

# Complications Related to Biocomposite Screw Fixation in ACL Reconstruction Based on Clinical Experience and Retrieval Analysis

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*The prevalence of soft tissue graft in anterior cruciate ligament (ACL) reconstruction, as well as the preference for bioabsorbable fixation continues to grow in clinical practice. This paper presents one complication related to biocomposite screw fixation used in ACL reconstruction found in clinical practice associated with a retrieval analysis of a broken biocomposite interference screw made by PLLA-HA (75% PLLA, 25% HA), arthroscopically removed from the tibial site at 8 months after ACL reconstruction with soft tissue autograft in a young patient. The fragment of broken screw was analysed in terms of surface and structural analysis following an established implant retrieval protocol. The retrieved implant surface shows cracks and breakdown signs characteristic to the final phase of resorption but incomplete probably due to biomechanical stress. The present study is important since it is one of the few cases recorded for both a composite implant as well as for an early complication, supporting the idea that the breakage of biocomposite screws should be considered during ACL reconstruction.*

*Keywords: biocomposite screw, biodegradable polymer, ACL reconstruction, retrieval analysis, SEM*

The anterior cruciate ligament (ACL) reconstruction has massively evolved during the last decades. Not only the number of cases continuously grows but also the surgical technique sustains numerous improvements and modifications. When we deal with ACL reconstruction, several factors should always be taken into account: the graft type, the surgical technique, as well as the fixation type and the rehabilitation protocol. As there was a modification concerning the graft option, from the bone-tendon-bone graft (BTB), used massively in the 90's towards soft tissue graft (ST) - now used in more than 53% of the cases [1]. The reasons behind this modification are: the donor morbidity is decreased as well as postoperative pain and the tensile strength of quadrupled graft of semitendinosus and gracilis has proved to be at least equivalent with that of the "golden standard" BTB graft. Different healing processes take place when different grafts are used, such as bone-to-bone healing type in BTB graft and bone-to-tendon healing in ST graft. As the tendon-to-bone healing is much slower - about 6 to 8 weeks - appropriate fixation type is required all through the healing process. In the last 10 years, numerous studies done on the biomechanical behaviour of the restored ACL, stated that the anatomical placement of the graft is correlated with better performances in terms of antero-posterior and rotatory stability. So, gradually, the surgical technique moved from trans-tibial to anatomical placement of the graft. This technique demands excellent arthroscopic skills as well as new fixation devices. The graft fixation is critical for primary stability of the graft; no proper rehabilitation protocol may be started without adequate fixation. If for femoral fixation there are several fixation systems available, for the tibial site interference fixation type is still the most used [2]. For many years the metallic interference screw was the "golden standard" in ACL graft fixation. As the inconveniences related to magnetic resonance imaging (MRI) artefacts, possible graft laceration during

insertion or removal, as well as the difficulties encountered at screw removal, new materials for screw fabrication were researched, including biodegradable polymers, biostable polymers and biocomposites with polymeric matrix. Accordingly, polyglycolic acid polymer (PGA) was used to elaborate the first class of biodegradable polymer biomaterials studied for such applications. PGA is a hydrophilic and highly crystalline polymer that degrades in 3-6 months (50% strength lost at 2 weeks and 100% strength lost at 4 weeks) [2]. The use of PGA was associated with fast resorption rate, often before the healing inside the tunnel; this caused loss of fixation and recurrence of instability. In addition, foreign body reaction, synovitis and effusion were frequently reported [3].

The second class of materials used was based on poly-L-lactic acid (PLLA), a polymer which has good strength and long degradation period (2-5 years). In terms of strength of fixation and pull out strength the results were very good but complications related to their behaviour in human body, both on short and long terms, were published. Among them, most quoted are tunnel enlargement, osteolysis and cyst formation. Inflammatory reaction and cyst formation are among the documented complications of polymeric interference screws. In a recent study, published in 2014 Ramsingh et. al [3] reported a 5% rate of these complications and recommend that such complications should be considered when performing ACL reconstruction with biodegradable polymeric implants. As underoptimal polymer resorption phenomena are associated with many of the postoperative complications and the mechanical properties can also be improved, the development of new materials for interference screws based on bioinert polymers or biodegradable composites with polymeric matrix is justified.

From the class of the bioinert polymers most commonly used is polyetheretherketone (PEEK), a rigid, semi-crystalline polymer, with a high resistance to chemical and

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thermal degradation and excellent mechanical properties. PEEK offers the advantages of good stable fixation and postoperative imaging while not having the complications associated with polymer degradation. PEEK implants in animals have shown no acute inflammatory response and only mild chronic inflammation [4].

The commercial biocomposite interference screws are made from a polymer matrix, usually PLLA, reinforced with an osteoconductive bioceramic material like hydroxyapatite (HA) or tricalcium phosphate (TCP). The reason for addition of new bioceramic materials as reinforcement agents is to promote and sustain bone ingrowth so that, gradually, the newly-formed bone will replace the screw as this one undergoes the resorption process [5]. It was presumed that, as a result of these improved properties, complications related to plain biodegradable screws such as cyst formation, tunnel enlargement, and inflammatory reaction could be avoided. In addition, we mention that there are clear differences between the two osteoconductive bioceramics used as reinforcement agents for polymer matrices: TCP is an amorphous material with a quick resorption rate while HA is a crystalline material with a slow resorption rate, ideal for maintaining the structure [6]. Also, hydroxyapatite can lead to ingestion of particles in the surrounding tissue while TCP may resorb faster than the time needed for the new bone to fill the defect after resorption at the implantation site.

A briefly presentation of the commercially available biocomposite interference screws is shown in table 1.

In our clinical practice, we gradually switched from trans-tibial to anatomical technique and from metallic to biodegradable interference screws. As we followed the related events reported with the use of plain biodegradable screws, we incline to use mainly biocomposite screws in an effort to avoid possible complications. This statement

is valid for the tibial site because for the femoral site several fixation systems have been developed with good results in clinical practice like trans-femoral fixation or suspensory devices. Different adverse reactions related to bio-degradable screws founded in clinical practice were reported by some authors and these results are helpful in orientating the research for new screw design or to new biomaterials [7].

## Experimental part

### Materials and methods

In this paper we present the results of retrieval analysis of a broken biocomposite interference screw made by PLLA-HA (75% PLLA, 25% HA) arthroscopically removed from the tibial site at 8 months after ACL reconstruction with soft tissue autograft. The patient was a 28 years old female who was admitted with chronic instability due to ACL deficiency. An ACL reconstruction was completed with ST graft (quadrupled graft from semitendinosus and gracilis); an antero-medial drilling was performed for femoral tunnel. The fixation consisted of a suspensory system at femoral site and biocomposite interference screw (product type Biosteon, Stryker) on tibial site. The rehabilitation protocol started very next day and at six months the patient was able to resume her previous physical activities. In our clinical case, the patient felt a sudden pain and a blockage occurred at 8 months without any related trauma. Because at clinical examination no specific symptoms were noted, we decided to make a complex analysis using medical imaging techniques like MRI and Arthro CT. As we could see in the images from figure 1, the breakage of the screw was easily detected.

The tip of the screw was arthroscopically retrieved and analyzed using a Scanning Electron Microscope type Philips XL 30.

Manufacturer	Product Name	Composition
Arthrex	Bio-Cortical; Bio-Interference; RetroScrew; Bio-Tenodesis screw	PLLA
	PEEK Tenodesis Screw	PEEK
	Biocomposite Interference	70% PLDLA 30% BCP
ArthroCare	Graftlok Tapered	PLLA
	Bilok	70% PLLA 30% $\beta$ -TCP
ConMed Linvatec	SmartScrew ACL	PLDLA
	BioScrew	PLLA
Biomet	ComposiTCP	40% PLDLA 360% $\beta$ -TCP
	Bio-Core; Rattler; Gentle Threads	82% PLLA/12% PGA
Mitek	Bio-Intrafix	70% PLLA 30% $\beta$ -TCP
	Milagro BR	70% PLGA 30% $\beta$ -TCP
Smith & Nephew	BioRCI; Endo-FIX L	PLLA
	BioSure HA	75% PLLA 25% HA
Stryker	Bioabsorbable	PLLA
	Biosteon	75% PLLA 25% HA

**Table 1**  
COMMERCIALY  
AVAILABLE  
BIOCOMPOSITE  
INTERFERENCE SCREWS

PLDLA: copolymer of poly-D,L-lactide; BCP: Biphasic CaP; PLGA: lactic acid-glycolic acid copolymer

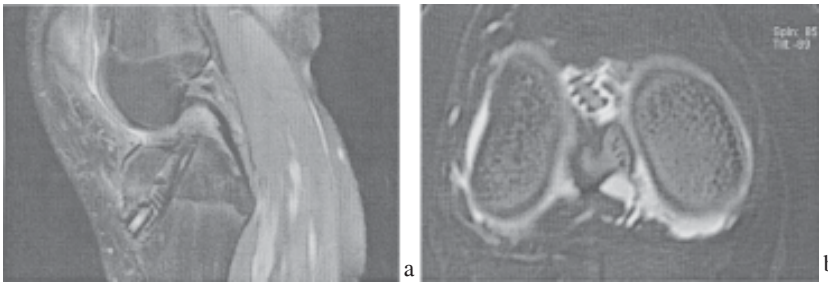


Fig. 1. Medical images obtained by different techniques for the investigated clinical case at 8 months follow-up with the screw broken inside the tibial tunnel: a) MRI sagittal imaging, b) arthro CT -computer tomography.

## Results and discussions

We often observed that small cracks may develop even at the time of insertion and go unrecognized; further progress of such defects may cause later failure of the implant. Fragmentation of bioresorbable or biocomposite screws may occur also during resorption process, combined with current accelerated rehabilitation protocols. Careful follow-up with imaging studies may identify such situation, frequently without clinical consequences. Numerous authors have described the breakage of the tip of the screw, from tibial or from femoral tunnel. Once broken, the tip of the screw may become loose inside the joint and may cause articular blockage and lesion on the articular cartilage. Such undesirable events represent the premises of the present study. The broken fragments may migrate; several locations were described for such migration: intercondylar notch is the most frequent and it happens when the broken screw migrates from the tibial tunnel. When the fragment breaks from the femoral tunnel, the path of migration may lead to the thigh, beneath the gastrocnemius tendon as well as in the posterior distal thigh [8, 9].

When a screw gets loose inside the knee a nonspecific-blocking syndrome develops. Sometimes, the right diagnostic is delayed mainly for two reasons: (1) the surgeons does not take into account the reconstruction secured with resorbable screw and (2) the implant is not visible on plain X-ray. The lesson to be learned is the need to examine the ACL status on MRI or Arthro-CT in search for implant deterioration every time when specific symptoms occur because the adjacent possible damage of structures such as cartilage or meniscus may as well be visualized on these examinations [10]. This aspects are well-supported by the specific medical imaging for our clinical case shown in figure 1. For proper interference fixation the length of the screw should be at least 25 mm but it should always be correlated with the tunnel length. In order to avoid mismatch of screw length with tunnel length a careful measurement should be done as well as a mandatory check-out at the aperture of tibial tunnel at the end of the arthroscopic procedure [11, 12].

It is important to mention that the period of time for post-operative breakage is also different and varies from 4 months postoperative to as long as 12 months. Papers are different in reporting a possible role for trauma in the process and some of them mention a traumatic event related to the screw breakage while others describe a sudden onset [13]. In our clinical case there was no trauma connection with screw breakage and this situation brings into attention the role played by resorption process.

In our case, arthroscopy was performed in order to remove the failed screw and solve the clinical problem. Relevant intraoperative images made during arthroscopy are presented in figure 2. The main clinical aspects observed are: the tip of the screw measuring 8 mm was found in the intercondylar notch; a grade II Outerbridge cartilage lesion was observed on medial femoral condyle; discreet synovial reaction was noted anterior to the screw.

The screw was analyzed in the term of surface properties as we could see in figure 4. It is possible to see a different surface morphology with degradation signs according to the different rate of resorption of the PLLA and HA. Also, some cracks of the polymeric matrix (PLLA) are visible on the surface. According to the options given by scanning electron microscopy, it was possible to analyze the morphological aspects and make some considerations about the structure and interface aspects. The breakage lines were noted close to the inner part of the screw and in the area of the bioceramic particles.

Also, in the figure 4 we could see that the breakage lines tend to confluence and delimitate fragments, which prove that fragmentation process has started. No lines or fragmentation zone were seen at the outside part of the screw. The overall shape of the screw was preserved, especially at its exterior part. These results confirm a slow resorption rate of the polymeric matrix for the time since implantation. An important observation is that important fracture lines are related to larger ceramic fragments, while smaller fragments within the biocomposite polymer present a more constant degradation aspect.

Interference screw fixation is one of the most used fixation type in ACL reconstruction, especially at the tibial

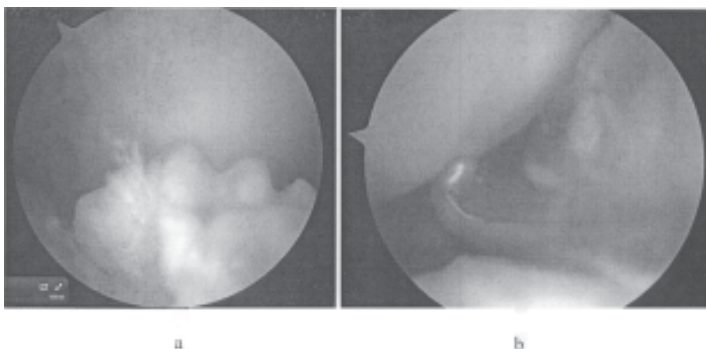


Fig. 2. Intraoperative imaging at arthroscopy: a) removal of the broken screw tip, b) cartilage lesion of the femoral condyle)

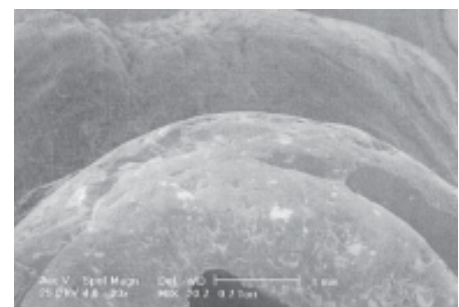


Fig. 3. SEM image showing a detail of the retrieved biocomposite interference screw surface with degradation aspects and without signs of remodelling



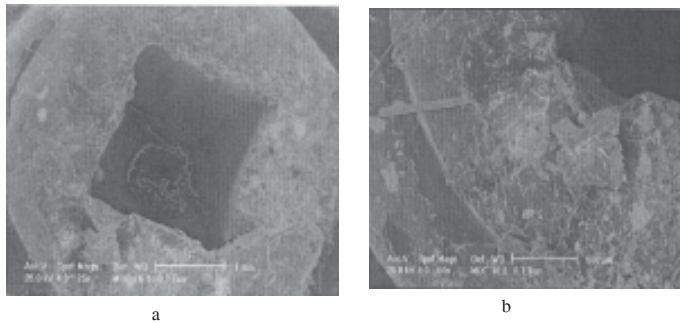


Fig. 4. SEM images of the biocomposite interference screw retrieved: a) general aspect, b) detail of the fragmentation process and small fracture lines

site. The rates reported for biocomposite graft fixation continues to grow and are based on their presumed benefits like avoid tunnel enlargement, cyst formation, and osteolysis and promote and sustain bone ingrowth but not all these benefits were proven in clinical practice. [14]

Breakage of biodegradable interference screws may occur at insertion time or at various times after their insertion. Concerning the risk of breakage at insertion time, the use of a guiding wire is mandatory for proper placement of the screw and for avoiding screw divergence; also careful handling during surgery is advised. The degradation process of bioabsorbable screws evolves in five stages: hydration, depolymerisation, and loss of mass integrity, absorption and elimination [15, 16]. On medical images obtained using MRI or CT, the loss of mass integrity may be quantified in percents of screw degradation. The screw degradation starts from inside, possibly from the interface between bioceramics particle embedded into the biodegradable polymeric matrix in case of biocomposite screws. The results obtained in our retrieval study confirm this consideration because breakage of the bioceramics particles was observed close to the inner part of the screw while the outside part shows no signs of resorption. As the resorption process progresses it may be presumed that it collapses to its inner, cannulated part. This may cause a decrease in its outside diameter and a premise for migration if the adhesion between the screw at the tendon – bone interface is precarious. This may be the case on tendon site for necrosis of the graft seen during the healing process to bone. As the degradation process continues, small particles bioceramics are released in the surroundings. Usually, the released particles undergo a phagocytosis process mediated by macrophages and this may be the trigger point for a local inflammatory reaction. As the mass of the screw is larger it may be presumed that higher debris quantity is generated during resorption and in some cases this may lead to inflammatory reaction. The frequency of nonspecific inflammatory reaction is variable [16]. The cyst formation was also reported after biocomposite screw usage [17] and this is in concordance with our experience, which at 8 to 12 months revealed feeble signs of resorption. It may also suggest that the resorption rates in vivo may be slower than those reported in vitro experiments as well as bone ingrowth.

Another reason for using biocomposite screw was to prevent tunnel enlargement. This presumption was not fulfilled and tunnel enlargement is still reported after biocomposite screw fixation. The aetiology of tunnel enlargement is complex because a lot of factors are related to: nonspecific inflammatory response, cells necrosis during tunnel drilling, avascular degradation of the graft, aggressive rehabilitation and no local stimulus active at tunnel wall. On the other hand, insertion of an interference screw not only compresses the graft to the tunnel wall but also lead to tunnel enlargement. For all this, a rigorous insertion technique should be used and a non-aggressive

rehabilitation protocol should be recommended for patients in which biocomposite screw was used for interference fixation. As several complications related to biocomposite screw use develop at long time after surgery patients operated with these devices should be on longer surveillance.

### Conclusions

The use of biocomposite interference screws in ACL reconstruction appears to be a valid solution for clinicians but the surgeons performing ACL reconstruction with these types of screws should be aware of complications. Patient who has undergone a reconstruction fixed with biocomposite screws should be on non-aggressive rehabilitation protocol and on long-term surveillance. Even it is obvious that the biocomposite screws have better mechanical properties than the polymeric screws, based on the retrieval analysis studies on ACL screw made of composite materials we could conclude that the differences in the resorption rates between the polymeric matrix and bioceramics particles used as reinforcement materials in composite screws could induce some potential complications. In our opinion, the long-term evolution of biodegradable composite screws is not completely understood and further studies are required to document long time behaviour of these implants. Retrieval analysis of the failed biodegradable interference screws in clinical practice could give us more details about the degradation process and useful information for establish the design of some new biocomposite materials for interference screws used in anterior cruciate ligament (ACL) reconstruction.

### References

1. KONAN S, HADDAD FS., A clinical review of bioabsorbable interference screws and their adverse effects in anterior cruciate ligament reconstruction surgery. *Knee* 2009;16:6-13.
2. SUCHENSKI M, MCCARTHY MB, CHOWANIEC D, HANSEN D, MCKINNON W APOSTOLAKOS J, ARCIERO R, MAZZOCCA A. Material Properties and Composition of Soft-Tissue Fixation, *Arthroscopy: The Journal of Arthroscopic and Related Surgery*, Vol 26, No 6 (June), 2010: pp 821-831
3. RAMSINGH V, PRASAD N, LEWIS M. Pre-tibial reaction to biointerference screw in anterior cruciate ligament reconstruction. *Knee*. 2014 Jan;21(1):91-4
4. KURTZ SM, LANMAN TH, HIGGS G, MACDONALD DW, BERVEN SH, ISAZA JE, PHILLIPS E, STEINBECK MJ. Retrieval analysis of PEEK rods for posterior fusion and motion preservation. *Eur Spine J*. 2013 Dec;22(12):2752-9
5. DACULSI G, UZEL AP, WEISS P, GOYENVALLE E, AGUADO E. Developments in injectable multiphasic biomaterials. The performance of microporous biphasic calcium phosphate granules and hydrogels. *J Mater Sci Mater Med*. 2010 Mar;21(3):855-61
6. AKSAKAL B, KOM M, TOSUN HB, DEMIREL M. Influence of micro- and nano-hydroxyapatite coatings on the osteointegration of metallic (Ti6Al4V) and bioabsorbable interference screws: an in vivo study. *Eur J Orthop Surg Traumatol*. 2014 Jul;24(5):813-9

7. PEREIRA H, CORRELO VM, SILVA-CORREIA J, OLIVEIRA JM, REIS RL, Espregueira-Mendes J. Migration of "bioabsorbable" screws in ACL repair. How much do we know? A systematic review. *Knee Surg Sports Traumatol Arthrosc.* 2013 Apr;21(4):986-94
8. APPELT A, BAIER M. Recurrent locking of the knee joint caused by intraarticular migration of bioabsorbable tibial interference screw after arthroscopic ACL reconstruction. *Knee Surg Sports Traumatol Arthrosc.* 2007; 15(4):378-380.
9. SHARMA V, CURTIS C, MITCHELL C: Extraarticular extraosseous migration of a bioabsorbable femoral screw after ACL reconstruction *Orthopedics Today* ,2008,31
10. HALL MP, HERGAN DM, SHERMAN OH. Early fracture of a bioabsorbable tibial interference screw after ACL reconstruction with subsequent chondral injury. *Orthopedics.* 2009 Mar;32(3):208
11. KOHN D, ROSE C: Primary stability of interference screw fixation :influence of screw diameter and insertion torque , *AmJ Sports Med* 21994,22, 334-8.
12. STADELMAIER D M, LOWE WR: Cycling pull-out strength on hamstring tendon graft fixation with soft tissue interference screw: influence of screw length .*Am J Sport Med* 1999:27,778-83
13. BARBER FA, BOOTHBY MH. Bilok interference screws for anterior cruciate ligament reconstruction: clinical and radiographic outcomes. *Arthroscopy.* 2007 May;23(5):476-81
14. MCGUIRE DA, BARBER FA, ELROD BF, PAULOS LE. Bioabsorbable interference screws for graft fixation in anterior cruciate ligament reconstruction. *Arthroscopy.* 1999 Jul- Aug;15(5):463-73
15. JOHN AH, JILL T Callaghan: Polymer-HA versus polymer interference screw in ACL reconstruction in large animal model ,*KSSTA* 2008,16,655-660
16. BARBER FA, DOCKERY WD. Long-term absorption of beta-tricalcium phosphate poly-L lactic acid interference screws. *Arthroscopy* 2008;24:441-447.
17. KOHN JC, PIENKOWSKI D, STERAGE E,: Interference screw fixation strength of a quadrupled hamstring tendon graft is directly related to bone mineral density and insertion torque, *AmJ Sports Med* 2000,28 ,750-10.

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Manuscript received: 25.02.2015