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HEALIX ADVANCE™ Family of Anchors

Torque Strength in Foam Media

DePuy Mitek, Inc. Research and Development

Introduction

The 4.5mm, 5.5mm, and 6.5mm HEALIX ADVANCE™ BR and HEALIX ADVANCE™ PEEK suture anchors are designed to be used for the repair of soft tissue defects to bone for multiple surgical indications. Reference the HEALIX ADVANCE Instructions for Use, IFU-100191, for a complete list of uses for which the HEALIX ADVANCE anchors are indicated for.

All three anchors are internally driven and utilize external threads to provide anchor to bone fixation similar to the 4.5mm, 5.5mm and 6.5mm HEALIX Family of Anchors™. The HEALIX ADVANCE anchors have been designed to maximize the torque strength of the implant, thus minimizing the risk of implant failures during insertion. A benchmarking study was initiated to evaluate the torque strength of the HEALIX ADVANCE anchors against several competitive devices.

Objective

To determine the torque strength of the HEALIX ADVANCE suture anchors. In addition, the torque strength of the following competitive suture anchors were also evaluated:

- Competitive Suture Anchors
  - Arthrex 4.5mm and 5.5mm BioComposite Corkscrew® FT Suture Anchors
  - ConMed Linvatec 4.5mm and 5.5mm CrossFT™-BC Suture Anchors
  - Smith & Nephew HEALICOIL PK 4.5mm and 5.5mm Suture Anchors

Materials and Methods

The torque strength of the anchors were measured by creating pilot holes in dense foam blocks using the recommended instrumentation and inserting the implants into each hole using a torque gage until failure occurred. 35D foam was used for the DePuy Mitek HEALIX ADVANCE BR and Arthrex BioComposite CorkscrewFT anchors, 55D foam was used for the DePuy Mitek HEALIX ADVANCE PEEK and Smith & Nephew HEALICOIL PK anchors.

The peak torque was recorded for each sample as well as the observed failure mode.

Results[i]

The results of the fixation strength testing are shown in *tables 1 & 2* and *figure 1* below

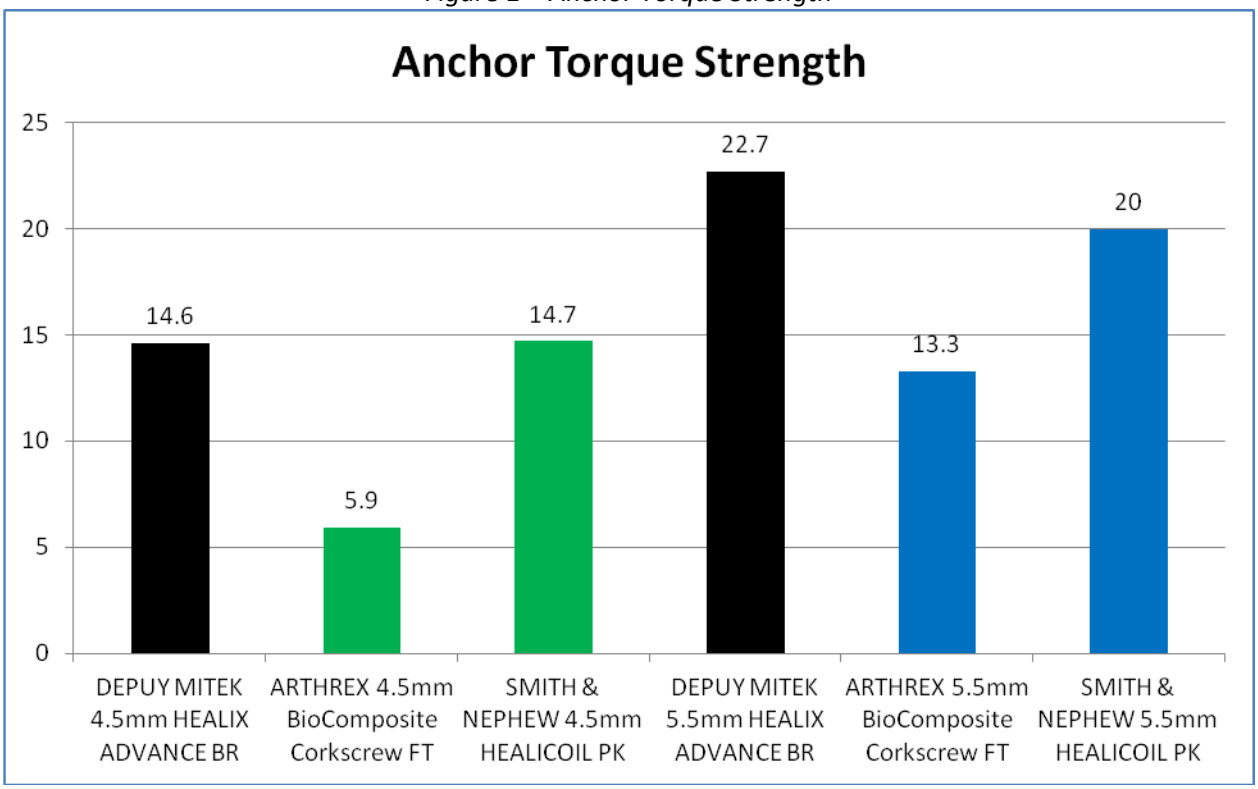
Table 1 – Competitive Anchor Data

Anchor	T.T.F. Average (in-lbs)	T.T.F. STDEV (in-lbs)
Arthrex 4.5mm BioComposite CorkscrewFT	5.9	0.3
Arthrex 5.5mm BioComposite CorkscrewFT	13.3	0.3
S&N 4.5mm Healicoil PK	14.7	0.4
S&N 5.5mm Healicoil PK	20.0	0.5

Table 2 – Healix Advance Anchor Data

Anchor	T.T.F. Average (in-lbs)	T.T.F. STDEV (in-lbs)
Mitek 4.5mm Healix Advance BR	14.6	0.4
Mitek 5.5mm Healix Advance BR	22.7	0.5
Mitek 6.5mm Healix Advance BR	23.5	0.5

Figure 1 – Anchor Torque Strength



[i] Data on file at DePuy Mitek Inc., Raynham, MA. July 2012