Searching for Ways to Enhance Tendon Healing in Revision Rotator Cuff Surgery: Letter to the Editor

Dear Editor:

We read with great interest the recent prospective study analyzing the effectiveness of the Regeneten Bioinductive Implant (Smith & Nephew) in revision surgery. Specifically, in their article "Revision Rotator Cuff Repair With Versus Without an Arthroscopically Inserted Onlay Bioinductive Implant in Workers' Compensation Patients," Ting et al[8] evaluated the retear rate and clinical outcomes of patients who underwent revision rotator cuff repair (RCR) augmented with this bioinductive implant. These patients were match-paired according to age and tear size with a cohort of patients in whom the bioinductive implant was not added. The authors demonstrated no differences in repair integrity or clinical outcomes between patients who underwent revision RCR with versus without the bioinductive implant.

Rotator cuff tears (RCTs) are common injuries affecting around 50% of patients older than 60 years.[7] As the volume of RCT surgery goes up, the volume of RCR failure goes up as well, and with that comes revision surgery.[2] When we consider RCR failure, there are so many factors at play[3]—patient age, comorbidities such as hypothyroidism and diabetes, tear size, tendon quality, fatty infiltration or atrophy, surgical technique, and so forth. No matter whether RCT repair techniques have been optimized, the rerupture rate is still as high as 20%[1] (which may be even greater in revision cases[6]), suggesting that other factors, such as an unfavorable biological environment, may prevent the cuff from healing. Recently, attempting to help biology, augmentation of the repair with a bovine bioinductive collagen scaffold has been described. Successful clinical outcomes and healing rates in the treatment of partial, full-thickness, and massive tears have been demonstrated.[5] However, there is a paucity of studies evaluating the results of the patch in revision surgery. Given the low intrinsic healing potential of tendon tissue in the setting of a rotator cuff retear, revision surgery seems to be the ideal scenario for using the collagen patch.

That is why we find the study presented by Ting et al[8] relevant. And, certainly, to genuinely assess the device's effectiveness, the results should be compared with a homogeneous population that did not receive the patch. The authors should be commended for their efforts at improving patient selection and finding 2 homogeneous populations for the comparison. However, only age and tear size were considered in the matching process, and parameters such as obesity, diabetes, smoking, and so forth, also considered potential nonhealing risk factors, were not. There may be potential bias of the cohorts in that those potential risk factors were not included in the matching process. And what about cuff fatty infiltration or atrophy? Both parameters are associated with a negative prognosis of surgical repair, but they were not included in the matching process and were not even assessed.

This is our primary reason for considering the use of ultrasound for the assessment of retears lacking. We are aware that ultrasound has developed into an accepted tool for evaluating RCTs and that its use has risen sharply in recent years, but it still does not replace magnetic resonance imaging (MRI) as the gold standard. In fact, when analyzing muscle atrophy and infiltration, agreement between MRI and ultrasound has yet to be improved.[9] In addition, in their postoperative ultrasound evaluation, the authors only included tendon integrity and tendon stiffness, but there is no report on healing or tendon thickness after the repair. It would be good to see whether the patch improves tendon quality and healing or not, which, again, may be better assessed using MRI. Therefore, despite the sophisticated ultrasound analysis conducted by the authors, several critical questions remain: Are atrophy or fatty infiltration affecting the outcomes of revision surgery? Is the postoperative tendon quality better or the same? In the future, to minimize selection bias and improve the internal validity of the study, a randomized controlled study involving 2 matched cohorts considering all known retear risk factors and including MRI as an assessment tool should be conducted.

There may also be some concern with the clinical evaluation. The authors reported no differences in any patient-reported outcome measurements between the 2 groups at 6 months postoperatively. However, Polce et al[4] recently established the time required to achieve clinically significant outcomes for patient-reported outcome measurements after an arthroscopic RCR at 12 months. Therefore, the time frame for clinical evaluation does not appear to be enough.

Overall, while this publication is a welcome addition to our body of knowledge, it is important to understand the setting of the study to avoid misinterpretation. First, the authors admit the study was underpowered to detect differences between groups. Thus, no significant difference at a given sample size does not mean there is no effect. Further studies with larger sample sizes are needed to detect statistically significant differences in clinical and imaging-related outcomes after revision RCR with versus without the bioinductive implant. Second, only workers' compensation patients were included, which may limit

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the generalizability of the study, as workers' compensation status is known to be a negative prognostic factor.[4] Moreover, this study only reported on outcomes within a single surgeon's practice. Therefore, external validity may be limited in terms of both patient population and surgical technique. Taking this into account, it cannot be stated that the collagen patch was not able to enhance the results of RCR in the setting of revision surgery.

In conclusion, this study sheds light on a fresh approach to dealing with rotator cuff retears, a challenging situation that still lacks a definitive solution. Although the study reported no differences in tendon integrity and clinical outcomes between patients with and without the Regeneten implant, we wanted to point out that, in our opinion, the conclusions made by the authors were not supported completely by the results. More high-quality studies are needed to determine whether the Regeneten implant is able to improve radiological and clinical results in revision surgery or not.

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