

Bone & Joint Science

Our Innovation in Focus

HEALICOIL[◇] REGENESORB Suture Anchor: Comparison of bone ingrowth at 18 months with a solid body anchor implant in an ovine reconstruction model

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1 Research goal

To demonstrate superior bone ingrowth for the HEALICOIL REGENESORB suture anchor compared with the Arthrex BioComposite Corkscrew[®] FT at 18 months in an ovine model.¹

2 Type of evidence



3 Clinical relevance

- Rotator cuff injuries are the most common shoulder condition leading patients to seek therapy. However, it is estimated that current surgical repair fails to heal in 20% to 95% of patients.²
- Although suture anchors are one of the most important advancements in arthroscopic rotator cuff repair, efforts continue to improve their design and composition. The goal of these changes is to enhance bone formation and repair strength in order to facilitate improved clinical outcomes.³
- HEALICOIL REGENESORB (Smith & Nephew, Inc.; **Figure 1**) suture anchors have a unique open-architecture design, eliminating material between threads in order to allow blood and bone marrow to enter the implant. They are manufactured using a novel poly (L-lactide co-glycolide; PLGA) based biocomposite material that contains β-tricalcium phosphate (β-TCP) and calcium sulfate, both previously demonstrated to be osteoconductive.⁴⁻⁷

4 Key result

- At 18 months, the HEALICOIL REGENESORB suture anchor showed significantly greater bone ingrowth ($p < 0.001$), as compared with the poly-L-lactic acid (PLLA)/β-TCP-based Arthrex BioComposite Corkscrew FT (**Figure 2**).¹
- HEALICOIL REGENESORB demonstrated faster material absorption at 18 months (70% vs 57%, respectively; $p < 0.001$).¹

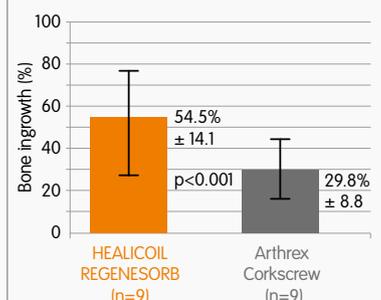
5 Important considerations

- Although encouraging, animal study outcomes do not necessarily correlate with human outcomes.

Figure 1: HEALICOIL REGENESORB suture anchor.



Figure 2: Percentage of bone ingrowth volume within defect site at 18 months.¹



Background

- Rotator cuff injuries are the second most common musculoskeletal pathology, and the most frequent shoulder condition leading patients to seek therapy. Currently, rotator cuff repair fails to heal in 20% to 95% of patients, depending on factors such as patient age, tear size, and surgical treatments. Therefore, there is a clear need to develop new and improved techniques for treating rotator cuff tears.²
- The goal of rotator cuff repair is to achieve tendon healing, which has been aided in recent years by the excellent results obtained with suture anchors. Ongoing efforts to further improve suture anchors include modifying their design and composition, thereby enhancing biological healing, bone formation, and repair strength.³
- The HEALICOIL[®] suture anchor features a novel fenestrated, open architecture design to allow for tissue ingrowth during healing. Unlike solid-core implants, the open-architecture eliminates the material between threads, to allow for blood and bone marrow from surrounding cancellous bone to enter the implant. A pre-clinical ovine study has previously shown new bone fills the fenestrations between the threads and into the central channel by 12 weeks post-implantation.⁸
- REGENESORB is an advanced biocomposite material comprised of the co-polymer PLGA combined with two components, calcium sulfate and β -TCP, which have different mechanisms of action but have each been demonstrated to be osteoconductive.⁴⁻⁷ β -TCP provides sustained bone formation over 18 months⁴ and acts primarily as a scaffold for enhancing bone formation.⁷ The suture anchor is designed to deliver the early release of calcium observed with other REGENESORB devices⁹ (Figure 3). Calcium sulfate works in the early stages of bone healing (4–12 weeks)⁴ and is associated with increased levels of local growth factors.¹⁰ REGENESORB is designed to remain mechanically stable for a minimum of six months before being absorbed and replaced by bone within 24 months.¹¹
- The development of the HEALICOIL[®] REGENESORB suture anchor (Smith & Nephew, Inc., Andover, MA, USA; Figure 4) combines the open-architecture of HEALICOIL PK with the absorbable biocomposite material of REGENESORB.
- There are currently no data on the in vivo performance of HEALICOIL REGENESORB. The current animal study¹ was therefore designed to provide information on its resorption and replacement by bone. To do so, HEALICOIL REGENESORB was compared with a traditional solid body anchor, the Arthrex BioComposite Corkscrew[®] FT (PLLA/ β -TCP), in an ovine model that allows for detailed collection of imaging and histological data over a number of significant time points. It was hypothesized that HEALICOIL REGENESORB would lead to significantly superior bone ingrowth at 18 months follow up.

Figure 3: Calcium release from a 6 x 25mm BIOSURE[®] REGENESORB screw.⁹

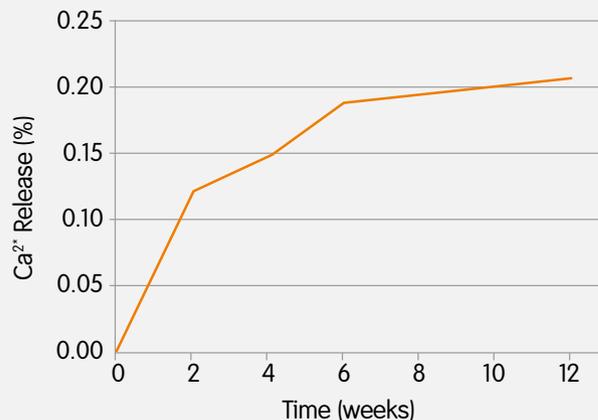


Figure 4: HEALICOIL REGENESORB suture anchor.



Methods

- Implants were randomly assigned to nine sheep in each group with a bilateral contained defect of the medial distal femur.
- Both implants were screwed into place 1mm below the surface. For each limb, the distal end of the femur was disarticulated at the stifle joint and the femur cut no less than 2cm above the trochlear groove.
- Bone ingrowth was evaluated for each implant via micro-computed tomography (μ CT) and histology at 12 and 18 months. Percentage bone ingrowth was calculated from μ CT data. Mean bone ingrowth for the different groups was compared using a one-sided paired t-test.
- To evaluate bone ingrowth and implant absorption, the histological specimens of distal femur were embedded into resin and thick sections cut and ground using the EXAKT system. An observational assessment of the slides was performed and images captured to determine local bone reaction and inflammation at the implantation site. Area measurements of stained histology sections were completed for bone, implant-material and fibrous tissue.

Results

Bone Ingrowth

- At 12 months, μ CT imaging showed significantly greater bone ingrowth into the HEALICOIL REGENESORB suture anchor compared to the Arthrex BioComposite Corkscrew FT ($39.7\% \pm 5.0$ vs. $32.6\% \pm 7.9$, respectively; $p < 0.05$).
- At 18 months, μ CT imaging showed HEALICOIL REGENESORB suture anchor had a significantly greater bone ingrowth ($54.5\% \pm 14.1$ vs. $29.8\% \pm 8.8$, respectively; $p < 0.001$). This appears to be partly attributed to areas of increased radiopacity of the HEALICOIL REGENESORB's implant material (Figure 5).

Absorption

- Histomorphometry showed a faster absorption of HEALICOIL REGENESORB, with 70% absorption at 18 months compared with 57% for the PLLA/ β -TCP-based Arthrex BioComposite Corkscrew FT ($p < 0.001$).
- Histology samples stained for the presence of bone revealed new bone ingrowth into areas of absorbed implant in the HEALICOIL REGENESORB group (Figure 6)

Figure 5: Comparisons of absorption, measured via μ CT, at six and 18 months.¹

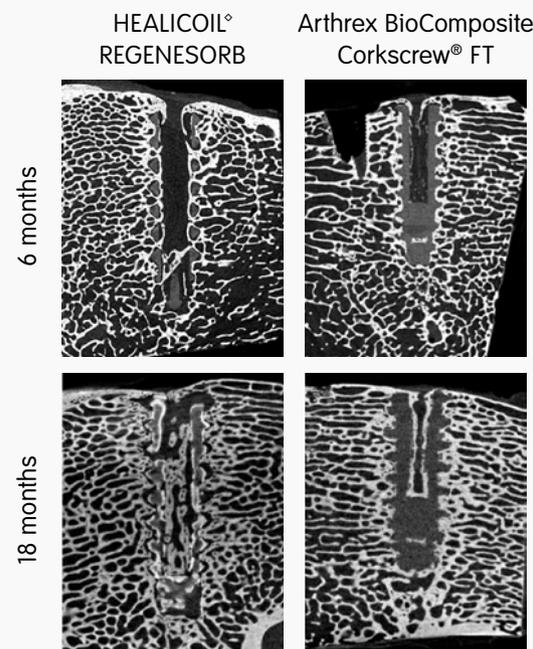
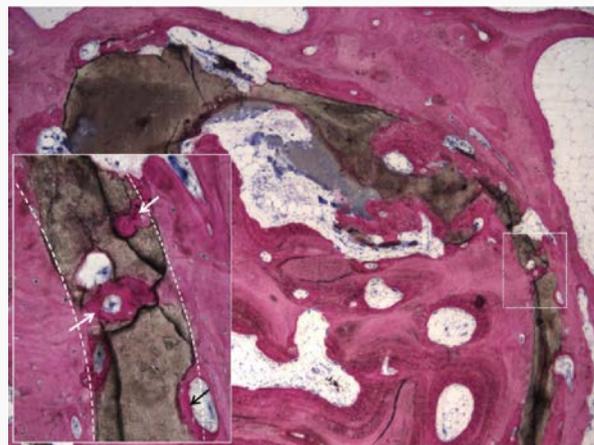


Figure 6: Inset of image shows new bone ingrowth (indicated by arrows) into areas of absorbed HEALICOIL REGENESORB suture anchor at 18 months. Sanderson's Rapid Bone stain at 25X magnification.¹



Conclusions

At 18 months, superior bone ingrowth was demonstrated in the original defect site with the open-architecture design of the HEALICOIL® REGENESORB compared to that of a solid body Arthrex BioComposite Corkscrew® FT, as evidenced by μ CT and histomorphometry data in an ovine model. Histology and histomorphometry also demonstrated faster material absorption of the HEALICOIL REGENESORB compared with the PLLA/ β -TCP-based solid body anchor implant. Although encouraging, animal study outcomes do not necessarily correlate with human outcomes.

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