J Shoulder Elbow Surg (2016) 25, 1041–1050

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

BASIC SCIENCE

Analysis of severely fractured glenoid components: clinical consequences of biomechanics, design, and materials selection on implant performance

CrossMark

Farzana Ansari, PhD[a,*], Taylor Lee[a], Louis Malito, MS[a], Audrey Martin, BS[b], Stephen B. Gunther, MD[c], Samuel Harmsen, MD[d], Tom R. Norris, MD[d], Mike Ries, MD[e], Douglas Van Citters, PhD[b], Lisa Pruitt, PhD[a]

[a]*Department of Mechanical Engineering, University of California, Berkeley, CA, USA*
[b]*Thayer School of Engineering, Dartmouth College, Hanover, NH, USA*
[c]*Department of Orthopaedic Surgery, Martha Jefferson Hospital, Charlottesville, CA, USA*
[d]*San Francisco Shoulder, Elbow & Hand Clinic, San Francisco, CA, USA*
[e]*Tahoe Fracture and Orthopaedic Clinic, Carson City, NV, USA*

Background: The longevity of total shoulder replacement is primarily limited by the performance of the ultrahigh-molecular-weight polyethylene (UHMWPE) glenoid component in vivo. Variations in glenoid design (conformity, thickness), biomechanics (joint kinematics), and UHMWPE material selection (sterilization, cross-linking) distinguish total shoulder replacements from hip and knee arthroplasty devices. These variables can lead to severe mechanical failures, including gross fracture.
Methods: Sixteen retrieved glenoids with severe fracture were analyzed. The explant cohort included 3 material groups (gamma-sterilized Hylamer; gamma-sterilized UHMWPE; and gas plasma–sterilized, remelted, highly cross-linked UHMWPE [HXL]) and a range of conformities (0- to 10-mm radial mismatch). Analysis included fractography (optical and scanning electron microscopy) and Fourier transform infrared spectroscopy for oxidative analysis.
Results: Fracture primarily occurred along the exterior rim for all 16 explants. Fourier transform infrared analysis and fractography revealed significant oxidative embrittlement for all gamma-sterilized glenoids. Fatigue striations and internal flaws were evident on the fracture surface of the HXL glenoid, with little oxidation detected.
Conclusions: Fracture initiated at the external rim of all devices. Elevated oxidation levels and visible material distortion for representative gamma-sterilized conventional and Hylamer devices suggest oxidative embrittlement as a driving force for crack inception and subsequent fracture. Brittle fracture of the

No Institutional Review Board approval was obtained for this study because it is limited to retrospective assessment of retrieved implants that were de-identified and provided to us with limited patient clinical data. Only age and time in vivo were recorded by the surgeon at time of revision and included in the packaged retrieved implant.

*Reprint requests: Farzana Ansari, PhD, 2121 Etcheverry Hall, Berkeley, CA 94709, USA.
E-mail address: ansari.farzana@gmail.com (F. Ansari).

http://dx.doi.org/10.1016/j.jse.2015.10.017

HXL glenoid resulted from a combination of elevated contact stress due to a nonconforming surface, an internal flaw, and reduced resistance to fatigue crack growth. This demonstrates that glenoid fracture associated with oxidation has not been eliminated with the advent of modern materials (HXL) in the shoulder domain.

Level of evidence: Basic Science Study; Implant Retrieval Study

Keywords: Total shoulder arthroplasty; glenoid failure; glenoid fracture; UHMWPE fatigue fracture; UHMWPE fatigue wear; glenoid rim damage

Total shoulder replacement (TSR) is the third leading reconstructive orthopedic procedure behind hip and knee replacements and the fastest growing segment in the arthroplasty market.[17] TSRs, like most total hip and total knee replacements, are composed of a coupled synthetic bearing system involving an ultrahigh-molecular-weight polyethylene (UHMWPE) glenoid articulating against a cobalt-chrome (CoCr) humeral head. Even with similar material bearings as those used in hip and knee arthroplasty, TSRs encounter complex joint kinematics that have led to highly variable reasons for failure, such as implant loosening, shoulder joint instability, infection, periprosthetic fracture, implant wear, and device fracture.[11,12,57] The majority of TSR failures involve the UHMWPE glenoid component[11] and are associated with the high contact stresses experienced in vivo that are believed to be as high as those observed in tibial inserts of total knee replacement.[8,51,53]

Glenoid loosening remains the primary reason for failure, and this can be attributed to both component design and material composition. Conformity between the humeral head and glenoid in TSR remains a highly debated topic among researchers and clinicians, with recommendations from 0 to 10 mm in radial mismatch obtained through cadaver, clinical, and experimental studies.[1,4,19,29,31,41,52,55] Greater radial mismatch has been shown to increase the patient's range of translation and rotational motion, but it also increases contact surface stresses and may cause an increased risk of shoulder joint instability.[41,51] Conforming glenoids reduce local contact stresses, but they also increase the risk of edge loading and can lead to complex eccentric loading known as a "rocking horse" motion.[1,4,21,30] With limited available bone stock in the shoulder joint, fixation of the glenoid under such edge loading can be compromised.[4,10] Different fixation mechanisms for this UHMWPE component have been developed to address this issue, including multiple pegs, a single keel, a keeled titanium base plate ("metal backed"), and circumferentially inset glenoid implants.[4,22,24,32,50]

Material evolution of UHMWPE in the glenoid has largely mimicked the progressive developments in hip and knee replacements. Until the early 2000s, TSR manufacturing has predominantly incorporated conventional UHMWPE and Hylamer (UHMWPE with enhanced crystallinity obtained through elevated temperatures and pressures), both exposed to 25 to 40 kGy of gamma irradiation (sterilization). The cross-linking benefits of irradiation on improved wear resistance in hips and knees led to the recent introduction of highly cross-linked UHMWPE (HXL; 50-100 kGy) to shoulders, minimizing the liberation of wear debris that can lead to osteolysis and subsequent implant instability.[23,25,26] However, ionizing irradiation has also demonstrated a significant reduction in oxidative stability, fracture toughness, and fatigue crack propagation resistance.[6,45] Despite improvements in oxidative stability through oxygen-free sterilization environments and postirradiation heat treatments (such as remelting), instances of in vivo fracture remain a clinical challenge in cross-linked UHMWPE components, especially near complex design features in hips and knees that act as stress risers.[3,5,20,25,54]

The interplay of design and material composition in shoulders presents a distinct challenge from total knee and total hip replacement components. The small thickness of glenoids (<6 mm) and varying degree of nonconformity contribute to elevated stress at the bearing surface that approaches or exceeds the yield strength of UHMWPE.[8,51,52] Such cyclic stresses are manifested in fatigue damage on the surface of retrieved Hylamer and conventional UHMWPE glenoids in the form of delamination and pitting, akin to that seen on explanted tibial inserts of knees.[23,26,40,48] Eccentric loading (rocking horse motion) further exacerbates this stress state, and little is known about its particular effect on modern HXL glenoids. This work presents several instances of severe fracture in a collection of retrieved glenoids that span the evolution of TSR design and material variables during the past 20 years. We contend that modern HXL glenoid components are still at risk of catastrophic fracture in vivo in currently available TSRs.

Materials and methods

Clinical details

Sixteen explanted glenoid components (Table I) with catastrophic fractures were identified from a larger collection of 68 retrievals (Fig. 1). Catastrophic fracture was characterized by cracks traversing more than half the bearing surface (Fig. 1, *A, E*), disintegration of the glenoid into multiple smaller fragments (Fig. 1, *G, H, J, M, N*), fracture associated with severe wear-through (Fig. 1, *A, D, L, O*), obvious loss of original glenoid geometry (Fig. 1, *B, C, I, J, P*), or breakage across the inner bearing surface (Fig. 1, *F, K*).