

anchors, there have been a total of 5 reported complaints (one of these was Dr. Kelly's case) out of a total of 405,550 BioCorkscrew suture anchors that have been sold, for an incidence of 0.00001%. This is an incredibly low incidence of complaints/complications.

With all of the potential technical and biologic factors that may have contributed to failure in Dr. Kelly's case report, it is absurd to blame it on "suture anchor failure." It is regrettable that a truly outstanding suture anchor would be condemned on the basis of a single case report with poorly formulated conclusions. The science that led to the development of the BioCorkscrew was methodical and meticulous, confirming its superior function both in vitro and in vivo. Because of its proven superior performance, I preferentially use BioCorkscrew suture anchors in my patients with rotator cuff tears.

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#### Author's Reply

Thank you for the opportunity to respond to Dr. Burkhart's letter. Firstly, I did not imply haste on the part of Arthrex (Naples, FL). I have a great deal of confidence in Arthrex products and use their anchors, interference screws, cannulas, pumps, and pump tubing exclusively.

My statement regarding in vivo testing of products is only meant to point out the difficulty of actually performing these studies and extrapolating the data to human use. The statement in no way condemns the methodology of Arthrex in development of their products.

The case report does not condemn the Biocorkscrew anchor, rather demonstrates a potential mode of failure of *all* biologic suture anchors. In my patient, an osteoporotic woman with a chronic rotator cuff tear, the rotator cuff repair failed. While I would have expected suture anchor pull-out as the most likely cause in this case of early failure, the primary cause was anchor failure at the suture loop. The only conclusion one can make is that the strength of the suture anchor at the islet was less than the strength of the bone-anchor interface, the suture-tendon interface, and the

knot. Therefore, the weakest link in my repair was the suture islet of the anchor, and this is where the repair failed. Had the suture anchor *not* failed, other technical and biologic factors *may* have led to eventual failure in another manner. I do not consider this an “absurd” conclusion.

Suture islet failure is described by the article quoted by Dr. Burkhart, DeJong et al.<sup>1</sup> In their *in vivo* goat study of the Biocorkscrew 5.0-mm anchor (Arthrex), they showed 1/13 (7.7%) failure by suture islet loop pull-out during testing at 6 weeks. The average force of failure was significantly lower, 74 N, than compared with a mean suture breakage failure force of approximately 195 N. The testing temperature of this temperature-dependent anchor was not stated.

Failure of rotator cuff repair is multifactorial. My case report demonstrates a potential mode of failure associated with biologic implants. The report correlates with the report of Meyer and Gerber,<sup>2</sup> in which the sutures pulled out of absorbable anchor islets in 3 patients treated with arthroscopic bankart repair. The subsequent report by Meyer et al.<sup>3</sup> offers a potential explanation for this mode of suture anchor failure. Dr. Burkhart stated that this mode “must be extremely rare.” I believe it may be underappreciated and should be considered in the development of suture anchors in the future.

Dr. Burkhart described my case report of having “poorly formulated conclusions.” The only conclusion made by me is that this repair failed by disintegration of the anchor at the suture islet, and this mode of failure should be considered when surgeons use biologic suture anchors. The reader may conclude for his or herself the accuracy of this statement by reviewing the photographs in the article.

Finally, 29% of single-tendon tears do not heal completely, and the failure to heal is associated with poorer strength.<sup>4</sup> This group of patients may offer us the greatest potential for improvement in our results, and, if we want to improve our results, we should elucidate those factors that may be associated with failure, rather than dismiss them.

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