, and that the addition of a central femoral stem caused bone hypertrophy adjacent to the stem. In our study, bone apposition for both implants was observed adjacent to the sub cupola region, which may indicate proximal stress transfer. For the Copeland implant, stress transfer from the stem may be limited because of the poor quality bone in this region. Bone-implant contact was more uniform for the Epoca RH implant with no significant differences in bone-implant contact observed between the different implant regions. This may be attributed to the design and increased surface area of the crown leading to more beneficial stress distribution.¹⁰ In contrast to the Copeland implant, quantitative assessment showed the Epoca RH design to enhance osteoconductivity of bone on the HA coated surface.

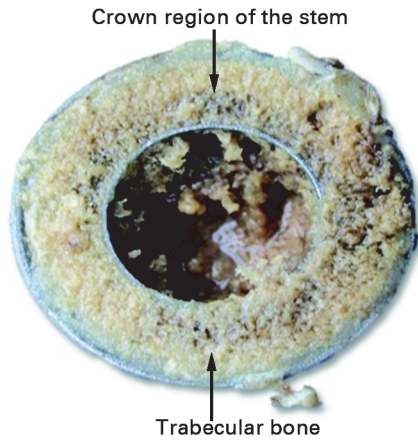


Fig. 9a

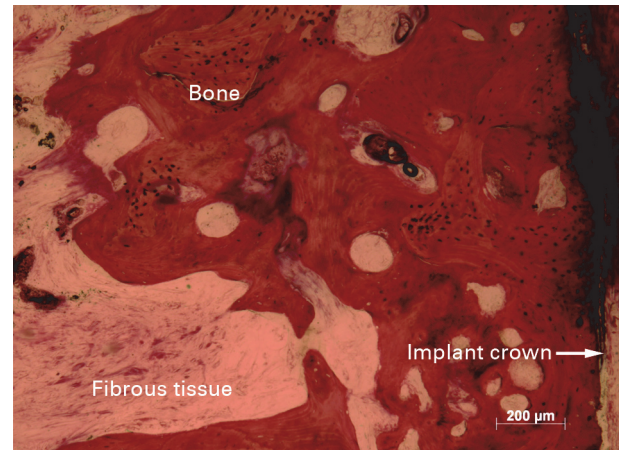


Fig. 9b

a) A photograph of a retrieved Epoca RH implant (duration *in vivo*, 84 months) following retrieval showing trabecular bone within the subcupola region and surrounding the conical crown b) A photomicrograph showing mature lamellar bone in direct contact to the implant surface. HA, hydroxyapatite.

One of the prerequisites to accomplish optimal bone fixation is primary implant stability at the time of surgery. Once primary stability is achieved as a result of press-fitting, bone remodelling will be initiated providing secondary stability.^{25,26} Implant design and surgical technique are two important elements in establishing effective initial fixation as it determines the relative movement between the implant surface and host bone.^{27,28} Formation of fibrous tissue at the interface adjacent to the Copeland implants, suggests insufficient primary stability. One of the reasons that Epoca RH implant showed more contact may be due to primary stability associated with larger implant area available for bone ingrowth which is positioned in denser cancellous bone.

Kasten et al²⁹ reported that the location of a bone defect and type of implant stabilisation have a high impact on primary stability of CRSA. Their study investigated micromotion of two CSRA designs (n = 5), namely the Epoca RH (Synthes GmbH, Oberdorf, Switzerland) and Aequalis (Tornier SAS, Saint-Ismier Cedex, France) with a central stem implanted with bone defects varying from 0% to 37% of humeral head volume. Results showed that Epoca RH implants had a decreased micromotion (< 150 μm) with all sizes of defect compared with the Aequalis design.²⁹ The initial stability of the conical crown design may be associated with enhanced longer term bone formation compared with the stem design investigated in our study.

Our study had several limitations. Firstly, it was a retrospective analysis in a small number of matched patients. Secondly, the orientation of the implants was unknown.

In summary, in this study the osteointegration of two different designs of shoulder resurfacing replacements has been investigated. All of the implants had been revised, though none for loosening. Comparison of the two designs suggested that implant design affected bone attachment and distribution around the implants and that osteointegration of CRSA may be dependent on implant design.

Therefore, this study suggests that the use of a central stem may not be necessary provided there is adequate peripheral fixation within good quality humeral bone.

Author contributions:

S. Ajami: Writing Paper, Data Collection, Data Analysis.
G. W. Blunn: Study Design, Data Interpretation, Writing Paper.
S. Lambert: Performed Surgeries, Data Interpretation, Reviewed Paper Drafts.
S. Alexander: Data Interpretation, Reviewed Paper Drafts.
M. Foxall Smith: Data Collection, Data Analysis.
M. J. Coathup: Study Design, Data Interpretation, Writing Paper.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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