The interference screw has been redefined.

\textit{mi·la·gro} (mi lā’gro), n. Spanish word for “miracle.”

The Milagro” Interference Screw is comprised of Biocryl Rapide, an evolution in materials that combines osteoconductive TriCalcium Phosphate (TCP) and a faster-resorbing polymer. In preclinical in-vivo studies, Biocryl Rapide has demonstrated evidence of completely absorbing and enhancing bone growth. \textit{usage: Milagro is for use in ACL Reconstruction to aid in anatomic restoration.}
In an effort to ascertain what issues are of greatest concern to orthopaedic surgeons during arthroscopic ACL repair procedures, DePuy Mitek organized a roundtable discussion with Drs. Marc Asselmeier, Claude T. Moorman, III, Cedric Ortiguera, Richard Sellers and John Zvijac, with Dr. Robert Burks as Moderator. As part of the discussion, the physicians also were asked how well DePuy Mitek’s MILAGRO Bioreplaceable Screw addressed their specific concerns during arthroscopic ACL repairs as compared to metal or PLA screws.

**Dr. Zvijac**

> In general, patients also seem to like the idea of a bioabsorbable material as opposed to a retained metal object.

– Dr. Zvijac

**Dr. Asselmeier**

Patient convenience, ease of further revision surgery and no metallic artifact.

**Dr. Moorman**

I am convinced that the current bioreplaceable polymer implants allow the advantage of fixation strength similar to first generation metal implants, but with the advantage of biodegradation and substitution of the patient’s own tissue over time.

**Dr. Ortiguera**

I prefer an absorbable interference screw for many reasons. They provide adequate initial strength and stability for aggressive rehabilitation, eliminate the need for hardware removal, facilitate postoperative radiologic imaging and, in some cases, allow for easier revision surgery if needed.

**Dr. Sellers**

An absorbable screw allows future diagnostic studies (both MRI and plain X-rays) with negligible artifact and distortion. After the implant is absorbed, bone stock is preserved, which provides more surgical options in the event of revision ligament surgery or future reconstructive procedures.

**Dr. Burks**

Why do you use a biocomposite interference screw as opposed to a metal or PLA screw?

**Dr. Asselmeier**

Increased strength and durability. More complete absorption and transformation to bone.

**Dr. Zvijac**

What are the reasons/benefits of using an absorbable (biocomposite) interference screw?

**Dr. Moorman**

The biocomposite interference screws offer different advantages versus each of these first or second-generation implants. The advantage of the biocomposite screw has to do with the material characteristics of the implant and its biosubstitution over time. This eliminates issues of MRI compatibility and screw management in the revision scenario. With the current PLGA/TriCalcium Phosphate composites, there is no need to remove the implant for either of these purposes. As far as advantages over the traditional PLA screws, there have been concerns with tunnel widening, prolonged bioabsorption, and osteopenia that appear to be markedly reduced with the biocomposite screws. Furthermore, the addition of the bone salt in the TriCalcium Phosphate implants makes this much more biologically congruent (osteocductive).

**Dr. Ortiguera**

While metallic screws provide excellent initial strength, their presence can create difficulties with postoperative radiologic imaging, occasionally require hardware removal, and can create difficulties in the revision situation. PLA screws can provide adequate initial strength as well, but their degradation can be quite prolonged, also creating difficult revision situations. A biocomposite screw provides the best of both worlds, with excellent initial fixation and resorption with bony in-growth.

**Dr. Burks**

Metal screws cause artifact on MRI scans and create difficulty in evaluating future knee conditions. Metal screw fixation creates a more difficult surgical environment for revision ligament reconstruction procedures due to the void created when the screw is removed. The bony void makes it more difficult to place bone tunnels in the correct isometric position. Good fixation of a revision graft procedure requires the use of alternate fixation techniques, including:

- Bone graft to bony defect with delayed ligament reconstruction
- Use of extra-large screw (or multiple screws) to fill the void
- Non-screw fixation methods in conjunction with bone graft

**Dr. Zvijac**

In addition to the reasons given above for favoring a biocomposite screw over a metal screw, in terms of a PLA screw, there has been the suggestion of osteolysis of tunnels with the use of this. In addition, there have been studies that suggest that these screws do not resorb. The ideal situation would come from a biocomposite interference screw that allows for mechanical integrity until appropriate tissue fixation has occurred from a biologic standpoint, followed by resorption of the interference screw. This screw would aid in osteoconductivity and scaffolding for osseous formation. The goal of this, again, is to return the body to its normal state without areas of concern in terms of bone lysis or “empty hole.”

**Dr. Burks**

Personally, I did not have a problem with a PLA screw, but it took forever for it to disappear and so it seemed that it lost some of its value over simply using something like plastic.
**Dr. Burks**

**Do you routinely use BTB or soft tissue grafts? What do you utilize for fixation on the femoral and tibial tunnels, and why?**

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**Dr. Asselmeier**

I use both BTB and soft tissue grafts. I use biocomposite/MILAGRO screws for tibial side fixation, and RIGIDFIX® for soft tissue femoral side fixation.

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**Dr. Moorman**

In my practice, I like to have all of the arrows in my quiver. For this reason, I can see advantages for bone-tendon-bone, hamstring and allograft in different scenarios. The breakdown in my practice is approximately 70% BTB autograft, 25% hamstring autograft and 5% allograft. In my hands, fixation varies depending on whether I’m using a bone-tendon-bone graft or a soft tissue graft. For bone tendon bone fixation, I utilize the MILAGRO interference screws on both the femoral and the tibial sides. These appear and have been proven to give excellent fixation, allowing for immediate rehabilitation program. I tend to drill an 11mm tunnel on both the femur and tibia, and use a 7mm x 23mm MILAGRO screw on the femoral side and a 9mm x 23mm MILAGRO screw on the tibial side. This may change depending upon the age and size of the patient.

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**Dr. Ortiguera**

In the younger, high-demand athlete, my graft of choice remains BTB autograft. I believe soft tissue autografts, as well as allografts are reasonable choices for my lower-demand patients. For femoral fixation, I utilize either a MILAGRO interference screw or RIGIDFIX cross pin fixation. I prepare my femoral bone plug with the use of compaction pliers to compress the bone into a dense cylindrical plug. If I am able to obtain a snug fit between bone plug and tunnel, I will utilize the RIGIDFIX system. For less-than- optimum fill of the tunnel, I use the MILAGRO screw. I routinely use MILAGRO screws for tibial fixation.

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**Dr. Sellers**

I use BTB for routine ligament reconstruction.

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**Dr. Zvijac**

I use the most advanced technology for my patients, and right now, that’s MILAGRO. It provides excellent initial strength for an accelerated rehabilitation program, quicker resorption than PLA screws, and less concern for difficulties with future surgeries.

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**Dr. Burks**

Did you feel the animal data was compelling enough to try MILAGRO? What compelled you to try/utilize MILAGRO?

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**Dr. Asselmeier**

I routinely use bone-tendon-bone either autograft or allograft patellar tendon. There are instances when soft tissue grafts are utilized, either auto- graft hamstring or Achilles allograft. For all of these, I routinely utilize an interference screw on both the femoral and tibial sides. These appear and have been proven to give excellent fixation, allowing for immediate rehabilitation program. I tend to drill an 11mm tunnel on both the femur and tibia, and use a 7mm x 23mm MILAGRO screw on the femoral side and a 9mm x 23mm MILAGRO screw on the tibial side. This may change depending upon the age and size of the patient.

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**Dr. Ortiguera**

Yes, I believe the animal data available is reasonable. Until the introduction of the first generation Biocryl screws, I routinely used metallic screw fixation. I had an excellent experience with Biocryl, and when MILAGRO was introduced with the potential benefit of faster resorption, I had very little hesitation to try it. My concern, if any, was the use of PGA and its potential for adverse reactions.

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**Dr. Burks**

For my BTB patients, I use the RIGIDFIX, which I feel is a nice way of handling the length of the graft. On the tibial side, I tend to use a MILAGRO screw. For soft tissue grafts on the femoral side, I use an Endobutton. And on the tibial end, I fix with the MILAGRO screw and a post.

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**Dr. Asselmeier**

Yes, I feel comfortable with the animal data.

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**Dr. Moorman**

I was somewhat concerned that the PLA biocomposite screws may follow a similar absorption profile to the previous generation of PLA implants. With this in mind, I was quite encouraged to see that a new implant had been developed that had a shorter half-life. The animal data has demonstrated that the Rapide device is well on its way to being filled in with the patient’s own bone at 18 months and near completely biosubstituted by 24 months. This was compelling animal data. We also spent some time in our cadaver laboratory working with the device to ensure that the mechanical properties of the material would be suitable as well. These factors gave me the assurance to start using this in my patients.

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**Dr. Ortiguera**

While I do feel animal data is a useful starting point for understanding the physiology of any implant, and in this particular instance osteoconductive bioceramics, I was compelled to progress to the MILAGRO after doing human study on the Biocryl TCP/PLA interference screw. Our study at UHZ Sports Medicine Institute on this, utilizing CT examination and measuring Hounsfield units at intervals up to 24 months, postoperatively demonstrated that with this particular composite, there was osteoconductivity that had begun by the 6-month time interval and progressed over time. The MILAGRO screw is the natural progression of this Biocryl screw. With a TCP/PLA composite, there may be better resorption, and with an increase in TCP, possibly better osteoconductivity. This will require further study in this regard; however, at least from reviewing the prior studies and reviewing the recent animal studies on this, it seems a logical progression.

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**Dr. Zvijac**

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**“I was compelled to progress to the MILAGRO after doing human study on the Biocryl TCP/PLA interference screw.” — Dr. Zvijac**

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The images above depict in vivo PLA (Fig. 1) and Biocryl Rapide test rods (Fig. 2) implanted in the cortical bone of beagles. By 24 months, nearly the entire cross-section of the Biocryl Rapide test rods had been absorbed and replaced by either normal bone or bone with fibrous or adipose tissue. During the same duration, the L-PLA cross-sections showed only minimal absorption by comparison. The circular orientation of new osseous tissue was clearly apparent under polarized light (Fig. 3). In the images above (Fig. 2 & 3), newly formed bone can be seen as the cells begin to align in patterns similar to native bone.
Dr. Asselmeier

Non-homogeneous femur. In addition, the screw appears to be an advantage.

Dr. Burks

What have you seen in your patient follow-up regarding MILAGRO?

Dr. Asselmeier

I have seen no fixation failures to date from MILAGRO fixation. No allergic reactions, synovitis or foreign body reactions.

Dr. Moorman

My patients have been able to participate in the same early motion protocol that we have utilized with each generation of the screw, starting with the metallic implants moving into the bioabsorbable PLA implants and, subsequently, the third generation biocomposite Biocryl implant. I have been using MILAGRO in my practice for approximately a year now and have seen no difference in patient outcomes versus the first or second-generation screws. I do feel that the real advantage of the MILAGRO screw will be seen over time when the occasional patient will require an MRI or revision work.

Dr. Ortigueria

At short-term follow-up (1 year), I have seen no screw-related failures, tunnel widening or synovitic reactions.

Dr. Sellers

Healing of the graft to host bone.

Dr. Zvijac

I prefer the Pathmaker Tunnel Notcher over the Tap as it reduces the chance of damage to the graft or sutures in the femoral bone plug.

Dr. Sellers

I utilize both the Notcher and the Tap. I will evaluate the amount of clearance between the graft and the wall of the tunnel by using the tip of the screwdriver. If the tip cannot be inserted, or inserted only with difficulty, I will use the Notcher. I use the Tap routinely, but will vary the depth of insertion based on my assessment of the bone quality. The Tap is inserted one or two turns in softer bone, but to a greater depth in hard bone.

Dr. Asselmeier

I’ve routinely notched in the past. Now, I tap consistently for interference screw insertion.

Dr. Moorman

When utilizing a bone-tendon-bone graft, I prefer the Tap and I tend to leave the bone plug on the femoral side slightly proud to insure no contact with the soft tissue. The graft will then be advanced into the tunnel after the tapping to a suitable position and the screw inserted. For use with the soft tissue grafts, I tend to use the Pathmaker Tunnel Notcher. At times, when very tough cortical bone makes starting the Tap difficult on the bony surface, we have used the Pathmaker graft to get the Tap started.

Dr. Ortigueria

The available data indicate that the MILAGRO screw provides excellent initial strength that would allow an early motion protocol. It is early to make definitive comments on the MPD technology, as this potential advantage will be more borne out over time. Certainly the idea of a uniformed dispersal of the polymer within the tricalcium phosphate would seem to be an advantage.

Dr. Asselmeier

The strength of MILAGRO screws seems to approximate metallic screw fixation with less of the associated problems. MPD Technology seems to create a more homogeneous screw, minimizing the tendency for screw breakage from stress risers. This would be consistent with my clinical experience.
The majority of polymer synovitis with the Suretec device did occur within the first two months after the implantation. We now have well over 100 patients who have been treated with the MILAGRO screw on both femoral and tibial tunnels, and have not seen this complication to date. Hopefully, this will continue to play out over time.

**Dr. Ortizuera**

The amount of PGA used seems minimal and, to date, I have not seen any abnormal reactions.

**Dr. Sellers**

Tissue reactions occurred because PGA was degraded at a rate greater than the body could eliminate the breakdown products. I was initially concerned about the mere presence of PGA (even in minute amounts) in MILAGRO screws due to the history of synovitis/tissue reactions associated with PGA implants. I was told that MILAGRO is a co-polymer of PGA and PL, so assumed that PGA made up 50% of the mass of the solid material. I then learned that only 10% of the implant is PGA, and I thought that the amount of PGA is sufficiently small that the breakdown products can be eliminated as they are produced. The lack of local tissue reaction is confirmed by in-vivo studies in the canine model.

**Dr. Ortizuera**

We’ve all taken PLA screws out at 2 years plus, which look almost new with little evidence of resorption. The PLGA with its resorption curve would seem to minimize this likelihood.

**Dr. Moorman**

For BTB fixation, maximum strength should be maintained for at least 6 weeks to allow osseous integration of the graft. For soft tissue grafts, maximum strength should last for 12-18 weeks. After this initial period, resorption may occur. PLA has been found to have very slow resorption. Preliminary animal data is convincing that PLGA provides excellent initial strength when needed yet resorbs faster than PLA.

**Dr. Zvijac**

We have shown that this device in our hands to date. "...some studies that have shown the PLA implants to be near intact even 2 years out from ACL reconstruction. With this in mind, I do feel the Rapide material may offer some advantages in allowing this process to be accelerated."

**Dr. Ortizuera**

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**Dr. Sellers**

I prefer that the strength/resorption curve indicate an implant that retains sufficient fixation strength until the tissue is healed with subsequent rapid resorption of the implant. Strength should be maintained at least for 6 months and the implant should be largely resorbed by 12 months.

**Dr. Zvijac**

My experience with PLA has been that these screws remain intact even years after placement. While a PLA screw does answer our original concerns that we discussed some time ago (in questions 1 and 2), the fact that these screws remain over years does come with concern. A PLGA screw appears to have resorption qualities at least when comparing various polymeric compositions.

**Dr. Moorman**

Osteoconduction is the phenomena of stimulating the in-growth of vascularity, perivascular mesenchymal tissues, and the various osteoprogenitor cells… This benefit is seen with the MILAGRO screw."

**Dr. Asselmeier**

The ultimate goal of absorbable fixation would be turnover to bone. A screw that contains osteoconductive material increases this likelihood.

**Dr. Burks**

What would be the benefits of a screw that contains osteoconductive material, such as TCP?

**Dr. Sellers**

A screw that contains osteoconductive material encourages in-growth of bone, rather than fibrous tissue, as the screw is resorbed.

**Dr. Zvijac**

The benefits of a screw that contains osteoconductive material, again, are numerous. The most significant would be the ability of the material to support tissue in-growth and development of bone formation to occur. The ideal bioabsorbable screw would be comprised of osteoconductive material in order to remove the risk of finding a hole once resorption is complete.

**Dr. Burks**

Obviously, the more we can get bone to surround soft tissue and/or bone tendon bone graft the better, so it would seem that this would help with ultimate fixation of the tendon bone interface.
Dr. Sellers

Both materials are osteoconductive, but the rate of bone formation is dependent on particle dispersion in the material. TCP used with Micro Particle Dispersion is an optimal choice for an osteoconductive material.

Dr. Zvijac

There have been multiple studies demonstrating that TriCalcium Phosphate (TCP) as being a biodegradable ceramic that does induce osteoconduction at the implantation site by creating a scaffold in the bone tunnels, allowing for new bone formation. The osteoconductive nature of this allows for attachment, proliferation, migration, and pho-notypic expression of the bone cells leading to this direct formation of new bone. There have been studies, which have reported the advantages of TCP due to its ability to bond directly to bone without fibrous tissue at the implant bone block interface. While Hydroxyapatite has demonstrated osteoconductive properties, TCP has demonstrated early biodegradation. There have also been animal studies in which a combination of Hydroxyapatite and PLA composites in animal studies demonstrated no evidence of osteoconduction. This has not been the case with TCP and PLA composites.

Dr. Burks

Why do you use MILAGRO?

Dr. Asselmeier

My clinical experience from its introduction has shown me that the strength and ease of insertion are better than prior bioabsorbable screw fixation.

Dr. Zvijac

I believe further research needs to be undertaken to reach our ultimate goal by varying percentages of the combination of polymers and TriCalcium Phosphate. This appears to be a significant upgrade from our initial polymer screws.

Dr. Asselmeier

I have been very happy with my clinical experience using MILAGRO. X-rays allow to show bone transformation and I have had no problems with screw breakage or foreign body reaction. This fixation avoids future problems with MRI, allows easier revision and its fixation strength seems equal to anything on the market.

Dr. Burks

Any final comments about MILAGRO or fixation in general?

Dr. Asselmeier

I believe the MILAGRO screw is promising in terms of eliciting biodegradation and mineralization due to osteoconduction. I believe further research needs to be undertaken to reach our ultimate goal by varying percentages of the combination of polymers and TriCalcium Phosphate. This appears to be a significant upgrade from our initial polymer screws.

Dr. Burks

How easy is the insertion of the MILAGRO Screw?

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Dr. Burks

Are there any issues/problems you have seen with PLA?

Dr. Zvijac

As with any polymer, there are always concerns about both resorption and lysis, and the end effect of a defect in the bone that is not osseous. While this has not been a significant problem from a practical standpoint, clearly we would like to develop something better in terms of fixation than the PLA itself.

Dr. Burks

Insertion of the MILAGRO screw is easy and straightforward. The use of a Tap in conjunction with nothing of the tunnel increases the ease of insertion.

Dr. Zvijac

The ease of insertion of the MILAGRO screw is no different than that of any other type of screw. It is reproducible, requires no specific instruments other than a screwdriver, although there are people who like to use guide wires, but this has been demonstrated to be an easily reproducible fixation device.

Dr. Burks

Screw breakage on insertion and failure of the implant to resorb.

Dr. Zvijac

With the truth be known, I never totally embraced the PLA implants because of the problems with tunnel widening and concerns about the longevity of the implant. I really had only a handful of patients that had true PLA screw fixation before the advent of the bio-composites. With this in mind, I can’t see that I have encountered much with my own patients, but I have been concerned enough by the data in the literature that I never really embraced this technology.

Dr. Ortiguer

I want the most advanced technology for my patients, and right now, that’s MILAGRO. It provides excellent initial strength for an accelerated rehabilitation program, quicker resorption than PLA screws, and less concern for difficulties with future surgeries.

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