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Editorial

"In My Experience...Development of Novel Transosseous Rotator Cuff Repair Techniques and Technologies"

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The author reviews his experience with transosseous rotator cuff repair techniques and technologies

As a fellow studying shoulder at Massachusetts General Hospital, I was exposed early to the ideas of EA Codman, the father of modern Value and Evidence based practice. In his time, he was ostracized by his peers for pointing out that outcomes should be objectively tracked and put in context with the relative cost. 100 years later, the rumbling of value was returning as a business concept (value=outcomes/cost) to the medical industry from the likes of Michael Porter, who also hailed from Harvard.

An obvious project began to gel in my mind, one which came around once in a lifetime. There was a gold standard clinical technique with years of proven safety and efficacy, meeting a changing business paradigm (value-based care, bundled payment), which needed updating and innovation for the modern arthroscopic paradigm. This was the genesis of Tensor Surgical, a company which focused on modular reusable value-based anchoress platforms for soft tissue repair about the shoulder (Sanders, n.d.-a). When I began the journey interfacing with VC investors, companies, engineers and doctors to make this naive dream reality, I knew it would be contrary to the existing business model, and dependent on the intersection of two large business forces on the horizon: the concept of value and the physician owned surgery center, where the incentives and accountability for cost and quality are aligned more like classical free markets. The end user physician actually feels the pain of increased technology cost. This is in contradistinction to our current third-party payor system where payors have no accountability for quality, physicians don't feel the cost, industry can charge high prices because patients don't pay the bill. Hence, runaway exponential technology cost increasingly threatens healthcare delivery rather than becoming more accessible and cost effective over time as in other tech fields. I really wasn't qualified as a health economics expert and I had limited business experience, but I later found that bucking the system takes more passion and courage than brains, as well as a little luck to get a concept off the ground. Persistence, friends, and other truth-seeking colleagues help give the Courage that is required to face potential pillory or skepticism by political and business establishments invested in the status quo.

I wasn't the first to be captured by this idea in history - giants in shoulder surgery (Neer, Hawkins), former ASES presidents, and even Codman himself all knew Transosseous technique was safe and effective. Many even had their own devices and techniques. What did they know that the rest of the crowd didn't routinely hear? When arthroscopy was introduced, there was no good way to per-

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Conflicts of Interest Statement for Dr. Sanders

form the TO repair, which opened the door for anchor-based repairs as surgeons were transitioning from open to mini open to arthroscopic. Because of the ease of use arthroscopically, profitability for the companies, and high initial time zero strength, anchors were adopted rapidly, but at a financial and clinical cost. The initial results of single row repair anchor based arthroscopic repair were found to be worse in a classic study by Yamaguchi showing 93% failure rate (Galatz et al. 2004). Bishop showed twice the failure rate of arthroscopic versus open (Galatz et al. 2004; Bishop et al. 2006). It took the anchor industry a decade to catch up to the powerful Cerclage effect of TO repairs, by adding 4 more independent anchor-based fixation points in what became known as the Transosseous Equivalent (TOE) repair, using "double row" anchors in a new terminology. The thinking progressed from Single row to double row, to TOE with increasing cost and bone voids, all while each TO tunnel is an intrinsic "double row" footprint reconstruction. The respect for TO technique is right there in the name of the favored anchor construct: "Transosseous Equivalent" (Park et al. 2006). The designers are trying to simulate what TO already does with less cost and hardware by adding hardware for arthroscopic applications. Companies rapidly cottoned on to this "pseudo-transosseous" technique as it increased the technology profit margin for a cuff repair and facilitated adoption of arthroscopic techniques. While this new technique was strong and stiff at time zero, it came with a new anchor induced catastrophic failure mode: the Cho type 2 failure, wherein the tendon is transected by the overly stiff anchor construct, resulting in difficult and expensive revisions where your fixation point of choice is already burned by a piece of plastic or metal, and the tendon may be permanently compromised. Moreover, it introduced more cost, pain, tendon stress, imaging artifact (Sano et al. 2007; Randelli et al. 2017; Black et al. 2016; Tashjian et al. 2018; Narvy, Ahluwalia, and Vangsness 2016)., with less blood flow (Urita et al. 2017).

In the early 2000's, Dr Sumant Krishnan developed the first mover in the space which became the Arthrotunneler at Tornier, under the commercialization efforts of Justin Anderson, global VP of sales. At the time it was believed that the market wasn't ready for value and the device was made disposable, impairing the cost efficacy and impairing targeting accuracy and reproducibility because the device was made with flexible disposable materials. However, there were encouraging clinical results and obvious cost advantages. The market for anchors was increasing, as reimbursements decreased. What could we do to improve adoption of a philosophically sound principle? Our design showed enhanced targeting and ease of use. It was clear there was surgeon concern over soft bone. We removed drilling in favor of compacting with an awl, eliminated steps, changed geometries, enhanced targeting accuracy and reproducibility and landed on the improved design ready for value with a reusable platform: the Tensor TransOs (Sanders, n.d.-a).

Along the way, we have learned various salient technical points about transosseous cuff repair, looking at it from an arthroscopic perspective (Stenson et al. 2023). One of the most common concerns is biomechanics. The range of force necessary for healing remains controversial, but many constructs can achieve satisfactory repairs. Ultimately, the strength depends on the number of sutures in the construct, which may be varied by the surgeon to the point of superseding the physiological need. Interestingly, TO technique appears to have a completely different biomechanical healing mode that reduces medial row stress and more naturally matches the elastic modulus and mechanobiology, leading to type 1 failure rather than type 2. This requires more formal biomechanical investigation but is a major advantage in revision surgery on the tendon. On the bone side, TO does not leave any inert material behind causing bone voids and will reconstitute (heal) for later surgery. This occurs even when sutures cut through, while anchors tend to pull out and leave bone voids. Tendon healing and reasonable bone healing occurs right up to the suture by 6 weeks, allowing tunnel-in tunnel revision or conversion to anchors or hybrid techniques (Jang Jeong et al. 2023; Sanders, n.d.-c). Having observed several patients with early traumatic failure, the failure mechanism largely appears to occur at the lateral bone tunnel suture interface, with limited damage to the tendon and preservation of the medial bone stock. This mechanism acts like a "crumple zone", protecting the valuable tendon while letting failure occur on a renewable resource. The bone tissue is capable of true regenerative healing, while the tendon can barely heal with scar in the best of circumstances and is prone to type two failure. Therefore, I believe there is a sound biological argument against the desire to transfer the failure to the tendon in a feat of anchor biomechanics which was viewed as a success in anchor development (Burkhart et al. 1997). It is clinically and biologically preferable to have the failure occur at the bone level and save the tendon remnant for revision, rather than purposefully transfer the failure to the tendon as anchors do.

"Soft" bone is a prevalent concern and fear of surgeons. This is a complex topic that requires careful thought. Firstly, soft bone is poorly defined and there is no available way of measuring it objectively in vivo. I suggest we should really be interested in something more akin to drilling energy in Joules or insertion torque, rather than surrogate measures of radiographic bone density (Perry, Collins, and Gilmer 2021). With the advent of Reverse TSA and earlier fixation of tears due to progression concern, indications of cuff repair have changed such that the prevalence of severely soft bone in RCR is lower than in the past. Multi-fixation point constructs can be used to pass more suture numbers through the bone, dispersing load and allowing repair in difficult cases (Bicos et al. 2007). Newer data has suggested the cut through of sutures may actually be lower than anchor pullouts, especially with all suture anchors (Jang Jeong et al. 2023). Although we believe bone anchors worsen truly soft bone in the healing zone through pull out and void creation, We have also tendered the True Transosseous Hybrid technique to address concerns over soft bone by utilizing limited anchor fixation outside the zone of pathologic bone (similar to the zone of injury concept

in trauma) (Sanders, n.d.-c). I have come to believe that TO techniques are actually the solution to pathologic bone because the ramifications of failure are so low compared to anchor pullout, as well as the ability to tunnel straight through large voids and let the cuff heal to fibrin clot. The sutures still fix in the hardest part of the construct , the tendon, and reduce it to the footprint with an appropriate vector and no extra risk of hardware failure. The True Transosseous Hybrid technique is a technical innovation that allows for backup very distal in the cortex as a bailout for complex and revision cases, utilizing the best of both strategies to maximize outcome in complex cases. Another technique innovation has been the TOCIS technique for biceps tenodesis (Transossous Cerclage in Situ) (Sanders, n.d.-b). This technique is implant free, uses suture cerclage (similar to an ACL graft whipstitch) around the small diameter biceps tendon, which is prone to failure with screws and suture anchors. There are 4 independent fixation points to prevent failure: two tunnels, soft tissue in the interval, and a small piece of labrum intra-articularly. The ability to make multiple fixation points in series independently without extra cost is an advantage. In addition, there is no axillary wound to get infected, and the length tension is preserved because it is performed "in situ". Failure rates have been the lowest I have personally seen, but this requires formal study.

Pain appears to be less after TO cuff repair, as shown in a level 1 study (Randelli et al. 2017). This has major implications for opioid sparing peri-operative pathways. The best way to reduce pain is not to cause it in the first place. TO surgeons commonly relate that their therapists come to them asking why their cuff repairs stopped hurting. Pain generators are poorly understood, but we hypothesize that inserting an anchor in a diameter mismatched hole plastically deforms the bone, causing fracture physiology and bone edema for up to 6 months. It also likely increases intraosseous pressure proportional to the volume of the anchor, and decreases vascular outflow, which have been linked with pain. Bone marrow vents, in distinction, have been linked with healing and likely decrease pressure in the bone. These differences require further study by independent parties.

Early experience has shown This technique is extremely promising on many fronts, offering a pandora's box of configurations, and synergistic application with all fixation modes as well as tissue grafts and biologics (Stenson et al. 2023). Another potential of this paradigm in modern times is to reduce the cost ceiling to allow more biologics, which are likely the future of cuff repair, to be introduced at the point of care in a sustainable manner. There is certainly low risk, reduced cost, and equivalent clinical outcomes with possibly reduced re-tear rate and less cyst formation (Jang Jeong et al. 2023). We have found that adoption of new surgical techniques tends to track more like a fashion fad with peer acceptance, marketing, and trade show presence being important fickle and costly variables. With the increase in physician owned surgery centers, we expect to see pressures for increased market adoption of TO-RCR, with TO cuff repair increasing in settings where incentives are aligned. In our practice, all current techniques can be performed fully transosseously including RCR, subscapularis repair, biceps tenodesis, revision RCR, allograft or autograft SCR, bone defects, and tendon transfers. Our medical system is flawed and complex, likely beyond the scope of one technique. However, In this small circumstance, listening to the echoes of the past experience and updating them with modern innovation can lead to local conservation of value for this common procedure, benefitting doctors and their patients alike.

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