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HEALICOIL◇ PK Suture Anchors:
Evaluation of a new suture anchor design in an ovine bone defect model

ABSTRACT

The objective of this study was to compare bone ingrowth in a new open-construct suture anchor, HEALICOIL PK Suture Anchor to the vented SwiveLock™ Suture Anchor from Arthrex, via micro-computed tomography (μCT), histology, and bone labeling. Both anchors are molded in polyetheretherketone material (PEEK-OPTIMA® from Invibio®) and have the same 5.5 mm outer diameter. A total of 12 animals underwent surgery for direct bilateral placement into a contained defect in the distal medial femur. Anchors were randomized prior to implantation, but each animal received 1 of each implant type. All animals survived to the end of the 12 week time point. Outcome measures were focused primarily on examining bone ingrowth within and around the suture anchors via μCT relative to undisturbed femoral bone. Fluorescent bone labeling and histological observations were also used to evaluate the new bone ingrowth and tissue response to the implants. This study was conducted under Good Laboratory Practices (GLP) guidelines.

This study showed there was significantly more bone ingrowth in the HEALICOIL PK Suture Anchor compared to the SwiveLock Suture Anchor.

INTRODUCTION

Suture anchors are surgical implants placed into bone to allow the reattachment of a tendon that has been torn from its insertion site. The HEALICOIL PK Suture Anchor design has an open architecture and contains very little material while providing excellent insertion and pullout strength.[1] The objective of this study was to evaluate bone ingrowth into the fenestrations and central channel of two suture anchors – the HEALICOIL PK Suture Anchor and the vented SwiveLock Suture Anchor relative to normal femoral bone. The latter has more material and less open space compared to the HEALICOIL PK Suture Anchor (Figure 1), measured via SolidWorks Premium software (Dassault Systems, Waltham, MA).[2]
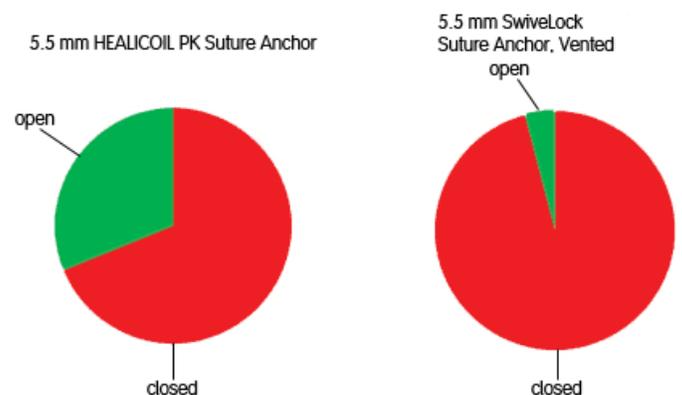

Figure 1. Open surface area comparison between the HEALICOIL PK Suture Anchor and the SwiveLock Suture Anchor.

The high rate of repeat tears in rotator cuff repairs is well known and using a suture anchor with less material or a resorbable material could result in fewer complications in revision surgeries.[3, 4] In these cases, having less material and greater bone ingrowth would be advantageous compared to other solid core suture anchors, especially when multiple anchors are used in the repair.

A double-row rotator cuff repair technique increases the tendon-bone contact area and creates a more anatomic footprint.[5] Restoring the anatomic footprint may improve the healing and mechanical strength of repaired tendons. An anchor with less material may interfere less with the capacity of the tendon to reattach to its footprint. The amount of surface area available at the supraspinatus footprint is limited to an average of 368 mm^2. In a traditional double-row repair the surface area of the HEALICOIL◇ PK Suture Anchors (10.2 mm^2) is approximately 3 times less than that of the 4 SwiveLock™ Suture Anchors (32.4 mm^2). When compared to the SwiveLock Suture Anchor the proximal open architecture of the HEALICOIL PK Suture Anchor may provide more opportunity for tendon-to-bone contact (Figure 2).[6]

METHODS

Biomechanical Testing

Twelve skeletally mature Blue-faced Leicester cross ewes were prepared for sterile surgery and a defect measuring 4.5 mm x 20 mm was drilled into each medial distal femur. Each implant was placed into an individual defect per the manufacturer's instructions. Each animal had 1 of each type of implant and the surgical placement was randomized. The animals were allowed to heal without a formal rehabilitation protocol. The 12 week time point was chosen based on both peer-reviewed literature and our previous experience with this model.[7, 8]

μCT scanning was used to quantify the volume of ingrowth of new bone formed in the implant defect site. The μCT scans were performed using the Skyscan 1172 (Skyscan, Belgium) and data sets were reconstructed using NRecon software. The percentage of new bone relative to the volume of the defect originally created for the suture anchors (4.5 mm x 20 mm cylinder) was calculated. As a control measure, the same volume of trabecular bone was scanned within the same femur, approximately 1 cm from the suture anchor placement from each sample limb. The specimens were processed and resin embedded using standard histological techniques for analyses. For each implant, 3 sections were cut at 4 mm intervals along

the length of the implant. The sections were ground down and stained with Sanderson's Rapid Bone Stain (RBS). Slides were photographed and examined under blinded conditions. In addition, postoperatively 3 different fluorochromes were injected at different time points to visualize active bone formation at the different time points throughout the healing phase. Calcein (green) was injected at 2 weeks postoperative, alizarin complexone (red) at 5 weeks postoperative, and oxytetracycline (yellow) at 8 weeks postoperative. Evaluation of fluorescent labels was performed on unstained histology sections.
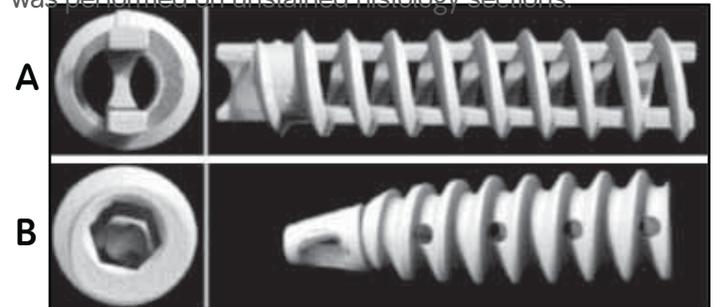
Devices

A. HEALICOIL PK Suture Anchors, 5.5 mm
   (Smith & Nephew P/N 72203379)

B. SwiveLock Suture Anchors (PEEK), vented
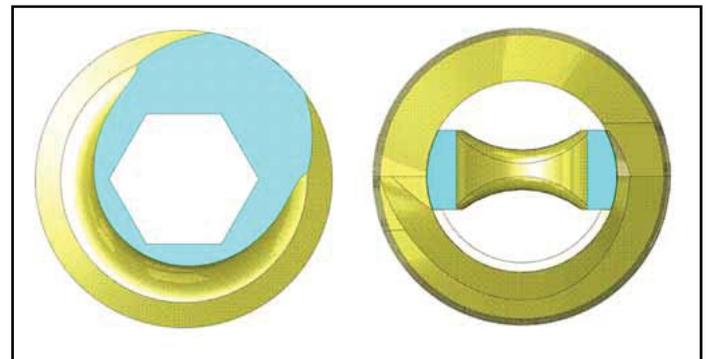   5.5 mm (Arthrex P/N AR-2323PSLC)

Figure 2. Surface area at the footprint of tendon attachment (represented in blue) for SwiveLock Suture Anchors (left) and HEALICOIL PK Suture Anchors (right).
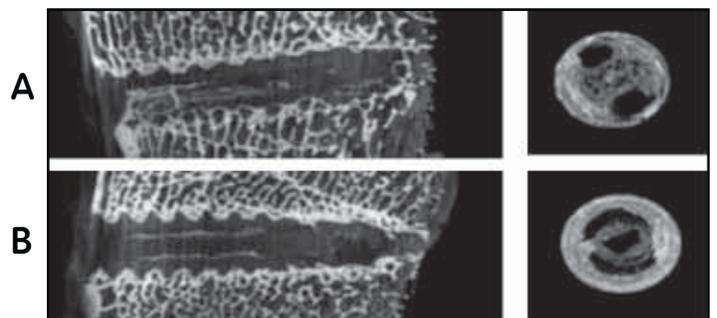

Figure 3. Representative μCT images at 12 weeks showing HEALICOIL PK Suture Anchors (A) and SwiveLock Suture Anchors (B).

Statistical Analysis

Mean percentage bone ingrowth was compared between the HEALICOIL◊ PK Suture Anchors, the SwiveLock™ Suture Anchors, and the control bone groups using a 1-way ANOVA with Tukey method of multiple comparisons adjustment. P-values <0.05 were considered to be statistically significant. Analysis was performed using SAS v. 9.1, (SAS Institute, Cary, NC).

RESULTS

The µCT images from the HEALICOIL PK Suture Anchor implants showed new bone extending from the fenestrations into the central cannulation in every sample. It was evident that in these scans, bone ingrowth was seen longitudinally as well as in multiple cross sections. In the SwiveLock™ Suture Anchor images, bone did not appear to penetrate the entire length of the anchors after examination of cross sections. Representative images can be seen in Figure 3.

Figure 4. Percentage bone ingrowth at 12 weeks including femoral bone (n=12).

The percentage of new bone ingrowth in the original defect created for the suture anchors (4.5 mm x 20 mm cylinder) was quantitatively calculated by µCT from the 3-D reconstructed image stacks. For the HEALICOIL PK Suture Anchor samples, the mean percentage of bone ingrowth was 21.9% of the total implant ingrowth while the SwiveLock was 13.9%. The average bone volume for normal, undisturbed femoral bone in a 4.5 mm x 20 mm region of the distal medial femur was 34.5% (Figure 4). Compared to the control femoral bone volume measured from the same animal, the HEALICOIL PK Suture Anchor contained 63% of the control bone volume and the SwiveLock Suture Anchor contained 40% of the control bone volume. A 1-way ANOVA comparing mean percentage of bone ingrowth from the µCT data showed that the new bone ingrowth into the HEALICOIL PK Suture Anchor was significantly greater than that for the vented SwiveLock Suture Anchor 12 weeks after implantation.

Histologically, no adverse tissue response was observed in either the HEALICOIL PK Suture Anchor or the SwiveLock Suture Anchor implants. Bone was clearly evident adjacent to both implants and within the threads, however, there appeared to be more bone within the central canal of HEALICOIL PK Suture Anchors compared to the SwiveLock Suture Anchors, consistent with the µCT data. The fluorochrome bone labels were used to determine when new bone ingrowth was occurring (Figure 5).

These compounds are systemically administered to the sheep during the live phase of the study and deposit in new bone after administration. The second week labeling (calcein=green) was visibly located both adjacent to and within the threads of both of the anchors. In contrast, the HEALICOIL PK Suture Anchors displayed a greater prevalence of the 5th week labelling (alizarin= red) particularly within the central regions of the implant. These results demonstrate that while both anchors displayed active new bone formation during the 2nd week postoperative, the HEALICOIL PK Suture Anchors displayed greater active new bone formation within the central cannulation of the anchor at the 5th week of the implantation period (Figure 4).
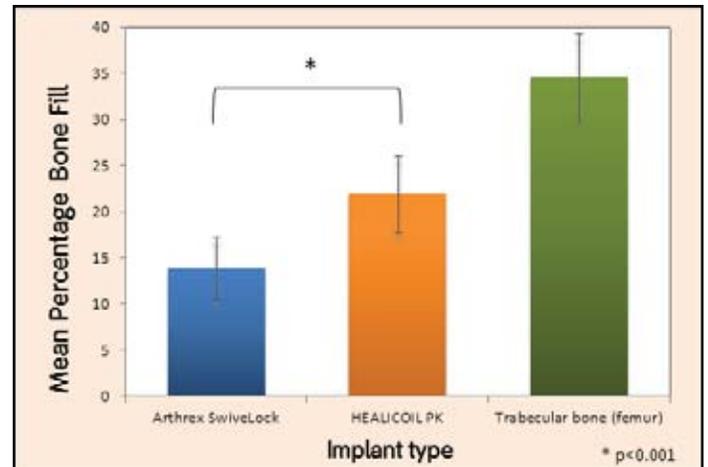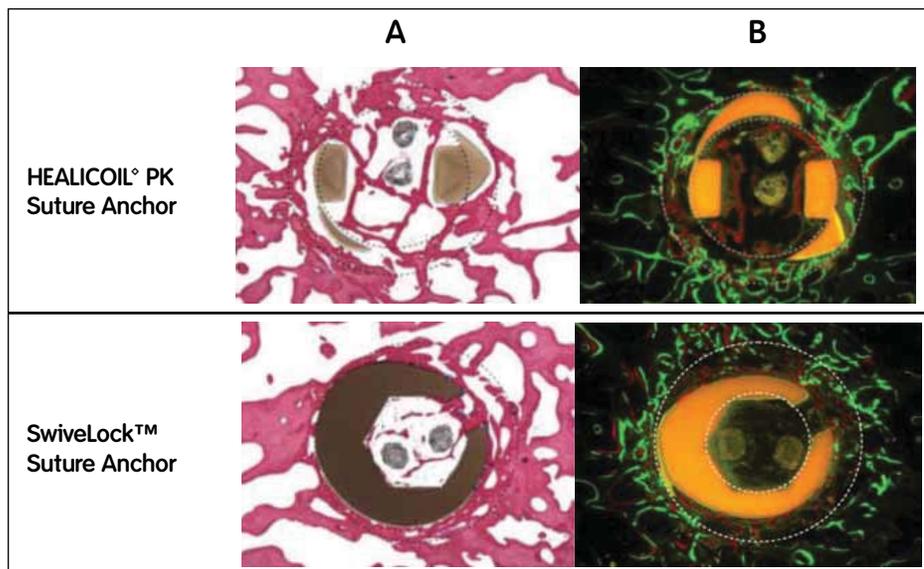
Figure 5. Representative histology sections demonstrating bone ingrowth between threads and through the central channel. Sections in column A demonstrate RBS stained slides and sections in column B show fluorescent labelled slides. Calcein (green, 2 weeks), alizarin complexone (red, 5 weeks), and oxytetracycline (yellow, 8 weeks), 12.5X magnification. PEEK anchor cross sections appear orange.

CONCLUSION

Overall this study showed that both of the PEEK suture anchors were well-tolerated and both supported bone ingrowth. However, these results demonstrate that the new, more open architecture of the HEALICOIL PK Suture Anchor showed 36% more new bone to fill the fenestrations between threads and into the central channel compared to the SwiveLock Suture Anchor and 63% of the volume of intact bone at 12 weeks.

Note: Animal data is not necessarily indicative of human clinical outcomes. These results have not been demonstrated in humans having a variety of bone quality based on specific disease states such as osteoporosis. The effect of formation of new bone on pullout strength was not shown.

References

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9. All data is on file at Smith & Nephew in Validation 15001193 and in WRP TE024–94.