Chapter 2

Knee Surgery Complications Related to Biomaterials

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Summary

Recent years have seen a growing interest in biomaterials and use of these materials in the clinical setting is increasing. Despite their advantages, they have also been cited as the source of specific complications and/or failures. Problems such as screw breakage, tunnel enlargement, allergic or foreign body reactions, cyst and abscess formation, or even delayed migration of supposedly biodegradable screws/implants have been reported. This chapter aims to review the basic science and clinical experience with biomaterials currently employed in fixation devices for knee surgery. Information on the clinical implications of biodegradable screws is still limited. Surgeons tend to focus more on the emerging successes of innovations than on the complications and failures (publication bias) of older devices, making it difficult to reliably assess the incidence of such events. Moreover, the complexity of possible reactions occurring in the human body cannot be reproduced under controlled laboratory conditions.Nevertheless, surgeons and patients must be aware of both the advantages and the complications of these devices. Only in this way can informed choices be made, so that both parties are prepared to face and overcome the undesired complications, and the improvement of future implants can become a reality.

1 Introduction

Anterior cruciate ligament (ACL) repair related to sports participation at any level remains one of the most frequent orthopedic procedures of the knee.[1] Thus, the development of implants has been largely associated with the development of ACL (or posterior cruciate ligament) repair techniques. More recently, there has been widespread use of biomaterials in other knee surgeries, such as peripheral ligament, meniscus or medial patellofemoral ligament (MPFL) reconstructions. Advantages, pitfalls and clinical aspects of implant-related complications must be understood in terms of the specific anatomy and physiopathology of each injury. For example, in some cases, smaller devices with high resistance to pull-out are more desirable. In others, the "ideal" device would be either stiffer or more flexible, or "softer" and less aggressive to soft tissues, or perhaps even more prone to resorption into bone tissue. Many issues surrounding the ideal graft-fixation option remain unclear, and the best properties of the material used in medical devices for ligaments repair have not yet been defined.[2] Metal interference screws have been used for ACL fixation. These provide both strong initial fixation and favorable osseous integration if grafts include bony parts.[3] However, the early models increased the risk of damaging the graft and the risk for slippage, resulting in less stable constructions. This has led to a growing interest in and greater demand for soft tissue grafts[4].

Some of the recognized disadvantages of metal implants include problems for future magnetic resonance imaging (MRI) evaluation and more complex ACL revision surgery (since implant removal might be required).[3,5-7]

To overcome these limitations, the ideal implant for a more biological repair, involving minimal changes in native anatomy, should be biocompatible, biomimetic, and biodegradable and/or bioabsorbable.[8] Moreover, an effective initial fixation avoiding graft damage must be possible.[9] If the device had these properties, the need to remove implants (secondary surgery) in some orthopedic applications could be avoided in the future. Developments in bioengineering and biomaterials have come up with several options and interesting results are being observed.[2] Nevertheless, continuous monitoring by orthopedic surgeons is still required.[2]

Despite claims that bioabsorbable screws will degrade and be excreted through the body within months after implantation, this may fail to occur.[2] The clinical implications of failure to degrade range from insignificant (a radiological finding with favorable clinical outcome) to severe, e.g. delayed foreign body reaction ultimately requiring revision surgery. Our group has recently published a systematic review of bioabsorbable screw migration, concluding that this is another possible cause of complication or failure, with a currently unknown incidence.[2]

Although clinical outcomes with bioabsorbable devices are generally as good as with metal screws,[3] higher prevalence of knee effusion has been related to the use of these products.[10]

Problems associated with the use of bioabsorbable interference screws include: implant damage/breakage during surgery, inflammatory/foreign body reaction, incomplete absorption, joint effusion, encapsulation or screw migration.[7] Similar biological complications have been reported when similar materials were used for meniscus repair[11] or even bone osteosynthesis.[12]

We present a review of biomaterials used as fixation devices currently employed in knee surgery. Complications of anterior cruciate ligament (ACL) surgery related to biomaterials based on the authors' clinical experience will be discussed. Complications of medial patellofemoral ligament (MPFL) and meniscus repair associated with biomaterials will also be briefly discussed.

2 Biomaterials currently used in knee fixation devices (partial content from Pereira *et al.* reprinted with permission from Springer)[2]

Polyglycolide or polyglycolic acid (PGA), the simplest aliphatic polyester, is a thermoplastic polymer which has been around since 1954.[2] Itcan be obtained by several different processes starting with different materials. Given its sensitivity to hydrogenolysis compared with other synthetic polymers, its use was limited to a period of several years. However in 1962 this polymer was used to develop the first synthetic absorbable suture. When exposed to physiological conditions, polyglycolide is degraded by random hydrolysis, and apparently it is also broken down by various enzymes, particularly those with esterase activity.[7] This is believed to be the cause of the difference in degradation found *in vitro* and *in vivo*.

Poly-glycolide-co-trimethylene carbonate (PGA TMC) screws have been used in clinical situations (e.g., EndoFix; Smith & Nephew Endoscopy, Andover, MA).

Fink *et al.*[13] published a controlled study comparing polyglyconate and metallic interference screw fixation for patellar tendon grafts. The use of bioabsorbable screws was not found to be associated with increased clinical complications or significant osteolysis. Moreover, fixation and clinical outcomes equivalent to those of titanium screws were observed. However, "replacement of the screw with bone did not take place for up to three years postoperatively".[13] However, other studies reported possible complications, including effusion, cyst formation and tunnel widening.[11,14,15]

Konan *et al.*[16] described a high rate of adverse biological reactions with the clinical use of bioabsorbable PLC screws. The authors reported a wide range in the average time of foreign body reaction from three weeks to four months.

This is considered typical of the possible consequences of early wide scale uncontrolled novel application of any given biomaterial.

Stereoisomers of the lactic acid molecule, poly-L-lactic acid (PLLA) and poly-D-lactic acid (PDLA) have also been used. Polylactic acid or polylactide (PLA) is a thermoplastic aliphatic polyester (and not a polyacid) derived from renewable resources, such as corn starch, tapioca roots, chips or starch, or sugarcane.[17] Given the chiral nature of lactic acid, there are distinct forms of polylactide and its nomenclature can be quite confusing. Poly-L-lactide (PLLA) is the L isomer of polylactic acid[18] and is the product resulting from polymerization of L, L-lactide (also known as L-lactide). This polymer (PLLA) is the most frequently used biomaterial in orthopedics, and several papers have reported good results.[19,20] PLLA has a crystallinity of around 37%, a glass transition temperature between 60-65°C, a melting temperature between 173-178°C and a tensile modulus between 2.7-16 GPa.[18] It is hydrophobic and, due to its semi-crystallinity, degradation time is long.[12] Adverse effects from their degradation (acidity resulting from the release of lactic acid) can be observed up to three years after implantation.[12] The most common complications of PLLA screws in ACL surgery found in the literature are intraoperative screw damage, postoperative delayed screw damage and intra-articular migration.[21-27]

There is also a poly (L-lactide-co-D, L-lactide) (PLDLLA)[18,26] that is an amorphous polymer with a Tg of 60˚C. Poly-DL-lactide (PDLLA) screws (Figure 1) are aimed at preventing some reactions to the L-isomer and generally improving the implants. However, they have also been associated with complications, such as tibial and pretibial cyst formation.[28] Macarini *et al.*[29] also reported three cysts detected by MRI and suggested that osteointegration

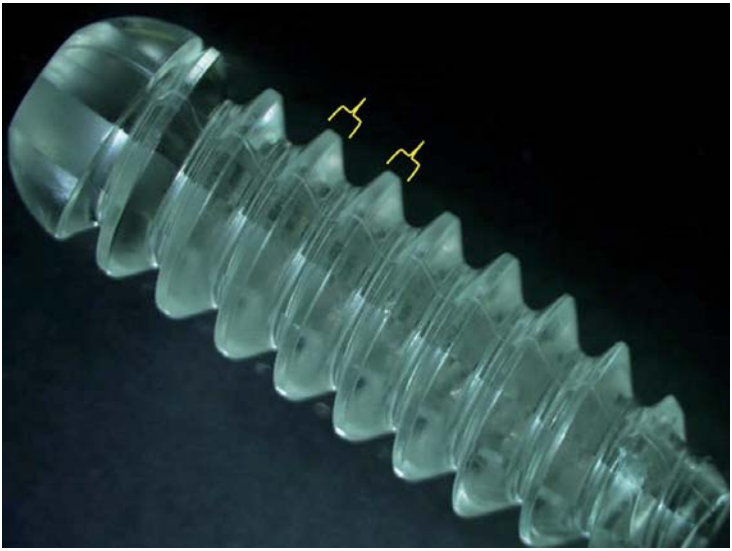

Figure 1

Slight amplification of PLLA screw (Arthrex, Naples, FL) removed after one year of implantation. No major structural differences were observed. The most noticeable effect is the blunting of the original sharpness of the screw crest (yellow brackets).

would only be achieved three years after implantation. However, no clinical complications derived from the implant were reported.

Polylactide carbonate (PLC) screws combine poly-DL-lactide-co-glycolide (an amorphous polymer), and calcium carbonate, acting as a neutralizing and osteoinductive agent.[16,30] Thiswas the component used in the Calaxo screw (Smith and Nephew, Andover, MA) that received so much widespread publicity. Konan *et al.*[16] reported that, in contrast to the predictable degradation ratio and osteoinductive properties reported in the ovine model,[30] their clinical series registered high rates of complications. In their series, 39% of patients using PLC had significant complications, including synovitis in 15% and prominent tibial swelling in 34%. The authors concluded that “the unpredictable screw degradation and the reaction to it can lead to serious clinical consequences”, underlining the need for monitoring the clinical application of any new material.

During the nineties, copolymers of polyglycolic acid/poly-lactic acid (PGA/PLA) were also tested and found to be associated with significant articular effusion.[12,31] Tunnel widening was reported by Lajtai *et al.*[32] to be greater on the femoral than the tibial side. However, pre-tibial drainage and material breakage were also reported.[12]

Biocomposite materials made from the aforementioned polymers and osteoconductive materials, such as calcium phosphates, hydroxyapatite

(HAp) and other brushites, have also been used in ACL repair.[33,34] The addition of inorganic fillers similar to those in bone was expected to improve not only mechanical performance but also osteointegration with the biological tissue.

Several attempts have been made to improve the profile and clinical results of polymer-based interference screws. However, follow-up in all related studies is short and clinical experience is still limited.

Järvelä *et al.*[35] compared hamstring ACL repair in three groups enrolling 77 patients: single bundle with bioabsorbable screw; double bundle with bioabsorbable screw and single bundle with metallic screw. At two years follow-up, no adverse reactions to poly-L-lactide D-lactide–Tca screws were reported.

At least one case of tibial cyst following the use of PLDLLA/TCP interference screws has been reported in literature.[36] So, despite the theoretical improvement derived from this combination, biological adverse reactions cannot be claimed to be absent.

PLDLLA/TCP scaffolds have also been developed for bone tissue engineering,[37] but there is still a long way to go. PLDLLA/HAp composite screws (BioRCI-HAp; Smith & Nephew, Andover, MA) have been reported to be clearly visible 24 months after ACL reconstruction.[38] These findings are in accordance with the two clinical cases shown in Figures1 and 4. Despite the theoretical rationale and pre-clinical findings, the practical clinical effect of the combination of osteoinductive components must be questioned. Notwithstanding, Robinson *et al.*[39], in a retrospective study comparing PLLA screws with and without HAp, proposed that combination with HAp might reduce the phenomenon of tunnel enlargement.

Most of the problems observed in the clinic are intimately related to the process of polymer resorption, which greatly depends on type, crystallinity, size and geometry, molecular weight, and surface properties of the polymer used to manufacture the implant.[34] However, resorption of synthetic polymers usually depends on a process of hydrolysis, *i.e.* there is water uptake by the polymer, which leads to a non-specific chain scission and a decrease in molecular weight. This is followed by a decrease in the mechanical properties of the implant, which then can break and cause formation of particles of different sizes that can be taken up by the cells of immune system. Foreign body reactions and ultimately fibrous encapsulation of the implant can consequently take place.[2] Simultaneously, the degradation products (e.g., glycine and lactic acid) resulting from the process of hydrolysis can be metabolized and excreted, but some complications can arise as a consequence of the acidification of the surrounding implantation site.[33] The different biological and chemical reactions occurring as a consequence of the implantation are so complex that it is difficult to identify the etiology of the complications.

3 Clinical experience

3.1 Complications of anterior cruciate ligament (ACL) surgery related to biomaterials used in fixation devices

There are no differences in clinical outcome between metal and bioabsorbable screws.[3,10] However, episodes of joint effusion are more frequent when using bioabsorbable screws.[10] Similarly, the use of bioabsorbable cross-pins for femoral fixation have also been associated with intraoperative and postoperative complications, ranging from lateral pin slip and tunnel widening to implant protrusion and breakage of bioabsorbable cross-pins.[40,41] Iliotibial band friction syndrome secondary to such implants[42] has also been documented and usually can be solved after implant removal.

The obvious advantages of bioabsorbable implants include absence of interference with subsequent MRI studies and, in case of revision surgery, it might facilitate the procedure (e.g. it is possible to overdrill).[7]

Despite the considerable efforts of industry in the development and promotion of bioabsorbable implants, scientific knowledge concerning their biologic behavior in human clinical use is still limited.

In a recent systematic review,[2] it was reported that most studies involve the use of PLLA-based screws and one PLLA/PLGA-based screw. The low number of reported cases and scant information limited further statistical analysis. However, migration in both the tibia (n=8) and the femur (n=1) was reported in a period ranging from 3 to 22 months postoperatively. The data were unclear in one study. Hamstring grafts were used in eight cases, one used patellar tendon (PT), one posterior tibialis and another Achilles allografts. Four papers reported the migration of an integral ("intact") screw at three, six, seven and twelve months after the original operation. Limited and inconsistent information about tunnel and bioabsorbable screw sizes was provided. From our own experience, three more related-to-topic cases have been reported: one associated with a tibial PLLA-HAp screw that could be removed intact twelve months after implantation; a second related to intra-articular migration of a PLLA femoral screw at twelve months; and another which involved partial intra-articular migration of a PLLA-HAp femoral screw.[2] Patellar tendon (PT) graft was used in all these cases.

More recently, another patient (a 38-year-old man) was treated for late tibial migration, 18 months after surgery (ACL repair with quadruple hamstrings). In this case, the screw was made of a composite blend of 40% PLDLA and 60% beta tri-calcium phosphate (TCP). The graft and tunnel were 8 mm in diameter and the screw was oversized by 1 mm (9 × 30 mm screw). Despite favorable outcome and return to sporting activity, the patient started to experience pain and local swelling on palpation of the proximal tibia at the site of the tibial tunnel operative scar, for no obvious reason. Within one

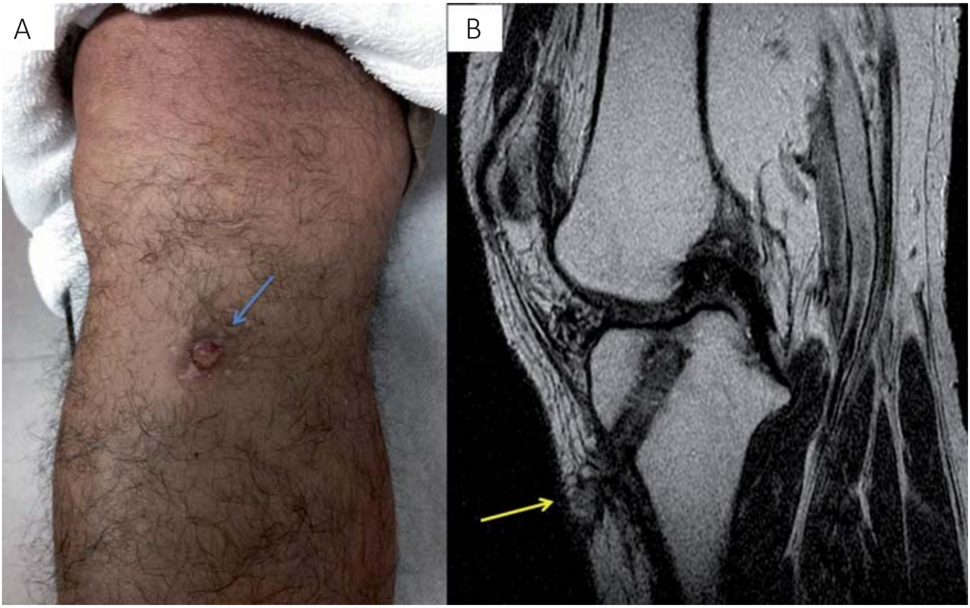

Figure 2

Late (18 months) migration of composite screw (40% PLDLA and 60% beta-TCP) with skin lesion (A – blue arrow) and MRI confirmation (B – yellow arrow).

month, the patient developed a skin lesion (Figure 2) with greyish content and small granules that were hard on palpation. The subject was operated and screw remnants in the form of a paste mixed with hard granules were removed (Figure 3). The graft was fully integrated and joint stability could be confirmed when the patient was anesthetized, so only cleaning of remnants

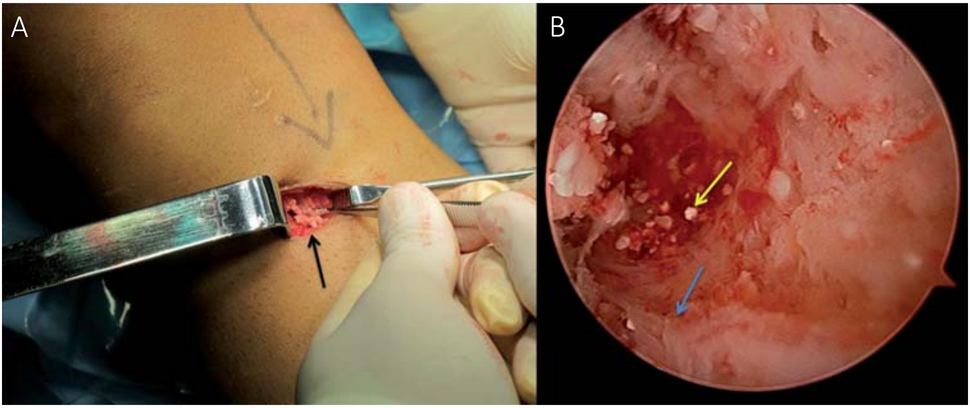

Figure 3

Intraoperative images. Whitish-grey, toothpaste appearance of screw remnants (A – black arrow); osteoscopy view (B) inside tibial tunnel confirming graft integration (blue arrow) and existence of composite granules, hard on palpation (yellow arrow).

was performed. No further complaints were reported in the twelve months after the cleaning. The patient resumed his previous activities within one month after the intervention. On histology, hematoxylin and eosin (H & E) staining showed large granules of PLLA material and increased mononuclear cell activity (Figure 4).

Although some studies favor composite screws, stating lower predisposition to inflammatory response, in this case we found that such an

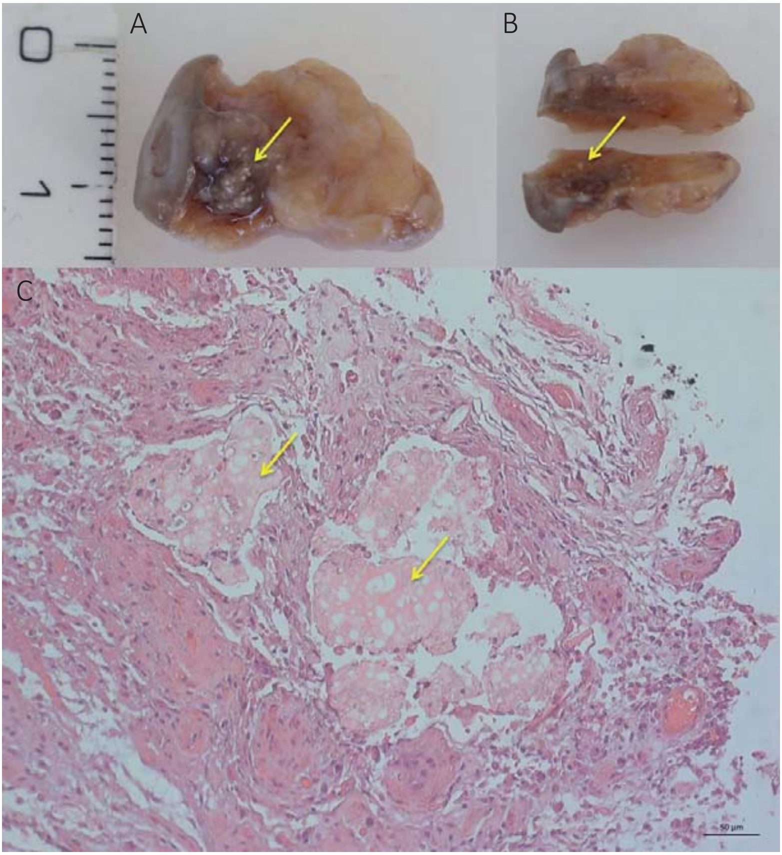

Figure 4

En bloque removal from skin to bone of the tissue encompassing screw remnants (A); cut in two halves for histological analysis with 2-D control of localization (B); Hematoxylin and eosin (H&E) staining showing granules of screw remnants (yellow arrows).

adverse reaction can occur even at a later stage.[34,43] Increased amounts of TCP have been shown to stimulate the proliferation of osteogenous cells.[34] TCP reportedly buffers the pH near poly(lactic acid)-poly(glycolic acid) implants undergone degradation, and this pH buffering causes less toxicity.[44,45] HAp can also buffer the acidic breakdown products of PLLA.[33]

Likewise all polymers, screw breakage during insertion can also be a problem for biocomposite implants. Moreover, as our case demonstrates, late migration and foreign-body inflammatory reaction also remain a possibility.

3.2 Complications of MPFL repair related to biomaterials used infixation devices

Interest in MPFL repair has been increasing in recent years.[46] Several techniques involve the use of biomaterials anchored by interference screws or other devices.[47] The possibility of late onset pain related to the use of such implants must be acknowledged and late screw migration might also be observed (Figure 5).

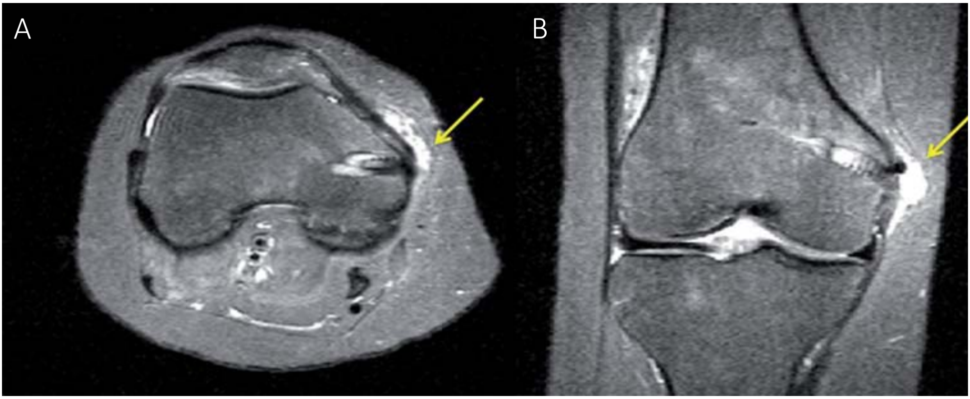

Figure 5
Axial (A) and frontal MRI (B) showing swelling and femoral screw migration after MPFL reconstruction (yellow arrows).

3.3 Complications of meniscus repair related to biomaterials used in fixation devices

Meniscus injuries are one of the most frequent causes for orthopedic surgery and meniscus repair is a growing trend.[48]

Several attempts have been made to use bioabsorbable implants (screws, arrows, anchors) for meniscus preservation and repair.[15,31]

Meniscus screws and arrows have been developed with the aim of achieving effective fixation while avoiding knot-tying and the need for additional sutures, and reducing surgical time.[15] Their bioabsorbable profile would obviate the need for implant removal and prevent secondary joint damage.

Despite the favorable clinical outcome reported for some series, and some problems related to mechanical stability of the achieved repair, the bioabsorbable implants have been associated with different problems, including local inflammatory response, delayed degradation and secondary cartilage damage.[31,49]

The resorption pattern is unpredictable, and some implants persist longer than 32 months[49], while *in situ* PLLA crystals have even been observed up to 5.7 years after implantation.[50]

4 Discussion

Irregular resorption and/or migration patterns are possible complications of bioabsorbable orthopedic implants.[2] Complications might include implant breakage, tunnel enlargement, allergic or foreign body reactions, cyst or abscess formation or delayed migration.

The clinical presentation of bioabsorbable material-related complications ranges from asymptomatic situations to mimicking meniscus injuries,[22,26] pain and swelling,[27,51-54] mechanical complaints,[23,27] wound dehiscence[25] or palpable masses.[25,54]

The authors have identified thirteen cases from literature and clinical practice related to migration of interference screws from ACL repair alone. An understanding of the basis of this phenomenon could help explain several other findings, such as cyst formation.[26,27,52] Most probably, many more cases exist but remain unreported. If indications are broadened to meniscal or peripheral ligament repair the number of affected patients will surely increase.

These pitfalls are frequently reported in studies involving implantation of PLLA-based implants, most probably because PLLA is the substance most frequently used in orthopedic sports medicine.[3,10,21]

Surgeons and researchers tend to be more predisposed to publishing positive results from innovative techniques than their inherent complications. It is possible that more information related to such problems exist but the data are not shared or made available to the scientific community. This would be a serious obstacle in the development of new and superior biomaterials for orthopedic procedures.

Basic knowledge of biophysical properties and possible biologic reactions of the materials used in manufacturing of such implants is mandatory for orthopedic surgeons.

5 Conclusions

Bioabsorbable implants present attractive advantages; however, the main possible handicaps, including potential adverse biological responses, late migration or foreign body reaction, must also be considered and discussed with patients. Currently, knowledge of the biological and chemical reactions occurring after the implantation of bioabsorbable screws is limited. It is not easy to extrapolate the findings of *in vitro* or *in vivo* animal model studies to what will happen in the clinical setting within the human body. Clinical studies involving new biomaterials should be performed under research conditions following well-designed protocols, before widespread usage can be recommended.

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