EnFix® Implants for Enthesis Repair

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Unmet Clinical Need

There are 500,000 rotator cuff surgeries performed annually in the USA[1]. Operative treatment is still far from perfect, with repair failure rates of 20% to 94% reported in the literature. Ratcliffe et al's[2] review of the literature reported failure rates for rotator cuff repair as assessed by MRI or ultrasound imaging. Their results are shown in Table 1 below. The cost of failed rotator cuff surgery in the USA was estimated to be over $430m in 2022[3]. Longo et al[4] in a systematic review and meta-analysis found that the radiographic re-tear rate was 15% at 3 months follow-up, 21% at 3–6 months follow-up, 16% at 6–12 months follow-up, 21% at 12–24 months follow-up, and 16% at follow-up longer than 24 months.

Tear Size	Failure Rate ± SD	Range
Small to Medium (1 – 3 cm)	22 ± 7%	10 – 40%
Large (3 – 5 cm)	46 ± 21%	10 – 95%
Massive (2 or more tendons)	58 ± 12%	37 – 76%

Table 1. Rotator Cuff Failure Rates from Ratcliffe et al[2].

In the uninjured state, the tendon-bone interface, or enthesis, has a fibrocartilage transitional region that exhibits gradations in cell phenotype, matrix composition, tissue organization, and mechanical properties. These natural gradations facilitate the effective transfer of load between two materials of greatly differing stiffness by reducing the potentially damaging stress concentrations that would otherwise arise at their interface. Numerous studies[5,6,7,8] have shown that the enthesis has a poor healing potential and a weaker scar tissue generally forms. The resultant repair has a lower strength[5,9]. Enhanced biologic repair at the interface between tendon and bone would be a major advance.

Over several decades, biologic tendon scaffolds derived from human and animal tissues have been generated, and synthetic scaffolds have been manufactured from absorbable and non-absorbable polymers to reinforce and replace tendons and ligaments. These patch products are placed on top of the tendon and do not seek to, nor do they accomplish, healing between the bone and the tendon which then becomes the weak point of the construct leading to future failures.

Bone marrow aspirate has been investigated as a biological augmentation of rotator cuff repair. Snyder[10] termed the phrase "crimson duvet" to describe the microfracture technique to access bone marrow elements. Recently Hong et al[11] in a randomized clinical study failed to show benefit for bone marrow stimulation. Cole et al[12] in a randomized study of the injection of bone marrow aspirate concentrate showed that it failed to improve treatment failure rates or patient reported outcomes.

The importance of enthesis repair was highlighted in a 2017 NIH / NIAMS hosted roundtable on Innovative Treatments for Enthesis Repair[13]. Preclinical research has investigated several strategies to generate an enhanced biologic repair including growth factors, demineralized bone matrix, tissue engineering, cell therapy, hyperbaric oxygen therapy, shockwave, and low intensity pulsed ultrasound. While some of these studies have shown promising results, the translational research requirements to commercialization have proven to be significant.

Demineralized Bone Matrix and Enthesis Repair

The seminal work of Marshall Urist's initial discovery of bone morphogenic proteins (BMP)s in 1965[14] came from his observation that bone implants created from demineralized bone matrix (DBM) had the ability to induce the formation of new bone in experimental animals. He hypothesized that DBM contained a factor that could stimulate bone growth, and subsequent experiments led him to isolate and characterize the first BMPs. The various BMPs that have been identified reach beyond just bone and their physiologic roles impact the entire musculoskeletal system. These are tabulated in Table 2.[15] Urist's discovery has had a significant impact in orthopedics and has led to the development of new treatments for bone and joint injuries and diseases. BMPs are used clinically in spinal fusion surgery and other orthopedic procedures to promote bone healing and regeneration. Allograft DBM has also been shown to be a potent biomaterial, with significant clinical usage as a bone void filler and graft material in spine surgery[16].

BMP	Nomenclature	Main physiological roles
Bone morphogenetic proteins		
BMP-2	BMP-2a	Cartilage and bone morphogenesis/heart formation
BMP-3	Osteogenin	Negative regulator of bone morphogenesis
BMP-3b	GDF-10	Negative regulator of bone morphogenesis
BMP-4	BMP-2b	Cartilage and bone morphogenesis/kidney formation
BMP-5	–	Limb development/bone morphogenesis
BMP-6	Vrg1, Dvr6	Hypertrophy of cartilage/bone morphogenesis/oestrogen mediation
BMP-7	OP-1	Cartilage and bone morphogenesis/kidney formation
BMP-8	OP-2	Bone morphogenesis/spermatogenesis
BMP-9	GDF-2	Bone morphogenesis/development of cholinergic neurons/glucose metabolism
BMP-11	GDF-11	Axial skeleton patterning/eye development/pancreas development/kidney formation
Cartilage-derived morphogenetic proteins		
BMP-12	CDMP-3, GDF-7	Ligament and tendon development/development of sensory neurons
BMP-13	CDMP-2, GDF-6	Cartilage development and hypertrophy
BMP-14	CDMP-1, GDF-5	Chondrogenesis/angiogenesis
Others		
BMP-8b	OP-3	Spertmatogenesis
BMP-10	–	Heart morphogenesis
BMP-15	GDF-9b	Ovary physiology
BMP-16	Nodal	Embryonic patterning
BMP-17	Lefty	Embryonic patterning
BMP-18	Lefty	Embryonic patterning

BMPs known to induce complete bone morphogenesis are underlined.

Table 2. BMPs in bone and their physiologic roles[15].

There have been some studies of the effect of demineralized bone matrix products on enthesis repair reviewed by Hexter et al[17] in 2017 and Villarreal-Espinosa et al[18] in 2024. Sundar et al[19] produced strips of demineralized allogenic bone to use in a sheep model of tendon enthesis healing. Strips of DBM 15 x 30 x 2-3mm were interposed between tendon and bone and held in place using suture anchors. The treated group had less early failures than the control group, and histological analysis at 12 weeks demonstrated reformation of the enthesis in the DBM treated group but not in the control group. Smith et al[20] studied rotator cuff healing in a dog model using a demineralized cancellous sponge loaded with PRP. They demonstrated improved histology, MRI scores, and repair strength at 12 weeks. Lovric et al[21] showed that DBM powder introduced into the bone tunnel of an ACL repair in a rodent model demonstrated increased graft strength at 4 and 6 weeks. Heuberer et al[22] injected DBM powder into the tendon footprint of sheep and showed less scar tissue and a more physiologic enthesis morphology at 4 weeks.

The Solution

Tetrous® EnFix implants are the first-to-market, procedure-specific implants manufactured using patented Demineralized Bone Fiber (DBF) technology focused on enthesis healing initially in rotator cuff repair surgery. Tetrous was spun out of TheraCell, a regenerative medicine company, in 2019 to further its patented DBF technology for application in sports medicine before TheraCell was sold to ISTO Biologics in April 2022.

The EnFix products are allogenic tissue products that conform to the Food and Drug Administration's (FDA) regulations governing human and cellular tissue-based products (HCT/P) according to 21 CFR Part 1271 and Section 361 of the PHS Act. The processes used to manufacture EnFix products were designed to cause minimal changes to the allograft tissue and to maintain the osteoinductive potential. The products are 100% cortical bone and contain no additives or excipients.

While DBM is a potent biomaterial, in its most used form as a powder its handling characteristics are lacking and moreover it lacks osteoconductivity. Excipients used to make DBM powder easier to handle are deficient in that they can contain up to 70% extraneous binding materials that have no beneficial value as biomaterials or to overcome the lack of osteoconductivity. Demineralized bone fiber technologies offered a means to improve osteoconductivity as superior putties but had no means to yield shaped allograft. Tetrous utilizes a highly differentiated and patented next-generation fiber technology approach that yields uniform long and strong fibers amenable to new bone-textile processes and overcomes many of the limitations of earlier manufacturing methodologies. This provides a means of producing procedure specific shaped products via methodologies such as the proprietary water-assisted injection molding (WAIM) while simultaneously yielding highly osteoinductive and osteoconductive properties. The technology also facilitates retention of the nanotopography of the collagen fibrils[23]. DBF implants produced using this technology have been used in an estimated 150,000 spine procedures in the past 5 years. Recently, they have been used in over 1,500 sports medicine procedures.

To exploit the technology in sports medicine, initially focusing on rotator cuff, two versions of the EnFix product have been produced, EnFix RC™ and EnFix TAC®. The EnFix RC implant is designed to be used in conjunction with suture anchors. It is suture anchor agnostic and works well with most widely used threaded suture anchors of sizes 4.5mm - 6.5mm, whereas the EnFix TAC implant is intended to be used independently of the suture anchor, being placed in the footprint between the medial and lateral anchor rows in a double row repair[24]. This allows the increasingly popular all suture anchors to be used. A single row repair technique has also been developed.[25]

The EnFix RC design rationale required use of DBF to provide optimal biologic performance while also making it easy for the surgeon to use with minimal disruption to the surgical technique. This was achieved by molding and manufacturing the DBF fibers into a "Top Hat" shape wherein the shaft of the implant is simply inserted into in the awl hole used for suture anchor insertion using the inserter shown in Figure 2 below. This allows the implant to be held in place in the bone, as opposed to patch type product formats that the surgeon must sometimes literally chase around the joint. Additionally, placement into the bone cavity allows the fibers to access the marrow space allowing cells and other endogenous local factors to wick up from the subchondral bone to the top surface of the implant that sits at the interface between bone and tendon. The top of the implant is 8.5mm in diameter, allowing optimal spacing of suture anchors, and the peg portion is 13mm long.

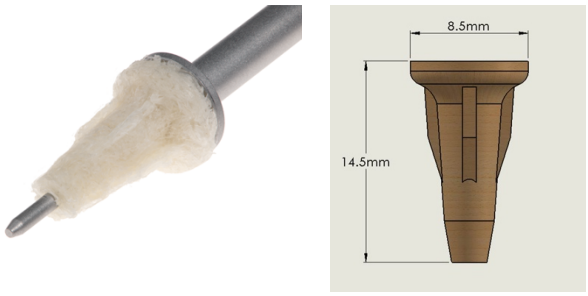


Figure 2. The EnFix RC implant

Use of EnFix RC does not require the surgeon to change their surgical technique and adds less than 2 minutes to the surgery time. The EnFix RC implant is placed into the awl hole created for the suture anchor and then held in place using the suture anchor, as shown in Figure 3. The implant is tapered with four ribs designed to resist rotation during suture anchor insertion. An additional benefit of the usage of the EnFix RC implant is that the peg portion of the implant enhances fixation of the suture anchor into bone, in the same manner as TheraCell's award winning Fibrant™ Anchor enhances pedicle screw fixation in compromised pedicle bone.

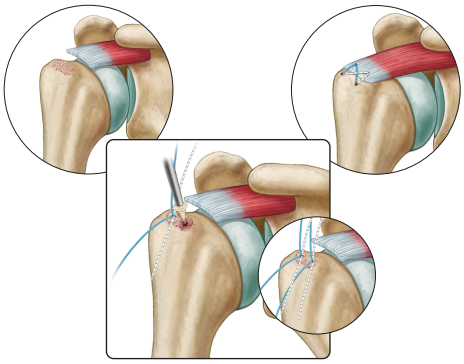


Figure 3. EnFix RC surgical placement

During the controlled launch of the EnFix RC product, two of the surgeons determined that placing the device between the medial and lateral anchor rows (rather than at the medial row) allowed more optimal placement of the device relative to where the enthesis regeneration was desired, while also allowing the placement to be independent of anchor type allowing use of all suture anchors. To optimize for this application, a new version of the EnFix device was developed with two formats; the TAC-O with an 8.5mm round top and the TAC-T with a 10mm x 4mm top. This affords the surgeon a choice of format to optimize placement based on the size of tear and the anatomy. Their dimensions and placement are shown in Figure 4 below.

The EnFix products are cannulated, allowing for easy introduction into the joint using the Introducer. The cannulation allows blood and bone marrow elements from the subchondral bone to flow up into the healing site, providing a superior type of "crimson duvet[10]" with a funnel from the subchondral space wherein the factors are absorbed in the implant's demineralized bone fibers and wicked up into the healing bone-tendon interface. The unique peg feature of both the RC and TAC products also allows ease and speed of insertion without impacting the surgeon's repair technique.

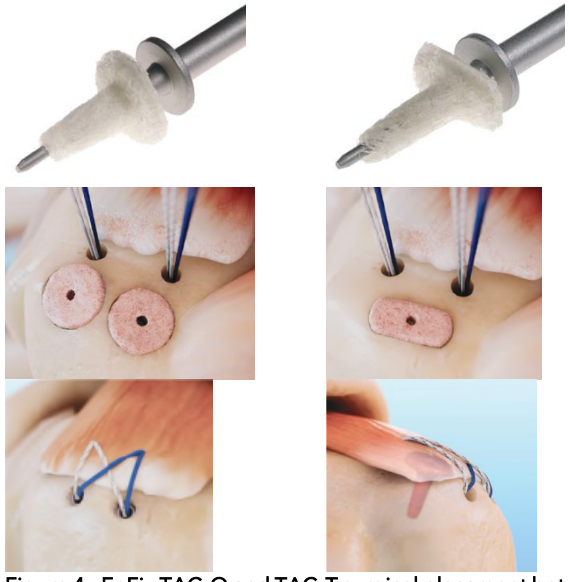


Figure 4. EnFix TAC-O and TAC-T surgical placement between medial and lateral row anchors

Preclinical Studies

The EnFix technology has been evaluated in multiple bench-top, laboratory and preclinical studies.

Traditional demineralization techniques apply acid treatment after the fibers are cut from the mineralized bone, deleteriously etching the surface nanotopography (surface features) away. Tetrous' unique patented and proprietary process demineralizes the bone struts first and then cuts/cleaves fibers along the bone's long axis, thus maintaining their important nanotopography, and creating long and strong fibers. See Figure 5 below.

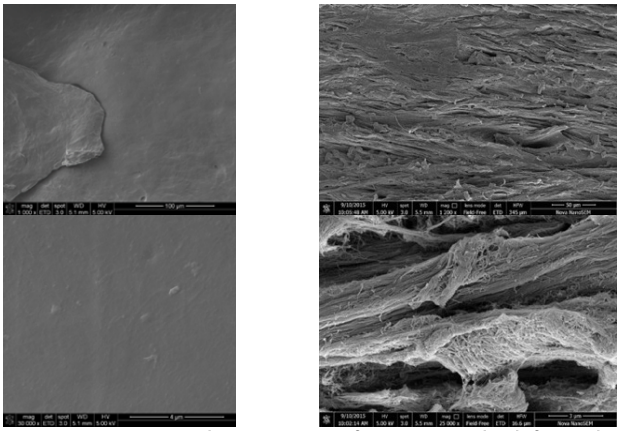


Figure 5. Conventional DBM / DBF surface topography, left panels, Tetrous DBF right panels. Conventional DBM processing results in a smooth surface due to powdered bone being demineralized in acid, while Tetrous DBF retains natural nanotopography as a result of demineralization prior to fiber cutting[23].

One design feature of the implant is the ability to allow cells and bone marrow to be wicked up and proliferate through the implant to the enthesis. Mercury Intrusion Porosimetry was used to characterize the implant and showed a porosity of 39% with an average pore size of 160 µm. In Figure 6, comparison is shown to two enthesis repair products that use electrospun fabrics. These materials have a very small pore size that is less than 10 microns and too small for cellular transport.

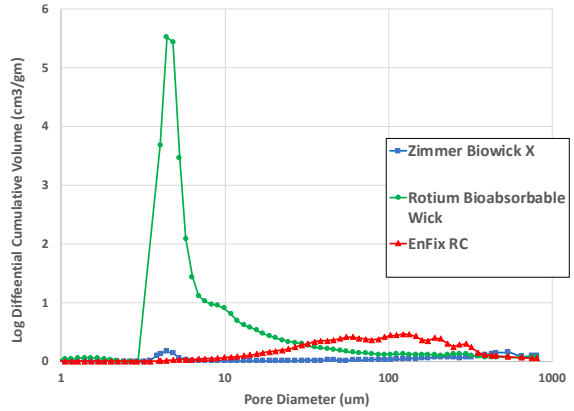


Figure 6. Pore diameter distribution for EnFix compared to competitor products[26].

Production of implants with intricate geometries required the development of a proprietary patented water assisted injection molding (WAIM) process that allows fibers to be suspended as a slurry and injected into shaped molds. A further process, designated Formlok™, causes the shape to be retained to control implant integrity even in a wet environment such as is experienced in arthroscopy. Figure 7 below shows the effect of water immersion on the integrity of the implant without Formlok versus with Formlok.

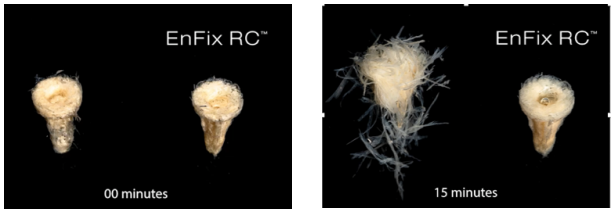


Figure 7. The implant on the left is untreated and loses shape rapidly on immersion in water. Implant to the right is Formlok™ treated[26].

As the only additive to the process is water, the manufacture of the DBF and the formed implants conforms with the requirements of minimal tissue manipulation as defined and regulated by the FDA.

While enhanced fixation is not the main purpose of the implant, evaluation of suture anchor fixation in the EnFix RC implant was performed in a laboratory model. Sawbones 10pcf cellular rigid polyurethane foam (Pacific Research Laboratories, WA, USA) is a well-accepted analog for osteopenic cancellous bone and is specified for screw testing in ASTM standards and FDA Guidance documents[27]. A Mark 10 motorized test stand with a 1500N Force gauge was used for pull out testing with a pull out rate of 20mm/min. A Zimmer Biomet Quattro 5.5mm PEEK suture anchor was either placed directly into the Sawbones foam block or into an EnFix RC implant that was placed into the Sawbones foam block. The maximum pull out force data are shown in Figure 8 below, with standard deviation, n=5. The EnFix RC is shown to provide an improvement in fixation.

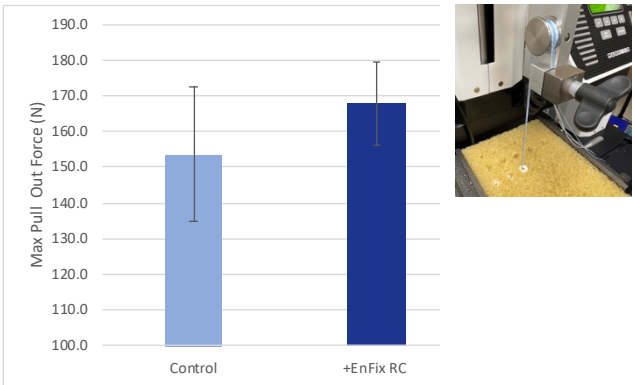


Figure 8. Photograph shows test set up for suture anchor pull out. Chart shows maximum pull out force observed[26].

DBF has become one of the most commonly used bone grafting materials and the ability of the Tetrous DBF to promote bone healing was evaluated in a critical sized distal femoral defect in a skeletally mature rabbit model. The results demonstrated rapid bone formation, growing from the outside of the defect toward the center at two weeks with complete remodeling of the DBF into bone seen at four weeks, as shown in Figure 9 below.

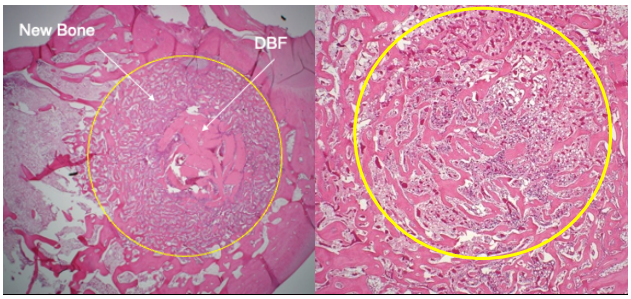


Figure 9. H&E stained histology shows rapid early woven bone formation at 2 weeks, left and 4 weeks, right.

In a sheep model of enthesis repair, presented as Poster # 105 at the 2023 AOSSM meeting[28], a DBF sheet was placed at the interface between tendon and bone. Histology (Figure 10) showed enthesis reformation at 12 weeks with Sharpey's Fibers in the treated group, but not the control.

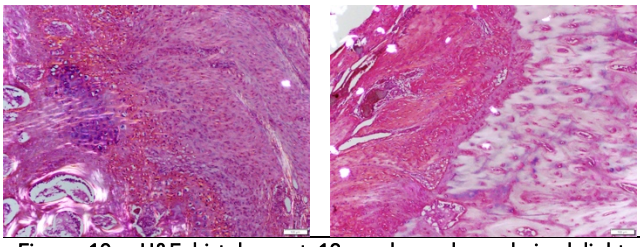


Figure 10. H&E histology at 12 weeks under polarized light confirmed Sharpey's fibers in the DBF treated group (left) not present in the controls (right).

In a separate study, 6.5mm diameter bone screws were placed into fiber sleeves mimicking the peg portion of the EnFix RC implant and placed into skeletally mature sheep distal femoral condyles. The study showed that new bone formation occurred around the screw facilitated by the DBF fibers. These data are shown in Figure 11 below. New bone formation can be seen at four weeks, with some residual DBF, while at 12 weeks all of the DBF has remodeled into new woven bone in the areas between the screw threads.

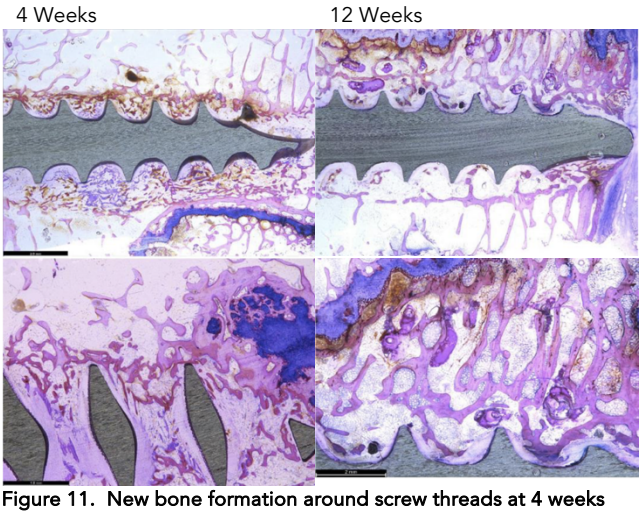


Figure 11. New bone formation around screw threads at 4 weeks (left) and 12 weeks (right)[26]

A rabbit model of tendon repair was investigated using the infraspinatus tendon. Two bone tunnels were placed using a 1mm K-wire lateral and medial to the infraspinatus tendon insertion footprint. The infraspinatus tendon was sharply dissected from its insertion. Modified Kessler 3-0 sutures were placed through the tendon and then reattached by passing the two free ends of the suture through the bone tunnels using a straight mayo needle. In the treatment group an EnFix DBF sheet approximately 1mm thick and 5mm wide was placed in between the tendon and bone. In the control group the tendon was reattached without an EnFix implant.

Tensile testing of the repaired rotator cuffs was performed and the treated versus non treated repairs compared at 6 and 12 week timepoints. No. 1 Ethibond sutures were passed through the infraspinatus tendon, and interfaced to an MTS 858 Bionix Testing Machine (MTS, Eden Prairie, MN, USA). The humerus was secured in a jig. The infraspinatus tendon–humerus complex was positioned to allow tensile loading in the longitudinal direction of the infraspinatus tendon. The repair sutures were cut prior to mechanical testing in order to isolate the testing to the healing interface alone. Specimens were preconditioned for 5 cycles of loading and unloading with 5% strain of the initial length at a cross-head speed of 6 mm/min, and then loaded to failure at a speed of 6 mm/min. The results of this testing are shown in Figure 12 below. The cuff repairs deploying the DBF implant required greater force (21% at 6 weeks and 26% at 12 weeks) to detach the tendon from the bone than the control.

The results of the two preclinical rotator cuff studies demonstrate that the EnFix technology stimulates biological enthesis reformation and in turn yields better bone to tendon healing providing a biomechanically superior repair to the control scar tissue.

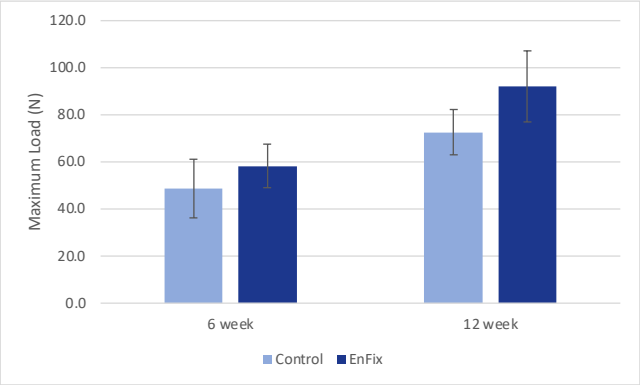


Figure 12. Maximum load of the infraspinatus tendon repair[26].

Commercial Status

The EnFix products were initially commercialized in Australia and the USA in a controlled launch July 2023 with 7 surgeons who completed over 250 cases utilizing 500+implants in the first 12 months. The second phase of commercialization is now allowing surgeons from our waiting list to begin using the product. EnFix is now being regularly used in the USA, Australia and New Zealand by a rapidly growing group of surgeons with 35 now having completed over 700 cases to date (May 2025).

The rotator cuff tendon entheses are just a few of the many entheses in the human body and surgeons using EnFix have identified a number of other areas where they can use EnFix RC and EnFix TAC to augment their repairs. EnFix has been used in proximal/distal biceps tenodesis, insertional Achilles tendinopathy, gluteus medius and proximal hamstring reattachment, lateral epicondyle repair, and subscapularis repair during total shoulder arthroplasty.

Clinical Results

EnFix devices have been used in cases ranging from primary repairs to complex revisions. Surgeons have been monitoring their patient outcomes and seeing positive benefits from their usage of EnFix.

A US surgeon has performed MRI assessment of repairs using the EnFix RC and EnFix TAC products on patients at 3 months and 6 months post op[26]. A 6 Month post-op MRI is provided in Figure 13. The MRI demonstrates excellent healing of the supraspinatus tendon repair at the greater tuberosity footprint with clear tendon-to-bone integration. High quality coverage of the greater tuberosity footprint by the repaired tendon, similar in morphology to a native tendon-bone interface, is clearly visible. The only evidence that a tear has been repaired, other than the bone anchors themselves, is a mild intermediate T2 signal in the tendon substance. The subtle T2 signal between the tendon and the adjacent footplate bone suggests a robust tendon-bone enthesis. The EnFix RC shows successful integration into the surrounding bone, with nearly no visible evidence of the EnFix RC such as marrow edema, cystic change or adverse localized soft tissue reaction. The PEEK suture anchor is well seated in the bone and is easily visible with no artifact obscuring the tendon insertion.

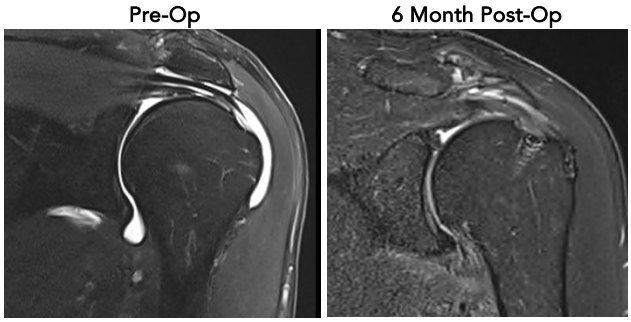


Figure 13. Example of MRI

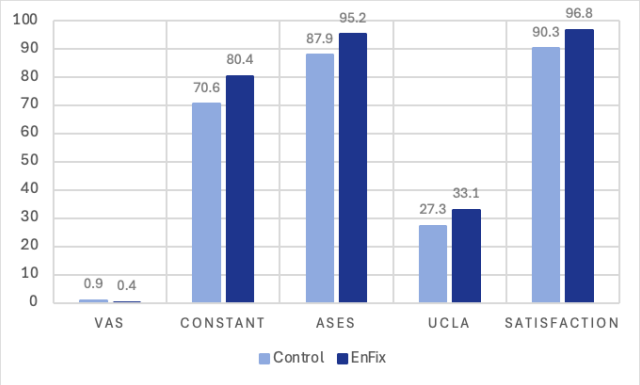
An Australian surgeon did a retrospective review of his rotator cuff repairs pre and post availability of EnFix[26]. Prior to EnFix usage his failure rate was 8.3%, while with EnFix (94 cases) his failure rate was 5.3% - a 36% reduction.

Another Australian surgeon has performed a review of prospectively collected data from patients who underwent arthroscopic rotator cuff repairs augmented with EnFix RC from August 2023 to October 2024[29]. A matched control group based on age, sex, repaired tendons, tear characteristics, and follow-up period was selected from the database of patients who underwent rotator cuff repair without EnFix augmentation. Indications for the use of Enfix RC included large to massive rotator cuff tears, tears with poor tendon quality, and revision surgeries. Whenever appropriate, muscle slide and advancement with suprascapular nerve release were performed, especially for the large and massive retracted rotator cuff tears, to ensure tension-free repair.[30,31] Standard double row repair technique was performed. For delaminated tears, separate repair of the deep and superficial layers was completed using the double layer Lasso loop technique.[32] Visual analogue scale (VAS) for pain, ASES, Constant score, active range of motion, and strength of lateral elevation were collected preoperatively and at 6 months postoperatively using a data collection platform (Akunah PROMs, Brisbane, Australia) as part of standard clinical practice. Noncontrast MRI was obtained preoperatively for rotator cuff tear evaluation and

at 6 months postoperatively for assessment of healing and enthesis reformation. These variables were then compared with the 6-month outcomes of the matched cohort who did not have EnFix augmentation with the repair.

A total of 31 patients from the augmented group and 31 patients from the matched control group with mean age of 54.8 years were included in the study. The mean follow-up period was 8 months. The majority of the patients had at least two-tendon tears with Patte 2 to 3 retraction and low-grade fatty infiltration (Goutallier 0 to 2) with comparable distribution between the two groups.

The tendon thickness in the treated group was 8% greater than in the untreated group at 5.3mm mean thickness for the group treated with EnFix and 4.9mm for the untreated. Other patient reported outcomes (PROM's) at 6 month follow up are shown in Figure 14 below.



	Control	EnFix	Change	p-value
VAS	0.9	0.4	-55.6%	p=0.094
Constant	70.6	80.4	13.9%	p<0.001
ASES	87.9	95.2	8.3%	p=0.001
UCLA	27.3	33.1	21.2%	p<0.001
Satisfaction	90.3	96.8	7.2%	p=0.612

Figure 14. Patient Reported Outcomes at 6 months[29]

Notably, all the PROMs including VAS, Constant, ASES, UCLA were statistically significantly better in the EnFix treated group compared to control. It was also observed that the treated group at 6 months had PROMs that the untreated group did not achieve until 12-months.

New Multi-Center Study

A new multi-center prospective clinical study with 6 surgeons at 6 centers (in Australia, New Zealand and the USA) was initiated in May 2025 to further explore the benefits of EnFix across a broad group of surgeons, each using their own rotator cuff repair technique.

Patents / Intellectual Property

The demineralized bone fiber technology used in Tetrous products, which was developed by the Tetrous science team before TheraCell was sold to ISTO Biologics, is licensed exclusively to Tetrous for use in sports medicine from TheraCell, Inc. In addition to this, and independently, Tetrous has had five US patents issued covering the EnFix products and methods of manufacture and use. The granted US patents applicable to the products are provided in Table 3 below. Other patents have been issued in other jurisdictions, and further applications in the USA and other jurisdictions have been filed for additional coverage for products to treat rotator cuff and other entheses.

Products	US Patents
EnFix RC	US 9,486,557 US 9,572,912
EnFix TAC-O	US 11,660,373
EnFix TAC-T	US 11,759,548 US 12,036,338

Table 3. US Patents

EnFix®, EnFix RC™, EnFix TAC®, Tetrous® and "It's all about the Enthesis"® are trademarks of Tetrous, Inc.

FormLok™ and Fibrant™ are trademarks of TheraCell, Inc.

Conclusions

The need for a means of improving the outcomes of rotator cuff repair is clearly demonstrated by the clinical data. This is a problem that all sports medicine practitioners acknowledge. Tetrous has focused on bone to tendon healing to transform the healing paradigm in sports medicine. The Tetrous technology addresses multiple anatomies with the entry into the market in rotator cuff repair. This represents an opportunity of over $1B encompassing half a million cuff surgeries per year in the USA alone. Tetrous products apply in every one of these cases addressing the still unmet need to reduce the high surgical failure rates. There are countless types of suture anchors, sutures and, recently, overlay tendon patches used in these surgeries, but none of these adequately address the reattachment of the tendon to the bone at the enthesis. Yet that is the persistent point of failure today. When one reattaches the tendon it generates scar tissue at the interface even if a tendon overlay patch is used.

Tetrous flipped the script, going between the bone and the tendon, triggering the bone to re-attach to the tendon. The demineralized cortical allograft when implanted into bone starts a process of endochondral ossification in the bone. This recapitulates embryonic development of bone to

tendon attachment. The result, as demonstrated by multiple pre-clinical studies, is new healthy and strong tissue with continuity from the bone through the enthesis and into the tendon. Tetrous uses a novel next-generation demineralized bone fiber construct. These materials are a known potent orthobiologic material with significant usage in spinal fusion surgery. The product concept was borne out of a study of the literature on demineralized bone matrix materials for enthesis repair which was highly suggestive that DBM has efficacy for enthesis repair. Tetrous developed the EnFix family of products using unique patented methods to fabricate demineralized bone fiber into a consistent clinical product that can be easily introduced into the enthesis with minimal disruption of current surgical techniques. Extensive preclinical data and initial clinical data suggest that the EnFix products enable biological reformation of the enthesis, generating a repair that is stronger than the scar tissue that results from current surgical techniques that do not use augmentation between the bone and tendon. With over 1,500 implants used in the first 22 months of clinical usage of the EnFix product and first cases in other anatomies we believe that enthesis repair is now recognized as a need in sports medicine.

In summation, Nikhil Verma MD, Professor and Director, Sports Medicine and Shoulder. Midwest Orthopedics at Rush, Head Team Physician, Chicago White Sox said "Although advancements in rotator cuff technology have been made, limited changes in healing rates and time frames for recovery have been realized. The problem is biology. Current techniques are limited in regard to ease of use and widespread applicability. The Tetrous implant solves for these issues with a simple, reproducible technique designed to address the very foundation of tendon healing - enthesis regeneration."

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