Letters to the Editor

To the Editor:

I am writing this letter in reference to the case report by James D. Kelly II, MD, entitled "Disintegration of an Absorbable Rotator Cuff Anchor Six Weeks After Implantation," which was published in the April 2005 issue of *Arthroscopy*. I have some major concerns about this article and the assertions that the author made.

First of all, I have personally inserted more than 5,000 BioCorkscrew 5.0-mm suture anchors (Arthrex Inc, Naples, FL) in my patients, and I have never observed the phenomenon that Dr. Kelly attributes to this implant—namely pull-out of the eyelet from premature degradation of the biodegradable anchor. If it occurs, it must be extremely rare.

Unfortunately, the author concludes that the failure of his patient's repair was the fault of the anchor, and other potential causes of failure (technical errors, patient selection, poor biologic potential for healing, aggressive early rehabilitation) are not even discussed in this report.

Dr. Kelly states that manufacturers "have developed new anchors rapidly" in response to surgeon demand, and that "the speed at which these anchors reach the patients, exceeds our ability to test the anchors in vivo."

Unfortunately, Dr. Kelly's statements imply that manufacturers, in their haste to bring new products to the marketplace, do not adequately test their products before releasing them. In the case of the Arthrex BioCorkscrew, nothing could be further from the truth.

As the first surgeon to use the Food and Drug Administration–approved BioCorkscrew suture anchors, I had access to the voluminous data that was generated in the development of this implant. Contrary to Dr. Kelly's implications, Arthrex took every precaution to test all the variables that might affect the BioCorkscrew's performance. First of all, the implant's specific PLA copolymer was engineered to provide largely amorphous degradation characteristics combined with strength characteristics to resist maximal theoretical tensile loads generated by the rotator cuff (as based on an accepted cross-sectional area model). Next, pull-out force measurements and degradation variables (mass changes, molecular weight loss) were studied at an independent laboratory (Rice University, Houston, TX) sequentially over time by means of a proprietary in vitro degradation protocol that is widely accepted as predictive of in vivo behavior. Finally in vivo animal studies performed by Arthrex and by independent researchers[1] confirmed the safety and efficacy of the BioCorkscrew anchor.

My opinion, based on my prior research and publications,[2,3] as well as this anchor's outstanding performance in more than 5,000 BioCorkscrews that I have personally implanted, is that the BioCorkscrew suture anchor is exceptionally safe and effective. Ongoing quality assurance by Arthrex ensures that these high performance standards are maintained. Arthrex maintains a registry for complaints/complications related to its products. For BioCorkscrew

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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REFERENCES

1. DeJong ES, DeBerardino TM, Brooks DE, Judson K. In vivo comparison of a metal versus a biodegradable suture anchor. *Arthroscopy* 2004;20:511-516.
2. Athanasiou KA, Agrawal M, Barber FA, Burkhart SS. Current concepts: Orthopaedic applications for PLA-PGA biodegradable polymers. *Arthroscopy* 1998;14:726-737.
3. Burkhart SS. The evolution of clinical applications of biodegradable implants in arthroscopic surgery. *Biomaterials* 2000;21:2631-2634.

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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