

TRUESPAN® Meniscal Repair System

VALUE ANALYSIS BRIEF

Introduction and Methodology

This value analysis brief presents information on the design features and potential procedural benefits of using the TRUESPAN™ Meniscal Repair System. The system is designed to be simple, robust, versatile and low profile. TRUESPAN Meniscal Repair System features an ergonomic design with a single trigger deployment mechanism allowing a single-handed technique. The device is pre-loaded with two rigid implants and #2-0 ORTHOCORD® Suture to complete the repair. The implants and pre-tied knot sit on the back side of the meniscus after repair is completed, preventing any potential further chondral damage. The implant system comes sterile and pre-assembled. Potential procedural benefits include:

- **Simplifying Unit Deployment**
- **Increasing Surgeon Maneuverability**
- **Increasing Device and Implant Reliability**

The referenced data for this value brief were obtained through a search of MEDLINE for current meniscal repair published in the last 10 years and reference to existing internal research.

Note: The TRUESPAN Meniscal Repair System is unique to DePuy Synthes Mitek Sports Medicine.

Background

Meniscal repair has been performed for over a century, with some of the first procedures documented in 1885 [1]. Today, meniscal tears account for more than 400,000 ambulatory surgical visits each year in the United States [2] and they have become one of the most common knee condition requiring surgery [3, 4]. Commonly occurring in young adults, studies in the United States found that the incidence of meniscal injuries was 5.1 per 100,000 athlete exposures [5]. As a result of all meniscal injury and disease, some researchers estimate that the annual societal cost is between \$500 million and \$5 billion in the United States annually [6], therefore the need to identify effective treatment methods is of great importance.

In the past, meniscectomy was the preferred treatment for meniscal tears [4]. Recent evidence has reinforced the structural and functional importance of the meniscus which has created a movement towards preserving it through repair [7, 8]. As a response, new radial tear repair techniques have emerged as promising alternatives to meniscectomy [1, 9].

Ultimately, the goal is to preserve the meniscal tissue to minimize the risk for osteoarthritis particularly in the most commonly seen cases such as in young athletes [3].

Since the first generation of meniscal repair devices, many iterations have improved the strength of implants, reduced the invasiveness of procedures and reduced complications with more easily manipulative devices that allow greater access to hard to reach tears [1, 10].

There are several important factors to consider when evaluating meniscal repair devices for orthopedic procedures. These factors include:

- Reliability and strength of the repair
- Device's ease of use
- Device's maneuverability during the surgery

Product

The TRUESPAN Meniscal Repair System is designed to address the needs of today's orthopedic surgeons due to its:

- 1.7 mm needle with adjustable depth stop and varying needle angles
- Ergonomic trigger and handle
- ORTHOCORD Orthopedic Suture
- Refined suture routing system
- Pre-loaded and single-use design

These design elements translate into several potential procedural benefits to various stakeholders.

Potential Procedural Benefits

Simplifying Unit Deployment

As the healthcare environment is rapidly changing there is a growing need to identify products and procedures that will provide optimal value to all stakeholders in the system [11, 12].

Figure 1. TRUESPAN® Meniscal Repair System



The TRUESPAN Meniscal Repair System offers a variety of design features that provides reproducible deployment during meniscal repair:

- a. Single use – reduces the need for set up or reload time as the device comes pre-loaded, sterile and ready to use.
- b. Single Trigger – reduces the risk of misfires from pulling the wrong trigger and consequently the need to re-load the device or re-do the procedure.
- c. Re-useable pusher cutter – Reduces recurring purchase costs. This cutter can be autoclaved with other surgical equipment.

These features streamline the surgical set-up and perioperative procedures, saving operating costs in the form of surgeon utilization and efficiency. Future studies should seek to quantify the extent of operational efficiencies gained.

Increasing Surgeon Maneuverability

TRUESPAN Meniscal Repair System was designed to improve the user experience with an ergonomic single-handed technique, improving overall dexterity.

Increased maneuverability allows for easier access to difficult to reach angles. It is reported that increased control and maneuverability of meniscal repair devices would improve ability to position the device and subsequent implants resulting in decreased articular cartilage damage [1]. An adjustable depth stop and varying needle angles may also reduce the risk of harming adjacent neurovascular structures during the repair [1, 13].

Specifically, the design features that reinforce the maneuverability include:

- a. Low profile – Allows for greater maneuverability and movement during surgical manipulation.
- b. Single-handed technique – Increases overall surgeon dexterity.
- c. Varying needle angle – Available in 0, 12 and 24 degrees. Provides easy access to hard to reach areas.
- d. Adjustable Depth Stop: Allows user to adjust needle penetration depth between 10-20mm intraoperatively.

Further studies should seek to quantify reductions in surgical time and the number of surgical errors due to the increased accessibility and maneuverability.

Increasing Device and Implant Reliability

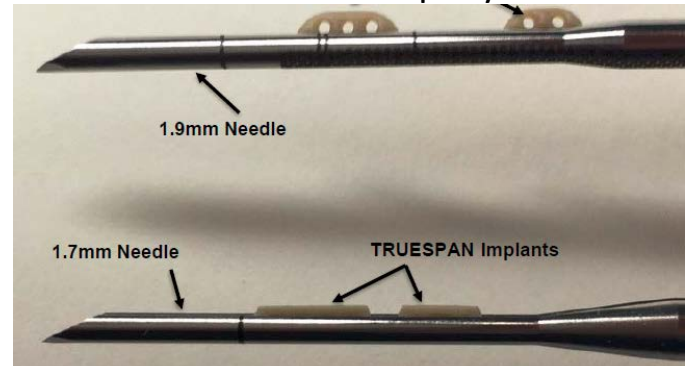
The size of the implant is critical to the long-term healing after meniscal repair. Various case studies present complications arising from intrusive bodies left on the meniscal surface [14, 15, 16].

Kumar and colleagues discussed a case of a young athlete presenting pain when moving from a sitting position four months after follow-up meniscal repair surgery [17]. Upon further inspection, they noted longitudinal grooves over the medial femoral condyles giving a tram track appearance [17]. The authors concluded that protrusion into the intra-articular space leaves the knee vulnerable to complications such as chondral damage, extra-articular migration, hematoma formation from a punctured saphenous vein and inflammatory foreign-body reaction, therefore the size of rigid fixation bodies should be controlled whenever possible.

Further case studies and reports have noted even large knots left in the articular surface also leave the post-repair meniscus vulnerable. Kelley and colleagues report on a meniscal repair case using the Mulberry Knot Suture Technique [18]. Four weeks after the initial meniscal repair the patient presented with increasing knee pain and was found to have a small nodule near the incision. Similar to the case of the rigid implant, follow-up arthroscopy revealed scuffing of the medial femoral condyle, in addition to synovitis of the meniscosynovial junction secondary to the tibial Mulberry knot suture. Any large foreign body left on the meniscal surface, from rigid implant to suture knot has the potential to result in post-operative injury.

The TRUESPAN Meniscal Repair System does not leave a large knot or implant in the articular surface and therefore may be less likely to result in chondral injury. Studies should be conducted to determine whether there is a reduction in post-operative complications from these reduced implant sizes.

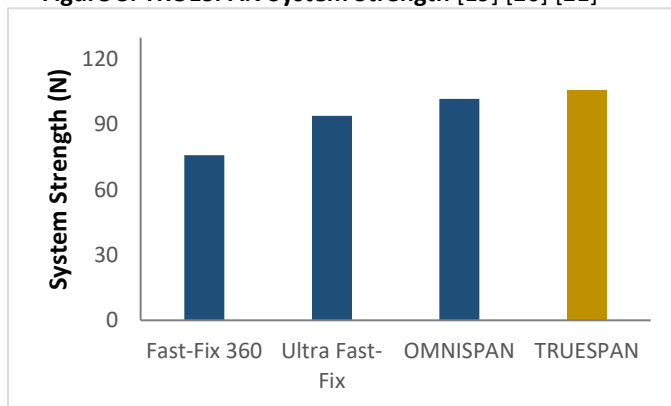
Figure 2. OMNISPAN® Meniscal Repair System and TRUESPAN® Meniscal Repair System



Ideal fixation techniques should have the fixation strength to permit rehabilitation without disconnecting the torn meniscus [10]. Currently, primary fixation with a vertical mattress suture based repair is the gold standard with regards to biomechanical strength [10].

In a biomechanical study characterizing the system strength of commonly used meniscal repair devices (n=5) by DePuy Synthes, TRUESPAN Meniscal Repair System demonstrated the largest load strength at 105.7 N (SD: 20.1) while Fast-Fix 360 was 75.9N (SD: 18.9), Ultra Fast-Fix was 94.1N (SD: 30.5) and the OMNISPAN® Meniscal Repair System was 101.7N (SD: 20.9) (Figure 3).

Figure 3. TRUESPAN System Strength [19] [20] [21]



19. Internal Data: Test Report 103248458

20. Internal Data: Notebook 2014-10, Pages 5-9

21. Internal Data: Notebook 2014-10, Pages 15-21

Altogether, the design features that cater to the increased reliability of the device include:

- Reduced Implant size** – Compared to the predicate device, OMNISPAN Meniscal Repair System, the implant size was reduced. Smaller implants allow for more fine movements and reduces damage to healthy native meniscal tissues.
- Rigid needle and shaft** – prevent misfires during manipulation which would otherwise require a new device/reloading.
- Redesigned implant** – Compared to other repair systems in Figure 3, the superior strength of the TRUESPAN system may decrease the failure rate. Does not leave a knot in the articular surface to prevent chondral damage.
- Refined suture routing** – Improves tensioning of the overall repair construct.

Conclusions

Overall, the TRUESPAN Meniscal Repair System is designed to address the needs of today's orthopedic surgeons. These improved design elements have the potential to simplify unit deployment, increase device maneuverability and increase device and implant reliability with the primary goal of

increasing operational efficiency and decreasing overall costs while providing quality.

Citations

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DePuy Synthes Mitek Sports Medicine:

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WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.

Indication for Use: The TRUESPAN Meniscal Repair System is intended for use in meniscal repairs and meniscal allograft procedures. The TRUESPAN Meniscal Repair System is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

Device Description: The proposed device is an all-inside meniscal repair system. The implant consists of two rigid backstops, ORTHOCORD suture and UHMWPE braid. The implant system and applier are pre-assembled, and the whole device is sterile, for single patient use only. Compression of the fixation point is accomplished by pulling on the suture post to allow the two suture strands creating the bridge between the implants to lay tight on the surface of the fixation point.

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