

Biodegradable Fixation in Hallux Valgus Correction



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Introduction

Hallux valgus is a very common deformity of the first metatarsophalangeal joint. Studies on the condition are few but data obtained from the National Center for Health Statistics states that it affects 1% of adults in the United States. The aetiology of the condition is vague and frequently cannot be determined, but there are a number of ways the problem can be corrected. Some procedures, however, have been shown to be flawed as a result of the use of metal fixation devices. Metallic devices, for numerous applications, have come under attack in recent years, which has allowed the progression of biodegradable implants as a superior alternative.

Hallux valgus and its current treatments

The deformity of the first metatarsophalangeal joint, presenting itself as a hallux valgus, shows lateral deviation of the great toe, outward angulation, separation of the heads of the first and second metatarsals, and prominent soft-tissue thickening over the medial surface of the head. There are many factors that may influence the formation of a hallux valgus. These include:

- Biomechanical instability
- Arthritic/metabolic conditions
- Neuromuscular disease
- Traumatic compromise
- Structural deformity

Treatment of the hallux valgus may be required for the sufferer to alleviate the pain, difficulty walking, chronic inflammation or rubor caused by its presence. The hallux valgus may also be responsible for an additional acquired foot disorder, e.g. neuritis/nerve entrapment, hammer digits, first metatarsocuneiform joint exostosis, sesamoiditis, ulceration or inflammatory conditions (bursitis, tendinitis), which may also need alleviation.

Where conservative treatments such as padding, physical therapy, orthotics or night splints fail to relieve the symptoms of the hallux valgus, surgical intervention may be required. To date there have been as many as 200 different types of procedure used to correct the deformity of the great toe (Kokavec et al. 2005) depending on the severity of the bunion. The severity is determined by the hallux valgus angle and the most appropriate procedure for the level of severity is carried out.

The most common procedure performed is osteotomy with wire, screw or pin fixation. There are various sub-types of osteotomy procedure, e.g. Akin osteotomy, Chevron osteotomy, distal osteotomy etc. each used depending on the individual case, however the basic technique is very similar. Resection arthroplasty is another widely used technique but is mainly reserved for elderly patients or those with degenerative joint disease, so is therefore a less common treatment for hallux valgus than osteotomy.

Where hallux valgus surgery is performed the remaining fragments of bone require stabilisation and this is often achieved by wire, screw or pin fixation and until recently the only available material for the production of fixation device was metal. Metal implants are being recognised as highly undesirable to work with, especially in fixation of hallux valgus osteotomies, for a number of reasons.

Disadvantages of metal

For the most part, in the case of hallux valgus corrective surgery, metal fixation is in the form of wires, screws or pins. General problems with all types of metal implants, including wire, screws and pins, e.g. imaging and radiotherapy interference (Castillo et al. 1988, Sullivan et al. 1994, Sirlin et al. 2001), accumulation of metals (Jorgenson et al. 1997, Katou et al. 1996, Kim et al. 1997, Rosenberg et al. 1993, Schliephake et al. 1993) and hypersensitivity to titanium (Hunt et al. 1994, Katou et al. 1996, Lalor et al. 1991) are a valid cause for concern, although it has also been frequently observed that there are distinct complications following the application of wire, screws and pins alone.

The most widely noted complication associated with metal pin, screw or wire fixation in hallux valgus treatment is infection. In one particular study, where metal fixation was used, 63% developed pin tract infections (Treadwell 2005). Infection results in additional discomfort for the patient and, if it is unresponsive to a course of antibiotics, the implant will need to be removed (Treadwell 2005). This subsequent surgery is distressing for the patient, costly for the health care provider and, with regard to the condition, may leave the bone incorrectly or inadequately stabilised.

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 physal fusion, flexor sheath infection and toxic shock syndrome (Birdsall and Milne 1999).

Evidence of breakage, loosening and migration of pins, screws or wires is also found very frequently amongst the literature (Coughlin 1995, Seipel et al. 2001, Larkin et al. 1997, Rajesh and Nair 1991, Priban and Toufar 2005, Regel et al. 2002, Treadwell 2005). 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). Also several cases of pins migrating from the clavicle to the spinal cord have been presented (Priban and Toufar 2005, Regel et al. 2002). Breakage, loosening or migration leading to loss of fixation, often require re-operation to remove or relocate the implant.

Pain or irritation from such metal implants has also been noted, for example with prominent screw heads (Mancuso et al.1992, Viehe et al. 2003). This could again be a cause for removal of the metal implants.

As can be seen, implant removal is a frequent occurrence with regard to metal pins, screws and wires. In a recent study 91% of participants stated that removal was the most negative aspect of metal implants this therefore strengthens the appeal of biodegradables as fixation devices.

Inion products and their advantages

Since 1999, Inion has been dedicated to developing and manufacturing novel biodegradable polymer implants to more effectively meet the needs of surgeons, patients and healthcare providers.

Inion has perfected the process of blending common biocompatible polymers to produce a library of polymer blends with varying strength and degradation profiles that can be tailored for use in many surgical areas. These innovative implants have achieved excellent results, showing many benefits over previously used metal fixation devices as well as over early biodegradable devices.

The development of the Inion OPTIMA™ library of polymer blends has introduced implants which degrade completely and within the appropriate length of time for each application. Because Inion OPTIMA™ materials consist of several monomer types, they are amorphous and degrade completely.

Inion OTPS™ biodegradable pins and screws (2.5, 2.8 and 3.1mm) have been indicated, and successfully used, for maintenance of alignment and fixation of

osteotomies as well as bone fractures, arthrodesis or bone grafts in the presence of appropriate additional immobilisation (e.g. rigid fixation implants, cast, brace).

The implants are designed with adequate strength for their intended purpose, minimising breakage and ensuring sufficient fixation of the metatarsal is achieved. The implant's strength remains whilst it is required for bone healing and then is gradually lost after 18-36 weeks, progressively loading the bone to aid regeneration. Total biodegradation occurs within two to four years. 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.

Infection, the most common complication associated with metal fixation of hallux valgus, is less of a concern where biodegradable pins and screws are used. The implants are single-use and are supplied sterile, significantly reducing the risk of cross-contamination. Also, no hardware is left exposed – as with K-wires - leaving no tract for the infection to gain entry.

Pain or irritation, commonly experienced when using metal screws with prominent heads, is avoided where biodegradables are used the screw head will degrade or, if initially prominent, may be cut off. This is very easily done due to the malleability of the material.

In addition to these benefits are the inherent benefits of biodegradable systems:

- The lack of interference with imaging techniques e.g. X-rays, enabling the fracture and bone healing to be easily observed
- No long-term implant palpability or temperature sensitivity
- Ease of traceability as the implants are supplied sterile with batch coded labels

Implant strength

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

Pin

Methods

Inion OTPS™ biodegradable pins (2.00 x 40mm) were tested within ovine proximal phalangeal osteotomies using four-point bending (figure 1) (constant speed of 10mm/min) to determine the strength of pin fixation.

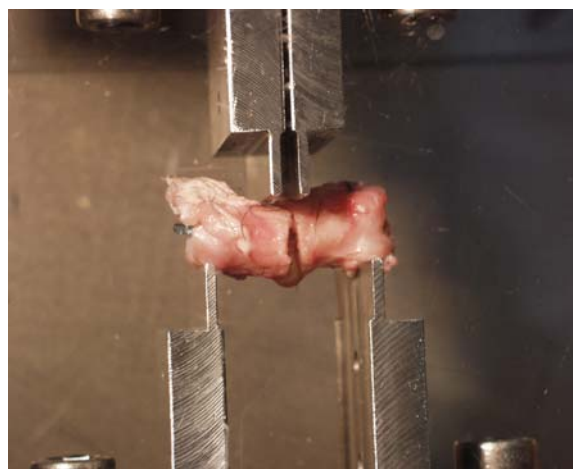


Figure 1. Four-point bending test in Inion OTPS™ biodegradable pins.

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

Screw strength has also been investigated by Nurmi et al 2005.

Inion OTPS™ 2.5 mm screw

Methods

Inion OTPS™ 2.5 mm screws were tested within porcine cadaver fibula using a pull-out test (figure 2) and a four-point bending test (figure 3) (constant speed of 10mm/min).



Figure 2. Pull-out test on Inion OTPS™ 2.5mm screws

Pull-out test: screws were inserted monocortically and then loaded parallel to the long axis of the screw.

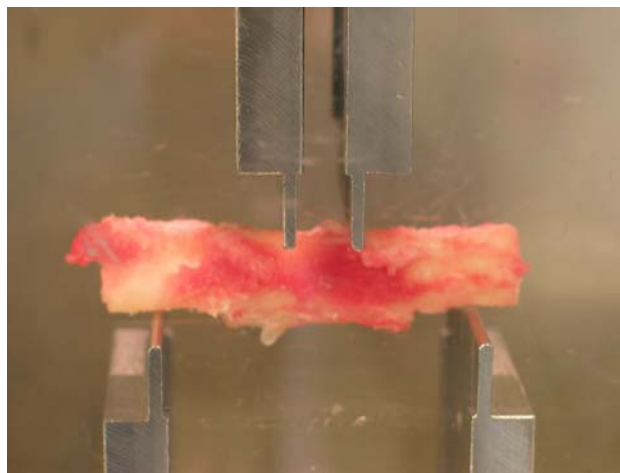


Figure 3. Four-point bending test on Inion OTPS™ 2.5mm screws

Four-point bending test: an oblique (30° from the long axis of the bone) osteotomy was made in the middle of each bone, a screw was inserted bicortically across the osteotomy line, and thereafter the strength of the fixation was tested.

Results

Pull-out test:

Max failure load	190N
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Four-point bending test:

Stiffness	337N/mm
Yield load	379N

Conclusion

It has been widely recognised that a more acceptable treatment than metal fixation is necessary for hallux valgus correction. This has been observed as a result of the many complications associated with metal including infection, migration and irritation. These complications, apart from the general challenges already established, i.e. imaging interference, need for removal etc., presented an opportunity for the advancement of novel materials.

Inion's biodegradable implants offer the ideal solution as they eliminate the majority of complications seen with metal. As well as providing adequate strength for their use, the implants degrade naturally in the body, and ensuring removal is not necessary. This is a huge burden of metal implants, which is effectively lifted by the Inion OTPS™ pins and screws.

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