Value Analysis Brief—
MILAGRO® BR INTERFERENCE SCREW

Methods
This value analysis brief presents information on the potential clinical, economic, and humanistic benefits of using absorbable biocomposite interference screws in orthopedic surgery procedures. The screws are made of osteoconductive β-tricalcium phosphate (β-TCP) and poly-lactide co-glycolide (PLGA). The referenced data were obtained through a search of MEDLINE for biocomposite interference screws used in ACL reconstruction as well as economic studies of bioabsorbable screws used in ACL surgery. Conference proceedings and unpublished studies were also included in this analysis due to limited published data for β-TCP / PLGA interference screws.

Note: The MILAGRO BR biocomposite (β-TCP / PLGA) screw type and its material composition are unique to DePuy Mitek.

Background
Achieving optimal clinical and functional outcomes after orthopedic procedures, such as joint implantation and ligament reconstruction, depends on a variety of factors. Perhaps foremost is expert surgical technique but even seemingly minor details such as appropriate hardware selection may contribute to long-term clinical success.

As orthopedic surgery has advanced to include minimally-invasive approaches, so too has the medical technology used in the operating room. Where metallic interference screws were once the norm, polylactic acid (PLA) screws became popular due to their absorbable nature. The subsequent generations of interference screws now include biocomposite materials that promote osteoconduction while maintaining their biodegradable characteristics. As these products have evolved the requirements and design goals have also evolved; we are now balancing degradation time, strength, ossification of the implant site and ease of use for orthopedic surgeons.

The MILAGRO BR Interference Screw achieves a number of important objectives:

- Strength of metal screw fixation at t=0;
- Homogeneous composition for strength, absorption profile and safety;
- Proven bone formation at the implant site over time;
- Facilitates postoperative radiologic imaging; and
- Simplifies revision procedures.

The design elements of the MILAGRO BR Interference Screw translate into a number of clinical and economic benefits to providers, payers, and patients alike.1,2,3,6,8

Potential Clinical Benefits

An optimized and homogenous blend of copolymers and osteoconductive material results in improved strength and absorption time.

The MILAGRO BR Interference Screw is comprised of BIOCRYL® RAPIDE™—a second generation composite material consisting of 30% osteoconductive β-TCP and 70% PLGA. A proprietary Micro-Particle Dispersion (MPD) manufacturing process ensures a homogenous dispersion of the composite materials reducing the incidence of stress risers, while ensuring osteoconductive β-TCP is in close apposition with the surrounding bone tissues during the absorption process. MPD technology ensures there is always β-TCP at the bone surface, enabling bone cells to migrate inward as the implant absorbs.9

While earlier generation polylactic acid (PLA) screws were designed to be absorbable, in practice, screws often were found to have degraded minimally even several years after implantation. BIOCRYL RAPIDE has demonstrated more favorable absorption and ossification characteristics relative to PLA materials. Testing conducted in an animal model demonstrated near complete absorption and ossification of the implant site at 24 months.7,3

In a long-term (Mean 39 months) study in humans, CT scans show that the MILAGRO BR Interference Screws absorbed and promoted bony replacement at the implant site.1,4 Bone plugs in all patients were fully incorporated into the adjacent tunnel wall with varying degrees of ossification present in 81% of screw sites and complete ossification in 19% of screw sites.1
MILAGRO BR interference screws promote ossification of the implant site and restore the anatomy rather than leave metallic or plastic components implanted long-term. If a future surgery is required, a MILAGRO BR implant alleviates needs for hardware removal, potentially having to insert the implant in a non-desirable location and may preserve bone stock depending on the timepoint. In contrast, metallic and plastic implants have several drawbacks. In the case of a Cruciate Ligament reconstruction, a re-injury of the ligament requires removal of the non-absorbable metallic or plastic implants. This requires identification of the existing implants, identification of instrumentation for removal and lengthier operating procedures. Use of metallic or plastic implants may also require bone tunnels to be relocated, since voids are left in the bone upon their removal. If sufficient bone stock is not available and tunnels must be relocated, it may require the surgeon to place them in a sub-optimal and less anatomic position. In the case of future joint replacement surgery, metal or plastic components may require removal prior to preparing the femur or tibia during a total knee replacement procedure.7

Potential Economic Benefits

Reducing the need for revision surgery or performing easier revision procedures when needed may translate into cost savings.

Based on the analysis of US national hospital procedures, the mean charges for a complex ACL revision surgery (mechanical complication of internal orthopedic device, implant, or graft) is $57,687.5 This is substantially more than the charges associated with the initial ACL reconstruction surgery ($38,040).5 The costs of revision surgeries may be significantly reduced with an easier revision procedure.

Should a more effective fixation and bone substitution lead to even a small reduction in the need for revisions, cost savings could be substantial given the number of orthopedic surgeries performed in the US each year.

Potential Humanistic (Patient) Benefits

Patients prefer a Biocomposite material to a metal, non-absorbable or absorbable polymer.

Patients tend to prefer implantation of a more natural, biologically congruent material than an object that is permanently retained or retained for an extended period. The excellent initial strength of the MILAGRO BR interference screw enables rehabilitation protocols consistent with that of metal screws, while potentially reducing stress shielding over time. Additionally, MILAGRO BR may facilitate a less difficult revision procedure should it be needed.

Citations