WHITE PAPER

Advantages of Biodegradable Pins Over Metal Fixation

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Introduction

The field of internal fixation has long been dominated by the use of metal implants, in particular those manufactured from stainless steel, cobalt chrome and, in more recent years, titanium. However, despite widespread use and availability, utilisation of metal implants in fracture repair is not without its disadvantages.

Metal implants e.g. plates, pins, wires, mesh etc. have been associated with many physical problems including:

- Pain (Alpert and Seligson 1996, Schmidt et al. 1998)
- Corrosion (Agins et al. 1988)
- Accumulation of metals in 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)
- Imaging and radiotherapy interference (Castillo et al. 1988, Sullivan et al. 1994, Sirlin et al. 2001)
- Stress shielding - metal implants can prevent appropriate stimulation of the bone. Without loading, weakness and atrophy of the underlying bone can occur (Brodke et al. 2001, Kennady et al. 1989[1], Kennady et al. 1989[2], Uhthoff and Finnegan 1983, Uhthoff et al. 1994)
- Growth restriction in children (Yaremchuk 1994)

Metal pins, for example in the form of Kirschner wires (K-wires), can be used in the repair of many types of bone defects, e.g. fractures and osteochondral/chondral lesions. These implants in particular have been linked to several other problems. The most evident of these is the need to remove the implant once its purpose has been served (Jani and Parker 2004), specifically to remove protruding wires involved in the repair of hand and foot fractures. This causes added stress and discomfort to the patient and necessitates a further expensive and time-consuming procedure.

Additional disadvantages of using metal pins include infection and pin migration, bending or breaking. There is, therefore, an obvious need for the widespread adoption of improved materials, and biodegradable polymers were introduced to alleviate the problems seen with metal. Poor initial results with first-generation biodegradable implants meant that surgeons could not justify the use of biodegradable pins (Korner et al. 2001), however, recent major developments mean that their use now has to be re-evaluated.

A new generation of biodegradable implants has been created using the Inion OPTIMA™ family of materials. By blending L lactide, D lactide, TMC (Tri-Methylene Carbonate) and occasionally also Glycolide (when particularly fast degradation is required), Inion has been able to establish a 'library' of materials from which to select those with the most appropriate strength, toughness and degradation profile to meet specific clinical requirements.

Problems with metal

The most obvious disadvantage of metal implants is the need for an additional procedure to remove the implant. This is especially relevant in fractures involving the hand and foot as often a length of the pin is left protruding from the site of the repair. This protruding end enables the pin to be pulled out. Although not a very painful procedure and general anaesthetic is usually unnecessary, the patient can still experience a lot of discomfort.

As well as the general problems with metal implants, there are specific disadvantages to using metal pins including:

- Infection – In the case of protruding K-wires (Hargreaves et al. 2004) infections are relatively common and, if neglected, complications can include osteomyelitis, septic arthritis, early physeal fusion, flexor sheath infection and toxic shock syndrome (Birdsall and Milne 1999).

- Pin migration, bending or breaking. There have been reports of metal pins migrating from the extremities as far as the heart and the spleen (Seipel et al. 2001, Larkin et al. 1997, Rajesh and Nair 1991). There have also been several cases of pins migrating from the clavicle to the spinal cord (Priban and Toufar 2005, Regel et al. 2002).

- Inadequate fixation (Jani and Parker 2004). K-wires may also fall out prematurely – accidental loss of fixation secondary to displacement or pullout may occur (Petrik et al. 1996).

- Skin erosion (Jani and Parker 2004).

- Protruding K-wires can restrict movement (Arata et al. 2003).

- When K-wires are used in the foot, they are usually left exposed. The wires protrude from the toe requiring the use of a special shoe (Petrik et al. 1996).

These disadvantages affect patients, surgeons and healthcare providers and can also lead to increased cost. Even before the cost of the potential complications is taken into account, increased cost can immediately be seen. Patients treated with K-wires need additional procedures, to remove implants, compared to those treated with biodegradable pins (Jensen and Jensen 1996).

K-wires can be buried under the skin to reduce infection rates, however, the disadvantage is that, if removed, the procedure will usually be carried out in a day surgery unit where resources may already be under pressure. This has further cost implications (Hargreaves et al. 2004).

Biodegradable materials

Biodegradable materials, which provide strength during bone healing and then disappear, offer an obvious solution to the problems experienced with metal. Biodegradable implants have, therefore, been in use for many years, but some earlier materials caused problems. Some degraded too quickly causing tissue reactions or took too long to degrade offering no real advantages over metal (Andriano et al. 1994).

The polymers Poly L Lactide (PLLA) and Polyglycolide (PGA) have been used in the past and exhibit distinctly different degradation behaviour (Wu et al. 2003). PGA is hydrophilic and degrades very quickly (Andriano at al. 1994), losing virtually all strength within one month and all mass within 6-12 months. During this phase of rapid degradation, large quantities of the Glycolide monomer are released and the degradation rate can exceed the capacity of the surrounding tissue. This can result in the formation of sterile abscesses (Böstman and Pihlajamäki 2000). PLLA has a much slower rate of absorption (Andriano et al. 1994). This homopolymer of L Lactide is highly crystalline due to the ordered pattern of the monomers and has been documented to take more than five years to absorb (Bergsma et al. 1995) conferring little advantage over metal.

Inion OTPS™ Biodegradable Pins

Recent advances in the blending of biodegradable materials have culminated in the development of Inion OPTIMA™, a library of new generation biodegradable implant materials. Different blends to modify strength and degradation are used to reflect different clinical requirements.

The Inion OPTIMA™ library of polymer blends was designed to overcome the limitations of early biodegradable materials and is composed of varying proportions of L Lactide, D Lactide and TMC. The blend selected for the Inion OTPS™ pins means they have a tailored degradation profile and appropriate strength for the clinical application.

Because Inion OPTIMA™ materials consist of several monomer types, they are amorphous and degrade completely. The implants also remain amorphous after manufacturing due to Inion's carefully controlled production processes (some other copolymers become semicrystalline during manufacture). In comparing the degradation of Inion OPTIMA™ to PLLA and PGA: PLLA degrades slowly with crystalline debris usually remaining; PGA degrades completely but too quickly (Andriano et al. 1994); Inion OPTIMA™ degrades completely and within the appropriate length of time for each application.

The strength of the implants remains whilst it is required for bone healing. The implants degrade by hydrolysis and, over a period of time, are metabolised through natural processes in the body into carbon dioxide and water, which are then exhaled and excreted.

The Inion OTPS™ biodegradable pins have been indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis or bone grafts (i.e. autografts or allografts) in the presence of appropriate additional immobilisation (e.g. rigid fixation implants, cast, brace). The pins are available in several diameters and lengths to suit a range of applications including, but not limited to:

- Radial head fractures
- Humeral condyle fractures
- Osteochondral fractures
- Foot fractures and osteotomies
    - Hallux valgus
    - Hammertoe
    - Bunionectomy
    - Reverdin/Green Osteotomies
    - Metatarsal fractures and arthrodeses
- Hand and wrist fractures and osteotomies
    - Phalangeal fractures and arthrodeses
    - Carpal fractures
    - Distal radius fractures

Benefits of the Inion OTPS™ Biodegradable Pin

As the Inion OTPS™ biodegradable pins are designed specifically to be absorbed within the body there is no need for a removal operation. This is one of the many advantages for both patient and clinician:

Patient:

- Does not protrude so tract infections associated with K-wires are avoided
- No additional surgery
- Reduced trauma
- Reduced rehabilitation time
- No permanent implant in the body
- Safe and biocompatible material; no risk of metal allergic reaction

Clinician:

- Compatible with Magnetic Resonance Imaging (MRI) for effective post-operative diagnosis
- Reduced radiographic scatter/obstruction
- Minimised risk of obstruction during any follow-up surgery
- Increased patient satisfaction

Additional benefits:

- Reduced total cost
- Reduced treatment duration
- Supplied sterile to reduce risk of cross infection

Removal operations cause undue trauma to patients especially in the case of protruding K-wires. Surveys have shown that patient satisfaction for K-wire removal procedures carried out in outpatient clinics is poor (Moholkar et al. 2003). Given the choice, the majority of patients would choose a biodegradable implant. In a recent publication, 91% of patients who participated in a questionnaire saw the removal operation as the most negative aspect of a metal implant (Mittal et al. 2005).

In addition to eliminating the need for a removal operation, the degradation profile of the biodegradable pin is tailored to progressively load bone to aid bone regeneration. This prevents the occurrence of stress shielding, possible with metal implants. Degradation of the pin also results in simultaneous regeneration of bone in the resulting void - new bone is deposited on and within the implant channel - therefore there is no weakness remaining in the bone after the complete degradation of the implant (Sirlin et al. 2001).

Biodegradable pins have recently been compared with standard K-wires in the fixation of fractures, arthrodeses and osteotomies in the hand and no differences in time to union or complication rates were found (Jensen and Jensen 1996).

Inion OTPS™ Pin strength

The biomechanical properties of the Inion OTPS™ biodegradable fixation system have been determined in a study by Nuurmi et al. 2005.

Methods

Inion OTPS™ biodegradable pins (2.00 x 40mm) were tested within bovine proximal phalangeal osteotomies using four-point bending (constant speed of 10mm/min) to determine the strength of pin fixation.

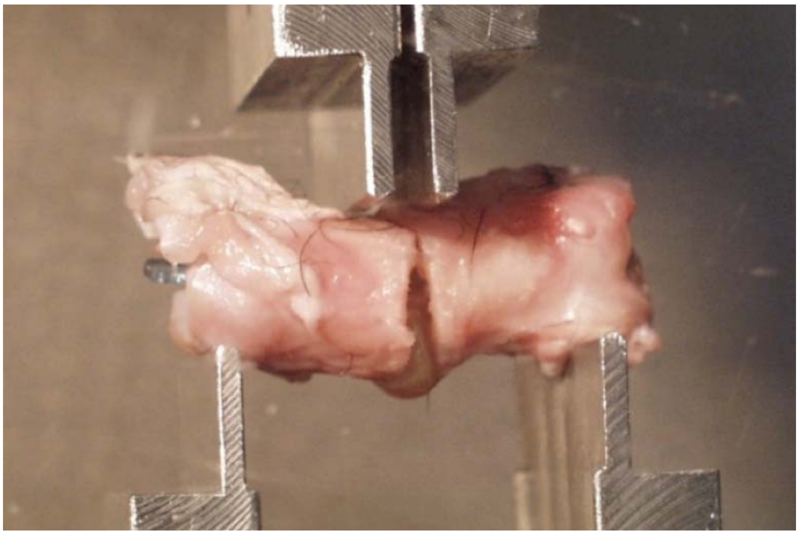

Figure 1. Four-point bending test

The osteotomy was in the middle of the phalanx and the pin inserted parallel to the long axis of the bone.

Results

Stiffness	44N/mm
Yield load	28N

Conclusion

Metal pins and wires have some common disadvantages that can be avoided by using biodegradable pins. A solution for patients and clinicians exists in the form of Inion OPTIMA™, the new generation of biodegradable polymers from Inion, from which the Inion OTPS™ pins are created.

The gradual rate of degradation allows for an optimal transfer of support to the bone as it heals and allows subsequent regeneration of the bone at the site of the implant. Inion OTPS™ pins in conjunction with appropriate additional immobilisation provide appropriate fracture fixation, combining adequate strength retention and degradation rate, whilst eliminating most of the disadvantages of metal.

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