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Migration of "bioabsorbable" screws in ACL repair. How much do we know? A systematic review

Hélder M. D. Pereira · Vítor M. Correlo · Joana Silva-Correia · Joaquim M. Oliveira · Rui L. Reis CEng · João Espregueira-Mendes

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Abstract

Purpose Although bioabsorbable screws promise to degrade within months up to several years after implantation, often this does not happen. In fact, other problems such as screw breakage, tunnel enlargement, allergic or foreign body reactions, cyst or abscess formation, and delayed migration of "biodegradable" screws have been reported. This study aims to provide relevant basic science knowledge and recent insights concerning "biomaterials" currently used in fixation devices for anterior cruciate ligament (ACL) repair. A systematic review on the topic of screw "migration" is provided.

Methods A PubMed search combining all the key terms was done looking for complications related to late migration of "bioabsorbable" screws used in ACL reconstruction without inferior time limitation up to January 2012. Only clinical reports were included. Reference lists of reports were checked to detect others not identified by the original search. A pre-publication search was performed to identify the most recent relevant articles.

Results A total of ten articles referred to migration of "bioabsorbable" interference screws. Most cases reported on poly-L-lactic acid-based screws. Migration was noticed between 3 and 22 months postoperatively. It was noticed both in the tibia and the femur and with the application of several types of graft.

Conclusion Migration is a possible complication of "bioabsorbable" interference screws. The information related to all clinical implications of the so-called "biodegradable screws" remains scarce and probably suffers from the phenomenon of publication bias. The complexity of possible reactions occurring in the human body is difficult to reproduce under controlled laboratory conditions.

Level of evidence Systematic review including case-reports, Level V.

Keywords ACL · Bioabsorbable · Interference screw · Polylactic acid · Polyglycolic acid · Migration

Introduction

Anterior cruciate ligament (ACL) repair remains one of the most frequent orthopedic procedures, particularly related to sports participation at any level [14]. Several techniques are in current use with success rates (return to same level of activity) between 65 % [16] and 95 % [10].

Many questions remain to be clarified on aspects related to optimal graft-fixation techniques and the properties of the material used to fabricate the medical devices used in ACL repair. Over several years, fixation for ACL reconstruction has been performed with metal interference screws [3]. This

H. M. D. Pereira · V. M. Correlo · J. Silva-Correia · J. M. Oliveira · R. L. Reis CEng · J. Espregueira-Mendes
3B's Research Group—Biomaterials, Biodegradables and Biomimetics, University of Minho, Headquarters of the European Institute of Excellence on Tissue Engineering and Regenerative Medicine, AvePark, S. Cláudio de Barco, 4806-909 Taipas, Guimarães, Portugal

H. M. D. Pereira · V. M. Correlo · J. Silva-Correia · J. M. Oliveira · R. L. Reis CEng · J. Espregueira-Mendes
ICVS/3B's—PT Government Associate Laboratory, Braga/Guimarães, Portugal

H. M. D. Pereira · J. M. Oliveira · R. L. Reis CEng · J. Espregueira-Mendes
Saúde Atlântica Sports Center—F.C. Porto Stadium, Minho University and Porto University, Porto, Portugal

H. M. D. Pereira (✉)
Orthopedic Department Centro Hospitalar Póvoa de Varzim—Vila do Conde, Porto, Portugal
e-mail: heldermdpereira@gmail.com

system proved to achieve strong initial fixation and to provide osseous integration in grafts with bony components [10]. However, several concerns have arisen as a consequence of its application in soft tissue grafts [18], for example, due to the risk of graft damage or of providing more fragile reconstructions. Furthermore, the use of metallic devices creates some disturbances in MRI evaluation [9], and sometimes requires implant removal during ACL revision surgery, thus imposing increased difficulty in an always demanding procedure [10, 37].

For all these reasons, and with developments in the bioengineering and biomaterials fields, it has been stated that the ideal implant should be biocompatible, biomimetic, and biodegradable [1], while warranting strong initial fixation with minimal graft damage [39].

A recent Level II meta-analysis from Emond et al. [10] has shown that there are no significant differences in clinical outcomes associated with bioabsorbable screws as compared with metal screws for ACL reconstruction. Previously, Shen et al. [46], also in a meta-analysis of 10 randomized controlled trials comprising 790 patients, found no clinical difference between groups but noticed a higher prevalence of knee effusion with bioabsorbable screws. Medical device companies have made strong investments in the development of "bioabsorbable" implants and continue to promote their benefits. However, limited information is provided about the biologic characterization of such implants and on possible foreign body reactions.

Concerns associated with the use of bioabsorbable interference screws include intraoperative screw breakage, inflammatory response leading to accelerated or incomplete absorption, joint effusion, encapsulation, screw migration with further damage (articular or not), increased cost, and the potential for bone tunnel widening (even if its clinical implications are not yet clearly understood) [2, 6, 10, 11, 13, 21–23, 30, 38, 40, 41, 53, 54]. Although metal screws can also migrate after bony implantation, the underlying mechanism is very different [39].

This paper aims to provide relevant information concerning one of the most important and least understood complications related to the clinical application of bioabsorbable interference screws, i.e. the problem of migration. A second goal is to determine the prevalence of this phenomenon from a literature review. Furthermore, we summarize basic knowledge regarding the different synthetic polymers and composite materials used to fabricate implants that are applied in ACL repair which might be of interest to knee surgeons.

Materials and methods

Three independent reviewers performed a search using the electronic database PubMed without an inferior time limit up to January 2012, using all combinations of the following words: "anterior cruciate ligament"; "ACL";"reconstruction"; "bioabsorbable"; "interference screw"; "complications"; "polylactic acid"; "polyglycolic acid"; "tricalcium phosphate"; "migration". Only clinical references to the migration of screws classified as bioabsorbable were included. Studies at Levels I to IV and Level V case reports were accepted but not reviews or expert's opinions. The reference lists of manuscripts included were checked in order to detect other reports not identified by the original search. A pre-publication search was performed in January 2013 to identify the most recent relevant articles.

Final agreement on inclusion was discussed among all authors and if consensus was not obtained the final author made the definitive decision.

Results

Our initial search, combining all "key words" provided 387 studies. From these, 285 were excluded after being they were classified as non-related to the topic. A total of 102 studies related to "bioabsorbable screws complications" were identified. Among these, only 10 case reports on screw migration were identified. No articles were included from reference lists examination or from the pre-publication search.

The ten articles meeting the inclusion criteria (Table 1) refer to 11 patients submitted for ACL repair [4, 7, 19, 25, 29, 32, 42, 44, 45, 55]. In one study, a complication related to posterior cruciate ligament (PCL) repair was also described in another patient (referred in the Table, but without further consideration). All studies were case reports. Nine of ten cases involved the use of poly-L-lactic acid (PLLA)-based screws and one PLLA/poly lactide-co-glycolide (PLGA)-based screw. The low number of reported cases made any statistical calculations impossible.

Migration was noticed in a period ranging from 3 to 22 months postoperatively. It was noticed both in the tibia ($n = 8$) and the femur ($n = 1$). In one study, this information was not clear. In eight cases, hamstring grafts were used, one used patellar tendon (PT), one *posterior tibialis* and another Achilles allografts. Four papers reported the migration of an integral ("intact") screw at 3, 6, 7, and 12 months after the original operation.

Few studies provided information regarding tunnel and screw sizes. It was not possible to determine if the correlation between tunnel diameter and screw dimension can influence migration.

From our own experience, we briefly report three related-to-topic cases:

- The first concerns a post-traumatic re-rupture of ACL after 12 months reconstruction. Surprisingly, and in

Table 1 Clinical reports on interference screw migration in ACL or PCL reconstruction

Study	Type of material	Surgery	Screw placement	Migration site	Graft type	Graft failure	Screw status	Time from implantation to diagnostic of migration	*n*	Implications
Bottoni et al. [21]	PLLA	ACL reconstruction	Tibia	Intra-articular	Hamstrings	No	Intact and no evidence of resorption	7 months	1	Clinical presentation mimics meniscus lesion; arthroscopic removal
Shafer and Simonian [22]	PLLA	ACL reconstruction	Tibia	Intra-articular	Hamstrings	No	Broken	15 months	1	Pain and swelling; arthroscopic removal
	PLLA	PCL and posterolateral corner reconstruction (revision surgery)	Femur and tibia (1999)	Intra-articular	Achilles tendon allograft	No	Broken	23 months	1	Mechanical symptoms lateral side of knee; Effusion; Aarthroscopic removal
Werner et al. [23]	PLLA	ACL reconstruction	Tibia	Intra-articular	Hamstrings	No	Broken	5 months	1	Sudden locking; limited ROM
Sassmannshausen et al. [24]	PLLA	ACL reconstruction	Tibia	Extra-articular (transcutan eous)	Hamstrings	No	Intact and no evidence of resorption	12 months	1	Erythema, palpable mass; wound dehiscence
MacDonald and Ameja [25]	PLLA	ACL reconstruction	Femur	Intra-articular	Hamstrings	No	Broken	11 months	1	Clinical presentation mimics lateral meniscus tear; arthroscopic removal
Lembeck and Wiilker [26]	PLLA	ACL reconstruction (Revision surgery⁻)	Tibia	Intra-articular	Hamstrings	No	Broken	12 months	1	Persistent swelling and intermittent locking; severe chondral lesion; arthroscopic removal
Baums et al. [27]	PLLA	ACL reconstruction		Intra-articular	PT	No	Broken	22 months	1	Symptoms after knee twist during sports
Krappel et al. [28]	PLLA	ACL reconstruction	Tibia (double fixation: suture disk augmented by screw)	Intra-articular	Hamstrings	Yes	Intact	3 months	1	Effusion, limited ROM; mimics infection (negative microbiological assay)
	PLLA	ACL reconstruction	Tibia (double fixation: suture disk augmented by screw)	Intra-articular	Hamstrings	Yes	Broken	4 months	1	Pain, effusion, locking
Sharma et al. [29]	PLLA	ACL reconstruction (Revision surgery)	Femur	Extra-articular	Achilles tendon allograft	No	Intact no evidence of resorption	6 months	1	Pain, effusion, joint line tenderness; Concurrent tear both menisci
Hall et al. [30]	PLLA / PLGA	ACL reconstruction	Tibia	Intra-articular	Posterior tibialis tendon allograft	No	Broken (chondral damage)	4 months	1	Effusion, palpable loos body

concordance with pre-operative CT and MRI evaluation, the tibial PLLA-HA screw could be removed intact (Fig. 1);

- The second is a case of intra-articular migration of a PLLA femoral screw referred to our center which could be removed intact (Fig. 2). We could analyze it by micro-computed tomography after 12 months of implantation. Minimal changes were observed besides fainting of the crests (Fig. 3);
- The third one presents partial intra-articular migration of a PLLA-HA femoral screw (Fig. 4).

In all these cases, a patellar tendon (PT) graft was involved.

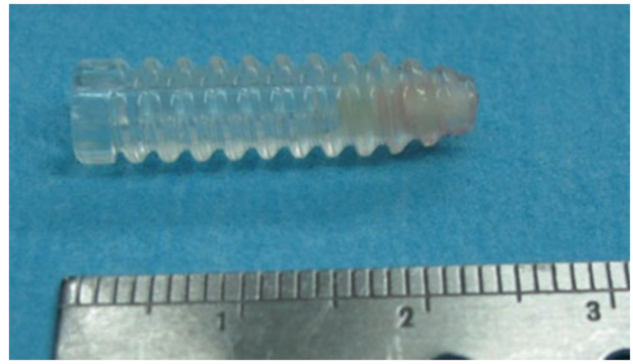

Fig. 2 Clinical case 2: 28-year-old male. Patellar tendon graft ACL reconstruction 12 months before. Pain, effusion and joint blocking subsided. PLLA screw from Arthrex (Naples, FL, USA) removed after 1 year of implantation in the human body

Discussion

Screw migration is a possible complication related to some characteristics of the so-called "bioabsorbable" interference screws.

We have identified ten case reports in the literature related to the migration of interference screws, enrolling 11 patients. The fundamentals of this phenomenon could help to understand several other findings such as cyst formation [25, 29, 32]. These problems are mostly reported in studies involving implantation of PLLA-based screws. This observation can probably be explained by the fact that, up to now, this polymer is the most frequently used in ACL surgery [10, 21, 46]. From our analysis, it seems to be more frequent in the tibia [7, 19, 25, 29, 42, 44, 55] and during application of hamstring grafts [7, 42, 44, 55], but the low

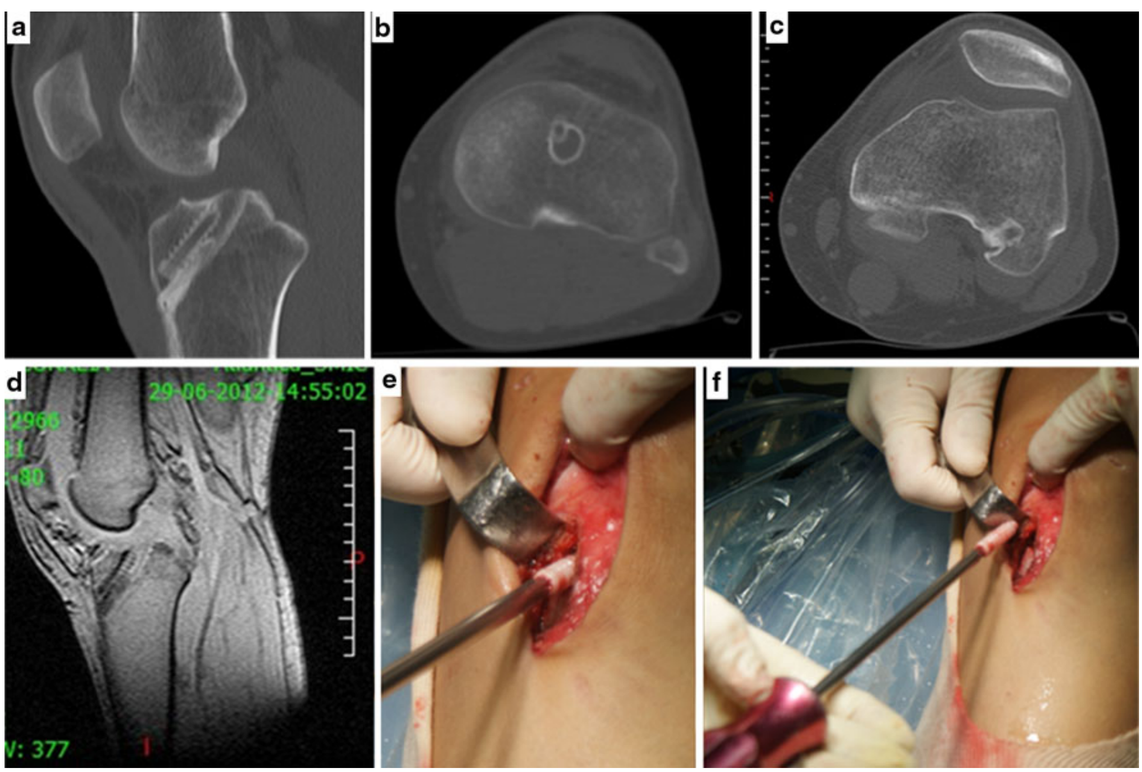

Fig. 1 Clinical case 1: 26-year-old soccer player. Patellar tendon graft ACL reconstruction with PLA/HA interference screws (BioRCI-HA; Smith & Nephew, Andover, MA, USA). Return to sports 6 months postoperatively. New trauma and re-rupture 13 months after surgery. **a–c** CT scans where the integrity of the tibial screw and integration in the femur is visible. **d** MRI scan showing integrity of the screw. **e**, **f** Removal of the screw for revision was possible using a normal screw driver. Macroscopically, it had fainting of the crests but kept its structure and resistance

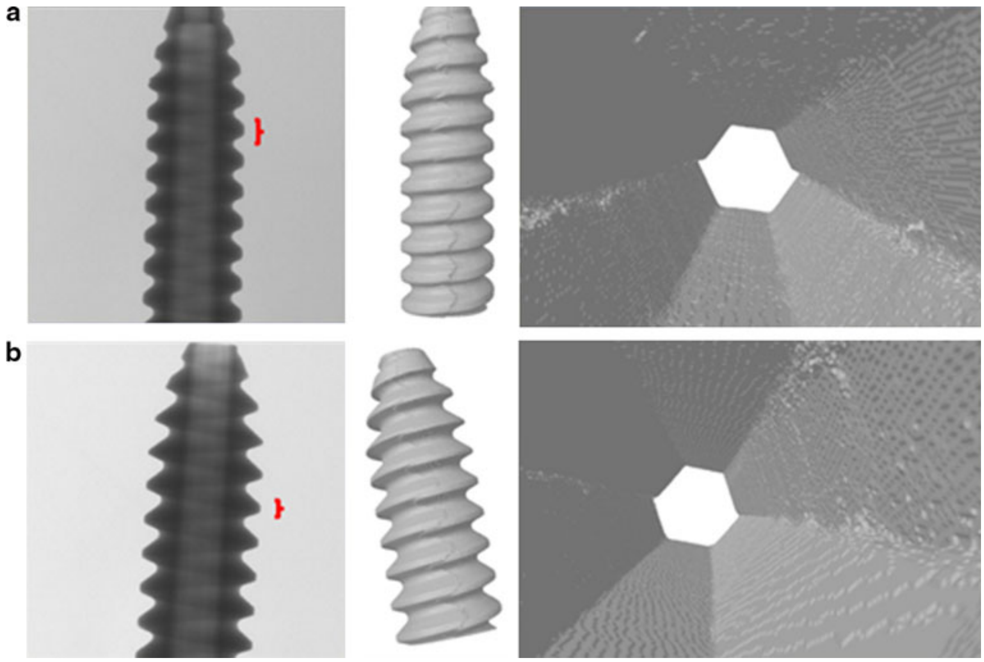

Fig. 3 Micro-computed tomography 2D and 3D images of the PLLA screws (Arthrex, Naples, FL, USA): **a** implanted screw, and **b** non-implanted screw. No major structural differences occurred. The most noticeable is the fainting of the original sharpness of the screw crest (*red* braces)

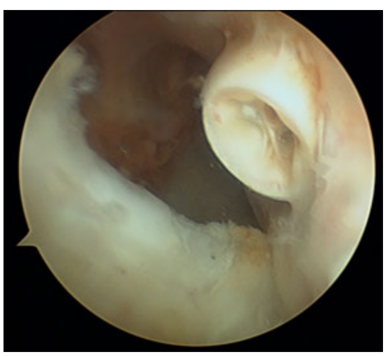

Fig. 4 Clinical case 3: 34-year-old male. Patellar tendon graft ACL reconstruction with return to previous activity. No complaints related to this surgery. Operated after new trauma. Arthroscopic image of non-integrated and partially migrated (intra-articular) PLDLLA/HA interference screw after 16 months of implantation

number of cases impairs further insights. Furthermore, we have registered two more cases of intra-articular interference screw migration, both related to PT grafts and both occurring in the femur. One was an incidental finding of asymptomatic partial migration and the other was correlated to complete migration of an "intact" screw causing pain, blocking and effusion.

MacDonald and Arneja [32] reported one case of intra-articular migration of a femoral screw, while Sharma et al. [45] described extra-articular, extra-osseous migration, also from the femur. Sassmannshausen and Carr [42] reported another case of extra-articular, transcutaneous migration, but in their case occurring in the tibial side. All other reports [4, 7, 19, 25, 29, 32, 44, 55], including our two cases, subsided in intra-articular migration.

There are four reports [7, 25, 42, 45] of retrieval of an intact screw from a period of 3–12 months after implantation. The description of our clinical cases 1 and 2 reinforce that this phenomenon (minimal physical changes in implanted screw in variable time frame) is a real possibility, and its biological fundaments require further research.

Screw migration can be asymptomatic or have relevant clinical implications. It can mimic meniscus injuries [7, 32], cause pain and swelling [19, 25, 29, 44, 45], mechanical complaints [29, 55], and wound dehiscence [42]. It can also be associated with the appearing of a palpable mass [19, 42]. Some limitations of the present studies must be considered. First, we lack control of the prevalence of similar complications arising from the use of metallic screws or different "bioabsorbable" fixation devices (e.g., expansion bolts and cross-pins). Second and probably the most relevant is the low number of cases identified and the low evidence level of studies (case reports). No controlled trial has reported such complications in the literature. The limited data on tunnel and screw sizes that has been reported impaired further considerations regarding the effect of tunnel/screw mismatch in migration. However, even with due caution, one can consider that migration is a possible complication of "bioabsorbable" screws, possible both in the tibia and femur, with several types of graft, intra- or extra-articular, and from a period ranging from 3 to 22 months.

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

Biomaterials currently used in ACL repair

Polyglycolide or Polyglycolic acid (PGA) is a thermoplastic polymer and the simplest aliphatic polyester, and known since 1954 [15]. Polyglycolide can be obtained through several different processes starting with different materials. Given its sensitivity to hydrogenolysis when compared with other synthetic polymers, it had limited use for 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 some enzymes, particularly those with esterase activity [17]. This is believed to be the cause of the difference in degradation found in vitro and in vivo.

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

Fink et al. [12] 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, equivalent fixation and clinical results compared with titanium screws was observed. However, "replacement of the screw with bone did not take place for up to 3 years postoperatively" [12]. Nevertheless, other studies reported possible complications including effusion, cyst formation, and tunnel widening [2, 5, 51].

Konan et al. [22] described a high rate of adverse biological reactions in their clinical use of bioabsorbable PLC screws. They found a wide variation in the average time of foreign body reaction from 3 weeks to 4 months. This is considered to be a paradigm of possible consequences deriving from precocious large-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 [47]. Given lactic acid's chiral nature, there are distinct forms of polylactide and its nomenclature can be quite confusing. Poly-L-lactide (PLLA) is the L isomer of polylactic acid [36] 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 orthopedic applications with several papers reporting good results [8, 33]. PLLA has a crystallinity of around 37 %, a glass transition temperature between 60 and 65 °C, a melting temperature between 173 and 178 °C, and a tensile modulus between 2.7 and 16 GPa [36] There is also poly(L-lactide-co-D,L-lactide) (PLDLLA) [32, 36], which is one of the most frequently used biomaterials in orthopedic applications with several papers reporting good results [8, 33]. It is hydrophobic and, due to its semi-crystallinity, has a long period of degradation [24]. Adverse effects from their degradation (acidity resulting from the release of lactic acid) can be observed up to 3 years after implantation. The most common complications of PLLA screws in ACL surgery found in the literature are intra-operative screw damage, postoperative late damage to the screw, and intra-articular migration [7, 21, 29, 32, 42, 43, 55].

Poly-DL-lactide (PDLLA) screws aimed to prevent some reactions occurring with the L isomer and global improvement of the implants. However, complications related to them have also been reported, such has tibial and pretibial cyst formation [35]. Macarini et al. [31] also reported three cysts detected by MRI, and proposed that osteo-integration would only be achieved at 3 years after implantation. However, no clinical complication derived from the implant has been registered.

Polylactide carbonate (PLC) screws combine poly-DL-lactide-co-glycolide (an amorphous polymer) and calcium carbonate, acting as a neutralizing and osteo-inductive agent [22, 52]. It was the component used in the Calaxo screw (Smith & Nephew Endoscopy), which has had relevant publicity and widespread distribution. Konan et al. [22] reported that, unlike the predictable degradation ratio and osteoinductive properties reported in the ovine model [52], their clinical series registered high complication rates. In their series, 39 % of patients using PLC presented relevant 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" reinforces the need for monitoring the clinical use of any new material.

During the 1990s, copolymers of polyglycolic acid/polylactic acid (PGA/PLA) were also tested. They were related to a significant prevalence of articular effusion. Tunnel widening was reported to be greater on the femoral than the tibial side by Lajtai et al. [26, 27]. However, pre-tibial drainage and material breakage were also reported [49].

Biocomposite materials which are made of combination of the previously listed polymers and osteoconductive materials, such as, calcium phosphates, hydroxyapatite (HA) and other brushites have been also applied in ACL repair. The addition of inorganic fillers similar to the existing in bone was expected not only to improve the mechanical performance but also the osteointegration with the biological tissue.

Several attempts have been made to improve the profile and clinical results of polymer-based interference screws. However, all related studies comprise short-term follow-up and there is still limited clinical experience. Järvelä et al. [20] compared hamstring ACL repair in 3 groups enrolling 77 patients: single bundle with bioabsorbable screw; double bundle with bioabsorbable screw; and single bundle with metallic screw. At 2 years follow-up, no adverse reactions to poly-L-lactide D-lactide–Tca screws were reported. It has been reported in the literature that there has been at least one case of tibial cyst following the use of PLDLLA/TCP interference screws [34]. So, despite the theoretical improvement derived from this combination, the absence of biological adverse reactions is not warranted.

PLDLLA/TCP scaffolds have also been developed for bone tissue engineering [28], but there is still a long way to go. PLDLLA/HA composite screws (BioRCI-HA; Smith & Nephew Endoscopy) have been reported to be clearly visible 24 months after ACL reconstruction [50]. These findings are in accordance with the two clinical cases observed in Figs. 1 and 4. The practical clinical effect of the combination of osteoinductive component must be questioned, despite the theoretical rationale and pre-clinical findings. Despite this, Robinson et al. [41], in a retrospective study comparing PLLA screws with and without HA, proposed that the combination with HA might reduce the phenomenon of tunnel enlargement.

Most of the problems observed in the clinics are intimately related to the process of resorption of polymers, which greatly depends on type, crystallinity, size and geometry, molecular weight and surface properties of the polymer used to fabricate the implant. But the phenomenon of resorption of synthetic polymers aforementioned usually occurs through a process of hydrolysis, i.e. there is a water uptake by the polymer which leads to a non-specific chain scission and a decrease in the molecular weight. It is followed by a decrease in the mechanical properties of the implant, which then can break, leading to scissionformation of particles of different sizes that can be taken up by the cells of scissionimmune system. Foreign body reactions and ultimately fibrous encapsulation of the implant can consequently take place. 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 surroundings at the implantation site. The different biological and chemical reactions occurring as a consequence of the implantation are so complex that it makes it difficult to identify the aetiology of the complications.

Clinical experience and authors' opinion

Even our short experience reinforces the fact that the persistence of some publication bias is possible [48] concerning this issue, once authors and journals tend to be more prone to publish positive results from innovative techniques than their complications. It is possible that more such complications exist but scissioninformation does not flow. This would be a serious obstacle in the search of better biomaterials for orthopedic use. Besides the properties of the materials, the possibility of tunnel/screw size mismatch might influence the biologic response. Higher compressive forces by use of a larger implant, leaving less void spaces, might help to prevent encapsulation and foreign body reaction. Clinical studies involving use of new biomaterials and formulations of both synthetic and natural-based polymers should undergo controlled trials with specific and adequate protocols.

Conclusion

From present study, we conclude that migration is a possible complication from "bioabsorbable" interference screw application, with the potential for major clinical implications. Methodological limitations of published papers impaired the characterization of the prevalence of this phenomenon. At present, biological and chemical reactions occurring after the implantation of "bioabsorbable" interference screws might lead to encapsulation and implant migration. "Bioabsorbable" implants present attractive advantages; however, the surgeon must also take into account their possible disadvantages, including potential adverse biological responses, and share this information with patients.

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