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SPEEDTRAP™ Graft Preparation System

VALUE ANALYSIS BRIEF

Introduction and Methodology

This value analysis brief presents information on the design features and potential procedural benefits of using the DePuy Synthes Mitek Sports Medicine SPEEDTRAP™ Graft Preparation System, a whipstitch suture delivery device created to simplify soft-tissue graft preparation. The SPEEDTRAP System is designed to apply uniform, consistent whipstitches to the graft faster and easier than traditional techniques. The needleless application helps minimize the risk for needle stick injuries to the surgeon and operating room staff while the suture maintains the strength required to meet clinical conditions. The even distribution and uniform pattern of whipstitches enables tubularization of the graft for easy passage through the tunnel. This high strength suture construct is offered pre-loaded on a sterile, single-use delivery device. Potential procedural benefits include:

- **Simplifying soft tissue graft preparation**
- **Improving operating room efficiency and helping to control costs**
- **Minimizing risk of needle stick injuries for surgeon and operating room staff**
- **Maintaining quality of soft tissue and maximizing strength of the graft construct**

The referenced data for this value brief were obtained through a search of MEDLINE for current trends in soft-tissue graft preparation as well as biomechanical and clinical studies of graft preparation systems published in the last 10 years.

Note: The SPEEDTRAP System is unique to DePuy Synthes Mitek Sports Medicine.

Background

Repair or reconstruction of damaged ligaments such as the anterior cruciate ligament (ACL), posterior cruciate ligament, collateral ligament, or medial patellofemoral ligament, are some of the most frequently performed orthopaedic surgeries in the United States. Approximately 150,000 anterior cruciate ligament reconstruction procedures are performed annually.[1,2]

Arthroscopic surgical techniques have evolved such that tissue grafts, either from a cadaver (allograft) or the host body (autograft) have been utilized with clinical success for ligament reconstruction procedures.[3] Favorable characteristics of graft options for ligament reconstruction include those that have similar structural and biomechanical characteristics of the native ligament, allow for secure fixation, permit rapid biologic incorporation, and have limited donor site morbidity.[4] Ideally, the graft selected should allow for early, active rehabilitation and the eventual restoration of the physical and mechanical properties of the native ligament.[4]

Autografts can be harvested from the bone-patella tendon-bone (BTB), hamstring tendon, or from the quadriceps tendon. Allografts typically include cadaveric forms of these same types of autologous grafts as well as tibialis anterior and Achilles tendon grafts.[3,4] The hamstring tendon autograft and the BTB autograft are the most popular grafts used for ligament reconstruction procedures.[5] Whipstitching the ends of the semitendinosus and gracilis tendons has long been advocated for both harvesting and preparing the hamstring tendon graft to permit adequate tensioning of the graft.[6] However, placement of the running, locking stitches at each end of the harvested tendons can be time-consuming, and there are several potential disadvantages such as the risk of damaging the tendon when the needle passes through the tendon graft and the potential for needle-stick injury to the user while sewing the stitches.[6] Thus, there is a clinical need for graft preparation techniques that reduce the amount of time to prepare the graft construct and reduce the exposure to needles.

There are a number of important factors to consider when evaluating graft preparation systems for orthopedic procedures. These factors include:

- Speed and efficiency of graft preparation,
- Safety and reliability of the application,
- Strength of the construct for graft tensioning, and
- Ease of graft passage through tunnel.

The SPEEDTRAP Graft Preparation System is designed to address the clinical needs of today's orthopedic surgeons due to its:

- Needleless design,
- Reinforced suture spine with anchored winding sutures,
- Strong suture construct,
- Even distribution and uniform pattern of whipstitches,
- Pre-loaded, single-use delivery design.

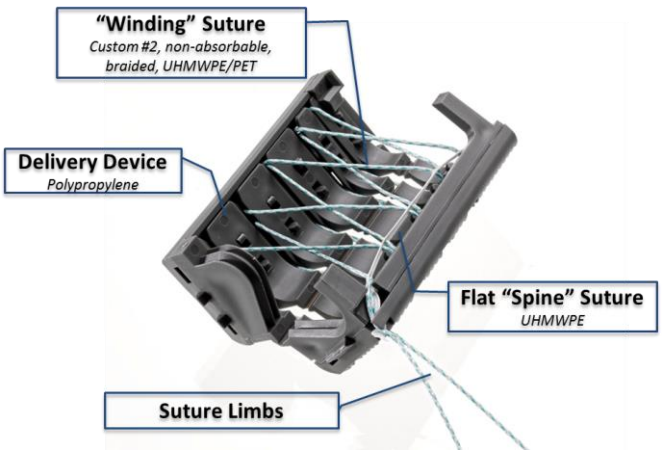
These design elements translate into a number of potential procedural benefits to various stakeholders.

Potential Procedural Benefits

Simplifies soft tissue graft preparation

The SPEEDTRAP System is an all-suture based construct designed to simplify soft tissue graft preparation (Figure 1).[21] The high strength suture construct reinforces grafts through constriction rather than piercing through the graft. This type of construct is advantageous when small, wispy grafts are used.

Figure 1. SPEEDTRAP System



The SPEEDTRAP System offers a variety of design features for simplifying soft tissue graft preparation:

- Flat spine suture anchors the winding sutures to evenly distribute the whipstitches along the graft rather than piercing through the graft,
- Pre-packaged, disposable delivery design facilitates deployment of the sutures on to the graft and minimizes graft preparation time,
- Strong suture construct maintains the strength required to meet clinical conditions yet does not lacerate graft during tensioning and cyclic loading,
- Needleless suture design minimizes graft damage and the risk of needle stick injuries to the surgeon or operating room staff, and
- Even distribution and uniform pattern of whipstitches enables tubularization of graft for easy passage through the tunnel.

These design features enable the surgeon to correctly use the SPEEDTRAP System following just one demonstration.[7] Overall, the SPEEDTRAP System simplifies the soft tissue graft preparation process and allows operating room staff to efficiently prepare grafts for a variety of surgical procedures.

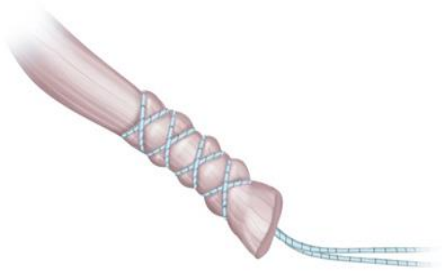
Improves operating room efficiency and helps control costs

Hospitals and ambulatory surgery centers must continually balance the costs of advancing medical technology, diminishing insurance reimbursements, and the logistics of running an operationally complex and successful facility while maintaining safe and high-quality health care for patients.[8] Increasing operating room efficiency and controlling operating room costs can often be achieved by streamlining the existing steps that are involved with patient care preoperatively, intraoperatively, and postoperatively while still providing high-quality, technologically advanced surgical services.[8]

During ACL reconstruction procedures with double looped hamstring autografts, the free ends of the tendons are usually sutured to improve intraoperative handling and to permit adequate tensioning of the graft.[9] A commonly used technique for the suturing of the tendon ends involves the application of a whipstitch to the ends of the graft.[9] However, this method of harvesting and preparing the tendon graft is time consuming and often times requires a physician's assistant to help with the graft preparation. A study by Hantes colleagues in sixty patients undergoing ACL reconstruction reported a mean hamstring graft-preparation time of 19 minutes (range 16-21 minutes) and a mean time-interval between graft harvesting and implantation of 35 minutes (range, 26-40 minutes).[5] Similarly, the preparation of BTB grafts often requires surgeons and physician's assistants to employ multiple steps and tools (i.e., manual bone shapers, shavers, ball burrs, etc.). The same study by Hantes and colleagues reported a mean BTB graft-preparation time of 10 minutes (range 9-14 minutes) and a mean time-interval between graft harvesting and implantation of 35 minutes (range, 26-40 minutes).[5]

The SPEEDTRAP System is a whipstitch suture delivery device created to simplify soft-tissue graft preparation by applying uniform, consistent whipstitches to the graft faster and easier than traditional techniques (Figure 2).

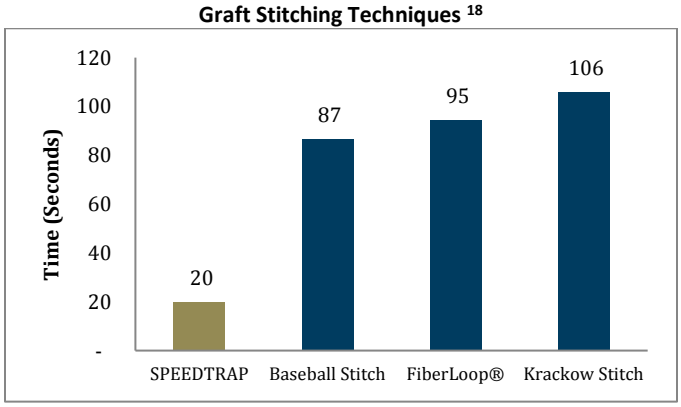
Figure 2. Whipstitching with the SPEEDTRAP System



The SPEEDTRAP System provides significant operating room efficiencies by reducing overall operating room time compared to traditional graft preparation methods, eliminating the need for whipstitching with a needle and suture.

A preliminary cadaveric study (n=44 deployments) by DePuy Synthes comparing the graft preparation times among various stitching techniques found that the SPEEDTRAP System reduces the time to whipstitch the graft by 77% compared to the baseball stitching technique, by 79% compared to the time to stitch with FiberLoop®, and by 81% compared to the Krackow stitching technique (Figure 3).[18]

Figure 3. Speed Comparison (in Seconds) Among Graft Stitching Techniques [18]



Assuming the cost of operating time is about $54 per minute for orthopedic procedures,[11] then the estimated cost savings from a 77%, 79%, or 81% reduction in the time to whipstitch four soft-tissue graft ends would be $241, $270 or $310, respectively. Further research should aim to validate these findings in the clinical setting.^

Overall, the SPEEDTRAP System may provide significant operating room efficiencies by reducing overall operating room time and helping to control costs compared to traditional graft preparation techniques.

Minimizes risk of needle stick injuries for surgeon and operating room staff

There are a number of potential procedural benefits for both operating room staff and patients that may be achieved when using the SPEEDTRAP System. These benefits may include minimizing the risk of needle prick injuries to the operating room staff,[6] reducing tourniquet time for the patient, and minimizing the risk of infection by decreasing the time to prepare the graft.[12]

One of the disadvantages of current soft tissue whipstitching techniques is the potential for needle-stick injury to the user.[6] Accidental exposure to blood caused by needle injuries carries the risk of infection by blood-borne viruses such as the hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).[13] Although the risks of contracting the virus may be small (i.e.,5-40% for HBV 3-10% for HCV, 0.2-0.5% for HIV), immediate action following the exposure is mandatory and may include taking blood samples (for both the clinician and patient), follow-up examinations, and antiviral prophylaxis.[13] The needleless application of the SPEEDTRAP System potentially minimizes these risks associated with needle-stick injuries.

SPEEDTRAP System reduces graft preparation time which may lead to reduction in procedure time and possibly tourniquet time. Potential risks associated with tourniquet application include vascular injury, nerve palsy, post-operative swelling and stiffness, and muscle damage.[14,15] Other less frequent complications associated with tourniquet use include reactive hyperaemia and wound healing disorders due to perioperative hypoxia and reduced post-operative tissue perfusion.[14,15]

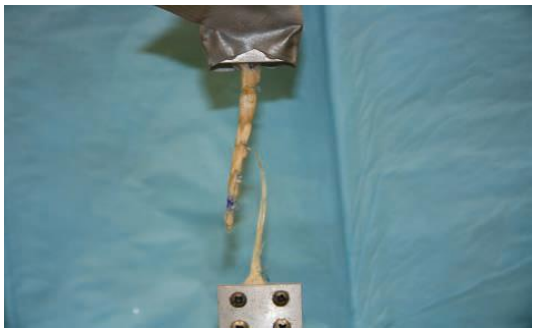
Some surgeons have postulated that the *time* from graft harvest to implantation may be a risk factor for contamination and infection.[5] Preparation of hamstring tendon grafts require more excessive and prolonged manipulation in comparison with BTB grafts because of the need for tissue removal and tendon suturing.[5] Consequently, there may be an elevated risk of contamination due to a prolonged exposure to air, the surgeon's gloves, or surgical instruments during the graft preparation process. For example, a study by Brophy and colleagues found that prevalence of infection was 0.3% in patients receiving BTB autograft compared with 1.3% in patients receiving hamstring autograft and 1.0% in patients receiving other grafts.[12] However, a study by Hantes and colleagues found no difference in the rate of bacterial contamination between hamstring autografts and BTB autografts for ACL reconstruction.[5] Further research is needed to determine why infection rates vary by graft type.[16]

Maintains quality of soft tissue and maximizes strength of the graft construct

One of the procedural benefits of SPEEDTRAP System is that it reinforces grafts through constriction rather than piercing through the graft. This "atraumatic" characteristic maximizes the available tendon while maintaining the quality and strength of the soft tissue. A study by Wang and colleagues evaluated how the structural and mechanical properties of semitendinosus grafts change with tubularization.[17] This biomechanical study examined peak tensile load to failure

and stiffness in cadaveric semitendinosus tendons that were tubularized using interrupted sutures (n=10) versus cadaveric semitendinosus tendons in their native form (n=10). The authors found that the nontubularized tendons had a higher peak tensile load to failure and higher stiffness than the tubularized group.[17] More specifically, the authors observed that when passing the needle and suture through the tendon, multiple holes were created, resulting in disruption for the tendon fibers and creating "soft tissue risers".[17] Additionally, the results indicated that the mode of failure of the tubularized tendons occurred along the needle/suture holes.[17]

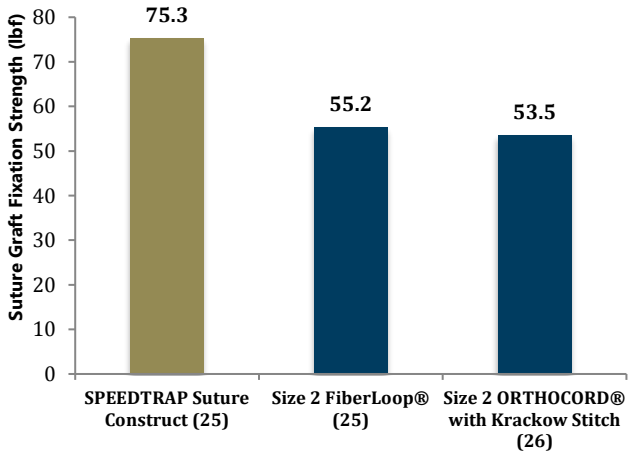
Figure 4. Mode of Failure Through a Tubularized Specimen [17]



The authors concluded that tubularization of the semitendinosus graft using interrupted sutures weakens its structural and mechanical properties.[17]

Another intended benefit of the SPEEDTRAP System is the strong suture construct. A recent biomechanical study by DePuy Synthes evaluating the construct ultimate strength among leading graft preparation techniques found that the SPEEDTRAP System's suture-graft construct maintained the strength required to meet clinical conditions and was significantly stronger than FiberLoop® and ORTHOCORD® Suture constructs (Figure 5).[19,20] The strength of the suture in the FiberLoop® was negated due to an undesirable failure mode (suture cheese wiring through the graft).[19,20] Further research should aim to validate these potential strength benefits in the clinical setting.

Figure 5. Suture Graft Construct Strength [19,20]



Conclusions

Overall, the SPEEDTRAP Graft Preparation System is designed to address the clinical needs of today's orthopedic surgeons due to its needleless design, reinforced suture spine with anchored winding sutures, strong suture construct, even distribution and uniform pattern of whipstitches, and pre-loaded, single-use delivery design. These design elements have the potential to simplify soft tissue graft preparation, improve operating room efficiency, help control operating room costs, minimize the risk of needle stick injuries for operating room staff, and maximize the strength of the graft construct while maintaining the quality of the soft tissue graft.

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DePuy Synthes Mitek Sports Medicine:

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Not all products are currently available in all markets.

Indication for Use: The SPEEDTRAP suture construct is indicated for use in soft tissue approximation in orthopedic procedures.

Device Description: The SPEEDTRAP Graft Preparation System consists of a suture construct provided on a disposable delivery device. The SPEEDTRAP Graft Preparation System is offered in long and short configurations with white (undyed) and green/white (undyed) color options, including single and multi-pack (Qty. 4) offerings.

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DePuy Mitek, Inc.
325 Paramount Drive
Raynham, MA 02767-0350
USA

Johnson & Johnson Medical Pty Ltd t/a DePuy Synthes
1-5 Khartoum Road,
North Ryde, NSW, 2113
Australia

Johnson & Johnson (NZ) Limited
507 Mt Wellington Hwy,
Mt Wellington, Auckland, 1060
New Zealand

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^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