The interference screw has been redefined.

mi·la·gro *(mi lä´grō).*

n. Spanish word for "miracle." The Milagro™ Interference Screw is comprised of Biocryl Rapide, an evolution in materials that combines osteoconductive TriCalcium Phosphate (TCP)[1] and a faster-resorbing polymer[2]. In pre-clinical in-vivo studies, Biocryl Rapide has demonstrated evidence of completely absorbing and enhancing bone growth[2]. ***usage:*** **Milagro is for use in ACL Reconstruction to aid in anatomic restoration.**

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[1]Data on file [2]Data on file from pre-clinical evaluation

MATERIALS • INSTRUMENTS • TECHNIQUE

DePuy Mitek
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IT'S ABOUT RESULTS

mi·la·gro™

Bioreplaceable Screw

Roundtable Discussion

Moderator

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University of Utah Orthopaedic Center
Salt Lake City, Utah

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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 Bioreplacable Screw addressed their specific concerns during arthroscopic ACL repairs as compared to metal or PLA screws.

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

Dr. Burks

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

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. Zvijac

There are a multitude of benefits from the use of a biocomposite interference screw. The most practical reason for using this type of screw has to do with any further tests that the patient may require over time, such as an MRI. Metal screws cause a scatter effect that often is not optimal for full evaluation with MRI. That is the most practical reason for the use of this type of screw. However, there are other reasons often suggested, such as negating the foreign body effect of permanent hardware, the potential for stress risers from a metal screw and the ease of revision reconstruction, which allows for drilling through these biocomposite screws. In general, patients also seem to like the idea of a bioabsorbable material as opposed to a retained metal object.

Dr. Burks

I agree that, in some situations, it is good not to have metal around the knee for purposes, such as MRI. A screw that disappears over time potentially can make certain revision issues easier. Particularly a screw that would be replaced by bone would obviously have some advantage over a screw that would be replaced by more space or fibrous tissue.

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. 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.[1] Furthermore, the addition of the bone salt in the TriCalcium Phosphate implants makes this much more biologically congruent (osteoconductive).

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. Sellers

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.[2] 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?

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.

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 as fixation alone. For the hamstring autograft and soft tissue allograft reconstructions, I utilize an EndoButton™* for femoral fixation with aperture fixation, utilizing a MILAGRO screw. On the tibial side, I use a post and washer backed up by MILAGRO for aperture fixation.

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.

Dr. Sellers

I use BTB for routine ligament reconstruction.

Dr. Zvijac

I routinely use bone-tendon-bone either autograft or allograft patellar tendon. There are instances when soft tissue grafts are utilized, either autograft hamstring or Achilles allograft. For all of these, I routinely utilize an interference screw on both the femoral and tibial side. 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.

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.

> *"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."*
>
> — Dr. Ortiguera

Dr. Burks

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

Dr. Asselmeier

Yes, I feel comfortable with the animal data.

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 would be suitable as well. These factors gave me the assurance to start using this in my patients.

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

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 hesitance to try it. My concern, if any, was the use of PGA and its potential for adverse reactions.

Dr. Sellers

Yes, the data was sufficiently compelling and was the primary factor in my decision to utilize MILAGRO as my standard for ACL fixation. I was impressed by two groups of data on MILAGRO.

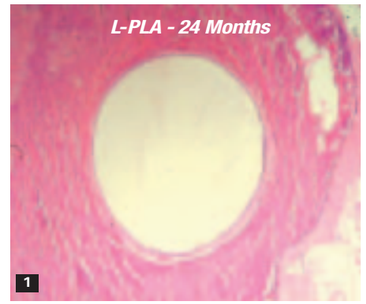
1. The design properties:

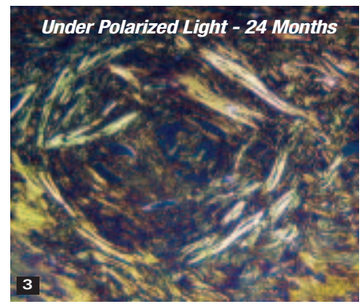
The use of TCP as a calcium-rich substrate encourages bone formation. Micro Particle Dispersion insures a homogeneous composition of the material. Lab data indicates that the mechanical properties of the material are such that there is no loss in strength (pull-out, torsional strength and bending strength) even though the PGA is now mixed with PLA and TCP.

2. The in-vivo data from implantation in beagle femora with both H&E staining and polarized microscopy sections shows absorption of MILAGRO implants, but the persistence of PLA implants. The use of PLA controls gave me more confidence to believe the accuracy of the MILAGRO absorption data.

Dr. Zvijac

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/PLGA 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.





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.[3] 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. 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 responses, 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. Ortiguera

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 have been pleased with the follow-up regarding the MILAGRO screw. I have not had any adverse events regarding the screw in terms of both fixation and any bony changes noted at the tibia or femur. In addition, the screw appears to have adequate torque strength when placing the screw to avoid breakage of the screw. I have not had a screw breakage on placement of this particular screw. ■

Dr. Burks

Do you utilize the Pathmaker Tunnel Notcher or the Tap and, if so, when do you utilize either of these tools?

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, we tend to use the Pathmaker Tunnel Notcher. At times, when very tough cortical bone makes starting the Tap difficult on the tibial surface, we have used the Pathmaker graft to get the Tap started.

Dr. Ortiguera

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. Zvijac

I do not utilize a Tunnel Notcher; however, I occasionally use a small burr or shaver to notch the superior aspect of the femoral tunnel. I routinely utilize the Tap to at least start the area of screw placement between the bone tunnel and bone plug. The extent of tapping depends upon the rigidity of the bone. For instance, in a young patient undergoing autograft reconstruction, I tend to tap the screw hole almost completely. Whereas in decreased bone density or allografts, I usually just start the tunnel and then utilize the interference screw. ■

Dr. Burks

How is the strength of the MILAGRO screw compared to other biocomposites or PLA screws you have tried? What do you think are the benefits of Micro Particle Dispersion (MPD) Technology?

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.

Dr. Moorman

The strength of the MILAGRO screw appears to be very similar to that of other biocomposites I have utilized previously, specifically the Biocryl screw. I have been impressed that the screw is perhaps less brittle and we have yet to have a breakage either on the femoral or the tibial side. This has been quite rewarding clinically. As far as the laboratory studies, the mean pull-out strength of the MILAGRO has been 890 newtons versus 650 newtons in side-to-side laboratory testing with the Biocryl device. This is similar to, or in excess of, previous testing that has been done on PLA screws. I do feel this gives very suitable initial fixation to allow for early motion protocols. 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. Ortiguera

The available data indicate that the MILAGRO screw provides excellent initial strength that would allow an early aggressive rehabilitation protocol.

> *"MPD Technology seems to create a more homogeneous screw, minimizing the tendency for screw breakage… This would be consistent with my clinical experience."*
>
> — Dr. Asselmeier

Micro Particle Dispersion allows for a more homogeneous mixture, likely reducing stress risers, increasing strength and potentially eliminating screw breakage / early failure.

Dr. Sellers

The laboratory data indicate comparable strength between MILAGRO and PLA/other composite screws. This has been qualitatively confirmed in surgery by the tactile sensation of the force I apply while inserting the screw. I have never had the tactile sensation during screw insertion that the torque on the screw is approaching failure of the material.

Dr. Zvijac

From a practical standpoint, the strength of the MILAGRO screw appears to be equal to that of a PLA screw in terms of its torque strength. Other biocomposites that I have tried in the past have been more brittle, and I have had an easier time of breaking the screw on placement. I have not had this particular difficulty with the MILAGRO screw. ■

Overview of Material Processing

A proprietary manufacturing process known as Micro Particle Disperson (MPD) Technology makes the Biocryl Rapide material a homogeneous blend of PLGA and TCP particles. Dispersion of the composite particles is critical to the material properties.[4] Non-homogeneous composites may result in material with compromised or variable strength properties due to stress risers within the material.[1]

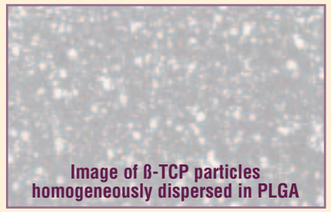


Image of ß-TCP particles homogeneously dispersed in PLGA

Dr. Burks

There have been some associated reactions with PGA, how do you feel about the amount of PGA in MILAGRO?

Dr. Asselmeier

This would seem to be a balanced percentage, which minimizes host reaction.

Dr. Moorman

I have had extensive experience with PGA anchors going back to the original Suretac™* devices, which we used for some period of time in labral repair in the shoulder. We did occasionally have some patients who had a polymer synovitis related to the rapid absorption of the device. I do not have these concerns with the MILAGRO device.

The majority of polymer synovitis with the Suretac 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. Ortiguera

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 PLA, 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. Zvijac

The appropriate construct of osteoconductive materials with other polymeric compositions to give us the best screw in terms of strength and resorption and bone construct being the end result still requires study. In reviewing prior studies, it does not appear that 10% PGA would have any significant adverse reactions and, in fact, may be beneficial in the progression of both osteoconductivity and reabsorption.

Dr. Burks

How long would you prefer the strength/resorption curve to last? How would you compare PLA to PLGA?

Dr. Asselmeier

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

An ideal implant in ACL surgery would last from 6-12 months, which should allow excellent initial bony fixation for early rehabilitation. In the animal trials done with the Biocryl Rapide material utilized in MILAGRO, the bony absorption appears to be well on its way by 18 months and complete by 24 months. This should allow some leeway for outliers in bony incorporation. With the PLA implants, there are several 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. Ortiguera

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 12-16 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. Sellers

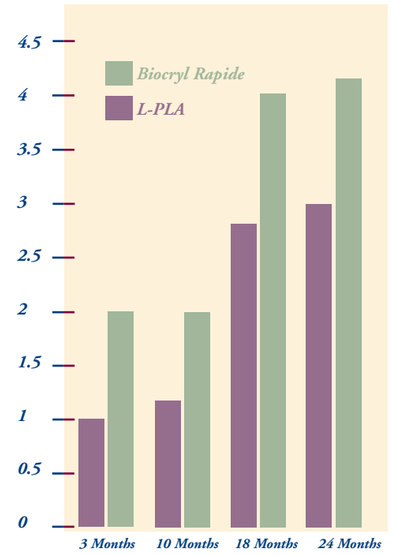
I prefer that the strength/resorption curve indicate an implant that retains sufficient fixation strength until the tissue is healed with subsequent rapid resorption of the implant. Strength should be retained at least for 6 months and the implant should be largely resorbed by 12 months.

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.

> *"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. Moorman

Absorption Score Averages in Cortical Bone [5]



CIEF = cracks, cell infiltrations, erosions and/or fragmentation

The ß-TCP/PLGA material exhibited marked absorption from 18-24 months[5], accompanied by a gradual increase in the proliferation of mesenchymal cells that differentiated toward the osteoblastic line. During the same duration, the L-PLA test specimens showed only minimal absorption by comparison.

Dr. Burks

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

Dr. Asselmeier

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

Dr. Moorman

Osteoconduction is the phenomena of stimulating the in-growth of vascularity, perivascular mesenchymal tissues, and the various osteoprogenitor cells from the host tissue into the structure of an implant or graft. Obviously, this is a positive feature for any type of implant that would ultimately hope to be incorporated into the host bone. This benefit is seen with the MILAGRO screw because it contains osteoconductive material.

Dr. Ortiguera

The potential benefit would be in faster bone in-growth and the ultimate replacement of absorbable screws with normal bone. This would greatly facilitate any future surgical procedures, such as revision ligament reconstruction, osteotomy or joint replacement.

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. Burks

Which do you feel is a better osteoconductive material: TriCalcium Phosphate (TCP) or Hydroxyapatite?

Dr. Moorman

There have been a number of osteoconductive materials, including Hydroxyapatite, TriCalcium Phosphate, demineralized bone matrix, Calcium Sulphate and other materials. Of these, the TriCalcium Phosphate and Hydroxyapatite have been the most commonly utilized in the third and fourth-generation biocomposite interference screws. My experience with the TriCalcium Phosphate and the Hydroxyapatite is that both work quite well as osteoconductive materials, but the material properties of the TriCalcium Phosphate appear to be less brittle and more easy to use and with less breakage. I think this is the true advantage of this device in our hands to date.

Dr. Ortiguera

Both TCP and HA are good osteoconductive materials. TCP is a more soluble material and may allow absorption rates that better coincide with the healing rate of bone.

> *"TCP used with Micro Particle Dispersion is an optimal choice for an osteoconductive material."*
>
> — Dr. Sellers

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 TriCalcuim Phosphate (TCP) as being a biodegradable ceramic that does induce osteoconductivity at the implantation site by creating a scaffold in the bone tunnels, allowing for new bone formation.[6] The osteoconductive nature of this allows for attachment, proliferation, migration and phenotypic 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.[6] 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. Moorman

First, the strength of the construct allows for excellent initial fixation and early motion protocols for ACL rehab. Second, the bioabsorption profile fits the bill for a faster resorption rate, while still maintaining the integrity of the fixation. Third, the osteoconductive properties of the TriCalcium Phosphate ensure that there is true bony substitution at the interface with degradation. And finally, the bioabsorption of the implant does provide for the advantages of repeat MRI compatibility and a lessened concern of implant problems in the revision scenario.

Dr. Ortiguera

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.

Dr. Sellers

When I perform revision ACL reconstruction, I have had to deal with bony defects caused by both metal screws as well as PLA screws that did not absorb, even after as long as 7 years. These defects require additional surgical planning and equipment availability, but can also compromise the isometry and ultimate function of a revision ACL graft. I use MILAGRO for several reasons:

- It does the job of fixation of ACL graft
- Good pull-out strength
- Instrumentation to insert the screw accurately with minimal risk of screw breakage

It disappears when the job is done, a significant improvement over metal and PLA screws. The screw resorbs much earlier than PLA screws, which preserves bone stock and decreases problems in a revision situation.

Dr. Zvijac

I believe the MILAGRO screw is an optimal answer to date from a screw allowing for both absorption of the screw, as well as osteoconductivity of the screw. Our goals of structural integrity, gradual biodegradation and osteoconductivity are all demonstrated in this screw composite.

Dr. Burks

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

Dr. Moorman

If 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 biocomposites. 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. Ortiguera

The main problem with PLA screws is their prolonged resorption period. I have revised many cases with previous PLA screws, some of which show little if any resorption 3-5 years after implantation. When the screws are partially degraded, their removal can be difficult and the bony defect remaining is similar to that left with metallic screws.

Dr. Sellers

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

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

How easy is the insertion of the MILAGRO Screw?

Dr. Asselmeier

Like all bioabsorbable screw fixation, security and ease of insertion is dictated by careful stepwise principles. I routinely tap my tunnels prior to insertion. This step assures proper placement and avoids iatrogenic injury to the graft. This easily and quickly can be carried out without significant delay in overall surgical time.

Dr. Ortiguera

Because the tip of the MILAGRO screw is non-tapered, the screw is slightly more difficult to engage compared to metallic screws. Use of the Pathmaker Tunnel Notcher or Tap minimizes this.

Dr. Sellers

Insertion of the MILAGRO screw is easy and straightforward. The use of a Tap in conjunction with notching 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

Any final comments about MILAGRO or fixation in general?

Dr. Asselmeier

I have been very happy with my clinical experience using MILAGRO. X-rays seem 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.[4]

Dr. Moorman

I do feel that the technology employed in the MILAGRO screw represents a considerable advance forward in our approach to ACL fixation. I do think the osteoconductive properties of the TriCalcium Phosphate and the enhanced resorption profile with the PGA component will make this an advantage, and I am happy to offer this advantage to my patients.

Dr. Sellers

I only wish that it had been available sooner!

Dr. Zvijac

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.

[1] "Poly-D L-Lactide Interference Screws for Anterior Cruciate Ligament Reconstruction," F. Alan Barber, M.D., F.A.C.S.
[2] "The Natural History of a Bioabsorbable Interference Screw Used for Anterior Cruciate Ligament Reconstruction With a 4-Strand Hamstring Technique," Michael J. Radfford, M.B.B.S., F.R.C.S. (Ed), F.R.C.S. (Tr & Orth), Jennie Noakes, B. Med, F.R.A.N.Z.C.R., John Read, M.B.B.S., F.R.A.N.Z.C.R., D.D.U., and David Wood, M.B.B.S., F.R.C.S.
[3] E-poster presented at the Spring 2005 meeting of the Arthroscopy Association of North America. Data on file
[4] Data on file [5] Data on file from pre-clinical evaluation
[6] Properties of Osteoconductive Biomaterials: Calcium Phosphates," Racquel Zapanta LeGeros, PHD
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> *"The technology employed in the MILAGRO screw represents a considerable advance forward in our approach to ACL fixation . . . I am happy to offer this advantage to my patients."*
>
> – Dr. Moorman