WHITE PAPER

Use of the Biodegradable Inion Hexalon™ Screw in ACL Repair

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Introduction

In current medicine, the use of metallic implants for surgical fixation is still very much the norm. However, with regard to Anterior Cruciate Ligament (ACL) injury, use of biodegradables has also become commonplace. ACL injury occurs frequently, especially amongst those very physically active, such as athletes, and 100,000 ACL reconstructions are performed annually in the US (Brown and Carson 1999). During reconstruction, an ACL graft is fixed to the femur and tibia with fixation devices. Interference screws (made out of metal or biodegradable polymers) are the most commonly used ACL graft fixation devices.

Disadvantages of metal implants are well documented and, despite becoming an accepted treatment, there have also been several problems associated with the use of early biodegradable devices in ACL repair. These limitations present an opportunity for improvement, one that Inion has taken.

Inion has developed a sports medicine product line that is focused upon treating soft tissue injuries. Included are the Inion Hexalon™ interference screw, the Inion Trinion™ meniscal repair screw and the Inion Anchron™ Plus suture anchor. The Inion Hexalon™ screw has been designed specifically to secure anterior cruciate ligament grafts in ACL reconstruction. Inion's vast knowledge of surgical biodegradable polymer applications and production processes, combined with continued understanding of the disadvantages of previous screw systems has enabled the production of a screw which overcomes several disadvantages of both metal implants (such as implant removal in revision cases) and existing biodegradable implants (which can degrade too slowly or too quickly).

Disadvantages of current screws

Metal screws are still frequently used when treating ACL tears, though the complications of this practice are well known and not limited to ACL repair. Metal implants have been know to cause localised pain (Alpert and Seligson 1996, Schmidt et al. 1998), corrosion (Agins et al. 1988), accumulation of metals in nearby tissues (Jorgenson et al. 1997, Katou et al. 1996, Kim et al. 1997, Rosenberg et al. 1993, Schliephake et al. 1993), hypersensitivity to titanium (Hunt et al. 1994, Katou et al. 1996, Lalor et al. 1991) and imaging and radiotherapy interference (Castillo et al. 1988, Sullivan et al. 1994, Sirlin et al. 2001). However probably the most discouraging problem associated with metal screw ACL fixation occurs when the screws used for securing the graft are left inside the femur and tibia. This gives rise to potential complications as, if

subsequent rupture is sustained, revision surgery will be very difficult. It is often challenging to drill the bone tunnels in the optimal position unless the old metal screws are first removed and even then, the void left by these screws may be so large that a bone graft is needed, stalling reconstruction for several months.

As a result of the limitations observed with metal screws, biodegradable alternatives were introduced with the hypothesis that as they degrade, the void in the bone begins to fill with bone. This, if subsequent injury or complication occurred, would allow for easier revision as new holes may be drilled into the regenerated bone or, if total degradation had not occurred, through the screws themselves. However, despite being preferable to metal implants, complications have also been observed with early types of biodegradable implants.

Some biodegradable implants, those that mainly consist of Poly L Lactic Acid (PLLA), have been known to have very long degradation times, sometimes up to four or five years (Radford et al. 2005, Bergsma et al. 1995). This provided a limited advantage over metal devices.

Others, which degraded too quickly, were linked with inflammatory responses. Incidence of this has been reported from 2.0 to 46.7% (Böstman and Pihlajamäki 2000, Pietrzak et al. 1997). These adverse reactions can occur if the rate of degradation exceeds the limit of tissue tolerance (Böstman and Pihlajamäki 2000).

Another of the key disadvantages of early biodegradable screws in securing a tendon graft to the bone is their tendency to break during insertion. This may be due to the brittleness of the previously-used materials, which could fracture under torque strains of insertion. Similarly, depending on the screw type and diameter, together with the screw/screwdriver interface design, torsional strength may be compromised if too much pressure is needed for insertion, causing weakness and possibly resulting in breakage (Costi et al. 2001). They have also been associated with rotation of the screwdriver in the screw head (Ahvenjärvi et al. 2002) causing rounding and rendering insertion very difficult.

Inion materials

Inion's combined expertise in biodegradable polymers is based on several decades' experience with these materials and is exemplified by the proprietary Inion Optima™ family of biomaterials. The Inion Optima™ library of blends is

created using L-Lactide, D-Lactide, TMC (Tri-Methylene Carbonate) and occasionally also Glycolide (when particularly fast degradation is required) to produce implants with optimal strength, malleability and degradation profiles to meet their specific clinical requirements.

A key benefit of Inion Optima™ materials is that they degrade naturally within the body and are metabolised into carbon dioxide and water, which are easily excreted. The rate of degradation is predictable and tailored to provide initial stability and then, as the implant loses its strength, to progressively transfer the load to bone to stimulate regeneration.

A recent study has shown that the Inion Optima™ implants fully degrade in two years *in vivo* without causing any clinically significant foreign body, inflammatory or other tissue reactions that some previous biodegradables have resulted in (Nieminen et al. 2006).

Inion Hexalon™

Through acquired competence in the manufacture of biodegradable implants, combined with gathered knowledge on improvements necessary for future ACL screws, Inion has developed a biodegradable screw that has a number of advantages over most available screws.

The Inion Hexalon™ screw retains 70-90% of its initial strength for up to 12 weeks, long enough to aid healing of the torn ACL. When its function has been performed, the screw then starts to degrade and its degradation products are excreted naturally. Most of the strength is lost within 18-36 weeks. The screws degrade completely within two years (Järvelä and Järvinen 2005. Nieminen et al. 2006), so if complication or subsequent injury occurs revision is far easier.

Inion Hexalon™ screws do not contain Polyglycolic Acid (PGA) therefore risk of tissue response or tunnel widening is not a concern. The degradation of the Inion Hexalon™ screw is harmless and eliminates the need for implant removal. Successful clinical use of Inion Hexalon™ screws has been shown by a number of studies including Lakovaara and Nurmi (2005) and Järvelä and Järvinen (2005).

The Inion Hexalon™ screw combines optimal design with optimal material composition to achieve a screw that has significantly reduced breakage. Until now, one of the key disadvantages of biodegradable ACL screws has been a

tendency to break during insertion, the Inion Hexalon™ screw has been designed so that the shape of the screwdriver socket is more resistant to torque forces than other biodegradable screws available. In a study performed by Ahvenjarvi et al (2002) it was found that the shape of the Inion Hexalon™ socket is superior to the others tested, effectively reducing stress forces and transferring the load to the screw body.

Inion's products are also designed with ease of use also a main priority. The Inion Hexalon™ screw has an optimised thread design and functional taper, which makes it self-tapping, resulting in a tighter fit. Its rounded thread also means damage to the graft is limited. The Inion Hexalon™ SET-4000 package includes four different screws in the most commonly used sizes. The package will save time, space and money and is easy to handle using the universal screwdriver provided.

Ease of use is also afforded by the colour of the screw. Inion Hexalon™ is the first biodegradable interference screw to have pigment added to it to allow clear arthroscopic visibility during an ACL reconstruction. The coloured screws are dyed green by a minimal amount of Drug and Cosmetic (D&C) Green No. 6, used commonly in biodegradable sutures.

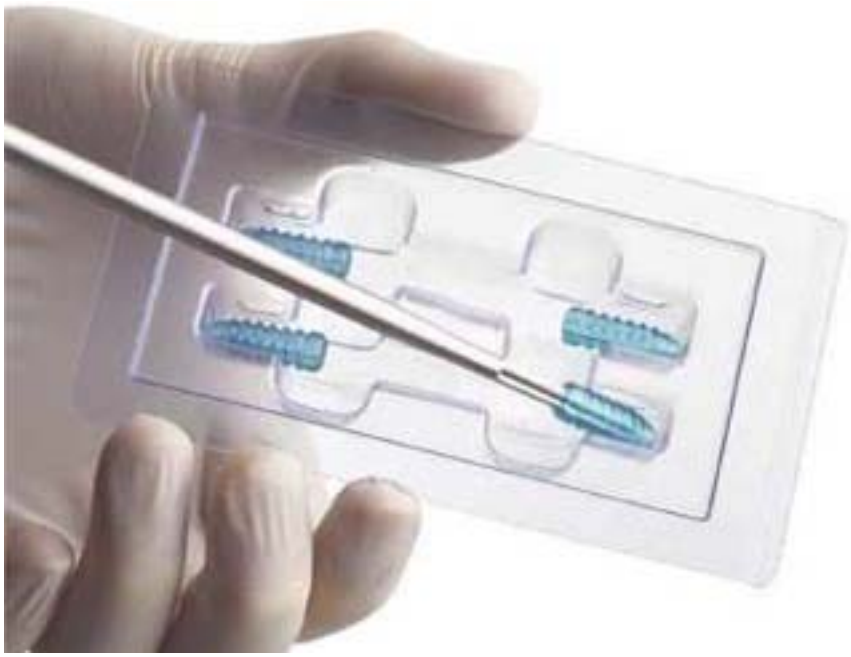

Figure 2. The Inion Hexalon™ SET-4000

Conclusion

Damage to the ACL is one of the most common injuries sustained in a sports environment. Reconstruction of the ligament with a tendon graft, secured by interference screws is commonplace. However, many of the screws used, both metal and biodegradable, have shown various disadvantages. The need for revision surgery following complication or further injury can be a major problem when there is previously-implanted hardware. The development of the Inion Hexalon™ system has provided a treatment method where the screw degrades completely over two years (Järvelä and Järvinen 2005, Lakovaara and Nurmi 2005) enabling easier revision than when metal screws are used.

There are many other features that give the Inion Hexalon™ system the advantage over both metal and previously used biodegradable screws i.e. its pigmentation, self-tapping thread and, thanks to its ergonomical socket shape and overall strength, the integrity it maintains during and after insertion. This ensures ease of use and assurance that the screw will not break or loosen. The Inion Hexalon™ system is already being used successfully for ACL reconstruction and because it degrades naturally within the body, a second operation for its removal is not needed.

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