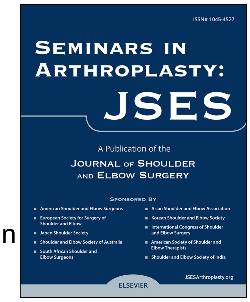
Journal Pre-proof



A Dual-Cup Reverse Shoulder Replacement Improves Impingement-Free Motion

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PII: S1045-4527(25)00004-5

DOI: https://doi.org/10.1053/j.sart.2024.12.004

Reference: YSART 51427

To appear in: *Seminars in Arthroplasty: JSES*

Received Date: 1 December 2024

Accepted Date: 9 December 2024

A Dual-Cup Reverse Shoulder Replacement Improves Impingement-Free Motion

Running-title: Dual-Cup RSA

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Institutional review board approval was not required for this basic science study.

Disclaimers:
Funding: No funding was disclosed by the authors.

Conflicts of interest: The authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

ABSTRACT

Background: Advances in reverse shoulder arthroplasty (RSA) design have improved functional outcomes, which approach those of the anatomic total shoulder arthroplasty (aTSA) in certain patients. However, restoration of motion, especially functional internal rotation, remains a concern following RSA. A novel dual-cup RSA design[1] was developed to improve impingement-free range of motion. The passive motion of the dual-cup RSA is compared to that of a commercially-available RSA design in a cadaveric model.

Methods: Five fresh-frozen cadaveric upper extremity specimens were included in the study. The scapula was rigidly fixed, allowing for isolation of glenohumeral joint motion. The novel dual-cup RSA design was tested with and without a flanged component. The dual-cup has an outer diameter of 36 mm, articulates with a 32+4 mm glenosphere, and provides 6 mm of glenoid lateralization. A 32+4 mm lateralized glenosphere and a 36+6 mm lateralized glenosphere served as controls. Measurements of motion were performed using an electromagnetic tracking device and modes of impingement were recorded. An Analysis of Variance (ANOVA) test was performed with a post-hoc Tukey test to compare the relative changes in range of motion among groups.

Results: The dual-cup *(without flange)* design improved external rotation (ER) at 0° abduction by 20.9° and improved IR by 11.5° compared to the 32+4 mm control ($p<0.01$). In 90° abduction, the dual-cup improved ER by 11.9° compared to the 32+4 mm control, a significant improvement relative to the 36+6 mm control ($p<0.05$). The dual-cup improved functional IR by 12.4° relative to the 32+4 mm control, a significant improvement relative to the 36+6 mm control ($p<0.05$). The dual-cup did not significantly improve IR at 45°or 90° abduction compared to control models. Humeral component impingement on the glenoid was not observed at any end-range of motion in the implant with the flanged design.

Discussion: The dual-cup design improves all rotational motions relative to control models except internal rotation with an abduction angle reaching or exceeding 45°. The dual-cup design improves impingement free motion, including functional internal rotation, without additional lateralization in this study. The dual-dup with flange design eliminates impingement of the humeral cup on the glenoid neck without significantly affecting most motions relative to control models.

Level of Evidence: Basic Science Study; Cadaveric Study

Keywords: Reverse Shoulder arthroplasty; shoulder replacement; Shoulder; biomechanics; cadaveric study

Reverse shoulder arthroplasty (RSA) is a well-established method for treating rotator cuff arthropathy, proximal humerus fractures, irreparable rotator cuff tears and is a valuable implant in revision shoulder arthroplasty. Patient outcomes are excellent and approach those of the anatomic total shoulder arthroplasty (aTSA).[19] Despite these results, RSA still presents unique challenges for patients and surgeons. When compared to patients with an aTSA, RSA patients are less likely to obtain functional levels of internal rotation that are necessary for some activities of daily living. [16,34] Greater levels of internal rotation have been associated with improved patient functional outcome scores.[13]

The reason for the loss of internal rotation following RSA is likely multifactorial and is influenced by both implant and patient-specific factors. Soft tissue considerations such as subscapularis status, have not been consistently shown to impact rotational motion. [6,13] Numerous studies have investigated the relationship between implant position or design and impingement-free range of motion. Hochreiter et al found less distalization of the greater tuberosity and thinner humeral inserts to be risk factors for poor postoperative internal rotation. [13] Multiple studies report that lateralized constructs improve rotational motion.[3,33] Larger glenospheres also increase motion by increasing the potential arc of contact between components.[3] Implant position, specifically humeral anteversion, may improve internal rotation but must be balanced with the corresponding decrease in external rotation. [3]

Dual mobility constructs were initially developed for total hip arthroplasty (THA). The dual articulation (femoral head and polyethylene liner, polyethylene liner and acetabular shell) has been to shown to provide a greater range of motion before impingement.[17] In THA, this provides a potential stability benefit, increasing the jump distance and thus the resistance to dislocation. For reverse shoulder arthroplasty, there is a potential for increased stability through additional lateralization.

Here, we present a novel dual-cup reverse shoulder arthroplasty implant design. This implant has a mobile dual-cup liner. The liner is designed with or without a flange and independently articulates with both the glenosphere and the humeral cup. A dual articulation has the proposed benefit of increasing the glenosphere diameter, increasing glenoid lateralization and increasing the arc of contact. The flange design prevents implant notching at the glenoid neck. In this pilot study, we compare the range of motion between the novel dual-cup RSA and traditional RSA designs in a cadaveric model. We hypothesize that the dual articulation will improve internal rotation and change the sites of implant impingement.

MATERIALS and METHODS

Five fresh-frozen cadaveric upper extremity specimens were included in the present study. The specimens were male in all cases with an average age of 71.4 years ± 6.2 years. The scapula was secured to a platform using a vise and reinforced using trans-scapular screws, creating a rigid construct, and allowing isolation of glenohumeral joint motion. A trans-articular amputation was performed through the elbow. Soft tissue was dissected from the humerus to allow placement of a Flock of Birds (Ascension Technology Corporation, Burlington, VT) electromagnetic tracking device directly on bone at the deltoid tuberosity. The sensor was secured using 4 zip ties. Tissue superficial to the deltoid muscle was resected and a posterior window was made through the deltoid and shoulder capsule to allow direct assessment of impingement.

A standard deltopectoral approach was performed. The humeral head cut was made at the anatomic neck in 135° of inclination and 30° of retroversion. The glenoid was reamed over a central wire in 5° of inferior tilt and native version. Attention was turned to the humerus which was broached and reamed to accept an inlay humeral cup. All humeral cups used in this study had a depth to radius (d/R) ratio of 0.45 matching the corresponding articulation element (glenosphere or dual-cup), to eliminate any variability from the humeral side. Stem and cup were inserted, and putty was used to secure a press-fit. The glenoid was revisited. A 24 mm baseplate was placed at the inferior margin of the glenoid and secured using 4 peripheral screws. A 32+4 mm glenosphere was placed and secured to the baseplate with a central screw. The following implants were tested:

1. 32+4 mm glenosphere

2. 32+4 mm glenosphere with a Dual-cup (36 mm outer diameter, +2 mm lateralization i.e. 6 mm total lateralization) (Figure 1a)

3. 32+4 mm glenosphere with a Dual-cup with flange (36 mm outer diameter, +2 mm lateralization i.e. 6 mm total lateralization) (Figure 1b)

4. 36+6 mm glenosphere

An adjustable tripod stand (Manfrotto 3246, Manfrotto Distribution USA) and a custom 3D-printed arm holder were used to secure the limb and isolate tested motion to a single plane (Figure 2). The limb was taken through a range of motion until a point of impingement was reached. Each implant was taken through the following motions: internal and external rotation in neutral abduction, internal and external rotation in 45° abduction, internal and external rotation in 90° abduction, maximal abduction in neutral rotation. Functional internal rotation was assessed by measuring internal rotation with the arm fixed in *45° of abduction and 30° of extension.*

Impingement was directly visualized and agreed upon by two independent investigators. The endpoint of motion (degrees, from resting position to impingement) and site of impingement were recorded. Each implant was tested 3 times through each motion in each specimen for a total of 15 trials per implant at each motion. Implants were exchanged until each implant was tested through a single plane of motion. After all implants had been tested at one position, the position was changed, and the next motion tested. This process continued until each implant was tested through each range of motion.

Statistical Analysis

Continuous variables were calculated and expressed as a mean and standard deviation. Motions were expressed as a difference in motion relative to the 32+4 mm control implant. A logarithmic transformation was performed to normalize the data. An Analysis of Variance (ANOVA) test was performed with a post-hoc Tukey test to compare the relative changes in range of motion among groups. A finding with a p-value < 0.05 was considered statistically significant. All statistical analyses were performed using Microsoft Excel 97 (Microsoft Corp., Redmond, WA, USA).

RESULTS

The absolute motions for the 32+4 mm control can be found in Table 1. The motions of the other implants are reported relative to motions of the 32+4 mm control (Table 1, Figure 3). The dual-cup (*without flange)* design improved external rotation in neutral abduction by 20.9° ± 13.0° relative to the 32+4 mm control (p<0.01) and improved internal rotation by 11.5° ± 14.9° relative to the 32+4 control, which was significantly greater than the relative improvement of the 36+6 mm control (1.6° ± 10.2°), (p<0.05). In 45° abduction, the dual-cup improved external rotation by 4.5° ± 5.7°compared to the 32+4 mm control, which was a significant improvement from the 2.9° ± 8.5° relative loss seen in the 36+6 mm control (p<0.01). In 90° abduction, the dual-cup improved external rotation by 11.9° ± 13.9° compared to the 32+4 mm control, which was a significant improvement from the 1.1° ± 18.4° gain of motion offered by the 36+6 mm control (p<0.05). The dual-cup improved functional internal rotation by 12.4° ±15.9° relative to the 32+4 mm control, significantly better than the increase of 0.01° ± 27.6° by the 36+6 mm control (p<0.05). The dual-cup did not significantly improve internal rotation at 45° abduction, or 90° abduction compared to control models. The dual-cup with flange design improved internal rotation in neutral abduction by 9.4° ± 8.6° relative to the 32+4 mm, compared to an improvement of 1.6° ± 10.2° by the 36+6 mm control (p<0.05). The dual-cup with flange improved external rotation in neutral abduction by 5.9° ± 11.8°, which was significantly less than the improvement with the 36+6 mm control (10° ± 5.9°), ($p<0.05$). Motion of the flanged implant was otherwise not significantly different from that of the controls. Humeral component impingement on the glenoid neck was not observed at any end-range of motion in the implant with the flange design (Table 2).

DISCUSSION

The present study demonstrated an increase in impingement-free range of motion using a novel dual-cup reverse shoulder arthroplasty implant design compared to an equally-lateralized RSA implant design. The dual mobility design with a flanged cup was also shown to change the mode of impingement at extremes of motion, eliminating humeral cup on glenoid neck impingement.

The design of the reverse shoulder arthroplasty has evolved over the past decade. While functional outcomes and postoperative range of motion following RSA are approaching those of an anatomic TSA,[19] restoration of rotational motion, most notably functional internal rotation, remains a concern following RSA. [21,34] In total hip arthroplasty, dual mobility designs are well established as a technique to improve stability and range of motion.[29] The dual mobility reverse shoulder arthroplasty was designed with these considerations in mind.

The dual mobility RSA increases impingement-free range of motion in several ways. First, the dual mobility design increases the lateral offset without lateralizing the glenosphere. There is a wide breadth of literature demonstrating that glenosphere lateralization restores rotator cuff tension, decreases impingement, and increases range of motion. [5,10,11,27,12,36] The dual mobility design also effectively increases glenosphere diameter, which has also been shown to improve impingement-free ROM,[4,23,36] though this has not universally been shown. [18] It is therefore not surprising that both the dual mobility implant and the 36+6 mm glenosphere were associated with a greater range of motion compared to the 32+4 mm glenosphere in most of the tested positions. Finally, the extra articulation allows for increased range of motion. Compared to the 36+6 mm glenosphere, the dual mobility implant saw a significant improvement in internal rotation with the arm at the side, external rotation at 45° abduction, external rotation at 90° abduction and functional internal rotation. While lateralization has been associated with increased range of motion, it comes at the cost of increased deltoid stress,[18,26] acromion stress [15,28,37] and stress at the glenoid-baseplate interface. [9,38] The dual-cup design theoretically decreases the stress at the glenoid-baseplate interface because the abduction torque is divided between the glenoid-baseplate and dual-cup-glenosphere interfaces. The decreased shear force at bone may allow for even further lateralization than current RSA designs.

The dual-cup RSA also improves motion because there is a degree of independent movement between the humeral cup and polyethylene line. While the 36+6 mm implant saw early impingement on the acromion in abduction, the dual-cup was able to pass beneath the acromion. As the arm moved into abduction, the dual-cup implant cleared the acromion first and was followed shortly thereafter by the humeral cup. A similar phenomenon was observed with internal rotation as the humeral implant passed beneath the coracoid process or conjoint tendon. However, as the arm was elevated to and beyond 45˚, the differences in internal rotation among implants decreased. While some have cited posterior capsular tension as a cause for decreased IR associated with increased glenosphere diameter,[18] the present study found the implant to impinge on the coracoid or conjoint tendon with internal rotation in abduction in most cases. Additionally, the dual-cup design effectively created a variable-angle glenosphere which improved rotational motion in the present study. This may also have implications for baseplate placement in the setting of limited glenoid bone stock, allowing a greater freedom to place the glenosphere in that position which optimizes fixation compared to the commercially available RSA implants.

Scapular notching is a common phenomenon following RSA and is due to contact between the humeral component and the scapular pillar. Scapular notching may lead to polyethylene wear [20,24] which can lead to osteolysis and component loosening.[2,7,14] Multiple techniques and alterations in implant design have been proposed to decrease the incidence of notching including lateralization of the glenosphere, inferior offset of the glenosphere and inferior tilt of the glenosphere. [8,10,22,25,31,35] The flange in the dual-cup design eliminates implant on bone impingement at the scapular neck without significantly sacrificing motion. While rim-wear has been described as the predominant wear pattern following RSA,[7] volumetric wear may be an increasing concern in the dual mobility design as the dual-cup may experience articular as well as back-sided volumetric wear. Cyclic wear testing and material property testing are required to explore appropriate thickness of the dual-cup, d/R ratio of the humeral socket, and materials for the implant in order to investigate this risk. A ceramic dual-cup may decrease the risk of accelerated polyethylene wear.

A comprehensive discussion of the limitations of the implant design are beyond the scope of the present study. Briefly, volumetric poly wear rates are a concern as well as dissociation of the dual-cup and glenoid-baseplate stress. Historically, high-lateralization bipolar designs have seen catastrophic failure. The design of the present implant differs from historic designs in several ways. The present design has less total lateralization than historic designs, utilizes locking screws in the glenoid baseplate, and the dual-cup design distributes shear forces to two interfaces. Future investigation with finite element analysis is underway. Regarding this study more specifically, there are inherent limitations to a cadaveric study. Specimens varied in local anatomy. There were variations in glenoid baseplate placement among specimens due to local anatomy. However, within each specimen the baseplate placement for all implants was identical. Each implant was tested in each specimen in attempt to minimize confounders introduced by specimen anatomy. Soft tissue was handled with care and implants were taken through gentle passive range of motion to minimize soft tissue trauma. There was significant variance in absolute measurements among specimens, however motions were averaged, the data normalized, and significant differences among implant motions were detected. The present study isolated glenohumeral motion, as has been the model in previous RSA design studies.[32] Scapulothoracic motion contributes to functional motion and the range of motion presented here does not reflect true functional range of motion. The observed differences in implant range of motion were modest in some cases. However, the improvement in passive adducted external rotation with the dual mobility design exceeded the established threshold for a minimal clinically importance difference (MCID) in active external rotation compared to the 32 + 4 mm RSA. [30]

CONCLUSION

Dual-cup reverse shoulder arthroplasty increases impingement-free passive glenohumeral range of motion compared to control implants. The dual dup with flange design eliminates implant-on-glenoid neck impingement without significantly changing most motion relative to control models. Future directions include finite element analysis to evaluate the stress at the glenoid-baseplate interface, deltoid, and acromion. Finally, bench research tests will need to be performed to assess the impact of cyclic wear, dual-cup dissociation, and stability. These tests are essential to determining the optimal material and size of components.

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FIGURE and TABLE LEGENDS

Figure 1: Dual-Cup Reverse Shoulder Arthroplasty Design

a) Dual-cup without flange; b) Dual-cup with flange

Figure 2: Cadaveric Model

Cadaveric models with superficial tissue dissected and a posterior window created to allow assessment of impingement. The arm-holder is demonstrated. The electromagnetic sensor was placed at the deltoid tuberosity.

Figure 3: Implant Motion Comparison

Comparison of the motion of various RSA implants. “32 mm Dual-Cup” refers to the dual-cup design without a flanged component.

Table 1: Range of Motion and Implant Design

P-value refers to ANOVA test

The motion of the 32+4 mm control is reported. Additional implant motions are reported relative to the 32+4 mm control. *statistically significant difference from 32+4 mm control; ¥statistically significant difference from 36+6 mm control

Table 2: Modes of Impingement and Implant Design

1 = Humeral bone or implant on bone; 2 = Humeral bone or implant on soft tissue; 3 = component max without true impingement

Table 1: Range of Motion and Implant Design

	32+4 mm Control	32 mm Dual-Cup	32 mm Dual-Cup with Flange	36+6 mm Control	
IR, neutral (degrees)	23.87 ± 6.10	11.53 ± 14.94¥	9.4 ± 8.58¥	1.6 ± 10.23	P = 0.014
ER, neutral (degrees)	44.67 ± 17.03	20.93 ± 12.99*	5.93 ± 11.75¥	10 ± 5.91*	P < 0.001
IR, 45° abduction (degrees)	36.6 ± 17.37	4.67 ± 11.20	-0.07 ± 7.31	4.93 ± 9.83	P = 0.60
ER, 45° abduction (degrees)	95.53 ± 12.35	4.47 ± 5.68¥	3.33 ± 8.33	-2.93 ± 8.47*	P = 0.004
IR, 90° abduction (degrees)	-11.73 ± 18.73	8.27 ± 13.28	9.13 ± 10.61	8.86 ± 9.93	P = 0.036
ER, 90° abduction (degrees)	89.33 ± 23.44	11.93 ± 13.87¥	7.73 ± 14.94	1.07 ± 18.41	P = 0.037
Maximum Abduction (degrees)	66.13 ± 19.45	15.53 ± 19.4	8.93 ± 11.91	4.93 ± 18.34	P = 0.10
Functional Internal Rotation (degrees)	55.07 ± 28.44	12.40 ± 15.94¥	2.67 ± 19.05	0.01 ± 27.60	P = 0.057

P-value refers to ANOVA test

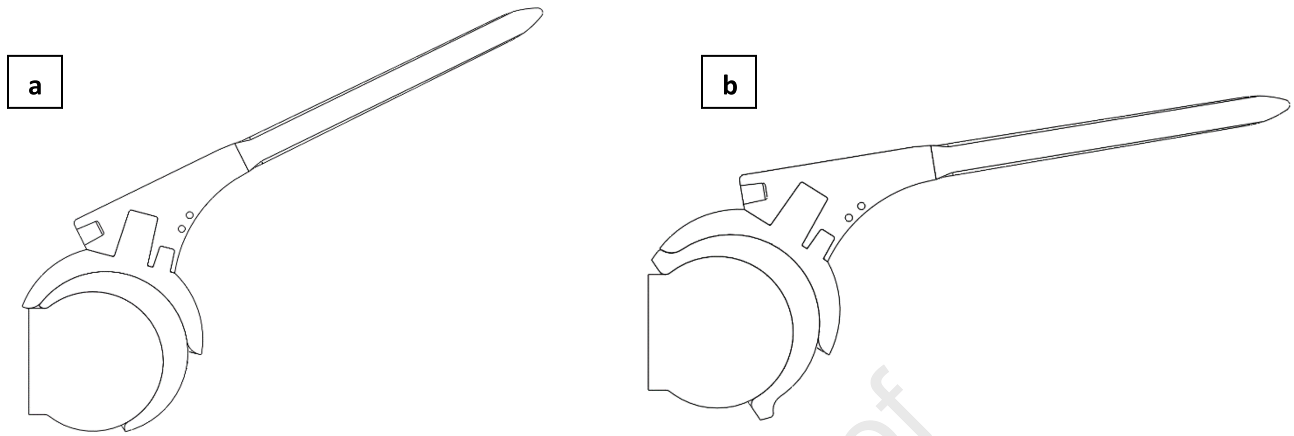
*statistically significant difference from 32+4 mm control; ¥statistically significant difference from 36+6 mm control

Table 2: Modes of Impingement and Implant Design

	32+4 mm Control	32 mm Dual-Cup *without* Flange	32 mm Dual-Cup *with* Flange	36+6 mm Control
IR, neutral	1	1 (2 in one case)	3	1 (2 in one case)
ER, neutral	1	1	3	1
IR, 45° abduction	1 (2 in one case)	1 (2 in one case)	1 (2 or 3 in one case each), **coracoid**	2 (1 in two cases)
ER, 45° abduction	1	1	3	1
IR, 90° abduction	1	1	1, **coracoid**	1, (2 in one case)
ER, 90° abduction	1	1	1 (2 in one case), **acromion**	1
Maximum Abduction	1	1	1 (3 in two cases), **acromion**	1
Functional Internal Rotation	1 (2 in one case)	2 (1 in one case)	1 (2 in two cases), **acromion**	1, (2 in one case)

1 = Humeral bone or implant on bone; 2 = Humeral bone or implant on soft tissue; 3 = component max without true impingement

Figure 1: Dual Cup Reverse Shoulder Arthroplasty Design

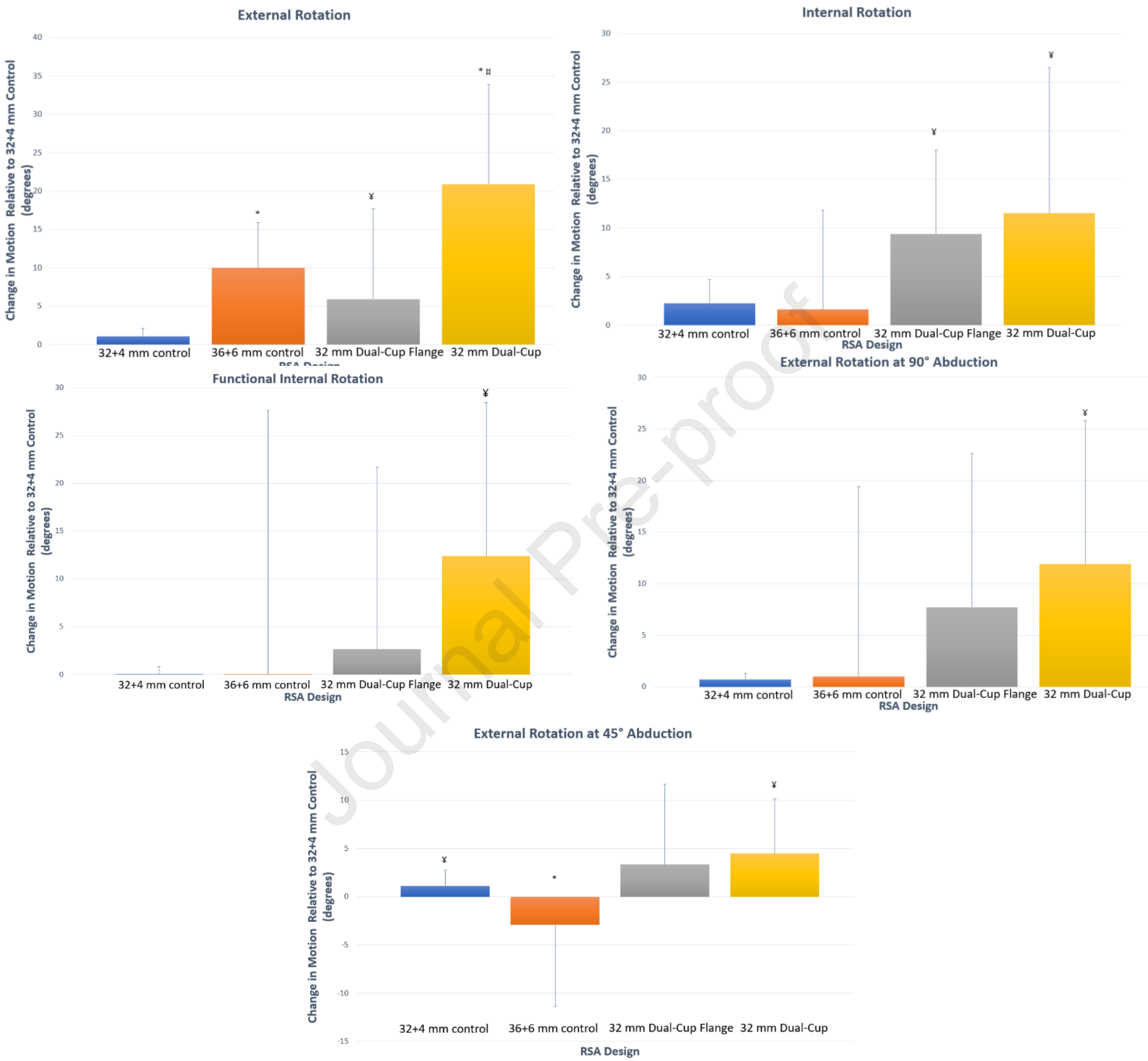


a) Dual-cup without flange; **b)** Dual-cup with flange

Figure 2: Cadaveric Model

Cadaveric models with superficial tissue dissected and a posterior window created to allow assessment of impingement. The arm-holder is demonstrated. The electromagnetic sensor was placed at the deltoid tuberosity.

Figure 3: Implant Motion Comparison



Comparison of the motion of various RSA implants. “32 mm Dual-Cup” refers to the dual-cup design without a flanged component.

<u>Conflict of interest statement</u>

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This author, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article

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This author, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article

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This author, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article

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Disclosures:

The authors do have a patent pending for a dual-cup RSA design. Application number: PCT/US2021/014396.

Funding

No external funding or grants were received in support of this work.