Letters to the Editor

Safety Profile of Bioabsorbable Shoulder Anchors

To the Editor:

We read with interest the article in the March 2007 issue entitled "Biodegradable Shoulder Anchors Have Unique Modes of Failure"[1] by F. Alan Barber. In Dr. Barber's article, he describes two cases as "sentinel events" to alert the physician of loose and degraded bioabsorbable anchor products within the glenohumeral joint, both of which caused mechanical symptoms and pain. The article does acknowledge that the incidence of these problems is very low.

We would like to emphasize the rare nature of these cases and emphasize that while no implant is "risk-free," a suture-on-suture construct is likely to be the safest configuration available. This is especially true when considering the alternatives of metal anchors or bioabsorbable anchors with hard suture posts, which might fracture or be harmful to the joint if they are left proud. Rupp et al.[2] have shown that in addition to the concerns of metallic implants described by Barber,[1] the metallic eyelet–suture interface is much more abrasive than a bioabsorbable suture anchor. Historically, the abrasive relationship of suture on metal was fraught with suture failure, leading to frequent suture loose body formation, none of which has been reported or observed to be associated with chondral damage. Contemporary anchors constructed of absorbable material can take upwards of several years to initiate appreciable degradation. Thus, early macro-failure is more likely a result of technical issues relevant at the time of anchor insertion (i.e., insufficient anchor depth and anchor fragmentation at the time of insertion).

Extensive research has been conducted by independent laboratories on the degradation of bioabsorbable polymers as well as the eyelet-suture interface.[3-5] The BioSutureTak (Arthrex, Naples, FL), one of the two anchors discussed in Dr. Barber's case report, has demonstrated similar strength and failure load[3] at up to 12 weeks of soft tissue healing. Since 1999, more than 6 million Arthrex suture anchors constructed of suture-on-suture eyelet configurations have been implanted. To date, fewer than 10 events regarding the unique modes of failure have been documented for all manufacturers with the US Food and Drug Administration Medical Device Reporting Database. If Arthrex were the only manufacturer, 10 reports of 6 million would represent a 0.000167% rate of occurrence. Only two reports of any damage within the joint were filed, neither of which were Arthrex devices.

The tolerance of articular cartilage to suture can be traced back to Carter Rowe in the late 1970s, when open transosseous Bankart repair was routinely performed without incident. Contemporary suture tying techniques often utilize multiple stacked half-hitches at the level of the articular surface, which have also not been shown to result in articular cartilage damage. In comparison to a loose piece of suture eyelet, one would anticipate these fixation points to be far more imposing to articular surfaces, yet there are no case reports describing this phenomenon. A similar scenario of intra-articular suture knots is an all-inside meniscal repair. The self-locking knots used in this application are in direct contact with the femoral or tibial surfaces, yet no reports of articular cartilage damage have occurred. While the incidence of suture-eyelet failure is not known and likely to be very low, it has not been reported as being associated with early failure at the time of revision surgery. On the other hand, alternatives such as metal or absorbable anchors that are left proud at insertion or become proud postoperatively are associated with devastating chondral damage.

Contemporary anchors constructed of absorbable materials can take upwards of several years to degrade, and early softening or fracture is unlikely to occur, especially before 8 to 12 weeks where secure soft tissue healing has already occurred. Thus, the "cases for concern" that Dr. Barber presents may serve to highlight the technical issues with anchor placement rather than the inherent biomechanical properties of the anchor. When inserting bioabsorbable anchors, one should keep in mind the composition of the anchor as well as the suture–anchor construct properties. The interface between the suture and anchor has been studied extensively, and has consistently been shown not to be the weakest link in the repair construct; rather, the tissue–device interface and suture pullout from the tissue remain the weakest points of fixation. Angle and depth of insertion, as well as suture–eyelet orientation on the glenoid (especially with metallic anchors) has been associated with suture abrasion and early failure. Finally, at the time of implantation, it is plausible that, should the surgeon inadvertently fail to neutralize forces as the loop limb is tightened over the post limb, the suture eyelet can fail at the time of implantation. Even if unrecognized, it is far more likely that the small limb of suture would lodge in the axillary pouch or become embedded within soft tissue rather than be associated with articular cartilage damage. Compared to a bioabsorbable suture post, which might fragment and come loose during differential absorption, one might prefer a joint-friendly suture over a bioabsorbable fragment.

We feel that there are numerous advantages to bioabsorbable anchors in the glenoid over metallic anchors, and there

are few data to suggest that this report is anything more than a phenomenon relegated to an isolated or exceptionally rare event.

We look forward to seeing additional research in the area of bioabsorbable implants, but feel that the currently available bioabsorbable anchors have an exceptional clinical safety profile, with very few complications.

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Author's Reply

The letter from Drs. Cole and Provencher underscores many of the points made in the March 2007 article "Biodegradable Shoulder Anchors Have Unique Modes of Failure."[1] I agree that the incidence of problems caused by suture anchors is indeed very low. While no implant is "risk-free," biodegradable anchors have few reported problems and are associated with excellent clinical outcomes.[2,3] As both the letter and article point out, while repair construct failure can occur at the bone, anchor, suture, tendon, or any interface between these components, the suture–tissue interface is the weakest link in the repair construct. New suturing techniques have been developed to address this specific challenge.[4,5]

I agree that technical issues with suture anchor placement, rather than the inherent biomechanical material properties of the anchor, are more likely to result in clinically relevant concerns.[6,7] However, the material properties of any implant (whether an interference screw, plate, or suture anchor) must be fully appreciated by the surgeon so that the technique for using that device appropriately reflects these material limits.

Research has shown that a suture-on-suture anchor eyelet construct (as opposed to a conventional solid suture eyelet) certainly demonstrates consistent ultimate failure strength independent of bone age[8] and a consistent mode of failure: specifically, the suture eyelet pulling out of the body of the anchor[8] in the same manner as was described in one of the sentinel cases. Whether this eyelet type proves to be the "safest configuration available," as Drs. Cole and Provencher suggest, must await prospective outcome data. Based upon their extensive use, the wide variety of biodegradable anchors currently available,[9] and the low incidence of reported problems, it is hard to imagine that one suture eyelet type or any one anchor will demonstrate a clear superiority over the others.

The Arthrex anchor (Bio-SutureTak; Arthrex, Naples, FL) mentioned in the article was introduced in mid-2000. At its release, internal testing of the anchor by Arthrex found the failure strength to be approximately 40 pounds at time zero, decreasing to 27 pounds at 12 weeks. The mode of failure at time zero was a combination of eyelet breakage and suture-eyelet pullout, and at 12 weeks only suture-eyelet pullout (personal communication, Arthrex). While Bio-SutureTak utilization has been 8,000 a month over the years, by 2004 Arthrex received only 10 surgeon reports of failure by eyelet pullout. A revised anchor was introduced in June 2005 that maintained load to failure strength at approximately 40 pounds at 16 weeks, with no change in the degradation profile. No reports of suture eyelet pull out have been received by Arthrex for this revised anchor.

I agree with Drs. Cole and Provencher that intra-articular suture knots have a good track record and are not associated with articular cartilage damage, especially in meniscal repairs. As was pointed out, the arthroscopically tied intra-articular knots in these sentinel cases did not cause articular cartilage damage. However, comparing the low-profile knots of a meniscal repair device with standard shoulder arthroscopic knots does not consider the multiple half-hitches and larger profile of the latter. A more comparable meniscal repair knot (the Mulberry knot) has been associated with articular damage.[10] Every attempt should be made to keep suture material out of direct contact with the articular surfaces.

As the letter points out, the "cases for concern" highlight not only problematic areas related to the biodegradable materials used in suture anchors but also, as was mentioned in the article,[1] the "careful attention [that] must be given to the insertion technique and postoperative regimen." These include insertion angle, depth, eyelet orientation, and secure knot tying.[11]

To conclude, I agree with Drs. Cole and Provencher that biodegradable anchors perform very well, are associated with excellent outcomes,[2,4] and offer significant advantages and decreased risks over metallic anchors. As stated in the discussion section of the article "Complications associated with bioabsorbable shoulder anchors are extremely uncommon and