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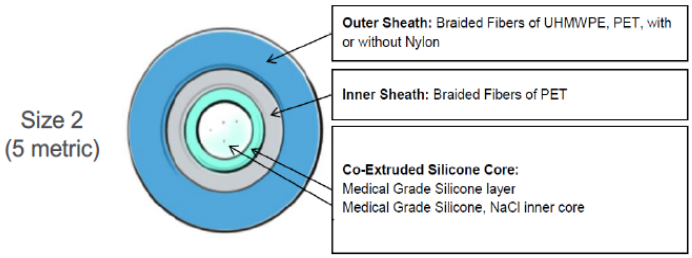
DYNACORD™ Suture for Indicated Soft Tissue Repair Procedures

VALUE ANALYSIS BRIEF

INTRODUCTION

This value analysis brief presents information on the potential benefits of using HEALIX ADVANCE™ Anchors with DYNACORD™ Suture (DePuy Synthes) during indicated soft tissue repair procedures. The DYNACORD Suture is a high-strength, orthopedic suture that minimizes suture laxity in soft tissue repair procedures in order to preserve consistent tissue approximation. DYNACORD Suture is uniquely designed to shorten when compression is lost, thereby minimizing micro-motion and reducing gap formation. The DYNACORD Suture design consists of an outer sheath with braided fibers of ultra-high molecular weight polyethylene (UHMWPE), polyester (PET), with or without nylon, an inner sheath with braided fibers of PET, and a co-extruded silicone core made of medical grade silicone and NaCl (Figure 1). This internal salt filled core helps the DYNACORD Suture resist laxity.

Figure 1: Cross Sectional View



CLINICAL UNMET NEED

Over the past few decades, soft tissue repair techniques have evolved from an open approach to an all-arthroscopic approach. One of the major benefits of the arthroscopic approach is the ability to repair soft tissues without detachment or manipulation of the surrounding muscles.[1] These procedures have been shown to reduce pain, improve motion, restore function, and improve the general health status of the patient.[2] However, failure of soft tissue repairs can occur. Two common failure modes for soft tissue repairs during the healing period are knot slippage and lack of consistent tissue approximation to bone.[11] This suggests that advances in repair techniques and surgical instrumentation are needed to optimize the healing environment after the repair in order to facilitate restoration of function.

Structural failure of the repair occurs in a substantial number of cases and can lead to an unsatisfactory result. For example, a recent meta-analysis of 8,000 rotator cuff repairs showed a mean re-tear rate of 26.6%.[3] Additionally, the percentage of revision surgeries has been reported to be as high as 30% for isolated supraspinatus tendon tears.[2] Advances in repair techniques are needed to optimize the healing environment after repair in order to minimize the risk of revision surgery.[2] Many studies have reported that the key features of an ideal rotator cuff repair are higher initial fixation strength, greater contact area and contact pressure at the tendon-bone interface, minimal gap formation, and sustained mechanical stability until the healing has been achieved.[2] Evidence from the pre-clinical and biomechanical studies shows the DYNACORD Suture has many of these attributes.[5-9]

Overall, the goal for soft tissue repair techniques and surgical instrumentation are to:[2]

- Provide high initial fixation strength
- Maintain the ideal tissue-to-bone approximation force at the tendon-bone interface
- Permit minimal gap formation
- Minimize micro-motion due to knot/suture slippage or suture laxity
- Sustain mechanical stability until healing has been achieved

Reduction in revision surgery may lead to improved outcomes and help reduce healthcare costs.

Direct cost estimates (as reported in the medical literature) for a rotator cuff repair range from $10,000 to over $17,000.[3,10] A recent micro-costing analysis in the ASC setting by Bisson and colleagues (2015) estimated the direct costs of rotator cuff repair at approximately $13,000.[10] From these figures, the total direct expenditure on rotator cuff repair in the United States may range from $6 billion to $8 billion.[3] Even with a small reduction in the incidence of revision procedures, healthcare cost savings could be substantial given the number of these types of procedures performed in the US each year. A 1% reduction in the current rate of revision (from 27% to 26%) for the estimated 601,000 rotator cuff repair procedures per year would yield a potential cost savings of $78.1 MM (reduction of 6,010 revision procedures at a cost of $13,000 per procedure). Revision surgery is not only costly to a healthcare system, but it may negatively affect a patient's well-being. In a cost, constrained healthcare system, avoidance of revision surgery may lead to improved overall care and save valuable resources.

DYNACORD SUTURE VALUE PROPOSITION

The design elements and material characteristics of the DYNACORD Suture translate into a number of potential benefits to various stakeholders. These benefits include the following:

- Shows no strangulation or necrosis of the tissue[5,7]
- Consists of various materials which do not exhibit an observed unfavorable tissue response[6]
- Maintains soft tissue approximation force closer to initial load as compared to tested competitive suture[7]
- Provides improved knot security than tested competitive suture[8]
- Demonstrates less tendon damage than tested competitive suture[9]

CONCLUSION

Clinical literature has shown that post-surgical gap formations, due to suture laxity, may lead to revision surgery. DYNACORD Suture has been uniquely designed to reduce gap formations with consistent tissue to bone approximation for indicated procedures.

CITATIONS

1. Romeo AA, Cohen BS, Cole BJ. Arthroscopic repair of full-thickness rotator cuff tears: Surgical technique and instrumentation. Orthopaedic Special Edition 2001; 7(1): 25-30.
2. Yeh ML, Hong CK, Su WR, et al. Current Biomechanical Concepts of Suture Bridge Repair Technique for Rotator Cuff Tear. International Journal of Orthopaedics 2015;23(3):284-288.
3. McElvany MD, McGoldrick E, Gee AO, Neradilek MB, Matsen FA. Rotator cuff repair: published evidence on factors associated with repair integrity and clinical outcome. Am J Sports Med. 2015 Feb;43(2):491-5
4. Lädermann A, Denard PJ, Burkhart SS. Management of failed rotator cuff repair: a systematic review. J ISAKOS. 2016 Jan;1(1):32-37.
5. DePuy Synthes. Evaluation of DYNACORD Safety Following Implantation in the Infraspinatus Tendon of Sheep – 5 Days and 6 Weeks. GLP Report#: 17T-46632-02. December 2017.
6. DePuy Synthes. A GLP Study to Assess Whether Silicone Debris Migrates to the Lymphatic System. Study #: 103313937. January 2018.
7. DePuy Synthes. DYNACORD Approximation Force Design Verification Report. Study #:103394861. August 2017
8. DePuy Synthes. Results of Knot Security Evidence Generation Study. Study Notebook 2017-14; page 20 -22.
9. DePuy Synthes. Results of Tissue Abrasiveness Evidence Generation Study. Study Notebook 2017-14; page 23-25.
10. Bisson L, Zivaljevic N, Sanders S, Pula D. A cost analysis of single-row versus double-row and suture bridge rotator cuff repair methods. Knee Surg Sports Traumatol Arthrosc. 2015 Feb;23(2):487-93.
11. Hurwit D, Journal of Arthroscopic and Related Surgery, Vol 30 No11; Page 1406-1412.

^Cost saving calculations may not be in local currencies. The economic analysis was performed according to hospital data set in countries outside of Australia and New Zealand.

DYNACORD Suture is unique to DePuy Synthes. Thus, all studies referenced herein pertain directly to this technology. Further research should aim to validate these findings in a clinical setting.

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