

# HEALIX ADVANCE™ Implant System

## Axial Fixation Strength in Foam Media

DePuy Mitek, Inc. Research and Development

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### 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 larger 4.5mm, 5.5mm and 6.5mm HEALIX Family of Anchors™. The HEALIX ADVANCE anchors have distal cancellous threads as well as secondary ‘cortical’ threads on the proximal aspect of the anchor to increase thread purchase in the more dense cortical layer of bone, maximizing anchor fixation strength.

### Objective

To determine the axial fixation strength of the HEALIX ADVANCE suture anchors in a representative foam model. In addition, the fixation strengths of the following competitive and predicate DePuy Mitek 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 Suture Anchor (4.5mm)
  - Smith & Nephew TWINFIX AB 5.0 Suture Anchor (5.0mm)
- DePuy Mitek Suture Anchors
  - 4.5mm, 5.5mm and 6.5mm HEALIX BR Suture Anchors
  - 4.5mm, 5.5mm and 6.5mm HEALIX PEEK Suture Anchors

### Materials and Methods

The foam blocks used in this study had a constant density of 10 pounds per cubic foot (pcf) to simulate the density of cancellous bone which may be encountered during typical product use.

Anchors were inserted into the foam test medium using the techniques defined by each implant’s product IFU. All anchors were inserted a minimum of 0.5 inches apart. After anchor insertion, the foam was attached to a servo-hydraulic testing machine and an axial tensile strength test was performed on each sample. The suture tails attached to each anchor were fixated to the testing machine using a pneumatic clamp. The suture tails were then pulled at a rate of 4.23 mm/second (10 inches/minute) until implant failure occurred. The maximum load to failure was recorded for each sample.

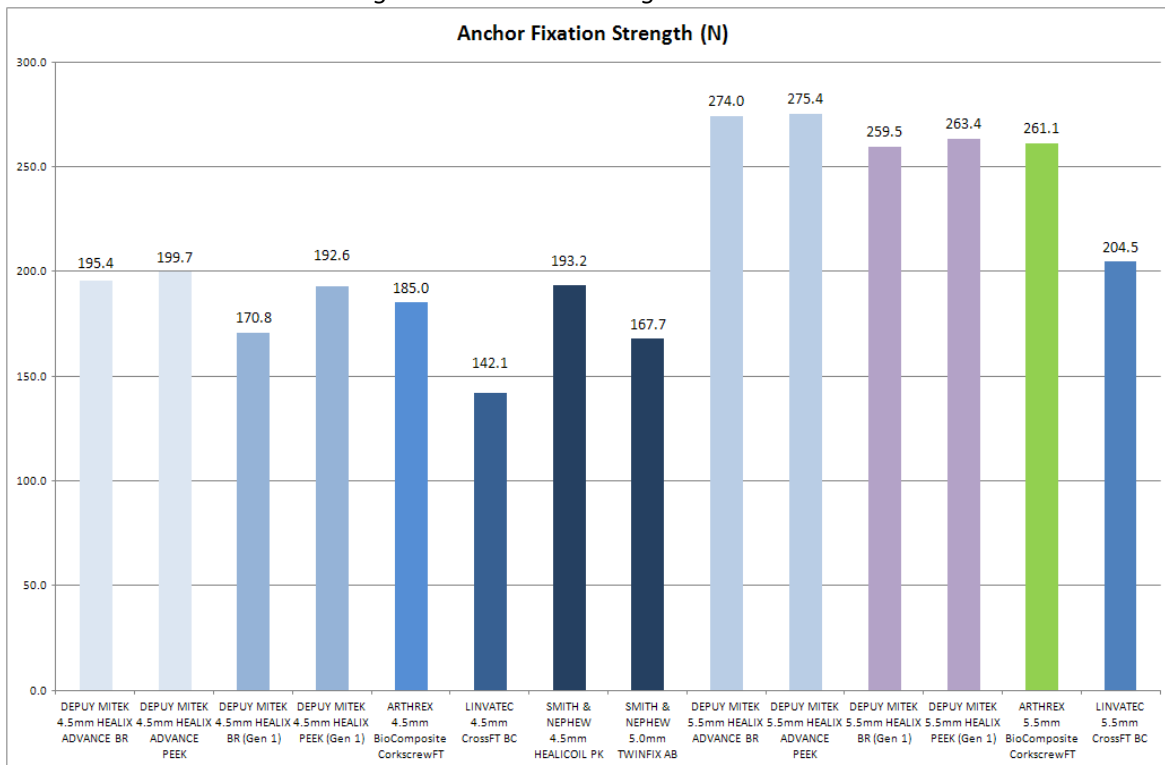
### Results<sup>i</sup>

The results of the fixation strength testing are shown in *table 1* and *figure 1*.

**Table 1 – Fixation Strength Test Results**

<b>4.5mm Anchor Data</b>		
Anchor	Anchor Fixation Strength	
	Average (N)	Standard Deviation (N)
4.5mm HEALIX ADVANCE BR	195.4	4.2
4.5mm HEALIX ADVANCE PEEK	199.7	7.4
4.5mm HEALIX BR	170.8	8.3
4.5mm HEALIX PEEK	192.6	9.3
4.5mm BioComposite Corkscrew FT	185.0	4.3
4.5mm CrossFT-BC	142.1	4.7
4.5mm HEALICOIL PK	193.2	8.1
<b>5.0mm &amp; 5.5mm Anchor Data</b>		
Anchor	Anchor Fixation Strength	
	Average (N)	Standard Deviation (N)
5.5mm HEALIX ADVANCE BR	274.0	15.2
5.5mm HEALIX ADVANCE PEEK	275.4	13.7
5.5mm HEALIX BR	259.5	15.8
5.5mm HEALIX PEEK	263.4	19.3
5.5mm BioComposite Corkscrew FT	264.1	12.1
5.5mm CrossFT-BC	204.5	11.2
5.0mm TWINFIX AB	167.7	2.8

**Figure 1 – Fixation Strength Test Results**



<sup>1</sup> Data on file at DePuy Mitek Inc., Raynham, MA. August 2012