ABSORBABLE FIXATION IN PODIATRIC SURGERY

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INTRODUCTION

Materials for the construction of absorbable fixation devices have been studied and evaluated since the late 1960s. Clinical applications were successful for repair of osteochondral fractures and osteochondritis dissecans of the knee, as well as the repair of phalangeal fractures and selected arthrodesis procedures of the hand. Recently, absorbable fixation devices have been approved for use in the foot. The biodegradable synthetic polymers being used for internal fixation will be reviewed in reference to past and present research and current availability. In addition, some techniques and clinical reviews of podiatric applications will be considered.

HISTORICAL REVIEW

Natural materials such as collagen and gut were the only absorbable materials available until synthetic polymers were produced. Polylactic Acid (PLA) was introduced around 1965 as the first synthetic absorbable suture. It was never marketed, however, since it took years to absorb.

Biodegradable synthetic polymers have been available for surgical use since 1970, when polyglycolic acid was introduced as a suture (Dexon®). About three years later, the copolymer of polyglycolic acid and polylactic acid (Vicryl®) was produced. In the early 1980s, polyparadioxanone (PDS®) was marketed. PDS appears to have superior tensile strength and absorption time.

Polylactic acid, polyglycolic acid, and polyparadioxanone all degrade mainly by hydrolysis. PLA is degraded into monomers of lactic acid which becomes incorporated into the tricarboxylic acid cycle and is excreted by the lungs as carbon dioxide and water. Polyglycolic acid is degraded into glycolic acid monomers and is excreted in the urine or used to produce pyruvate which can be used in the Krebs cycle.

The rate of hydrolysis is affected by chemical composition, the molar ratio of monomers in copolymers, crystallinity, surface area, and location of implantation. With Vicryl and Dexon, studies have shown that at two-weeks post-implantation, approximately 55% of the original tensile strength remains. At three weeks, approximately 20% of its original strength is retained. On the other hand, PDS, which has prolonged retention of tensile strength, retains approximately 70% of its strength at 2 weeks, and 50% at 4 weeks. Even at 6 weeks post-implantation, 25% of the original strength remains.

EXPERIMENTAL STUDIES

PDS pins for fixation of bone were originally marketed in 1985 in Europe by Ethicon of Germany under the trade name Ethipin®. Various studies were conducted at the time to determine its efficacy as a fixation device. For osteochondral fractures, it was shown that PDS rods maintained stability and allowed healing. In addition, the fixation of the rods in the bone was strengthened by the surrounding bone after a short time. PDS splints were also used for fixation of phalangeal fractures of the hand and metacarpal head fractures. No defective healing, infection of bone, or dislocation was observed.

Various studies were also performed using fixation devices fabricated of PLA and PGA. It was demonstrated that PLA and PGA are slowly

absorbed and well tolerated. Fixation was achieved with absorbable pins, sutures, plates, and screws. Cutright, et al. showed that absorption rates could be altered by using different proportions of PLA and PGA in the copolymer. Homopolymers require a longer period to absorb, with PGA absorbing at a slower rate than PLA.

Studies conducted at Helsinki University Central Hospital revealed that self-reinforced PGA rods had better initial strength retention after four weeks than a PLA/PGA copolymer. Biodegradable implants were used in 102 patients with displaced malleolar fractures. It was concluded that both anatomical and functional results of biodegradable fixation and conventional osteosynthesis with metal were equal. One disadvantage of utilizing biodegradable materials is that early mobilization of the ankle joint cannot be performed.

AVAILABILITY

The Orthosorb® Absorbable Pin (Johnson & Johnson Orthopedics) and the Biofix System (Acufex Microsurgical, Inc) are the only two absorbable fixation products presently available in the United States. The Orthosorb Absorbable Pin is made of polyparadioxanone and is approved for use in the foot, hand, and knee. The pin is completely absorbed in approximately six months. It maintains about 85% of its tensile strength at two weeks postoperative and approximately 60% of its tensile strength at four weeks postoperative. The result is that the bone gains strength as the pin gradually loses its tensile strength.

The Orthosorb® Absorbable Pin is available in two sizes. The first is 40 mm in length and 1.3 mm in diameter. The pins are packaged with appropriate application hardware. The second variety is a tapered pin that is attached to a 1.3mm stainless steel K-wire for drilling. The pin diameter is 1.0 mm at the narrow end (attached to the K-wire) and 1.35 mm at the wide end. The pin's tapered design allows it to be pulled through the bone until its base is wedged securely in place.

The Biofix® System makes use of pins constructed from a self-reinforced polyglycolic acid polymer. The rods have a slightly elliptical shape and are available in sizes ranging from 20 to 40 mm in length and 1.5 to 4.5 mm in diameter. In vivo degradation takes place in 4 to 8 weeks, with complete absorption in 6 to 12 months depending upon the location of the implant. The delivery system includes stainless steel, reusable applicators which come in different sizes, corresponding to the diameters of the Biofix® rods.

CLINICAL USE

In podiatric surgery, Patton et al. reported in 1990 using Orthosorb® absorbable fixation for digital arthrodesis (Fig. 1). Fifty-eight digits were arthrodesed at the proximal interphalangeal joint. None of the patients showed any sign of infection, foreign body reaction, vascular compromise, or excessive edema. Patton has also used the Orthosorb Pin for Austin and Reverdin/Green/Laird osteotomy stabilization. Two pins are used and directed from proximal-dorsal to distal-plantar in a slightly diverging parallel orientation (Fig. 2).

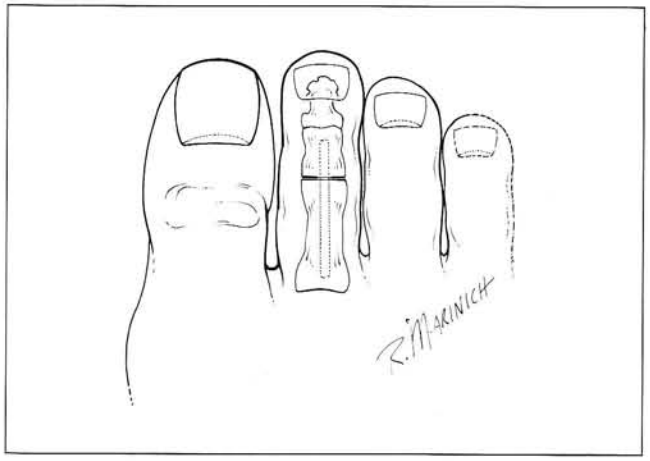

Fig. 1. Arthrodesis of the PIPJ of a lesser digit utilizing an Orthosorb Absorbable Pin.

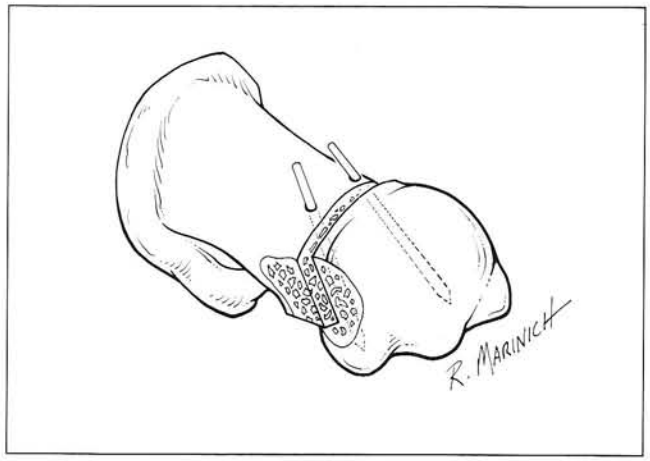

Fig. 2. Orientation of two Orthosorb Absorbable Pins utilized for fixation of an Austin bunionectomy.

As an alternative, Brunetti et al. described driving the pins across the osteotomy in a dorsal to plantar direction in converging parallel alignment such that the pin cross is in the proximal portion of the metatarsal. When the osteotomy site is located in friable metaphyseal bone, the first Orthosorb Pin should be placed in a proximal-dorsal to distal plantar direction through both cortices. The second pin is then driven in an oblique fashion from distal-dorsal to proximal-plantar across the osteotomy site. In a 1991 study of 30 Austin osteotomies, Brunetti et al. found no displacement of the capital fragment. Also, no cases of aseptic necrosis, allergy to PDS or apparent dislodgement of the Orthosorb Pin were reported.

A recent study by Francis et al. used the Orthosorb® Pin in stabilizing Austin, Reverdin/Green/Laird, and Tailor's osteotomies. Among the 37 procedures, the results were excellent or good for 89.2% and fair for 10.8%. There were no poor results reported.

Hirvensalo et al. reported using polyglycolic acid fixation in 22 chevron osteotomies. No failure of fixation was observed and bony union was uneventful in all cases. In addition, Yen et al. reported using the Biofix rods on ten patients for fixation of Austin bunionectomies. Nine out of ten osteotomies were stable throughout the postoperative course. In one case, excessive activity resulted in the dorsolateral subluxation of the capital fragment.

The use of absorbable fixation has many advantages. Compared to percutaneous K-wire fixation, the pin has no external exposure, therefore pin tract infections will be eliminated and the risk of pain and displacement from accidental movement is decreased. The result is more aesthetically pleasing and the patient will not experience anxiety from pin removal. Compared with buried K-wires and screws, the absorbable pin does not necessitate a second surgery for removal. In addition, the absorbable pin will not give continued stress protection as do rigid fixation devices.

The disadvantages to absorbable fixation should be considered before performing the surgery. The pins are very expensive. They are non-radiopaque, and placement of the pin cannot be evaluated postoperatively. The pins have less flexural strength than do K-wires and screws, therefore if the surgical area were subjected to a significant disruptive force, there could be an easier displacement of the fracture, osteotomy, or arthrodesis. When used for digital fusion the option of removing the pin postoperatively in a vascular compromised digit is lost. Finally, the pin cannot be used in osteoporotic bone or for fractures in which the anticipated healing period is protracted. Currently, there is no data available with regard to the performance of these devices in the face of bone infection.

CONCLUSION

Two types of absorbable fixation devices are now available in the United States and approved for use in the foot. The initial promising results of earlier experimental studies have led to some encouraging clinical reports in podiatric surgery. However, the surgeon must thoroughly weigh the advantages and disadvantages of absorbable fixation before considering its application.

Bibliography

Akeson WH, Savio LW, Rutherford L, Coutts RD, Gonsalves M, Amiel D: The Effects of Rigidity of Internal Fixation Plates on Long Bone Remodeling. *Acta Orthop Scand.* 47:241-249, 1976.

Beiser IH, Kanat IO: Biodegradable internal fixation: A literature review. *J Am Pod Med Assoc* 80:72-75, 1990.

Böstman OM: Current concepts review: Absorbable implants for the fixation of fractures. *J Bone Joint Surg,* 73A:148-153, 1991.

Böstman O, Hirvensalo E, Mäkinen J, et al.: Foreign-body reactions to fracture fixation implants of biodegradable synthetic polymers. *J Bone Joint Surg* 72B:592-596, 1990.

Böstman O, Vainionpää S, Hirvensalo E, et al.: Ankle Fractures Treated Using Biodegradable Internal Fixation. *Clin Orthop* 238:195, 1989.

Böstman O, Vainionpää S, Hirvensalo E, et al.: Biodegradable internal fixation for malleolar fractures. A prospective randomized trial. *J Bone Joint Sur* 69B:615, 1987.

Brady JM, Cutright DE, Miller RA, et al: Resorption rate, route of elimination, and ultra-structure of the implant site of polylactic acid in the abdominal wall of the rat. *J Biomed Mater Res,* 7:155-166, 1973.

Brunetti VA, Trepal MJ, Jules KT: Fixation of the Austin osteotomy with bioresorbable pins. *J Foot Surg,* 30:56-65, 1991.

Christel P, Chabot F, Leray JL, et al.: Biodegradable composites for internal fixation. In Winter GD, Gibbons Df, Plenk H, *Biomaterials* 1980, pp.271-280, Wiley, New York, pp. 271-280, 1982.

Cutright DE, Hunsuck EE, Beasley JD: Fracture reduction using a biodegradable material, polylactic acid. *J Oral Surg,* 29:393-397, 1971.

Cutright DE, Hunsuck EE: The repair of fractures of the orbital floor using biodegradable polylactic acid. *J Oral Surg,* 33:28-34, 1972.

Cutright DE, Perez B, Beasley JD, Larson WJ, Posey WR: Degradation rates of polymers and copolymers of polylactic and polyglycolic acid. *J Oral Surg* 37:141-152, 1974.

Francis D, Englert CM, Blackwell K, et al.: The use of poly-para-dioxanone absorbable pin fixation in podiatric surgery: Submitted for publication.