How Does Implant Wear Effect the Tissue Response in Reverse Total Arthroplasty?

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INTRODUCTION: Reverse total shoulder arthroplasties (rTSAs) were designed to address the problems associated with anatomic TSA (aTSA) patients with rotator cuff deficiency. While mid-term results have shown that rTSAs have improved patient reported outcomes, complications do persist, with aseptic loosening being among the main revision reasons. Another complication is scapular notching, first described by Sirveaux et al, which is a radiographic finding of a bony lesion in the scapular neck due to impingement of the medial side of the humeral polyethylene (PE) component against the inferior scapular neck and can lead PE wear and osteolysis [1]. Long-term complications due to particle-induced osteolysis have so far received little attention in TSA, but inflammatory tissue reactions to implant debris do occur [2]. Here we examine a series of retrieved rTSA designs to determine extent of implant damage and how it relates to notching, to characterize the nature of the corresponding periprosthetic tissue responses and how these may relate to implant loosening.

METHODS: RTSA components and periprosthetic tissues were consecutively retrieved from 44 patients. Implants revised for septic loosening (N=16) as well as revision rTSA cases (N=5) were excluded leaving a cohort of 23 primary implants (12 female, 11 male). Implants had been *in situ* for a mean of 2.93 years (0.2, 15.3) and were revised for aseptic loosening (n=14), instability (n=6), or pain with arthrosis (n=3). Implants were of 10 designs from 7 manufacturers. Implant damage was characterized by light microscopy. Metal bearing surfaces were graded 1-3 (mild, moderate, marked). Head/stem taper junction damage was graded 1-4 (minimal, mild, moderate, marked). An expanded grading scale was established to evaluate damage on polyethylene (PE) bearing surfaces accounting for 6 distinct wear features. A total score (maximum 14) was derived from the summation of the following: wear scar (0-4); polishing (yes=1); 3 pitting/embedded debris (0-3); rim damage (yes=1, excessive due to unintended contact=2); delamination (yes=1), and grooves/scratches (0-3). H&E-stained sections of periprosthetic soft tissues were evaluated using white and polarized light microscopy for the extent and type of cellular response. A semi-quantitative system was used to score (1=rare to 4=marked) the overall number of particle-laden macrophages, foreign body giant cells (FBGCs), lymphocytes, plasma cells, eosinophils, and neutrophils. Extent of metal, PE, bone cement and suture particles within histiocytes was scored (0=none visible to 3= ≥50% tissue involvement). Radiographs were examined to score for scapular notching using the Sirveaux classification (1 to 4 based on the size of the defect). Implant damage, radiographic analysis, histopathological patterns, and diagnosis of aseptic loosening were correlated using Spearman tests.

RESULTS: Generally, PE liners exhibited mainly polishing (Fig. 1A) and scratching. Delamination was rare, and the presence of embedded debris was less prominent than earlier reported for aTSA liners. Thirteen liners exhibited rim damage, of which 7 liners were scored as excessive because the rim damage extended into the bearing surface (Fig. 1B). The median PE wear score was 5 (1, 7). Metal bearing wear distribution was 25% mild, 56% moderate, 19% marked. Male and female taper damage was overall low with 47% and 31% minimal, 33% and 54% mild, and only 20% and 15% moderate. PE particles were observed in 91% of cases with 57% of the cases having >50% tissue involvement with abundant particles within macrophages and many larger shards of PE contained by FBGCs. Moderate to marked macrophage and FBGCs responses were observed in 87% and 78% of cases, respectively. The particle-laden macrophages tended to occur in broad sheets and contained metal, PE, bone cement and suture debris. Metal particles were seen in all but 2 cases with 6 cases having >50% tissue involvement and the tissue appearing blackened due to macrophages containing densely packed particles. Bone cement was seen in 44% cases and suture was observed in 78% cases. The Sirveaux classification scores were 0: N=11, 1: N=3, 2: N=2, 3: N=2, and 4: N=5. Spearman tests revealed that higher Sirveaux classifications correlated positively with more PE within tissue (p=.031) and the occurrence of rim damage (p=.002) and aseptic loosening (p=.028). Rim damage also correlated with larger presence of FBGCs (p=.0.009) and presence PE particles within tissue (p<.001). The macrophage response exhibited trends of positive correlation with the presence of PE (p=.056) and suture (p=.078) particles, but a negative correlation with PE bearing wear score (p=0.061). The PE bearing wear score was highest in cases with a Sirveaux score of 4 (p=.006). Cases diagnosed with aseptic loosening exhibited high metal bearing wear scores (p=.001). Neither PE nor metal bearing wear, nor taper damage scores nor tissue response scores correlated with time *in situ*.

DISCUSSION: This comprehensive rTSA retrieval analysis demonstrates many difficulties in correlating inflammatory tissue responses with implant wear and other periprosthetic factors such as Sirveaux classification. The results show a relationship between the severity of the FBGC presence and the presence of PE particles within tissue as well as overall PE bearing wear. This finding is in large part driven by the presence of large shards of PE, which was more likely in cases with rim damage. Rim damage was highly prevalent (57%) and was associated with higher Sirveaux class scores. The occurrence of FBGCs is in part also driven by the presence of large cement and suture particles in some cases. Interestingly, the macrophage response did not follow the same trends observed for FBGCs. It was independent of the PE particle presence within the tissue or that of other debris, and even exhibited a trend of negative correlation with the PE bearing wear score. There was also no relationship between the PE wear score and the presence of PE debris within tissue. These findings indicate the limitations in the assessment of PE wear severity. The humeral PE liner undergoes generally milder wear than an aTSA glenoid component. The predominant wear mode is sliding wear which corresponds with the predominant observation of polishing (Fig. 1A). Additionally, almost all liners are made from a crosslinked PE which is known to produce finer wear particles which were shown to have a higher osteolytic potential [3]. The combination of mild wear and smaller particles makes the histopathological evaluation difficult because fine PE particles cannot be seen under polarized light. Also, wear scores are generally low, even though a large amount of fine PE debris was likely released. Under the conditions of rim damage (Fig. 1B), larger particles are produced resulting in both more concerning appearing wear features and tissue scores (i.e., FBGC); however, the osteolytic potential of these particles is likely lower. Loosening in cases with rim damage is likely the result of mechanical factors due to the unintended mode of articulation than particle induced osteolysis. The higher metal bearing wear is likely a result of a loose implant and not the cause. Determining the cause of aseptic loosening in rTSA is difficult. While a Sirveaux classification is a clear indicator of aseptic loosening due to mechanical causes, the role of particle induced osteolysis remains unclear. A larger study cohort is needed to control the manifold patient, implant, and surgical positioning factors. Additionally, the presence of fine PE particles within periprosthetic tissues associated with seemingly low wearing PE components needs to be further investigated. Therefore, future work will utilize Fourier Transform Infrared Spectroscopic Imaging (FTIR-I), as previously reported in other implant systems [4], to detect fine intracellular PE debris that is not visible under polarized light. Finally, efforts have to be undertaken to quantify material loss from PE humeral liners. While the newly introduced PE bearing wear score is useful for a general damage assessment, it does not allow for the estimation of particle release of small PE particles.

SIGNIFICANCE/CLINICAL RELEVANCE: With the incidence of TSA surgery on the rise, it is imperative to understand the relationship between wear and corrosion of failed TSA prostheses and cellular reactions in the periprosthetic tissues. Aseptic loosening of rTSA can occur for several reasons. We need to rethink our tool kit for the implant and tissue retrieval analysis to allow for a correct assessment of the potential danger of particle induced osteolysis and ultimately enable maximum longevity of future implants.

REFERENCES: [1] Sirveaux et al, JBJS-Br, 2004, 86: 388-95; [2] Hall et al, Trans ORS, 2020, 45:2112; [3] Tipper et al, ASTM Int., 2006, 3(6):1-16; [4] Liu et al, Biotribol 2021, 26:100163

Figure 1 A) Distinct wear scar characterized by polishing, B) PE liner with severe rim damage and multiple other wear features.