CHAPTER 11

ABSORBABLE SCREW FIXATION

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Absorbable screws are a natural extension of interest in absorbable fixation that first became available as pins and rods. The formation of such materials is an evolution from the well-tolerated absorbable sutures in clinical use for over 20 years. Experimental research has been rapid and clinical trials continue to mount with encouraging results. The majority of the investigative work in the medical application of absorbable implants has been done at Helsinki University Central Hospital, and the Tampere University of Technology in Finland. The basic research work was completed between 1973-1984 on thousands of laboratory animals. Clinical trials on humans began in late 1985 with absorbable rods, and the first totally absorbable self-reinforced screw was used in 1987.

The basic thought behind the development of absorbable screws is that the ideal osteosynthesis device should remain firm enough for the duration of healing, gradually lose its strength and transfer the normal stress to the healing bone, and disappear from the body after healing is complete.[1] Therefore, interest was stimulated in bioabsorbables with strength and elasticity properties similar to those of bone itself. When the elastic modulus of an implant is close to bone itself, the implant allows near normal stress initially, and gradually increasing stress as the implant weakens and the bone heals.[2] This avoids stress shielding or stress protection osteopenia which is routine with more rigid fixation. More elastic and strength-losing implants allow controlled micromovements which encourage more rapid consolidation and earlier remodeling of bone.

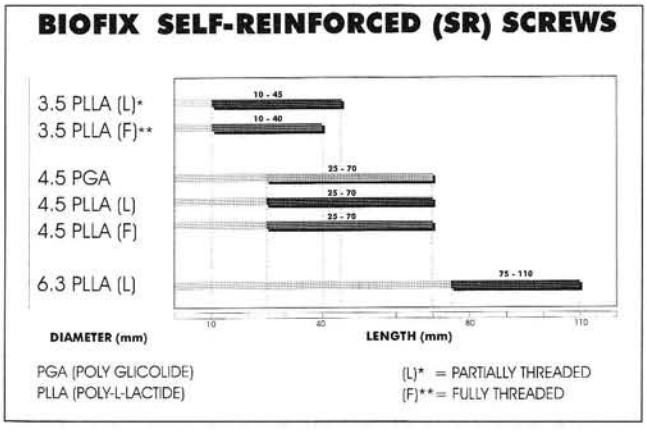
The excessive rigidity or stiffness of metallic implants does not allow natural movements or remodeling of bone. The result is weakening and porosity of neighboring bone tissue beneath the implants. For example, enlarging of screw channels and loosening of implants are attributable to the rigidity of metallic fixation. Stress-related remodeling will not occur unless the implants are removed.

The intent of this manuscript is two-fold. First, to summarize and highlight the available manufacturer product information. Second, to offer an objective podiatric perspective based on literature pertinent to foot and ankle surgery, and the early clinical impressions of the authors.

MANUFACTURER PRODUCT INFORMATION

As of September 1994, the absorbable screws available for clinical use are produced by Bioscience Limited of Tampere, Finland, under the trademark of BIOFIX.[3] The raw materials utilized are synthetic polymers of pure polyglycolide (PGA) and poly-L-lactide (PLLA). The screws are produced by a special self-reinforcing (SR) technique that sinters together fibers of PGA or PLLA at high temperature and pressure in a matrix of the same material. The self-reinforced technique adds 5-10 times the initial strength value of the screws, versus melt-molding or injection mold techniques that contain no geometrical structure or organization.[1,4] The final SR-PGA screw is beige in color, and the SR-PLLA screw is transparent. They are broken down in the body by hydrolysis, eventually entering the Krebs cycle, and finally excreted in the urine, feces, or expired as CO_2.

The available sizes and lengths are listed in Table 1. The SR-PGA screw is only available fully-



threaded, whereas the SR-PLLA screw is available fully- or partially-threaded. Current criteria for the use of BIOFIX screws include humeral head fractures, olecranon fractures, condylar fractures of the humerus, condylar fractures of the distal femur or proximal tibia, displaced ankle fractures, and ankle arthrodesis.[5] They have also been used successfully in subtalar arthrodesis.

The most significant difference between the SR-PGA and SR-PLLA screws is strength retention. The SR-PGA screw is stronger, but the SR-PLLA screw persists longer.[1] The SR-PGA screw loses its mechanical resistance in vivo between 30-60 days, and the SR-PLLA screw between 3-12 months. Biodegradation time, or time to complete absorption, is 5-10 months for the SR-PGA material, and varies from 15 to 60 months for SR-PLLA material. The actual time depends on shape, size, molecular weight, and variable tissue environments of implantation.

The initial resistance to shear and flexion forces of the screws is 20-30 times that of cancellous bone. Their modulus of elasticity is comparable to cortical bone, and roughly 2-3 times that of cancellous bone. By comparison, the modulus of elasticity of stainless steel is more than 20 times that of cancellous bone. Clinically, the decrease in bending strength is more rapid than that of shear strength.[3,5] The screws require a dedicated screw driver, tap, and countersink. All instrumentation pieces are compatible with the standard AO/ASIF quick release handles (Fig. 1).

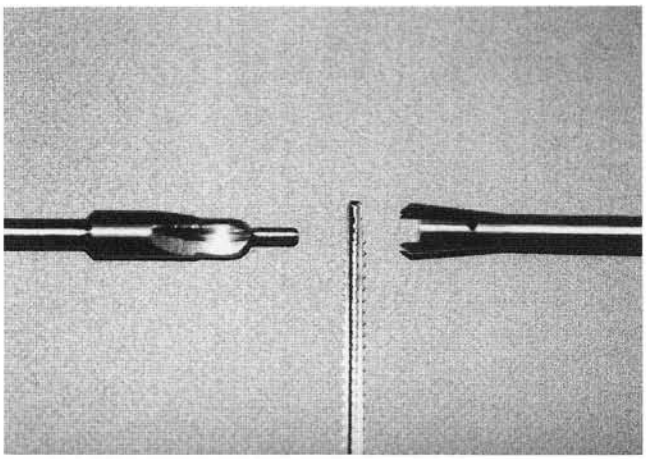


Figure 1. The tips of the screw driver, countersink, and tap required for the BIOFIX absorbable screws. Note the size of the countersink compared to a standard AO/ASIF countersink.

Screw Insertion

Insertion of the screws requires attention to technique, and the following specifics are recommended by the manufacturers. Reduction of the osseous components is achieved and stabilized with clamps. Specific to ankle fracture repair, the screw is inserted 75-85 degrees to the fracture line, as opposed to 90 degrees. If the reduction is exact, the direction of fixation is not the same as the rotational axis of the fragment, since rotation is not possible without a new fracture or failure of fixation.[2] The drill and/or over-drill hole is made with the corresponding size drills. Tapping is performed with care to ensure crossing the entire length of the hole. The near cortex is then countersunk. The screw channel is flushed with saline and the screw inserted. The head of the screw is then cut so that only 1 mm remains above the cortex.

Since the torsional strength of the absorbable screw is not as high as that of a metallic implant, care must be taken when inserting the screw. The screw must turn easily into the bone, otherwise it may break. If a screw breaks, the exposed portion of screw is cut flush with the bone, rather than attempting to remove it. A few reasons for screw breakage are suggested by the Finnish surgeons: the drill hole may not be long enough; the tapping may have been done improperly; or the drill hole may have been dry. Lastly, the longer the screw, the more chance for increasing the friction forces on the screw. Therefore, extra care should be taken during insertion.[5]

Advantages

In direct comparison with metallic screws, several features of absorbable screws are highlighted by the manufacturers. Absorbable implants essentially eliminate the financial burden of secondary procedures to remove internal fixation. This is often regarded as a psychological benefit as well, particularly in children. Magnetic resonance and computed tomography imaging are also possible without the scattering caused by metallic devices. The absorbable material is considered tissue equivalent. Absorbable screws may also be left in sites of infection as they are bacteriostatic. Growing bacteria do not affect the absorption of the screws. The relationship between these screws and the presence of stress protection or stress shielding has already been discussed.

Precautions

BIOFIX screws are not recommended in patients over 70 years of age. Caution is also advised in any patient with advanced osteoporosis or a comminuted fracture. In those patients with rheumatoid disease, and in cases of ankle arthrodesis, only the SR-PLLA implants are advised. Lastly, the SR-PGA screws are specifically recommended for transyndesmotic fixation when necessary in standard ankle fracture management. Further contraindications for their use include alcoholism or psychiatric disorders which limit the patient's ability to cooperate.

The most significant precaution regarding the bioabsorbable screws is the periodic development of a local fluid accumulation. This has been observed at 8-12 weeks after surgery utilizing SR-PGA screws and 18-36 months involving the SR-PLLA screws. The most recent literature reports a complication rate of 0-4%.

This appears to be a nonspecific, foreign body reaction that is noninfectious and unique to absorbable fixation. There are varying grades of presentation of this soft tissue response. If the reaction is clinically noticeable, but small and painless, it may only be observed. If it is red and inflamed, painful, and larger than 1.5 centimeters in diameter, it should be aspirated. On occasion, a sinus tract or fistula will form that should be incised and drained. The fluid is viscous, yellow to clear, and aseptic. The wound will completely resolve within 10 weeks. This reaction has no effect on the final outcome of the osseous surgery or functional recovery.

EARLY CLINICAL IMPRESSIONS AND A PODIATRIC PERSPECTIVE

The research and clinical experience regarding absorbable materials such as rods, screws, membranes, and tacks, is vast. More than 15 doctoral theses and over 600 scientific studies have been published entailing animal studies and human trials.[6] However, clinical and scientific investigation in North American literature is in its infancy in respect to absorbable screws. Our clinical use of these screws at this time is limited to first metatarsophalangeal arthrodesis, hallux interphalangeal arthrodesis, and proximal first metatarsal osteotomies. Any impression with regard to long-term efficacy in these applications is premature. Since this is the first report of such clinical use in the world literature, no comparisons are available. However, the authors offer some general observations regarding the feasible uses in podiatric surgery.

The currently available screw sizes are applicable to selected forefoot, midfoot, rearfoot and ankle surgical procedures. The thread geometry of the screws is unique. The profile most closely resembles a 3.5-mm AO/ASIF cortical screw with the pitch a 4.0-mm cancellous AO/ASIF screw, however, they are not identical (Fig. 2). The screw head is rectangular-shaped and slightly larger than an AO/ASIF screw of the same size (Figs. 3A, 3B). The screw head does not contain a hexagonal

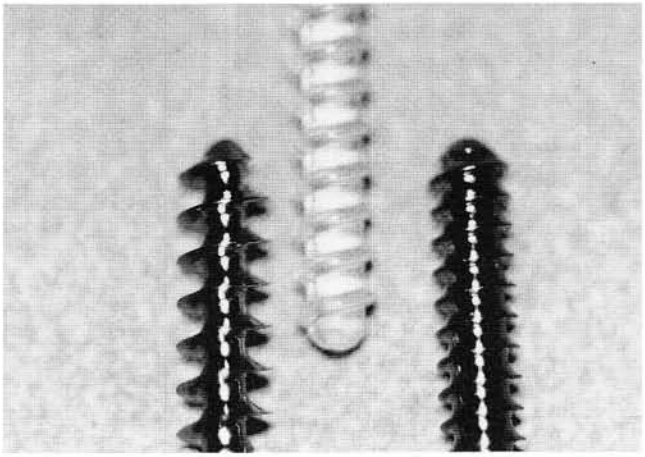


Figure 2. The thread pitch of a BIOFIX screw is 1.75-mm, the same as a 4.0-mm cancellous AO/ASIF screw. The thread profile is shallower and coarser in comparison to standard metallic screws. Left, AO/ASIF 4.0-mm cancellous, Center, SR-PLLA 3.5-mm, Right, AO/ASIF 3.5-mm cortical.

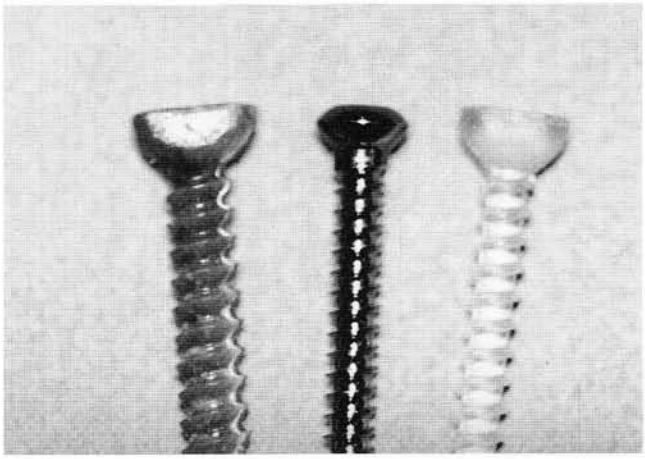


Figure 3A. A comparison of screw head sizes and shapes. Left, SR-PLLA 4.5-mm, Center, AO/ASIF 3.5-mm, Right, SR-PLLA 3.5-mm.

Figure 3B. Head profiles of same screws as shown in Figure 3A.

recipient for the screw driver as do AO/ASIF screws. Therefore, the screw driver is designed to grip the screw head circumferentially. The screw also possesses a small fissure at its tip, which reportedly opens when the fixation is firm enough. This screw driver tip-screw head design significantly increases the torque forces along the shaft of the screw and at the screw head-shaft junction during insertion. Excessive tightening of the screw can break the head or cause the screw to splinter along its shaft (Figs. 4A-4C). These torque forces are similarly increased if the screw hole has not been tapped completely and the screw is attempting to cut its own threads.

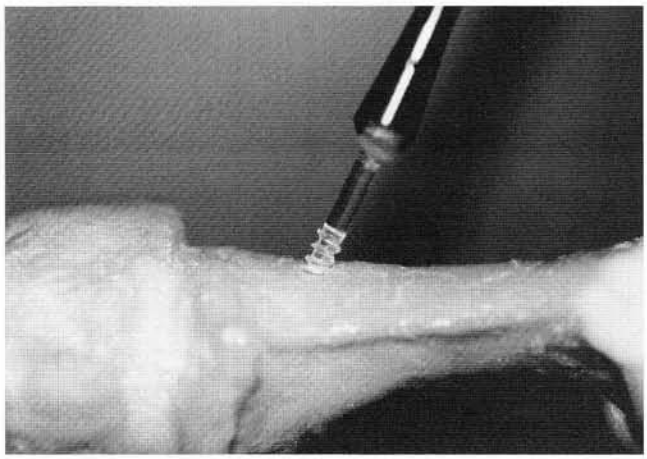


Figure 4A. Insertion of a SR-PLLA screw in a bone model to the point of resistance.

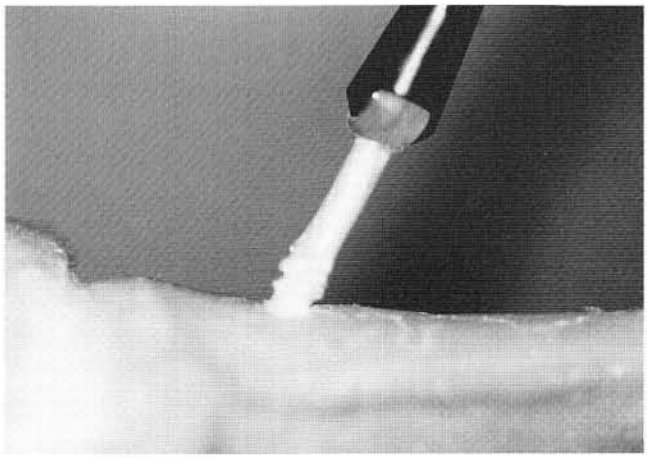


Figure 4B. Tightening of the screw past the point of resistance causes fatigue failure of the screw along its shaft. The linear strand configuration of the screw has disrupted (color change) as compared to Figure 5. The screw does not tolerate high torque forces well.

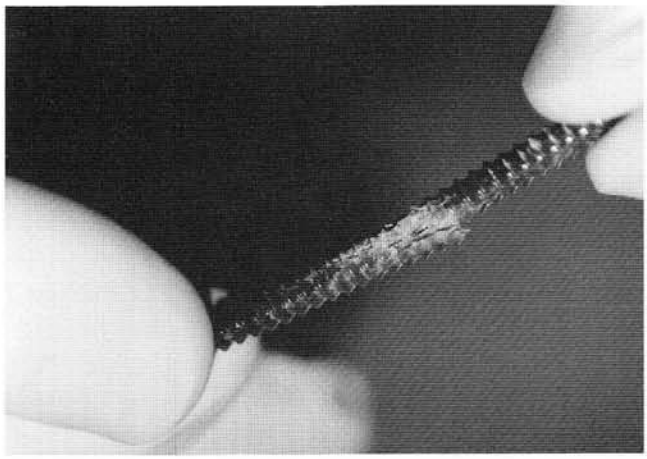


Figure 4C. This SR-PGA screw has splintered along its shaft due to excessive torque forces applied experimentally.

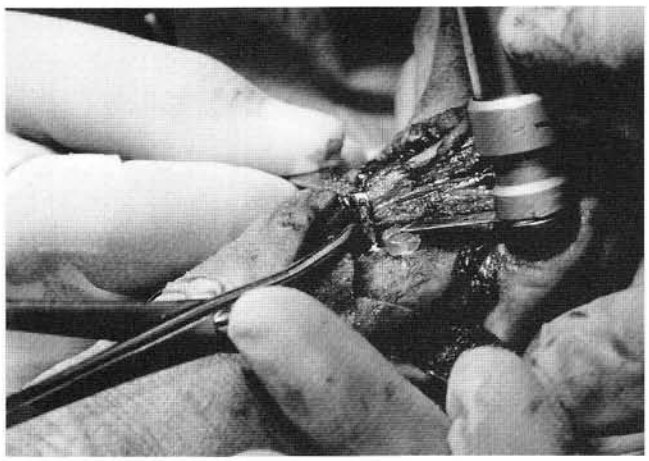


Figure 5. Reduction of the head of a SR-PLLA 3.5-mm screw with an oscillating saw.

The instrumentation and screws were initially developed for use in the tibia and fibula for ankle fracture repair. The countersink is quite large, and removes excessive bone from a smaller structure such as a first metatarsal. The authors have found it safer to create the countersink in a first metatarsal with a rotary burr. Generally, the screw head remains prominent, and the manufacturer's recommendations are to reduce the head to 1 millimeter above the cortex or cut it flush with a small saw (Fig. 5). This not only reduces the prominence but presumably diminishes the chance of an adverse soft tissue reaction postoperatively.

The most publicized benefits of absorbable fixation are a lack of need for removal, and reduction of stress shielding. The most commonly referred-to disadvantages of metallic fixation are stress shielding, corrosion, sensitization dermatitis (rare) and the need for removal.[7] However, metallic fixation has generally been used quite successfully with minimal complications in foot and ankle surgery. For absorbable screws to be clearly advantageous, they must offset these disadvantages, possess minimal detriments of their own, and provide adequate stability for bone union.

In the authors' opinion, three reasonable questions may be entertained regarding the use of these screws in podiatric surgery. Is the avoidance of removal of metallic fixation a benefit that will be consistently realized? Is the presence of stress shielding clinically significant? What is the clinical significance of the occasional soft tissue reactions to the implants?

The elimination of secondary procedures for retrieval of internal fixation is attractive in patient care, both economically and psychologically. However, this is an economic savings only if the practicing surgeon routinely removes hardware. Although the AO/ASIF school has recommended eventual removal of fixation to restore normal biomechanical forces on bone, the current range of practice likely exists between routine removal and routine retention. Although the possibility of soft tissue reaction to a long-standing foreign body (such as corrosion) exists, by far the usual reason for removal of metallic fixation is discomfort due to prominence beneath the skin.

Absorbable screws have this clear advantage regarding ankle fracture repair and the use of internal fixation in areas of limited soft tissue coverage. Articles exist showing favorable comparisons between metallic and absorbable fixation in this application.[1,2] Either SR-PGA or SR-PLLA screws have demonstrated clinical success in stabilizing all components of an ankle fracture: the fibula, medial malleolus, and posterior malleolus. In those podiatric procedures where removal of fixation may be performed under local anesthesia in the office, any economic or psychological savings from the absorbable screws are less well-defined. Savings may be further diminished in light of the additional initial expense of the absorbable screws.

The clinical significance of stress shielding depends largely on the anatomic region of the lower extremity. The stress protection created by a dynamic compression plate with screws in a femoral fracture is understandably more significant than that of a K-wire in a digital fusion. The premise exists that the stiffness of metallic screws may contribute to nonunions in ankle arthrodesis,[8] particularly if the screws are inserted in such a way that they prevent stress transfer to the uniting bone surfaces. An example of this is when a fibular onlay graft is stabilized with screws perpendicular to the axis of the tibiotalar surfaces. SR-PLLA absorbable screws inserted obliquely from the tibia and fibula, toward the uniting talotibial joint, have demonstrated an excellent fusion rate in conjunction with full-weight bearing in a short leg cast from the second postoperative day.[8]

Immediate weight bearing was also allowed in a series of subtalar extra-articular arthrodeses in children with spastic neuromuscular deformity. In five out of seven cases, those fixated with SR-PLLA absorbable screws demonstrated better radiographic union than their counterparts that were stabilized with metallic fixation. The remaining two cases were equal at one year.[9]

In such uses of absorbable screws pertinent to podiatric surgery, the common denominator appears to be minimally- to non-weight-bearing structures (fibula, medial malleolus), or axially loaded fusion sites (ankle, subtalar joints). The literature suggests better and faster radiographic union and less porosity with the absorbable screws. This is attributable to the modulus of elasticity of the implant which is near equal to bone initially, and gradually weakens as the bone gains strength. This reduction of stress shielding and the resultant benefits appear to be very real advantages of absorbable screws in these indications. The successful allowance of immediate weight bearing is in distinction to standard podiatric ankle or subtalar

fusion techniques with metallic fixation that require prolonged periods of non-weight bearing.

However, the pertinence of stress-shielding or stress-protection osteopenia in forefoot surgery is likely more procedure specific. For example, in the technique of hallux interphalangeal joint fusion, the absorbable screw does not seem advantageous. Stress shielding at this site is minimal, and if screw removal is necessary, it is easily performed under local anesthesia. Metallic fixation also subjectively offers firmer purchase and compression in the proximal phalanx than the absorbable screws. However, the forces acting upon a first metatarsal proximal osteotomy or a midfoot fusion are significantly larger due to the unique biomechanics of the foot in gait. The reduction of stress shielding afforded by the less rigid absorbable screws may encourage more rapid and solid osseous consolidation in these applications, similar to the success noted in ankle fusions.

Absorbable screws do contribute a potential soft tissue complication that must be clearly understood. This transient soft tissue reaction has been extensively studied since it was first noted with the early development of polyglycolide rods.[3] The exact reason for the reaction is unknown, but appears to be a unique foreign body reaction to the raw materials, alpha-hydroxy polyesters. Currently, there is no evidence that the reaction is immunologically mediated or infectious in nature. A lower incidence has been reported since the removal of the aromatic quinone (green) dye from the first generation polyglycolide rods and screws, but this is also clearly not the only factor. Since the advent of the colorless raw materials used to make the screws, the reported incidence of tissue reactions is less than 4%.[1]

The development of a clinically manifested reaction seems to be associated with the phase of liquefaction of the degrading polymer.[10] The clearance of liquid debris from the implant depends on local tissue tolerance and clearing capacity.[11] The relatively compact nature of cancellous bone may be a factor. Surgical technique may also play a role, such as when a large amount of screw head is left above the cortex in an area where soft tissue coverage is thin.

In general, reactions to the PLLA implants are reported less often. However, reactions have been seen with PLLA implants approximately 4 years after surgery.[12] The longer degradation time and association between clinical reaction and liquefaction phase of the implant may be a factor. Interestingly, the follow-up review of most articles rarely approaches four years, which theoretically might affect the number of reported reactions. Lastly, PLLA raw material from varying sources can differ considerably in thermal history, molecular weight, and crystallinity, resulting in different degradation patterns and tissue responses.

The actual tissue reaction may vary from local erythema that resolves in a few days to a sinus tract formation which requires surgical debridement. The incidence of sinus tract formation may be decreased or prevented by aspirating or incising local fluid accumulations. The reactions are apparently manageable without difficulty, and do not influence the functional recovery in any way. The authors have not had any experience with these reactions to date. It should be emphasized that reports in the podiatric literature of reactions to BIOFIX material were with the use of PGA pins, and prior to the removal of the green dye.[13,14]

Final observations are that the screws are radiolucent, and that the amount of interfragmentary compression seems less than that which is attainable with metallic fixation. Both factors may be disconcerting to surgeons accustomed to standard AO/ASIF techniques and materials (Figs. 6A,

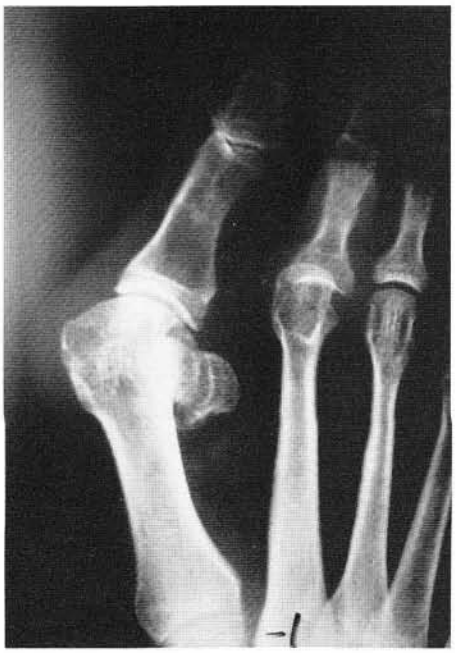


Figure 6A. Preoperative x-ray of a moderate-severe hallux valgus deformity.

6B). The radiolucency is a drawback in those procedures where confirmation of position of fixation is desirable. More reliance on the position of temporary fixation and the technical execution of the procedure may be necessary. The obtainable interfragmentary compression is a product of screw design and the operative technique recommended by the manufacturers. However, the more pertinent issue is whether the compression is adequate. Clinical studies clearly indicate that the difference in biomechanics of these implants, as compared with metallic screws, does not affect the radiographic or clinical outcome in the recommended uses.

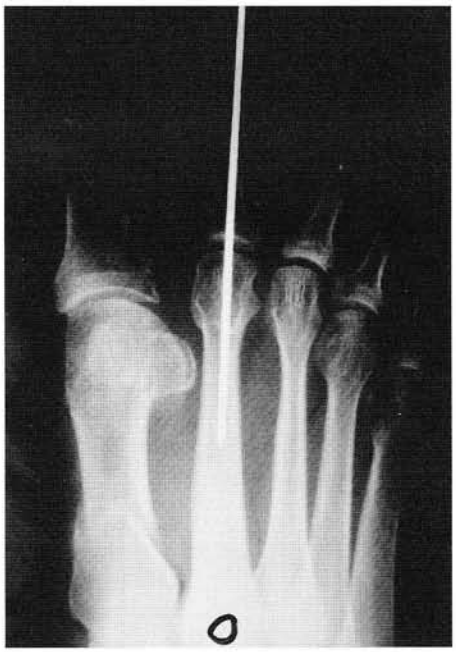


Figure 6B. Immediate postoperative x-ray of hallux valgus correction via a transpositional proximal osteotomy. The SR-PLLA 3.5-mm screw used for fixation is completely radiolucent.

The only absorbable screw available for clinical use in the United States at this time is the SR-PGA 4.5-mm fully-threaded screw. The literature supports its immediate use in ankle fracture repair. It is particularly well-suited to trans-syndesmotic fixation due to its relatively short strength duration and the elimination of a second procedure for fixation removal. The indications and uses of absorbable screws will expand in the ensuing years as other sizes and the SR-PLLA screws are released. They represent an exciting option in the selection of internal fixation devices currently available. Appropriate indications in podiatric surgery will require objective evaluation of matters such as those discussed here, and other factors elucidated by present and future scientific research.

REFERENCES

1. Partio EK: Absorbable screws in the fixation of cancellous bone fractures and arthrodesis. A clinical study of 318 patients. Academic dissertation, from the Department of Orthopaedics and Traumatology, Helsinki University Central Hospital. Helsinki, 1992.
2. Partio EK, Böstman O, Hirvensalo E, et al.: Self-reinforced Absorbable Screws in the Fixation of Displaced Ankle Fractures. A Prospective Clinical Study of 152 Patients. *J Orthop Trauma* 6:209-215, 1992.
3. Biofix-Tissue Management Systems, Implantes reabsorbibles auto-reforzados de acidos poliglicolido (SR-PGA) y polilactido (SR-PLLA), para la fijacion de fracturas. (product information) Bioscience Limited, Tampere, Finland.
4. Törmälä P, Vasenius J, Vainionpää S et al.: Ultra-high-strength absorbable self-reinforced polyglycolide (SR-PGA) composite rods for internal fixation of bone fractures: In vitro and in vivo study. *J Biomed Mater Res* 25:1-22, 1991.
5. Biofix, Absorbable Self-Reinforced Tissue Management Implants, *Workshop Training Manual, Part III, Full Thread Screws for Orthopaedics and Traumatology*. Bioscience Limited, Tampere, Finland, 1992.
6. Manuscript for the Biofix sales aid, Bioscience Limited, Tampere, Finland, 1994.
7. Böstman O, Partio EK, Hirvensalo E, Rokkanen P: Foreign body reactions to polyglycolide screws. Observations in 24/216 malleolar fracture cases. *Acta Orthop Scand* 63:173-176, 1992.
8. Partio EK, Hirvensalo E, Partio E, et al.: Talocrural Arthodesis with Absorbable Screws. *Acta Orthop Scand* 63:170-172, 1992.
9. Partio EK, Merikanto J, Heikkiä JT, et al.: Totally absorbable screws in the fixation of subtalar extra-articular arthrodesis in children with spastic neuromuscular disease. *J Pediatr Orthop* 12: 646-650, 1992.
10. Pihlajamäki H, Böstman O, Hirvensalo E, et al.: Biodegradable polylactide pins in the fixation of fractures and osteotomies. *XXVII World Congress of the International College of Surgeons*, Bologna, Italy, Monduzzi Editore, 1992, pp 617-621, 1992.
11. Suuronen R, Laine P, Sarkial E, et al.: Sagittal split osteotomy fixed with biodegradable, self-reinforced poly-L-lactide screws. A pilot study in sheep. *Int J Oral Maxillofac Surg* 21:303-308, 1992.
12. Rozema FR, Bos RRM, Boering G: Late tissue response to bone paltes and screws of poly (L-lactide) used for fixation of zygomatic fractures: report of 4 cases. *Proc 9th European Conference on Biomaterials* Chester, 1991, p 154.
13. Parks RM, Nelson G: Complications with the use of bioabsorbable pins in the foot. *J Am Podiatr Med Assoc* 32(2):153-161, 1993.
14. Johnson JD: Adverse reaction to absorbable rods.(letter to the editor) *J Am Podiatr Med Assoc* 83(7):427-428, 1993.

ADDITIONAL REFERENCES

Axelson PB: Fixation of cancellous bone and physeal fractures in dogs and cats. A comparison of the use of self-reinforced biodegradable devices to the use of metallic devices and external fixation. *Acta Vet Scand* 30:259-65, 1989.

Barfod G, Svendsen RN: Synovitis of the knee after intra-articular fracture fixation with Biofix. Report of two cases. *Acta Orthop Scand* 63(6):680-681, 1992.

Beiser IH, Kanat IO: Biodegradable internal fixation. A literature review. *J Am Podiatr Med Assoc* 80(2):72-75, 1990.

Dijkema AR, van der Elst M, Breederveld RS, Verspui G, Patka P, Haarman HJ: Surgical treatment of fracture-dislocations of the ankle joint with biodegradable implants: A prospective randomized study. *J Trauma* 34(1):82-84, 1993.

Eitenmüller J, David A, Muhr G: Treatment of ankle fractures with complete biodegradable plates and screws of high molecular weight polylactide. *Proc 92nd Congrès Francais de Chirurgie*, Paris 1990.

Fridén T, Rydholm U: Severe aseptic synovitis of the knee after biodegradable internal fixation. A case report. *Acta Orthop Scand* 63(1):94-97, 1992.

Frokjaer J, Moller B: Biodegradable fixation of ankle fractures. Complications in a prospective study of 25 cases. *Acta Orthop Scand* 63(4):434-436, 1992.

Gerbert J: Effectiveness of absorbable fixation devices in Austin bunionectomies. *J Am Podiatr Med Assoc* 82(4):189-195, 1992.

Lavery LA, Higgins KR, Ashry HR, Athanasiou KA: Mechanical characteristics of poly-L-lactic acid absorbable screws and stainless steel screws in basilar osteotomies of the first metatarsal. *J Foot Ankle Surg* 33(3):249-254, 1994.

Niskanen RO, Lehtimäki MY, Hämäläinen MM, Törmälä P, Rokkanen P U: Arthrodesis of the first metatarsophalangeal joint in rheumatoid arthritis. Biodegradable rods and Kirschner-wires in 39 cases. *Acta Orthop Scand* 64(1):100-102, 1993.

Partio EK, Hirvensalo E, Böstman O, Pätiälä H, Vainionpää S, Vihtonen K, Helevirta P, Törmälä P, Rokkanen P: Broches et vis bioresorbables: Une nouvelle methode de fixation des fractures de l'olecrane. Etude clinique prospective sur 41 malades. *Int Orthop (SICOT)* 16:250-254, 1992.

Pihlajamäki H, Böstman O, Hirvensalo E, Törmälä P, Rokkanen P:Absorbable pins of self-reinforced poly-l-lactide acid for fixation of fractures and osteotomies. *J Bone Joint Surg* (Br). 74(B):853-857, 1992.

Rokkanen P: Biofix symposiums in Italy. Question and Answer session. *Bioscience Limited* Tampere, Finland, 1993.

Yen RG, Giacopelli JA, Granoff DP, Steinbroner RJ: The Biofix absorbable rod. A preliminary report. *J Am Podiatr Med Assoc* 81(2):62-67, 1991.