Primary stability in reversed-anatomy glenoid components

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Abstract: Reversed-anatomy shoulder replacement is advocated for patients with poor rotator cuff condition, for whom an anatomical reconstruction would provide little or no stability. Modern generations of this concept appear to be performing well in the short-term to midterm clinical follow-up. These designs are almost always non-cemented, requiring a high degree of primary stability to encourage bone on-growth and so to establish long-term fixation. Six different inverse-anatomy glenoid implants, currently on the market and encompassing a broad range of geometrical differences, were compared on the basis of their ability to impart primary stability through the minimization of interface micromotions. Fixing screws were only included in the supero-inferior direction in appropriate implants and were always inclined at the steepest available angle possible during surgery (up to a maximum of 30°). The extent of predicted bony on-growth was, of course, highly dependent on the threshold for interface micromotion. In some instances an additional 30 per cent of the interface was predicted to promote bone on-growth when the threshold was raised from $20\,\mu m$ to $50\,\mu m$. With maximum thresholds of micromotion for bone on-growth set to $30\,\mu m$, the Zimmer Anatomical device was found to be the most stable of the series of the six designs tested herein, achieving an additional 3 per cent (by surface area) of bone on-growth above the closest peer product (Biomet Verso). When this threshold was raised to $50\,\mu m$, the Biomet Verso design was most stable (3 per cent above the second-most stable design, the Zimmer Anatomical). Peak micromotions were not a good indicator of the predicted area of bone on-growth and could lead to some misinterpretation of the implant's overall performance. All but one of the implants tested herein provided primary stability sufficient to resist motions in excess of $150\,\mu m$ at the interface.

Keywords: primary stability, reversed anatomy, shoulder replacement, glenoid components

1 INTRODUCTION

In cases of reversed-anatomy shoulder replacement, the alteration of the centre of rotation of the joint enables the surviving muscles of the shoulder to be more effectively recruited for humeral abduction than in an anatomical configuration [1]. This procedure has been shown to enable a level of postoperative function hitherto impossible to attain with some patients, whose rotator cuff muscles were in various stages of dysfunction, and for whom the stability of an anatomical prosthesis would be very low [2].

The most extensive literature on the performance of the reversed shoulder exists for the Delta III by Depuy, which is arguably the most well-recognized prosthesis of this type. Clinical history of the reversed or inverse shoulder design concept is not as extensive as for anatomical designs, because of their relatively recent introduction to markets outside Europe. However, the performance of this implant was judged to be comparable with that of anatomical designs in one of the only midterm to long-term clinical follow-ups present in the literature [3]. Shorter-term studies have indicated good

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performance of modern reversed designs across a sample of the spectrum of manufacturers [4–9].

In response to these positive clinical outcomes, numerous new inverse shoulder products have entered the market to address a growing surgeon demand. However, despite encouraging short-term to midterm successes, there is evidence that long-term outcomes for the reversed shoulder will not be as good. In a minimum 5 year follow-up study of 80 reversed shoulder prostheses, Guery *et al.* [3] identified that clear breaks in the survival curves were present at 3 and 6 years, representing both early loosening and a progressive deterioration of the functional result respectively. In the absence of extensive long-term clinical trials of all designs currently on the market, some comparison of the relative merits of each product versus a well-established benchmark (the Delta III being the natural choice because of its relatively extensive follow-up) is needed.

While anatomical glenoid components are often made from ultra-high molecular weight polyethylene and fixation is dependent on effective cementing, the preferred approach for fixing the reversed glenoid to the bone is initially through screws and press-fit, and ultimately through bone on-growth. A high degree of primary stability is required to encourage bone on-growth on to the implant, and it has been the objective of numerous computational and experimental studies to quantify the magnitude and influence of different interface motions (widely referred to as micromotions) [10–13].

The use of anchoring screws in one form or another is common among reversed glenoid components; however, other design parameters do vary between designs. These include the location of the centre of rotation with respect to the glenoid surface (referred to as lateral offset), the options for screw insertion and available arc of insertion, the distance separating the tips of the screws, and the concavity of and size of the interface. The Delta III, for example, uses a small lateral offset, up to four screws (two with a fixed inclination in the superoinferior axis and two with adjustable alignment in the anteroposterior axis), with a flattened bone–implant interface. By comparison, the Bayley–Walker prosthesis (Stanmore Orthopaedics) uses a large central screw to anchor the implant in order to achieve a stable fixation within the denser corticies.

This study will consider the relative capability of six different reversed-anatomy glenoid components to encourage bone on-growth at the bone–implant interface using finite element analysis (FEA), in an attempt to identify some broad relationships between design and primary stability.

2 METHODS

Experimental testing on the reversed glenoid prosthesis was presented by Harman *et al.* [4] for three reversed-anatomy glenoid designs currently on the market, these being the Delta III (DePuy) and two variations on the Reverse Shoulder Prosthesis (RSP) design from Encore. An earlier FEA study by the present authors and co-workers [15] simulated this experiment and demonstrated qualitative validation with the laboratory results for these three implant designs.

Computer models of the Delta III (Depuy), Anatomical (Zimmer), Bayley–Walker (Stanmore), Verso (Biomet), RSP-reduced (Encore), and RSP-neutral (Encore) reversed-anatomy glenoid components were developed, either from computer-aided design (CAD) data or reverse engineered from physical inspection, using the software packages AMIRA (Mercury Software) and MENTAT (MSC software, Palo Alto, California, USA). All prostheses consist of a spherical glenoid head of various depths, mounted on a metallic base plate. The major variables associated with the implant designs are listed in Table 1. The finite element (FE) models can be seen in Fig. 1; the meshes of the implants contained between 11 000 and 18 000 linear tetrahedral elements. Further refinement of the meshes did not influence the predictive quality of the model (in terms of micromotion). The implants were all modelled as possessing a stiffness similar to cobalt–chromium (Young's modulus, 220 GPa; Poisson's ratio, 0.3) and were linearly isotropic.

The interface between the glenoid head and the base plate was modelled as rigid for all modular implants, simulating recent efforts to eliminate disassembly *in vivo*, and relative motion between these parts of the glenoid implant was thus eliminated. Because more modern reverse designs have been designed to resist *in-vivo* disassembly or unscrewing, any screws that were used to anchor the implant to the bone analogue material were themselves modelled as being rigidly bonded to the implant. All screws were modelled as cylindrical structures composed of linear tetrahedra, following similar approaches presented in the literature [16]. The screws were all modelled as linear isotropic with Young's modulus equal to 110 GPa and Poisson's ratio equal to 0.3. For consistency, all screws were

Table 1 Design variables identified within range of reversed shoulder implants considered in this study

| Implant	Central screw or peg	Back-plate shape	Surface area of the back plate	Anchor screws	Screw diameter (mm)	Screw angle (deg)	Tip-to-tip screw length (mm)
Anatomical (Zimmer)	Peg (tapered, fins)	Convex	Large	Yes	4.5	30	57
Bayley–Walker (Stanmore)	Macro screw	Flat	Small	No	N/A*	N/A*	N/A*
Delta III (DePuy)	Peg (cylinder with grooves)	Flat	Large	Yes	3.5	17	36
RSP-neutral (Encore)	Screw (5 mm diameter)	Convex	Small	Yes	3.5	30	50
RSP-reduced (Encore)	Screw (5 mm diameter)	Convex	Small	Yes	3.5	30	50
Verso (Biomet)	Macro screw	Flat	Large	Yes	5.0	30	50

*N/A, not applicable.
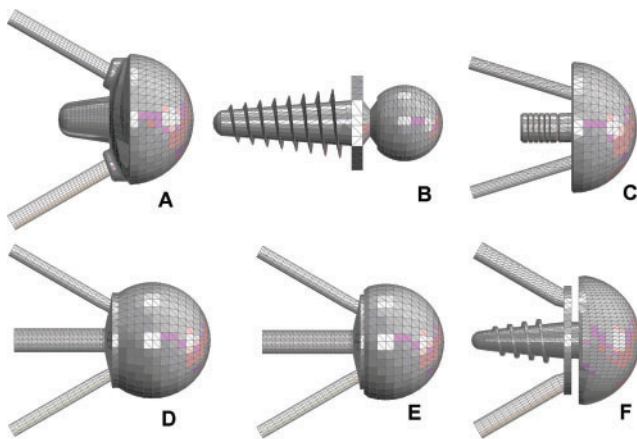
Fig. 1 FE models of the reversed-anatomy glenoid components (with screws) tested in this study: (a) Anatomical (Zimmer); (b) Bayley–Walker (Stanmore); (c) Delta III (Depuy); (d) RSP-neutral (Encore); (e) RSP-reduced (Encore); (f) Verso (Biomet)

set at 30 mm in length. The different diameters and inclinations of the screws are given in Table 1.

Based on the study by Anglin *et al.* [**17**], whose work helped to quantify material characteristics for an average healthy glenoid, the implant models were 'virtually' implanted into a block of polyurethane, which possessed material qualities similar to those identified in glenoid cancellous bone (E_{foam} = 193 MPa). The technique for generating the postoperative surfaces ensures that all nodes lying on the interface between the implant, polyurethane, and screws were coincident, allowing for an accurate description of the contact between these two materials. Consideration of a discontinuous interface, as would be achieved by inaccurate bone preparation or defects, was not considered in this study.

Two different types of interface were defined within the model. All screws were modelled to possess a rigid interface with the polyurethane material bone analogue, following a similar approach reported elsewhere in the literature [**16**, **18**].

All interfaces where the bone on-growth potential was to be considered were modelled as a Coulomb contact surface with a contact thickness of 5 μm. Sensitivity analyses identified no improvement in the predictive power of the modelling with further reduction to this contact thickness. The relative motion between coordinate matched nodes lying on the interface between the implant and the polyurethane were assessed during the analyses.

Bone on-growth is reliant on the minimization of interface micromotions across the bone–implant interface. The threshold for achieving good-quality bone on-growth has been reported to vary from 20 μm to 50 μm [**12**, **19**], with fibrous tissues forming above roughly 150 μm [**10**, **12**]. Results will be presented in 10 μm steps to indicate the capability of the bone to impart primary stability under conservative (20–30 μm) and optimistic (40–50 μm) thresholds.

Following Harman *et al.* [**14**] an axial point load of 756 N was applied to the centre of the surface of the spherical glenoid head, and an additional load of 756 N was then applied vertically, giving a resultant force of 1070 N. The magnitude of this loading was derived originally by Anglin *et al.* [**20**]. An example of the final FE model with applied loading can be seen in Fig. 2. All faces of the polyurethane block, apart from that which has the glenoid component inserted, were fully constrained against displacement.

3 RESULTS

Alterations to the coefficient of friction did not significantly affect the stability of the implant–bone interface, suggesting that the influences of geometry and screws were the most dominant factors. No further consideration of this will therefore be presented. Peak micromotions captured at the implant–bone interface during loading are presented in Fig. 3. The percentages of the implant–bone
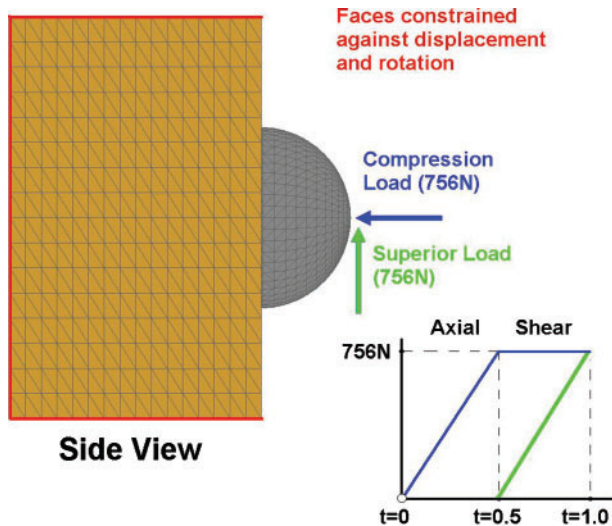
Fig. 2 The completed FE model of the reversed-anatomy glenoid component inserted into a polyurethane bone analogue
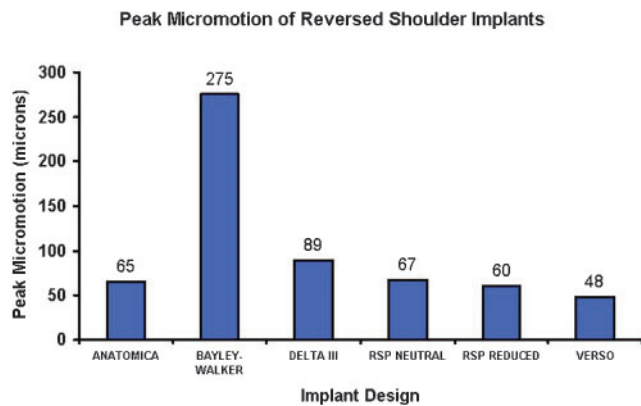

Fig. 3 Peak micromotions observed at the interface between the implant and polyurethane

interface predicted to promote bone on-growth for various thresholds of the critical level of permitted micromotion for bone on-growth are presented in Fig. 4. Figure 5 presents contour maps of the distribution of interface micromotions for each design.

4   DISCUSSION

Using FEA, an investigation was undertaken to determine the capability of six existing glenoid devices to resist interface motions under loading. FEA predictions were broadly validated in an earlier study and the methodology has been repeated in this study [15]. The predicted extent of bony on-growth was dependent on the maximum permitted interface micromotion, and in some instances an additional 30 per cent of the interface was predicted to promote bone on-growth when the threshold was raised from
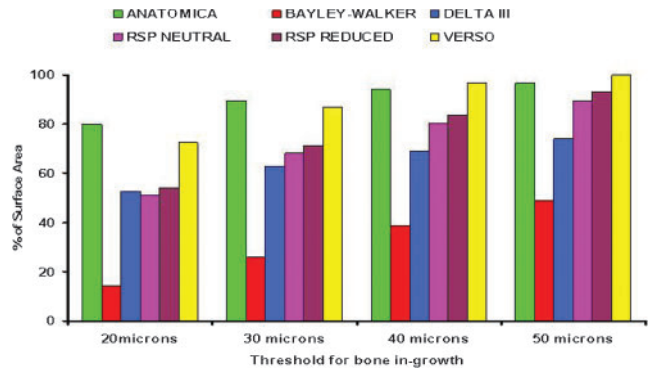

Fig. 4 Percentages of implant–bone analogue interfaces determined to achieve bone on-growth versus the applied threshold for interface micromotion
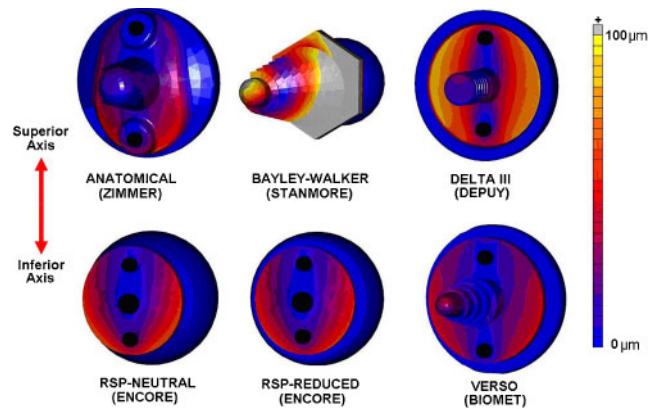

Fig. 5 Distribution of interface micromotions observed at peak loading

$20\,\mu m$ to $50\,\mu m$. When the maximum threshold for micromotion that would still permit bone on-growth was set to $20\,\mu m$ or $30\,\mu m$, the Zimmer Anatomical device was found to be the most stable of the series of the six designs tested herein, achieving up to an additional 8 per cent (by surface area) of bone on-growth above the closest peer product (Biomet Verso). When this threshold was raised to $40\,\mu m$, the Biomet Verso design was most stable (3 per cent above the second-most stable design, the Zimmer Anatomical). The Encore RSP designs showed the greatest benefit from an increased threshold for bone on-growth, where raising the threshold from $20\,\mu m$ to $50\,\mu m$ increased the area of predicted bone on-growth by approximately 40 per cent for both designs.

Comparing the peak micromotions presented in Fig. 3 with the percentages of the interface predic-

ted to achieve bone on-growth as shown in Fig. 4 emphasizes the fact that consideration of the entire interface motion pattern is necessary to capture the overall stability of the implant with respect to the bone. For example, peak resultant micromotions with the Verso and RSP-reduced devices were lower than those of the Anatomical design (48 μm and 60 μm versus 65 μm). However, a combination of the convex geometry and more widely spaced screw tips of the latter appeared to contribute to enabling a greater percentage of the interface to lie below 30 μm of relative micromotion, increasing the potential for bone on-growth.

Peak micromotion predictions, as well as the percentage of the interface existing outside of the 'safe zone' of, even optimistically, less than 50 μm, were notably higher in the Bayley–Walker design, the only prosthesis that did not make use of peripheral anchoring screws.

While several glenoid devices tested in this study have the capacity for additional screws to be used to provide extra anchorage options (four holes for the Delta III and RSP designs, and six for Verso), minimal or compromised bone stock can limit the incidence of their actual use. For the purposes of this study a worst-case analysis (where the glenoid would be too small to accommodate anything other than the superior and inferior screws) was considered a fair judge of the relative product performance. For the Delta III and RSP designs, anchoring screws of diameter 3.5 mm are used, whereas for the Anatomical and Verso designs diameters of 4.5 mm and 5 mm respectively are used. Increasing the effective surface area of the screws has been shown to correlate with an increase in stability of the fixation [15], and the relative stability of the Anatomical and Verso designs could be attributed in part to this design feature. A small investigation into the influence of screw thickness suggested that a 30 per cent increase in diameter would, in some cases, result in up to 10 per cent extra of the fixation lying below the uppermost threshold for the bone on-growth tested herein (50 μm). However, the problem with this particular design feature is that by increasing the diameter of the screws used in surgery, the volume of bone within which the screw can be 'safely' anchored, without perforating the corticies and endangering surrounding anatomy, is reduced. An investigation is currently under way to evaluate the optimal screw thickness that can be used in the reversed shoulder, attempting to achieve a balance between screw size, bone quality, and insertion angle across a range of scapular geometries.

The lateral offset of the glenoid sphere has been discussed in the literature [2, 14, 21], and the impact that this has on the potential for bone on-growth can be inferred to some extent from the results presented herein. The RSP-neutral and RSP-reduced designs differ only in the distance of the glenoid centre of rotation with respect to the glenoid surface. In the latter, the medialization of this centre of rotation led to a consistent increase in predicted bone on-growth area of between 1 per cent and 4 per cent. However, the differences in the lateral offsets do not appear to correlate strongly with the predicted interface micromotions, suggesting that this design feature is not solely responsible for the primary stability.

Drawing parallels between the results presented herein and those observed clinically is difficult, as a myriad of associative factors contribute to a loosened prosthesis, and isolating precisely the root cause of a failure can often be difficult. The overall performance of the Delta III from Depuy, considered to be the benchmark device in this prosthesis line, was found to be acceptable under conditions of aggressive loading as tested within this study, from the perspective of interface micromotion. This corresponds broadly to clinical data which suggest that survival and functional results with this product can compare favourably with the anatomical glenohumeral reconstruction [3]. The performance of the RSP designs from Encore was also predicted to be of a similar standard to the Delta III, which is also borne out by clinical follow-up [5]. At most only short-term and small-patient-sample-size clinical follow-up was found for the other designs [6], and so, without more exhaustive clinical histories (which should be published over coming years), direct comparisons with clinical data are not possible at this stage in the history of the reversed shoulder. However, based on the results of this study, it appears that the Anatomical and Verso designs offer the highest degree of overall stability of any of the six prostheses tested, and so the Zimmer or Biomet designs should provide for comparable or enhanced long-term fixation compared with the benchmark Delta III.

While the cumulative effect of each design's beneficial and detrimental features is shown through the relative comparison of the bone on-growth potential presented in Fig. 4, isolating entirely the most effective and/or dominant features of the devices was beyond the scope of this work. However, some qualified statements can be made.

1. Prostheses which are fixed into the bone using steeply inclined screws will be more stable than

those anchored with shallower screws, which in turn are more stable than implants without anchoring screws.

2. Thicker screws appear to stabilize the implant with respect to the bone and should therefore promote bone on-growth. However, the extent of this effect is not quantified herein, and the benefits of thicker screws may be mitigated by a reduction in the arc of 'safe' insertion angle and screw length.

3. A convex fixation interface will enable the screws to be placed further apart than a flat interface, and this will in turn provide greater mechanical resistance to interface motion.

4. A larger implant surface area should provide a greater overall resistance to interface micromotion than a smaller implant would.

There are some limitations to the predictive power of the modelling approach employed within this study, which should be highlighted and discussed.

1. The use of a homogeneous bone material block negates the benefits of a denser cortex, into which the devices with central or anchoring screws would ideally achieve capture [22, 23]. As the orientation and depth of the screws, as well as the alignment of the implants, will be patient specific and therefore difficult to control in terms of a comparative analysis, for the purposes of this study a consistent 'bone' material was used.

2. Detailed loading data for the inverse anatomy shoulder remain limited and are likely to be highly influenced by both the patient and also the success of the surgery in terms of alignment and position. As such, standardizing the loads in the current study to negate the effects of patient-specific anatomy, muscle condition, or surgical accuracy was considered an acceptable simplification to provide comparison between the designs.

3. Given that this series of FEAs was a non-linear contact, the boundary conditions at the interfaces must be discussed. The interfaces between the screws and the implant were modelled as rigid, as was the interface between the glenoid sphere and the base plate. This is based on the assumption that the implants themselves are designed to withstand disassembly *in vivo*. While the approach used herein is a simplification of the real mechanical environment, where screws can in theory become loose with respect to the implant owing to hardware failure, it was considered acceptable in the context of this study as

insufficient data for each product's capability to withstand disassembly are available at this time.

4. The use of non-manufacturer-specific material properties for each glenoid component, and also each screw, is a limitation as it does not account for different approaches to material treatment and manufacture. Detailed information regarding the material properties of each competitor's metals is generally limited to internal reports and was not readily available in the literature. However, given that these stiff materials are implanted within a relatively soft bone substitute material, it is reasonable to assume that the critical material properties that will influence the interface behaviour are those of the polyurethane.

A further possible limitation to this type of study that should be considered is the use of a single threshold for determining the potential for bone on-growth. While the protocol used in this study is an accepted approach that has been presented in numerous publications, bone is itself an inhomogeneous and anisotropic material whose response to mechanical stimulus is dictated by the direction, magnitude, and amplitude of loading; therefore, the same may be true of its response to interface micromotions. Currently, these interface motions are resolved so as not to consider the bone's potentially differing response to shearing or separating motions (i.e. sliding or gap forming), mainly owing to an absence of appropriate experimental data on which to base any computational modelling. Some pilot investigations by the present authors into the effect of varying the thresholds for bone on-growth under shearing or separating micromotions highlighted the fact that this could be an important consideration for future studies in this field, and further work to clarify whether the bone response is conditional upon the direction of relative interface motion is needed.

5 CONCLUSIONS

FE models of a series of six reversed shoulder glenoid components were tested to assess their relative response to superior shear loading when the implants were anchored within a bone substrate. The cumulative effect of each design's beneficial and detrimental features is shown through the relative comparison of the bone on-growth potential, which is assessed through the relative motion of the

implant and polyurethane foam at the interface. Peak micromotions did not fully explain the behaviour of the whole interface, and an analysis of the surface area exposure to micromotions is suggested to be more representative. Implants anchored using steeply inclined screws appear to be more resistant to relative motions at the interface. Thicker screws appear to stabilize the implant with respect to the bone; however, this benefit may be mitigated by a reduction in how safely a thicker screw can be inserted without risking intra-operative bone fracture. A convex fixation interface enables the screws to be placed further apart than a flat interface, which will in turn provide greater mechanical resistance to interface motion. A larger implant surface area can provide a greater overall resistance to interface micromotion than a smaller implant would.

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