Knot Height, Knot Volume and Knot Profile of Novel DFX Tensile Tape Suture System

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Background:

The development of arthroscopic procedures over last decade has led to introduction of several high-tensile strength non-absorbable sutures for several orthopedic applications including fixation of soft tissue to bone by means of anchors, tendon repairs, suture fixation of fracture fragments etc. The material composition and/or the braid characteristics of these sutures lead to varying biological reactivity thereby impacting the patient outcomes (1). Knot height, knot volume and knot profile are important braid characteristics which can cause irritation and impingement in several orthopedic procedures including closure of synovium in patella fracture, shoulder acromial space etc.

The purpose of this study was to compare the knot height, knot volume, and knot profile of the Dunamis Medical's 2mm DFX Tensile Tape System with the Arthrex's 2mm Fiber Tape. We hypothesize that the continuous flat-braid design of DFX Tensile Tape will eliminate the irritation and impingement by reducing the knot height and knot volume.

Materials:

<u>2mm DFX Tensile Tape Suture System</u>: The Dunamis MedicalTM, LLC (Greenville, AL) DFX Tensile Tape Suture System is a novel non-absorbable ultra-high molecular weight polyethylene (UHMWPE) continuous flat-braid suture tape.

<u>2mm Fiber Tape</u>: The Arthrex® (Naples, FL) Fiber Tape is a non-absorbable 2mm suture tape with polyethylene structure like No. 2 FiberWire (Arthrex®, Naples, FL) with thicker center and breadth (2). FiberWire is composed of an UHMWPE multifilament core surrounded by a braided poly-ester jacket (3).

Methods:

<u>Surgeons' Observation</u>: A product satisfaction survey was provided to the surgeons (N = 6) who have experience using both DFX Tensile Tape Suture System as well as the Fiber Tape. The questions in the survey included the comparison of knot profile and knot height for 2mm DFX Tensile Tape and 2mm Fiber Tape, and to determine whether knot height is a concern in superficial repairs.

<u>Knot Volume and Knot Height Determination</u>: Five 2mm DFX Tensile Tapes and Four 2mm Fiber Tapes were used to determine the knot volume. A set of calipers were used to measure the knot volume.

For the knot height, Five 2mm DFX Tensile Tapes and Four 2mm Fiber Tapes were used. A series of Five square knots were tied and a set of calipers were used to measure the total height of the knots.

<u>Statistical Analysis</u>: Statistical analysis was performed using a SPSS Statistics 22.0. The mean and standard error of mean values along with statistical analysis using independent-samples t-test was performed for knot volume and knot height. The results were considered significant when p<0.05.

Results:

<u>Surgeons' observation</u>: All the 6 surgeons rated knot height and knot profile of 2mm DFX Tensile Tape to be better compared to 2mm Fiber Tape. In addition, 4 out of 6 surgeons reported that knot height is a concern in superficial repairs.

<u>Knot Volume and Knot Height Determination</u>: The results suggested a significantly (p<0.05) lower knot volume (Figure 1) as well as knot height (Figure 2) for DFX Tensile Tape Suture System compared to the Fiber Tape.

Conclusions:

In conclusion, according to our product satisfaction survey, the surgeons believe that the knot height is a concern and rated Dunamis Medical's 2mm DFX Tensile Tape's knot height and knot profile to be better compared to Arthrex's 2mm Fiber Tape. This is in accordance with our laboratory testing results which demonstrated a significantly lower knot height and knot volume for DFX Tensile Tape compared to Fiber Tape.

References:

- 1. Carr BJ, Ochoa L, Rankin D, Owens BD. Biologic response to orthopedic sutures: a histologic study in rabbit model. Orthopedics. 2009 Nov;32(11):828.
- 2. Denard PJ, Burkhart SS. A load-sharing rip-stop fixation construct for arthroscopic rotator cuff repair. Arthrosc Tech. 2012 Mar 15;1(1): e37-42.
- 3. Arthrex, Inc. FiberWire_braided composite suture product brochure. Naples, FL: Arthrex, Inc.; 2005.

Figures:

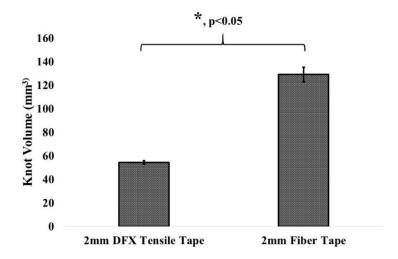


Figure 1: Knot volume (mm³) comparison of 2mm DFX Tensile Tape with 2mm Fiber Tape. * shows significant difference i.e. p<0.05.

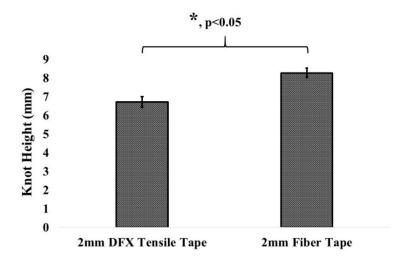


Figure 2: Knot height (mm) comparison of 2mm DFX Tensile Tape with 2mm Fiber Tape. * shows significant difference i.e. p<0.05.