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In vivo volumetric and linear wear measurement of reverse shoulder arthroplasty at minimum 5-year follow-up

Madeleine L. Van de Kleut, BMSc[a,b,c], George S. Athwal, MD, FRCSC[c,d], Kenneth J. Faber, MD, MHPE, FRCSC[c,d], Matthew G. Teeter, PhD[a,c,d,e,*]

[a]*Imaging Research Laboratories, Robarts Research Institute, Schulich School of Medicine and Dentistry, Western University, London, ON, Canada*
[b]*School of Biomedical Engineering, Western University, London, ON, Canada*
[c]*Lawson Health Research Institute, London, ON, Canada*
[d]*Division of Orthopaedic Surgery, Department of Surgery, Schulich School of Medicine and Dentistry, Western University, London, ON, Canada*
[e]*Department of Medical Biophysics, Schulich School of Medicine and Dentistry, Western University, London, ON, Canada*

Background: Reverse shoulder arthroplasty is quickly becoming the most frequently performed glenohumeral joint replacement. The purpose of this study was to evaluate the volumetric and linear wear rates of ultrahigh-molecular-weight polyethylene humeral liners in vivo at a minimum 5-year follow-up.
Methods: Radiostereometric analysis was used to image 15 patients at terminal range of motion in forward flexion, abduction, external rotation, and internal rotation and with the arm at the side. The relative position and orientation of the glenosphere and polyethylene were identified for each arm position. The apparent intersection of the glenosphere into the polyethylene was recorded as wear. Mean volumetric and linear wear rates were recorded, and Pearson correlation coefficients were applied to the 36-mm liners to assess the relationship between the wear rate and term of service.
Results: The mean reverse shoulder arthroplasty term of service at the time of imaging was 8 ± 1 years (range, 6-11 years). The mean volumetric and linear wear rates for the 36-mm liners (n = 13) were 42 ± 22 mm^3/yr ($r = 0.688$, $P = .009$) and 0.11 ± 0.03 mm/yr ($r = 0.767$, $P = .002$), respectively. The mean volumetric and linear wear rates for the 42-mm liners (n = 2) were 114 ± 44 mm^3/yr and 0.17 ± 0.01 mm/yr, respectively. No single arm position was able to capture all recorded wear individually.
Conclusion: This study showed volumetric and linear wear rates of approximately 40 mm^3/yr and 0.1 mm/yr, respectively, for the 36-mm polyethylene liners. The 42-mm liners showed higher wear rates, although a greater number of subjects is required for conclusive results. In vivo wear of reverse total shoulder arthroplasty is multidirectional and perceptible.
Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Reverse shoulder arthroplasty; polyethylene wear; radiostereometric analysis; ultrahigh-molecular-weight polyethylene; cuff tear arthropathy; shoulder replacement; survivability

Reverse shoulder arthroplasty (RSA) is an established surgical solution for patients with a number of shoulder pathologies. Although RSA was historically used as a salvage procedure for massive irreparable rotator cuff disease,

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*Reprint requests: Matthew G. Teeter, PhD, London Health Sciences Center, 339 Windermere Road, London, ON N6A 5A5, Canada.
E-mail address: matthew.teeter@lhsc.on.ca (M.G. Teeter).

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indications have expanded to include revision arthroplasty, care of acute fractures and their sequelae, glenohumeral instability, severe glenoid bone wear, and rheumatoid arthritis.[2,25,36,38] In response to a growing number of indications, the increased demand for active lifestyles by an older population, and good short- to mid-term clinical outcomes, RSA has shown exponential growth in the past decade and is predicted to become the most frequently performed glenohumeral replacement procedure.[5,27,29]

Excessive polyethylene (PE) wear that creates particulate debris and can induce osteolysis has been identified as a cause of aseptic implant loosening in the hip and knee literature.[28,37] Modern artificial hips and knees typically use highly cross-linked PE, with superior wear properties compared with its ultrahigh-molecular-weight counterpart, to mitigate the risk of osteolysis and implant loosening.[1,11,13,34] Despite the proven efficacy of highly cross-linked PE, however, ultrahigh-molecular-weight PE remains the current standard for RSA.

Simulation and retrieval studies have shown that abrasive wear of the RSA PE is common,[3,15,18,23,24,31,33,35] with the reverse shoulder experiencing loads of up to 0.7 body weight during abduction and a duty cycle of approximately 0.75 million cycles (MC) per year.[9,17,19] At present, to our knowledge, no studies have investigated in vivo wear rates of the RSA PE-bearing surface, and as these joint replacements age, it is important to understand their mid- to long-term behavior.

Model-based radiostereometric analysis is a calibrated dual-plane radiographic technique used to identify the 3-dimensional (3D) position and orientation of implants in space. Given the relative position and orientation of total joint components, penetration into the PE liner can be measured. This technique has previously been used to quantify 3D PE wear in the knee and hip with submillimeter accuracy, providing a more complete assessment of PE wear than 2-dimensional clinical radiographs.[6,7,10,26] The purpose of our study was to measure the in vivo volumetric and linear wear rates of the RSA PE using model-based radiostereometric analysis.

Materials and methods

Patient recruitment

This was a prospective case series. A medical chart review was completed to identify potential participants. The inclusion criteria were patients with the Aequalis Reversed II shoulder system (Wright Medical–Tornier Group, Bloomington, MN, USA), patients with a term of service greater than 5 years, and patients willing to travel to the radiostereometric laboratory for a specific series of radiographs. All procedures were performed by 1 of 2 board-certified orthopedic surgeons (G.S.A. or K.J.F.) between January 2008 and January 2013. Patients were excluded if they lived greater than 200 km from the study center, were deceased, were pregnant, were unable to read or write English, or were unable to provide informed consent because of cognitive decline. Initially, 95 patients who fit the inclusion criteria were identified. Of these, 59 were excluded prior to recruitment because of the distance from the study center or because they were deceased. In addition, 13 refused to participate (9 because of poor health and 4 because of the distance) and 8 were unable to be reached, leaving 15 patients who provided written informed consent.

Clinical and radiographic outcomes

In addition to radiostereometric imaging, patients were asked to complete the American Shoulder and Elbow Surgeons score and to rate their Subjective Shoulder Value, as well as their pain from 0-10. Active forward elevation, lateral abduction, and external rotation in adduction were measured using a handheld long-arm goniometer. Internal rotation was recorded as the highest point along the spine with the thumb pointing upward. One surgeon (G.S.A.) assessed scapular notching on the most recent anterior-posterior radiographs based on the grading system of Sirveaux et al.[30]

Imaging

Study imaging was completed from November 2018 through July 2019. Radiostereometric analysis examinations were performed with the patient sitting in front of a uniplanar calibration cage (Cage 43; RSA Biomedical, Umea, Sweden). To assess multivector PE wear patterns, exposures were taken at the limits of patients' active range of motion: in external rotation with the arm at the side, in internal rotation with the thumb extended upward along the spine, in lateral abduction, in forward elevation, and in a neutral position with the arm at the side (adduction).

To reduce the effect of potential joint distraction, patients were asked to hold a 2.3-kg weight during the neutral examination. The weight was not used during the other 4 examinations so as not to limit patients' range of motion. Radiograph energies were optimized for contrast while maintaining the "as low as reasonably achievable" principle in each patient, ranging from 8.0 to 16.0 mAs with 90 kVp.

Radiostereometric images were analyzed using commercial model-based radiostereometric analysis software (RSACore, Leiden, The Netherlands). Computer-aided design (CAD) models of the glenosphere and stem were provided by the manufacturer (Wright Medical–Tornier Group) and converted to 3D virtual surface models. Each surface model was aligned to its respective implant contour in the model-based radiostereometric analysis environment, and its global transformation matrix was recorded (Fig. 1).

Wear analysis

Our wear measurement methodology has previously been validated in vitro and was used for this in vivo assessment.[14] The CAD model of the appropriately sized PE liner was virtually inserted into the CAD model of the stem using Geomagic Studio (3D Systems, Morrisville, NC, USA). A notch on the PE corresponding to a protrusion on the stem model ensured the virtually inserted PE was in the correct orientation.

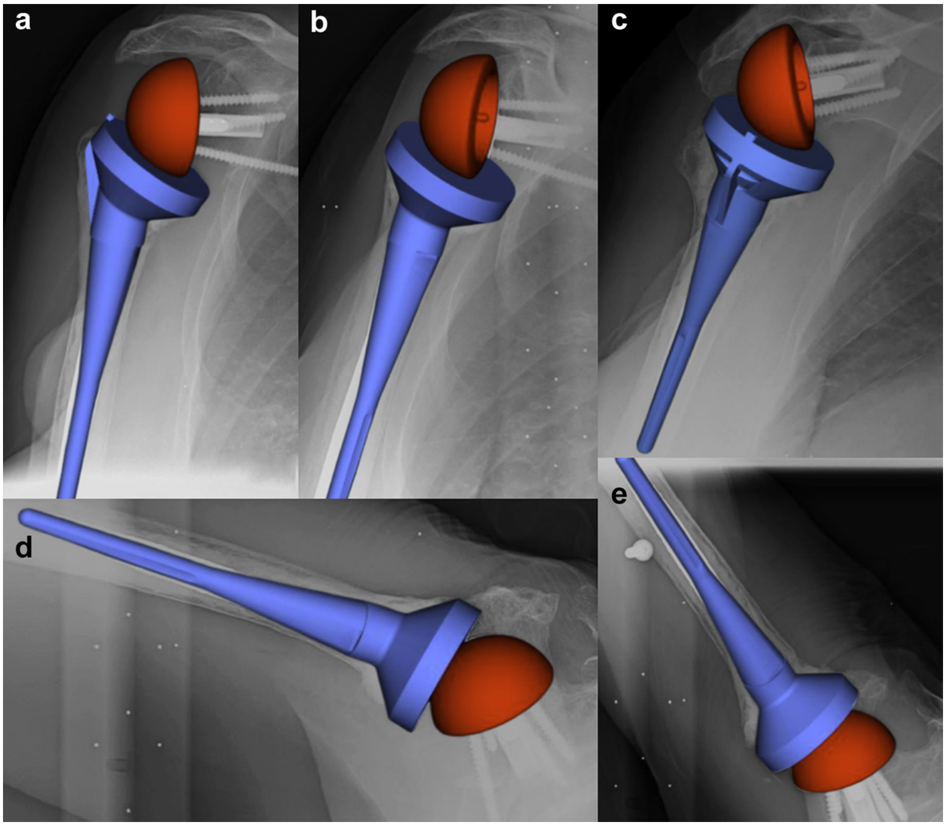

Figure 1 Alignment of glenosphere (*red*) and stem (*blue*) in neutral (**a**), external rotation (**b**), internal rotation (**c**), lateral abduction (**d**), and forward elevation (**e**) arm positions using model-based radiostereometric analysis.

A separate, previously validated software program, built in house, applied the transformations recorded from the model-based radiostereometric analysis software to the glenosphere and PE models at each arm position.[32] The PE model was then discretized into isometric voxels of 0.075 mm in length, with apparent intersection of the glenosphere into the PE recorded as wear. Each voxel intersection was added to the cumulative wear measurement, although intersections of the same voxel from different arm positions were only recorded once to eliminate overestimation. Maximum linear wear depth was measured as the largest surface normal from the PE surface to the intersected voxel. A wear map example is illustrated in Figure 2.

Statistical analysis

PE liners with different diameters were assessed independently. Statistical analysis was not applied to the 42-mm liners because of the small sample size (n = 2). Volumetric and linear wear rates were recorded as mean ± standard deviation. Pearson correlation coefficients were determined for volumetric and linear wear of the 36-mm liners to assess respective relationships with the term of service.

To spatially quantify volumetric and linear wear rates, each PE model was symmetrically divided into its superior, inferior, anterior, and posterior quadrants. The D'Agostino-Pearson test was used to assess normality. A 1-way analysis of variance with the Tukey post hoc test for normally distributed data, as well as the Kruskal-Wallis test with the Dunn test for multiple comparisons for non–normally distributed data, was applied to volumetric and linear wear data independently to determine any difference in wear rate between quadrants.

A 1-way analysis of variance with the Tukey post hoc test was applied to determine any differences in the proportion of observed wear from each independent arm position to the total wear volume, and separately, the Kruskal-Wallis test with the Dunn test for multiple comparisons was applied to determine whether certain arm positions contribute to wear in specific quadrants. Statistical significance was set at $P < .05$.

Results

The mean term of service at the time of study imaging was 8 ± 1 years (range, 6-11 years). Patient demographic characteristics are reported in Table I. The mean American Shoulder and Elbow Surgeons score was 77 ± 21; pain score, 1.5 ± 2.3; and Subjective Shoulder Value, 74 ± 19. Mean active forward elevation was 110° ± 18°; lateral abduction, 95° ± 20°; external rotation, 31° ± 18°; and internal rotation, to the posterior waist. Five patients had evidence of grade 1 or 2 scapular notching.

Implant survival analysis from the 95 potential participants indicated a 96.6% survival rate at 10 years postoperatively (Fig. 3). Three components were revised for

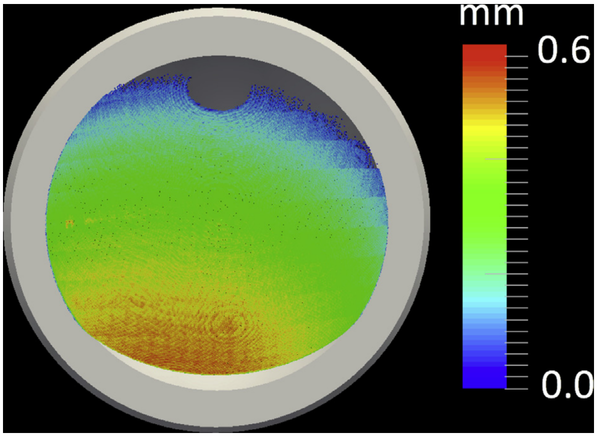

Figure 2 Wear map from neutral arm position (subject No. 07). Linear wear depth is visualized by the color bar, measured in millimeters. The unworn semicircle in the superior quadrant of the liner is the location of the glenosphere screw hole at the time of imaging.

instability, with stability achieved by exchanging PE liners and glenospheres for a larger size. Revisions occurred within 18 months postoperatively.

For the 36-mm PE liners, the mean volumetric and linear wear rates were 42 ± 22 mm^3/yr (r = 0.688, P = .009) and 0.11 ± 0.03 mm/yr (r = 0.767, P = .002), respectively (Fig. 4). There were no significant differences in wear rates between quadrants for these liners (Table II).

For the 2 subjects with the 42-mm liners, the mean volumetric wear rate was 114 ± 44 mm^3/yr and the mean linear wear rate was 0.17 ± 0.01 mm/yr. Average wear rates for each quadrant are recorded in Table III, but again, no statistical analysis was applied.

No significant differences were found in terms of the observed wear from each arm position as a percentage of the total wear volume (Table IV). Similarly, we noted no significant differences when comparing different arm positions and their contributions to wear in different quadrants (neutral, P = .294; external rotation, P = .616; internal rotation, P = .839; lateral abduction, P = .783; and forward flexion, P = .809).

Discussion

The purpose of this study was to investigate the in vivo wear rates of ultrahigh-molecular-weight PE in the reverse shoulder. Although a number of in vitro and in silico studies have simulated RSA wear patterns, there is a lack of biomechanically established test protocols and apparatuses that mimic in vivo loading and muscle tensioning. Consequently, the results of these simulations are variable, with wear rates ranging from 14.3 mm^3/MC to 126 mm^3/MC.[3,15,18,24,31,33,35] Using a mathematical model, Terrier et al[33] conducted a simulation study on the Aequalis Reversed II system and estimated volumetric wear of 44.6 mm^3 and linear wear of 0.13 mm after 1 year of simulated activity for the 36-mm PE. The in vivo mean volumetric (42 ± 22 mm^3/yr) and linear (0.11 ± 0.03 mm/yr) wear rates of the 36-mm PE presented in our study are similar to wear rates reported in simulation studies and show a strong correlation between both volumetric and linear wear and the term of service.

The osteolytic threshold for linear wear in the hip is set at approximately 0.1 mm/yr,[8] reinforcing the notion that with an average wear rate of 0.11 mm/yr for 36-mm PE liners and 0.17 mm/yr for 42-mm liners, RSA wear is clinically significant. No patient in our study, however, illustrated humeral stem or glenosphere loosening, suggesting that the observed wear rates are clinically acceptable in the short term.

The results for the 42-mm PE liners must be interpreted cautiously because only 2 patients were assessed, although both patients had wear rates of approximately double the 36-mm averages. It has been established in the hip literature that although a larger femoral head size increases volumetric wear, it decreases linear wear by reducing the contact stress transmitted through the femoral head.[22] This observation was recently supported by an in vitro study comparing the wear rates of 32- and 40-mm glenospheres in RSA.[12] Our results challenge these findings, as both volumetric and linear wear rates were higher with the 42-mm glenosphere-PE combination, and further investigation with a greater number of subjects is merited. Neither patient with a 42-mm liner had evidence of component loosening or scapular notching.

The volumetric and linear wear rates of the 36-mm PE liners with evidence of notching (n = 5) vs. those without notching (n = 8) were similar, at 47 mm^3/yr and 0.12 mm/yr, respectively, vs. 40 mm^3/yr and 0.11 mm/yr, respectively. As there were no incidences of grade 3 or 4 notching, we cannot make any conclusions about PE wear and its effect on the biological response in high notching cases.

It is interesting to note that there was no significant difference in the volumetric or linear wear rate between quadrants. The Aequalis Reversed II system has a 155° neck-shaft angle, measured as the angle between the long axis of the humeral stem and the perpendicular to the metaphyseal tray inclination line. More modern reverse shoulder designs, with a neck-shaft angle of 145° or 135°, aim to minimize abutment of the PE with the lateral pillar of the scapula. Compared with reverse shoulders with a lower neck-shaft angle, a 155° neck-shaft angle places the contact of the glenosphere within the PE equally between quadrants rather than more inferiorly at low abduction angles when the same glenosphere positioning is used.[20] Further studies ought to compare the effects of the neck-shaft angle on wear, as this variable may change the observed wear patterns.

Table I Patient demographic characteristics

Subject No.	Age at surgery, yr	Sex	Indication	Term of service at time of imaging, yr	PE diameter + offset, mm	BIO-RSA (1, yes; 0, no)	Scapular notching (grade 0-4)	Volumetric wear rate, mm^3/yr	Maximum linear wear rate, mm/yr
01	72	F	CTA	6.2	36 + 6	1	0	32.1	0.10
02	74	F	CTA	6.7	36 + 6	1	1	40.6	0.08
03	75	F	OA + RCT	6.8	36 + 6	1	0	39.3	0.09
04	78	F	CTA	6.8	36 + 6	1	0	23.8	0.11
05	62	F	PT OA	9.5	36 + 6	0	1	54.3	0.13
06	66	F	RA	9.2	36 + 6	0	2	31.4	0.10
07	68	F	PT OA	7.4	36 + 6	1	1	40.7	0.10
08	75	F	CTA	7.7	36 + 9	0	0	20.6	0.11
09	71	F	PT OA	10.5	36 + 9	0	0	94.4	0.16
10	59	M	CTA	6.9	36 + 9	1	0	58.5	0.12
11	60	M	CTA	6.5	36 + 9	1	2	66.6	0.17
12	69	M	CTA	7.1	36 + 9	1	0	7.4	0.10
13	69	M	CTA	9.0	36 + 9	1	0	41.8	0.09
14	87	M	CTA	6.5	42 + 6	1	0	144.6	0.18
15	72	M	CTA	6.9	42 + 9	1	0	83.0	0.16

PE, polyethylene; *BIO-RSA*, Bony Increased-Offset Reverse Shoulder Arthroplasty; *F*, female; *M*, male; *CTA*, cuff tear arthropathy; *OA*, osteoarthritis; *RCT*, rotator cuff tear; *PT*, post-traumatic; *RA*, rheumatoid arthritis.

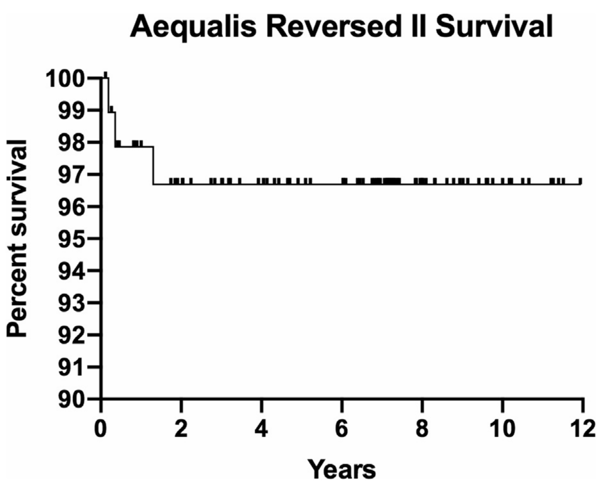

Figure 3 Survivorship of Aequalis Reversed II implant system.

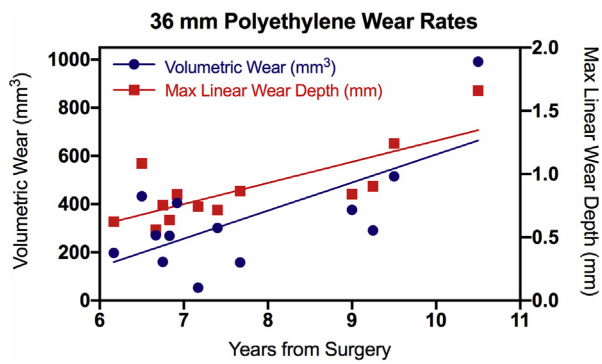

Figure 4 Volumetric (■) and linear (●) wear measurements for each 36-mm polyethylene liner. *Max*, maximum.

The wear recorded from different arm positions was distributed among quadrants for individual arm positions, and no single arm position was capable of capturing all recorded wear. This finding is important because it emphasizes that RSA wear is multidirectional, and multiple wear vectors are associated with different activities of daily living. Fluoroscopic imaging of a patient's full range of motion may provide a more complete representation of such wear vectors.

There are a number of limitations to this study. We do not have postoperative baseline measurements of these patients, which would allow for the calculation of bias. Our method also does not distinguish between creep and wear of the PE liner. In future studies, prospective imaging following surgery would allow for a measure of bias, and imaging between 6 months and 1 year would likely provide a measure of creep. Furthermore, although we used muscle contraction to minimize joint distraction, we had no way to ensure that the articulating components were contacting each other for all arm positions, and this may have underestimated the recorded wear rates.

The imaging technique is not capable of identifying extra-articular wear, and for this reason, it is incapable of quantifying PE damage due to scapular notching. Retrieval analysis has highlighted that damage to the inferior rim is common,[4,16,21,23] and although only 33% of our cases had evidence of low-grade notching, it is still likely that being unable to record this may have underestimated the total PE volume loss.

The proposed measurement method relies on the use of either CAD or reverse-engineered models of the implants

Table II Quadrant analysis of 36-mm-diameter polyethylene liners

	Mean ± SD (n = 13)				P value
	Superior	Inferior	Anterior	Posterior	
% of total wear volume	22 ± 13	27 ± 22	28 ± 17	23 ± 15	.743
Volumetric wear rate, mm^3/yr	10 ± 8	11 ± 8	13 ± 9	10 ± 5	.866
Linear wear rate, mm/yr	0.09 ± 0.04	0.10 ± 0.03	0.10 ± 0.04	0.09 ± 0.03	.947

SD, standard deviation.

Table III Quadrant analysis of 42-mm-diameter polyethylene liners

	Mean ± SD (n = 2)			
	Superior	Inferior	Anterior	Posterior
% of total wear volume	15 ± 11	33 ± 14	30 ± 1	22 ± 4
Volumetric wear rate, mm^3/yr	19 ± 18	35 ± 1	34 ± 12	26 ± 15
Linear wear rate, mm/yr	0.12 ± 0.06	0.17 ± 0.01	0.16 ± 0.02	0.13 ± 0.05

SD, standard deviation.

Table IV Observed wear volume as percentage of total wear volume from each arm position

	Observed volume as % of total volume, mean ± SD					P value
	Neutral	External rotation	Internal rotation	Lateral abduction	Forward elevation	
36 mm (n = 13)	51 ± 33	55 ± 25	32 ± 22	40 ± 26	40 ± 31	.242
42 mm (n = 2)	39 ± 1	45 ± 3	45 ± 50	57 ± 27	57 ± 18	NA

SD, standard deviation; *NA*, not applicable.

and liners under investigation. Implant manufacturers may be hesitant to provide such models, limiting the widespread use of this technique. Finally, we did not correlate the wear rate with clinical function and pain because of our small sample size. We encourage future studies with larger numbers to assess any relationships between these parameters.

Despite these limitations, we have presented the first study investigating the in vivo wear rates of the reverse shoulder. Our preliminary results have shown that in vivo RSA wear is appreciable and that further studies with different RSA designs, different PE preparations, increased patient numbers, and longer terms of service (10-15 years) are required.

Conclusion

This in vivo study showed a volumetric wear rate of approximately 40 mm^3/yr and linear wear rate of approximately 0.1 mm/yr for the 36-mm PE liners. The 42-mm liners showed higher volumetric and linear wear rates, although a greater number of subjects is required for conclusive results. In vivo wear of reverse total shoulder arthroplasty is multidirectional and perceptible.

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