WHITE PAPER

Economic Benefit of Biodegradable Ankle Fracture Fixation

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Introduction

The use of biodegradable implant materials in bone healing continues to gain popularity; this is largely due to the avoidance of a removal operation. In addition, it is widely accepted that the degradation of biodegradable implants allows a gradual transference of load from the implant to the bone, subsequently encouraging bone healing and reducing the prevalence of stress shielding.

In the past, surgeons and patients have been concerned about tissue reactions caused by the degradation products of biodegradable materials. A new generation of materials is now available from Inion, created from a blend of polymers, which has removed much of the concern surrounding tissue reactions.

Ankle fractures are among the most common skeletal injuries (Michelson 2003). The annual incidence has been reported as 187 per 100,000 population, with fractures usually due to sports-related trauma (Daly et al. 1987). If historical concerns over tissue reactions are addressed, the considerable benefits of biodegradable implants can be extended into this significant clinical area.

The two main benefits of biodegradable fixation are enhanced patient care and lower cost. Because the implants degrade completely, there is no need for a removal operation. Patients are spared the pain and inconvenience of additional surgical procedures and this also has an obvious effect on reducing overall healthcare costs

Background

Titanium is currently the most popular material for ankle fracture fixation. One of the disadvantages of using titanium and other metals is that they can, in fact, be too strong. Metal implants can be too stiff for optimal bone healing potentially causing stress shielding (Brodke et al. 2001, Kennady et al. 1989[1], Kennady et al. 1989[2], Uhthoff et al. 1983, Uhthoff et al. 1994); the load is almost entirely removed from the bone as it heals, removing stimulation and ultimately resulting in atrophy and weakness of the underlying bone.

The need for a removal operation is a considerable disadvantage particularly to patients. In some countries, removal of the entire ankle implant system is routine, in others the rate of removal varies, French data shows a rate of removal of 63.7% (ATIH 2003). Juutilainen *et al 2* states approximately 42 per cent of metallic plates and screws (and 100% of the metallic syndesmosis screws) had to be removed Metal Syndesmosis screws, however, have to be removed in all cases - approximately six to ten weeks postoperatively (Korkala O et al. 1999) - so that physiological function of the ankle can be restored. This adversely impacts on the efficient use of healthcare resources and surgeon time. Furthermore the majority of patients, 91% in a recent study (Mittal et al. 2005), see the possibility of a removal as the worst aspect of a metal implant.

Biodegradable plates and screws can eliminate the need for implant removal operations.

Biodegradable materials have, in the past, been associated with tissue reactions. Materials that degrade too quickly release degradation products at a greater rate than the surrounding tissue can cope with, causing inflammatory reactions (Bostman et al. 1992). Conversely, materials that degrade very slowly rarely cause tissue reactions, (Bostman et al. 1992) but the primary goal may be lost if the implants remain for over 5 years (Bergsmsa et al 1995)

The ideal situation is to have a fixation device that is sufficiently strong for the purpose and degrades completely with minimal tissue reactions once it is no longer required.

OPTIMA™

Innovations over the last few years have led to the development of a new generation of biodegradable implant materials. Inion has created the OPTIMA family of materials by blending biodegradable polymers, each blend being tailored to meet its specific application. This 'library' of materials has been developed to provide implants with appropriate strength and toughness and address the issues of biocompatibility previously seen with biodegradable implants. Very low levels of adverse tissue reaction (~0.1%) have been reported to Inion – compared to higher levels (up to 46%) seen with some other materials (Bostman et al. 2000).

The OPTIMA materials consists of varying proportions of L-lactide, D-lactide, Glycolide and Tri-Methylene Carbonate (TMC). The blends of materials give appropriate strength, toughness and degradation profiles. By varying the respective proportions and manufacturing techniques of these well-characterised and approved polymers, it is possible to create implants that have sufficient strength during bone healing which then degrade with minimal tissue reactions. Different blends are used across the range of products to reflect their different clinical requirements.

Benefits

There are numerous benefits of utilising this new generation of biodegradable material, specifically for ankle fracture fixation:

1. To patients
    - OPTIMA is sufficiently strong to be an effective alternative to metallic systems
    - There is no need for an additional surgical procedure to remove the fixation system once the fracture has healed
        - Reduced trauma
        - Reduced recovery time
        - Reduced social cost
        - Reduced time off work

2. To clinicians
    - The biodegradable plates are very easily adapted to the bone surface to promote optimum clinical outcomes
    - The time saved by eliminating the need for removal surgery allows a greater number of patients to be treated in the same amount of operating theatre time

3. To healthcare providers
    - The cost of an additional procedure is saved
    - Surgeon time is saved

The financial benefits and psychological advantages have been well documented (Rokkanen et al. 2000), in addition there are the inherent benefits of biodegradable systems:

- Lack of interference with imaging techniques e.g. X-rays, enabling the fracture and bone healing to be easily observed (compare figures 1 and 2)
- Reduced risk of cross-infection as the implants are supplied sterile
- Good results reported on the use of biodegradable screws and pins in ankles (Fuchs et al. 2003, Hovis et al. 2002, Korkala et al. 1999, Rokkanen et al. 2000, Sinisaari et al. 2002, Thordarson et al. 2001)

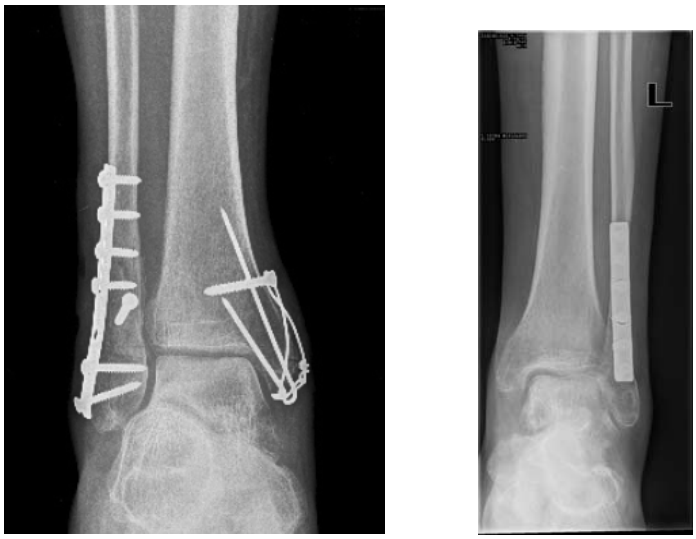

Figure 1. X-rays of ankle fractures fixed with metal. Visualisation of the fracture is obscured.

Figure 2. X-rays of ankle fractures fixed using biodegradable implants. Bone is fully visible.

There are also benefits of:

- Enhanced healing as a result of the load shifting gradually to the bone as the system biodegrades (Goetzen et al. 2005)
- Faster healing times as a result of micro-motion at the fracture site stimulating callus formation (Brodke et al. 2001)

In contrast to metal Syndesmosis screws, which have to be removed six to ten weeks postoperatively for physiological function of the ankle to be restored, Inion OPTIMA screws are specifically designed to break. This means the patient can begin physiotherapy at the appropriate time, instead of recovering from an additional operation.

There may be longer operation times with biodegradable implants in the earlier learning stages as surgeons adapt to the slightly different operative technique. However, once surgeons are familiar with the technique, operative time can be comparable to procedures with metal (Cheung et al. 2004).

Cost analysis

There are several studies that support the financial benefits of the lack of removal operation, particularly in ankle fractures:

Juutilainen T et al. 1997[2]

This study investigated the economic cost of ankle fractures treated with biodegradable screws or with metallic implants.

Patients in the study were divided into groups according to the fixation material used. The total expense of treatment in each group was then calculated.

The average total cost of an ankle fracture fixed with Self-Reinforced Polyglycolide (SR PGA) screws was found to be £3,503 compared to £4,514 in the metallic group.

	Biodegradable (SR PGA)	Metal
Operation	1,140.00	1,140.00
Initial hospital care	483.10	756.70
Sick Leave	1,484.00	1,513.00
Cost of implants	222.40	57.20
Radiographs	73.80	95.90
Outpatient visits	145.30	152.20
Removal of Syndesmotic screws	0	189.60
One day in hospital	0	96.90
Sick leave	0	96.50
Removal of rest of metallic implants	0	157.60
2.7 days in hospital	0	149.50
Sick leave	0	109.20
Total	**3,503.10**	**4,514.30**

Figure 3. Summary of costs found by Juutilainen et al in GBP Sterling (£).

Total expenses were £1,011 higher in the metallic group than in the SR-PGA group due to the removal operation, time off work, more outpatient visits and more radiographs (figure 4).

It should also be taken into account that, as these costs are based on Finnish 1997 data, the cost of a removal operation is relatively cheap. The cost of removal of Cranio-Maxillofacial (CMF) plates in Germany in 2003 was reported between €80 and €400 (Landes et al. 2003) - some CMF plate removal surgeries can be carried out under local anaesthetic. The current cost of removal surgery as a day case in the UK is now believed to be in the region of £1,000.

	Biodegradable (SR PGA)	Metal
Sick leave in days (mean)	60.6	68.2
Average number of radiographs taken	3.8	5.1
Average number of visits	3.3	4.4

Figure 4. Further resource savings shown in Juutilainen et al.

In conclusion, this study shows that biodegradable fixation devices are more economical than metallic implants in operative treatment of ankle fractures.

Bostman OM et al. 1996

This cost analysis, which included costs of medical care plus costs of lost time from work, was based on 994 fracture patients treated with biodegradable internal fixation devices and 1,173 patients operated on using conventional metallic devices.

The fracture types studied were uni and trimalleolar fractures of the ankle, fractures of the olecranon and metacarpal fractures.

When the costs for an implant removal procedure after metallic fixation were included, the average cost saved per patient by using biodegradable implants varied from $410 in fractures of the olecranon to $903 in unimalleolar fractures.

Bostman O et al. 1992

During the six year study period, the use of biodegradable implants in malleolar fractures made it possible for resources, that would otherwise have been taken up by several hundred metal implant removal operations, to be used for other purposes.

Summary

By eliminating the need for a removal operation, the use of biodegradable implants in ankle fractures offers an indisputable advantage over metal.

The effect of this is felt in many areas including:

- Reduced financial costs, increasing the number of patients that can be treated for any given budget (Bostman et al. 1992, Bostman et al. 1996, Juutilainen et al. 1997[1], Juutilainen et al. 1997[2], Springer et al. 1999)
- Reduced social costs as healing time is shortened, resulting in fewer days off work and reduced support costs e.g. sickness benefits
- Reduced psychological impact on patients and their families due to fewer surgical procedures

Biodegradable implants also prevent stress shielding (Juutilainen et al. 1997[1], Springer et al. 1999) and with the development of the OPTIMA library of materials there is reduced concern for inflammatory tissue reactions, whilst providing appropriate strength for bone healing.

References

Agence Technique de l'Information sur l'Hospitalisation (ATIH). www.atih.sante.fr 2003.

Bergsma JE, de Bruijn WC, Rozema FR, Bos RRM, Boering G. Late Degradation Tissue Response to Poly(L-Lactide) Bone Plates and Screws. Biomaterials 1995;16:25-31.

Bostman O, Hirvensalo E, Partio E, Tormala P, Rokkanen P. Resorbable rods and screws of polyglycolide in stabilizing malleolar fractures. A clinical study of 600 patients. Unfallchirurg 1992;95(2):109-12.

Böstman O, Pihlajamäki H. Clinical biocompatibility of biodegradable orthopaedic implants for internal fixation: a review. Biomaterials 2000;21:2615-2621.

Bostman OM. Metallic or absorbable fracture fixation devices. A cost minimization analysis. Clin Orthop Relat Res 1996;329:233-9.

Brodke DS, Gollogly S, Alexander Mohr R, Nguyen BK, Dailey AT, Bachus aK. Dynamic cervical plates: biomechanical evaluation of load sharing and stiffness. Spine 2001;26(12):1324-9.

Cheung LK, Chow LK, Chiu WK. A randomized controlled trial of resorbable versus titanium fixation for orthognathic surgery. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology 2004;98(4):386-397.

Daly PJ, Fitzgerald RH Jr, Melton LJ, Ilstrup DM. Epidemiology of ankle fractures in Rochester, Minnesota. Acta Orthop Scand 1987;58(5):539-44.

Fuchs M, Vosshenrich R, Dumont C, Sturmer KM. Refixation of osteochondral fragments using absorbable implants. First results of a retrospective study. Chirurg 2003;74(6):554-61.

Goetzen N, Lampe F, Nassut R, Morlock MM. Load-shift--numerical evaluation of a new design philosophy for uncemented hip prostheses. J Biomech 2005;38(3):595-604.

Hovis WD, Kaiser BW, Watson JT, Bucholz RW. Treatment of syndesmotic disruptions of the ankle with bioabsorbable screw fixation. J Bone Joint Surg Am 2002;84-A(1):26-31.

1. Juutilainen T, Hirvensalo E, Majola A, Partio EK, Patiala H, Rokkanen P, Kinnunen J. Bone mineral density in fractures treated with absorbable or metallic implants. Ann Chir Gynaecol 1997;86(1):51-5.

2. Juutilainen T, Patiala H, Ruuskanen M, Rokkanen P. Comparison of costs in ankle fractures treated with absorbable or metallic fixation devices. Arch Orthop Trauma Surg 1997;116(4):204-8.

1. Kennady MC, Tucker MR, Lester GE, Buckley MJ. histomorphometric evaluation of stress shielding in mandibular continuity defects treated with rigid fixation plates and bone grafts. Int J Oral Maxillofac Surg 1989;18(3):170-4.

2. Kennady MC, Tucker MR, Lester GE, Buckley MJ. Stress shielding effect of rigid internal fixation plates on mandibular bone grafts. A photon absorption densitometry and quantitative computerized tomographic evaluation. Int J Oral Maxillofac Surg 1989;18(5):307-10.

Korkala O, Kiljunen V, Salminen S, Kuokkanen H, Niskanen R. Biodegradable screw fixation of the syndesmosis together with metallic osteosynthesis. Preliminary experience of 7 ankles. Ann Chir Gynaecol 1999;88(4):295-7.

Landes CA, Kriener S, Menzer M, Kovacs AF. Resorbable plate osteosynthesis of dislocated or pathological mandibular fractures: a prospective clinical trial of two amorphous L-/DL-lactide copolymer 2-mm miniplate systems. Plast Reconstr Surg 2003;111(2):601-10.

Michelson JD. Ankle fractures resulting from rotational injuries. J Am Acad Orthop Surg 2003;11(6):403-12.

Mittal R, Morley J, Dinopoulos H, Drakoulakis EG, Vermani E, Giannoudis PV. Use of bio-resorbable implants for stabilisation of distal radius fractures: the United Kingdom patients' perspective Injury. Int J Care Injured 2005;36:333-338.

Rokkanen PU, Bostman O, Hirvensalo E, Makela EA, Partio EK, Patiala H, Vainionpaa SI, Vihtonen K, Tormala P. Bioabsorbable fixation in orthopaedic surgery and traumatology. Biomaterials 2000;21(24):2607-13.

Sinisaari IP, Luthje PM, Mikkonen RH. Ruptured tibio-fibular syndesmosis: comparison study of metallic to bioabsorbable fixation. Foot Ankle Int 2002;23(8):744-8.

Springer MA, van Binsbergen EA, Patka P, Bakker FC, Haarman HJ. Resorbable rods and screws for fixation of ankle fractures. A randomized clinical prospective study Unfallchirurg 1998;101(5):377-81.

Thordarson DB, Samuelson M, Shepherd LE, Merkle PF, Lee J. Bioabsorbable versus stainless steel screw fixation of the syndesmosis in pronation-lateral rotation ankle fractures: a prospective randomized trial. Foot Ankle Int 2001;22(4):335-8.

Uhthoff HK, Finnegan M. The effects of metal plates on post-traumatic remodelling and bone mass. J Bone Joint Surg Br 1983;65(1):66-71.

Uhthoff HK, Boisvert D, Finnegan M. Cortical porosis under plates. Reaction to unloading or to necrosis? J Bone Joint Surg Am 1994;76(10):1507-12.

