Complications Associated With Use of Anterior Cruciate Ligament Fixation Devices

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Abstract

Fixation devices used during anterior cruciate ligament (ACL) reconstruction are of numerous designs and materials. Untoward events following the use of these devices are not common. However, if unrecognized, they can lead to serious complications. This article summarizes some of the reported complications with ACL fixation devices. There are complications common to all devices but others are unique to the implant itself or to the material of which it is made. Surgeons must be aware of the potential adverse events that can occur with the particular device being used.

Anterior cruciate ligament (ACL) reconstruction is one of the most common orthopedic procedures. The original graft-fixation devices were staples, screw-and-washer posts, and sutures tied directly to bone. The most common complication of using these devices was pain over any prominent hardware. More serious were early fixation failures, fractures secondary to a stress riser at the fixation-device site, and damage to surrounding soft-tissue structures.[1]

Since ACL reconstruction was first described by Hey Groves[2] in 1917, reconstruction techniques and methods have evolved significantly. Now there are a variety of graft choices and new types of fixation devices. Current ACL reconstructions primarily use interference, suspensory, or transtunnel fixation devices. These implants are composed of metal, bioabsorbable, biocomposite, or plastic materials.

These new fixation devices have been associated with different and, in some cases, device-specific complications. In this review, I describe the reported and potential pitfalls related either to the nature of these devices themselves or to the material from which they are constructed.

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Interference Fixation

With the advent of the modern era of sports medicine, bone–patellar tendon–bone graft with interference fixation became the most popular ACL reconstruction technique. Interference fixation essentially places a device, most commonly a screw, between the graft and the tunnel wall. Fixation is maintained by interference fit and friction. Commonly used interference screws are composed of metal, bioabsorbable, biocomposite, or plastic materials.

Metal interference screw fixation was first described by Lambert[3] in 1983, but it was Kurosaka and colleagues[4] who popularized its use. The original screws were noncannulated and composed of stainless steel or titanium. These screws had several problems, such as graft laceration, fracture of bone plug on insertion, advancement of graft into tunnel, and incorrect screw placement.[5,6]

Migration of metal femoral screws into the posterior compartment, the intercondylar notch, or the lateral gutter has been frequently reported.[7-10] On the tibial side, backout of screws into subcutaneous tissues has been noted (C.M.F., unpublished data, 2005). Screw migration, either early or late, may be the result of technical issues: inadequate insertion, divergence, small screw size, screw thread design, and fracture of posterior tunnel wall. A nontechnical, biological issue is poor bone quality or bone resorption due to thermal necrosis caused by drilling.

Metal screws may complicate revision surgery as well. They can be difficult to remove and may leave a defect after removal. In addition, they compromise magnetic resonance (MR) and computed tomography (CT) images.

Bioabsorbable interference screws have advantages over metal ones. They are less likely to damage the graft, do not distort MR and CT images, and may allow for easier revision surgery. These devices, however, are associated with problems of their own.

The first screws were made of polyglycolic acid (PGA), which broke down rapidly and caused foreign-body reactions, synovitis, and aseptic effusions. Newer materials include poly-L-lactic acid (PLLA); poly-D, L-lactic acid (PDLLA); and PDLLA-co-PGA. Although these materials have longer resorption times and are generally less reactive, foreign-body reactions still occur, and they have been found as late as 12 years after insertion. These reactions include cyst formation,

Table. Benefits and Drawbacks of Fixation Devices

Device Type	Benefits	Drawbacks
Metal	Nonreactive Visible on radiographs Strong fixation Inexpensive	Visible on radiographs Distorts MRI Damages graft Leaves defect
Bioabsorbable	Not visible on radiographs Does not distort MRI/CT Strong fixation	Not visible on radiographs Reaction to biomaterial Fibrous defect after resorption Implant fracture Cost Resorption time unclear
Biocomposite	Not easily visible on radiographs Does not distort MRI/CT Strong fixation Defect fills with bone (?)[a]	Not easily visible on radiographs Reaction to biomaterial Implant fracture Cost Resorption time unclear
Plastic	Nonreactive Not visible on radiographs Does not distort MRI/CT Strong fixation Can be overdrilled	Leaves defect Not visible on radiographs Implant fracture Cost

Abbreviations: CT, computed tomography; MRI, magnetic resonance imaging.
[a]Animal studies conducted by manufacturers of biocomposite screws suggest that these screws are replaced by bone.[53] Early reports on their use in anterior cruciate ligament reconstruction in humans,[17-19] however, have not supported this claim.

wound dehiscence, sterile abscess, and chronic synovitis.

Stähelin and colleagues[11] reported chronic synovitis, 20 months after surgery, caused by fragmentation of a PLLA femoral screw. They also described a case in which remnants of a PDLLA-co-PGA tibial screw extruded through an incision 3 weeks after surgery. Sassmannshausen and Carr[12] reported the case of a patient who presented 12 months after surgery with the tip of an intact PLLA screw visible in the tibial incision. Martinek and Friederich[13] described a patient who developed pain and swelling over the tibial incision 8 months after surgery. MR imaging (MRI) showed a large cyst around the PDLLA screw. Kwak and colleagues[14] reported on a patient, who at 45 months, presented with a massive effusion. Joint arthroscopy revealed chalky debris secondary to a PLLA screw.

Bioabsorbable screws were initially thought to have an advantage of being resorbed and replaced by bone. Numerous reports do not support this. As noted, Sassmannshausen and Carr[12] removed an intact PLLA screw 12 months after surgery. Martinek and colleagues[15] reported finding an intact PLLA screw 2.5 years after insertion. In the case described by Kwak and colleagues,[14] the screw resorbed, but the defect had not been replaced by bone.

Thaunat and colleagues[16] reported a tibial plateau fracture occurring 4 years after surgery through the site of a bioabsorbable screw. The screw was completely resorbed, but the defect was filled with fibrous tissue. Those authors suggested that, when a screw resorbs without bony replacement, a stress riser may result, leading to fracture, or the bony defect could compromise revision fixation.

Biocomposite interference screws typically are composed of PLLA and an osteoconductive material, such as hydroxyapatite or β-tricalcium phosphate (β-TCP). The osteoconductive material promotes bony ingrowth as the screw resorbs, and should be less reactive to the surrounding bone. Similar problems of inflammatory reactions and lack of bone ingrowth have been reported with these screws as well.

Dujardin and colleagues[17] described formation of a tibial cyst and an intra-articular granuloma associated with use of a polylactide carbonate osteoconductive screw. Konan and Haddad[18] reported on a series of cases in which polylactide carbonate screws were used. Thirty-nine percent of the patients had complications, including synovitis, pretibial swelling, or both, 3 weeks to 4 months after surgery. Malhan and colleagues[19] reported on a patient who presented after 12 months with pain and swelling over the tibial incision. A screw made of PLLA and β-TCP had been used for tibial fixation. MRI showed cyst formation in the distal tunnel. Curettage of the defect revealed gelatinous material, no bone, and minimal screw remnants.

Plastics such as polyetheretherketone (PEEK) and polyethylene terephthalate (PET) are becoming popular in the manufacture of interference screws. These screws provide strong fixation, are inert, and do not distort imaging studies. They do not resorb but can be overdrilled in cases of revision surgery.

Almazan and colleagues[20] reported a complication

of PEEK use: inadvertent penetration of the tibial plateau by the screw of an Intrafix device (DePuy Mitek, Raynham, Massachusetts). The tip of the screw protruded through the top of the medial tibial plateau and damaged the femoral condyle. Those authors concluded that when the screw was inserted it diverged from the tibial tunnel and violated the articular cartilage. This complication is unique to this type of interference screw, as it is not inserted over a guide wire.

Another potential problem of plastic screws is that they can leave a considerable bony defect after removal, particularly with devices that consist of a sheath and a screw.

Fragmentation of bioabsorbable or biocomposite screws can occur during resorption. Numerous authors have described breakage of the tip of the tibial or femoral screw.[21-24] The broken tip can become loose in the joint and cause articular surface damage. Metcalfe and colleagues[25] reported acute knee-locking resulting from migration of the fragmented sheath of an Intrafix tibial interference screw into the joint 10 weeks after surgery.

These screws can migrate as well. They are typically found in the intercondylar notch and have the potential to damage articular cartilage.[26] In one reported case of femoral screw migration, the screw broke through the posterior cortex several months after surgery and became wedged under the head of the lateral gastrocnemius tendon.[27] In another case, a bioabsorbable femoral screw migrated through the tunnel and lodged in the posterior distal thigh.[28] I have noted 3 cases of extra-articular migration of bioabsorbable tibial interference screws less than 1 year postoperatively (C.M.F., unpublished data, 2011). Delay in diagnosis of a migrated or broken screw is common because of the radiolucent nature of these devices.

Nonmetallic screws may break on insertion, and another screw or an alternative method of fixation may be required. McGuire and colleagues[29] reported on a randomized study comparing bioabsorbable and metal screws. Twelve of 103 bioabsorbable screws fractured on insertion, and 7 of the 12 required secondary or alternative fixation. In addition, small cracks may develop in a screw on insertion, go unrecognized, and cause the screw to fail later.

Suspensory Fixation

Over time, different types of soft-tissue grafts, such as doubled-hamstrings and tibialis anterior allografts, have become popular. The lack of bony elements in these grafts prompted development of new modes of fixation. Suspensory devices now are commonly used for femoral fixation of these grafts. The suspensory device is secured on the femoral cortex or within the tunnel itself. The graft is "looped" over the device within the femoral tunnel. These devices are composed of metal, plastic or bioabsorbable material. The most well known is the Endobutton (Smith and Nephew, Andover, Massachusetts). Others are Retrobutton (Arthrex, Naples, Florida), ToggleLoc (Biomet, Warsaw, Indiana), Linx (Depuy Mitek), EZ Lock (Biomet), Aperfix (Cayenne Medical, Scottsdale, Arizona), and Tightrope (Arthrex).

Reported problems of suspensory fixation include failure to deploy in the proper position (that is, the device may not be flush with the femoral cortex, or it may deploy intraosseously in the tunnel).[30,31] In addition, the device can migrate into the joint.[32,33]

Another complication involved the 2-part Linx femoral fixator.[34] On insertion of this device into the femoral tunnel, its proximal component breached the anterior femoral cortex, impinging the undersurface of the quadriceps tendon and causing loss of motion.

Sheps and colleagues[35] reported the case of a femoral fracture that occurred 5 months after surgery at the cortical hole through which the suspensory device exited. During open reduction, they noted multiple holes through the cortex—consistent with multiple passes of the guide wire. They surmised either these additional holes weakened the bone, or the presence of the polyester tape had precluded bone remodeling in the area.

Suspensory devices fixed on the cortex are metallic, whereas intraosseous versions are bioabsorbable or plastic. In cases that require revision, large bony defects may be caused by resorption or removal of the device. Given the intraosseous nature of the device, these defects can be difficult to access and address. In addition, as is the case with nonmetallic screws, these devices could fracture and form loose bodies.

Transtunnel Fixation

Transtunnel fixation devices, such as RigidFix (Depuy Mitek), Bone Mulch screw (Biomet), or Transfix (Arthrex), either skewer the graft or provide suspensory fixation within the tunnel. These devices require additional incisions and additional bone tunnels for insertion. The implants are metal or bioabsorbable and some can be used in the femoral or tibial tunnel. Either bone–tendon–bone or soft-tissue grafts can be fixed with these devices. A common complication is pain over prominent hardware. The devices can be left proud on the medial or lateral side of the knee or protrude intra-articularly.[36-38] As with all bioabsorbable implants, these devices can fracture and migrate into the joint or soft tissues.[39,40]

Several investigators have used MRI to document how these devices fare after surgery. Cossey and colleagues[41] reported that, of 49 implanted Biotransfix devices (Arthrex), 5 broke—although without any apparent effect on clinical outcome. Studler and colleagues[42] studied the use of Biocross pins (Depuy Mitek) in the femoral tunnel. In 17% of their cases, the implant fractured; in 6%, a fractured tip migrated; in 25%, the implant breached the posterior cortex; and, in 3%, the implant remained proud. They also found no relation between implant integrity and clinical outcome. Choi and colleagues,[43] however, implicated the

fractured device as a cause of postoperative instability. They found that 39% of Biocross pins fractured and that KT1000 Knee Ligament Arthrometer (Medmetric, San Diego, California) values were significantly higher in patients with fractured cross-pins than in patients with intact pins. At 2 years however, there was no significant difference in Lachman and pivot-shift test results.

Two fractures have been reported with use of this type of device, specifically at the lateral femoral condyle tunnel created for its passage. One fracture occurred at 6 weeks, with no antecedent event,[44] and the other occurred 11 years after surgery.[45] Arriaza and colleagues[46] reported 2 cases of stress fracture adjacent to a bioabsorbable device and postulated that resorption around the device weakened the bone in the area and that, during aggressive postoperative rehabilitation, a stress fracture developed.

Discussion

There are varying complications associated with ACL fixation devices. Some complications are inherent to placing hardware in bone: distortion of imaging by metallic implants, stress risers leading to fracture, pain over prominent hardware, and damage to neighboring soft-tissue structures. Others are distinctive of the materials from which the implants are made or are specific to the particular device.

Resorption of bioabsorbable and biocomposite devices is responsible for several of their unique associated complications. Bioabsorbable implants degrade at variable rates; degradation is affected by polymer type, implant size, location, and local circulation. After implantation, a device becomes surrounded by a fibrous layer.[47] Histologically, there is a nonspecific response involving fibroblasts and macrophages and then multinucleated giant cells and polymorphonuclear leukocytes.[48] Degradation occurs by hydrolysis of the hydrolytically unstable polymer.[49] Accumulation of breakdown products (glycolic acid, lactic acid) creates a locally acidic environment.[49] Although lower pH stimulates resorption,[49] it is linked to inhibition of bone formation.[50] In addition, macrophage activation leads to bone resorption. The effect of the acidic environment on bone production combined with the initial fibrous encapsulation of the screw may contribute to the lack of bone ingrowth with bioabsorbable screws.

With biocomposite devices, 2 processes occur simultaneously. The biobasorbable component (usually PLLA) begins to degrade as just described. At the same time, the osteochonductive material begins the process of bony ingrowth. First, unlike the purely biobasorbable devices, the osteoconductive portion of the screw forms a bond with native bone, facilitating bony ingrowth.[47] Then, as the polymer portion degrades, the porosity of the implant increases, expanding the surface area for the breakdown of calcium and phosphate.[51] Release of calcium and phosphate stimulates osteoblasts and thereby further increases bone production. Basic salts released by the breakdown of the osteoconductive portion counteract the acidic byproducts of the polymer, negating their resorptive effects.[52]

Such resorption has several complications. As it progresses, a device weakens and may break, potentially producing an intra-articular loose body or causing loss of fixation, or both. In addition, a fractured fragment can migrate into the soft tissues. Inflammatory reactions to the breakdown products, even years later, can lead to synovitis, effusion, cyst or granuloma formation, sterile abscess, or wound dehiscence.

Bone resorption around a degrading screw can also result in loss of fixation and loosening or migration of screws, and it may be a factor in tunnel widening. Furthermore, as the screw resorbs, it may leave a defect larger than the screw itself, compromising revision surgery.

Other adverse events are particular to devices of any composition. Although fracture is not an uncommon complication of hardware placement because of stress risers, some fractures are related to the specific techniques required for device placement. In many cases, guide wires are passed to facilitate positioning. Postoperative fractures have been related to cortical defects created by multiple passes of the guide wire. In other cases, to introduce the device, a second tunnel must be created in the lateral femoral condyle, further weakening the bone. Finally, as postulated by Arriaza and colleagues,[46] resorption around bioabsorbable implants may cause the bone to weaken and lead to stress fracture, or fracture with minimal trauma.

Prominent ACL hardware can also be a problem. As these devices are often placed through small incisions, it can be difficult to ensure that the hardware is flush with the surrounding cortex. Size mismatches may result. When an implant is too large for a patient, it may become prominent. With radiolucent devices, such mismatches cannot be appreciated on routine radiographs.

The juxta-articular position of ACL hardware presents a distinct set of problems: Prominent intra-articular hardware may damage articular cartilage; fractures around the hardware or through tunnels created to pass the hardware may disrupt or damage the joint surface; an intra-articular fragment of a broken device can cause significant damage to the articular cartilage; and whole screws can migrate into the joint. As many of these devices are radiolucent, diagnosis of these complications may be delayed.

In conclusion, several statements can be made about ACL fixation devices.

- Compared with their bioabsorbable counterparts, metal and plastic implants appear to have fewer associated complications.
- Resorption of bioabsorbable implants can lead to well-described problems, including chronic synovitis, effusion, sterile abscess, and cystic defects.

• Reactions to bioabsorbable material can occur years after implantation.

• Resorption may weaken bone, making it more susceptible to fracture.

• Resorption weakens the implant. A fractured piece of a bioabsorbable device may become intra-articular. A high index of suspicion must be maintained with new onset of pain, locking, and swelling, particularly in the absence of new trauma.

• After removal, metal, plastic, and bioabsorbable implants leave a bony defect. Because of resorption, such defects may become larger than the device itself. Plastic devices with multiple components leave significant defects.

• In revision surgery, it is critical to use MRI to evaluate the status of the implanted fixation devices and any bone loss surrounding them.

• Multiple passes of a guide wire produce multiple stress risers with increased risk for fracture.

• Particularly with transtunnel devices, meticulous attention to detail is necessary to ensure correct positioning. A malpositioned device may cause fracture, soft-tissue irritation, fixation failure, or articular damage.

Many different implants have been developed for graft fixation in ACL reconstruction. All provide acceptable stability, and the vast majority have no complications. The ideal implant would provide rigid fixation during graft incorporation, resorb completely without significant inflammation and be replaced by bone, not interfere with imaging, be visible on plain radiographs for location verification, and be cost-effective. As no existing fixation device fulfills all these criteria, surgeons must remain aware of the potential risks and benefits of each (Table).

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