In the past few years, concern has grown regarding the adverse effects of metal implants in the human body. In foot surgery, the use of 1 or more metallic screws for fixing osteotomy sites is extremely frequent, and most of these screws are left permanently in situ. However, if the screw needs to be removed, it can be a demanding, invasive, and potentially risky procedure, as the screw is often completely embedded in the bone. For these reasons, clinicians and researchers are seeking alternative solutions for fixation and implants, and various bioabsorbable materials have been developed for use in orthopaedic surgery.

It has been more than 25 years since the use of bioabsorbable pins for bone fixation was first reported, and over the years, their use has expanded from their original application in ankle fractures to fracture and osteotomy fixation throughout the body. Given the good results that have been reported and the authors’ own experience with the fixation of lesser metatarsal osteotomies, the use of bioabsorbable pins for fixing osteotomies of the first metatarsal appeared to be appealing for several reasons. They allow early mobilization and do not require implant removal surgery, and if a second operation is required at a later date, it is easier to perform.

However, this fixation method is not completely without complications, which may include osteolysis, sterile sinus formation, foreign body reaction, fluid collection, implant extrusion, and loss of mechanical stability. Nevertheless, it seems that the level of complications is the same or lower than with traditional fixation methods, and certain bioabsorbable materials are less prone to these complications than others.

The purpose of this study was to evaluate the effectiveness, reliability, and complications when using a poly-L-lactide (PLLA) copolymer bioabsorbable pin fixation in patients with hallux valgus deformity.
undergoing distal chevron osteotomies. To our knowledge, this is the largest series reported in the literature.

**Methods**

Between January 2005 and December 2010, a single surgeon treated 251 consecutive patients (285 feet) for hallux valgus deformity with a chevron osteotomy of the first metatarsal fixed with a copolymer pin (see Table 1). Two hundred twenty-six patients were female and 31 were male, and the average age of the patients was 58.6 years (range, 19-74 years). Osteo-Tec absorbable pins (Textile Hi-Tec, Labastide-Rouairoux, France) were used for fixing the osteotomy. The pin was made of a copolymer of 70% PLLA and 30% poly-DL-lactide (PDLLA) and was 8 cm long, with a diameter of 2.5 mm. The proximal end was mounted on a handle, whereas the last 5 mm distally was tapered with a rounded point.

Over this period of time, the same surgeon performed the same surgical procedure but fixed the osteotomy with a metal screw on 132 consecutive patients (154 feet) in a different hospital. This hospital did not permit the use of bio-absorbable pins due to financial policy. In this second cohort, 124 patients were female and 8 were male, and the average age of the patients was 63.2 years (range, 21-80 years). A Bold cannulated metal compression screw (Integra LifeSciences Corporation, Plainsboro, NJ) was used for fixation.

The inclusion criterion for surgery in either group was a symptomatic hallux valgus, with an intermetatarsal angle >10 degrees and/or hallux valgus angle >12 degrees. Exclusion criteria were rheumatoid arthritis, severe osteoporosis, and severe osteoarthritis of the first metatarsophalangeal joint. Cases where concomitant procedures were performed were also excluded. All patients complained of pain (ranging from moderate to severe) related to the hallux valgus deformity. The time from the onset of symptoms to surgery averaged 3 years (range, 1-9 years) for the copolymer pin fixation group and 2.7 years (range, 0.75-8 years) for the metal screw fixation group.

All patients underwent a program of regular clinical and radiographic evaluations that were performed by a single examiner for each group. The clinical examinations were carried out preoperatively, at 1 week, 2 weeks, 1 month, 3 months, and 1 year. A final clinical follow-up was performed to provide the data for this study. The average follow-up was 27 months for the copolymer pin group and 31 months for the metal screw group. During the preoperative clinical examination, a score was assigned according to the American Orthopaedic Foot and Ankle Society’s (AOFAS’s) hallux-metatarsophalangeal-interphalangeal scale, and the inter-metatarsal (IM) and the hallux valgus (HV) angles were measured. This procedure was repeated again immediately postoperatively, at 1 year, and at final follow-up. The radiographic examinations (comparative anterior-posterior and lateral weightbearing radiographs) were performed preoperatively, immediately postoperatively, and at 1 month and 12 months postoperatively. The radiographs were checked for signs of infection, bone resorption and bone healing, and maintenance of the correction.

The Student t test was used to measure statistical significance of the pre- and postoperative AOFAS scores and the measurements for IM and HV angles for each group and to compare the outcomes between the 2 groups.

**Surgical Technique**

Intravenous antibiotic prophylaxis with 2 g of a third-generation cefalosporin (cefotaxime) was given preoperatively (30 minutes) and then regional anesthesia administered. A tourniquet was applied at the calf and inflated to 250 mm Hg of pressure. A 5-cm medial longitudinal incision was made, centered over the first metatarsophalangeal joint (MTPJ). The head of the first metatarsal was exposed through a dorsomedial linear capsulotomy. A lateral release procedure consisting of an intra-articular lateral vertical linear capsulotomy and release of the adductor tendon at the base of the proximal phalanx was performed, and the medial bone eminence was removed. A metatarsal osteotomy was performed in accordance with the technique described by Austin and Leventen. The angle created by the chevron osteotomy was approximately 60 degrees. The capital fragment was shifted laterally from 30% to 60% of the width of the metatarsal (usually corresponding to a distance of approximately 5 mm) and was impacted onto the metatarsal shaft. After the correct position of the capital fragment had been verified, it was then temporarily secured with a 1.2-mm K-wire introduced medially along the axis of the first metatarsal. Then, a second 1.2-mm K-wire was placed from dorsal proximal medial to plantar distal lateral, passing completely through the metatarsal head. This K-wire acted as a guidewire for a 2.2-mm cannulated reamer that created the tunnel for the absorbable pin. The proximal
Results

Of the 383 patients (439 feet) included in the study, 15.4% (59 patients, 62 feet) did not return for final follow-up. Twenty-seven of these patients were in the copolymer fixation group and 32 in the metal screw fixation group. The reasons for not performing a final follow-up were as follows: 46 were unable to come to the hospital, 8 could not be traced, and 5 had died. As can be seen from Table 2, we observed major improvements in all three measures pre- and postoperatively for both groups, which were statistically significant at $P < .001$. On a subjective level, all patients declared themselves satisfied or very satisfied with the procedure.

The results of the Student $t$ test, which compared the improvements in score of the study group against the control group, showed that there was no statistically significant difference in the outcomes except for the improvement in the IM angle ($P < .05$). The $P$ values were as follows: .053 for AOFAS score, .44 for HV angle, and .035 for IM angle.

The radiographs showed that bone healing occurred after about 3 months in both groups, as evidenced by the disappearance of localized translucency at the rim of the osteotomy.

| Table 2. Mean Pre- and Postoperative AOFAS Scores and HV and IM Angles |
|-----------------|-----------------|-----------------|
|                  | Preoperatively  | Final Follow-up |
| AOFAS score (points out of 100), mean (range) |         |         |
| Copolymer pin    | 48 ± 11 (20-68) | 92 ± 6 (77-100) |
| Metal screw      | 39 ± 13 (19-68) | 88 ± 9 (70-100) |
| IM angle, mean (range), deg |         |         |
| Copolymer pin    | 12.9 ± 2.9 (8-20) | 7.1 ± 2.6 (2-12) |
| Metal screw      | 12.8 ± 2.6 (10-19) | 7.8 ± 1.8 (5-12) |
| HV angle, mean (range), deg |         |         |
| Copolymer pin    | 29.2 ± 5.8 (16-39) | 14.4 ± 4.7 (8-25) |
| Metal screw      | 28.7 ± 4.3 (21-38) | 13.2 ± 3.7 (7-18) |

Complications

We observed no indirect signs of breakage of the pin during the bone-healing period or delay in the consolidation of the osteotomy, and there were no cases of avascular necrosis, infections, osteolysis, or pseudoarthritis. There was 1 confirmed case of a sterile giant cell granuloma and 1 suspected case (0.7%). The first patient (female, 48 years old) reported a painful dorsal lump on the first ray of the operated foot when she came for her 3-month check-up. On clinical examination, a tight subcutaneous swelling of about 1 cm in diameter was observed, which had adhered to the deep layers. It was painful when palpated and when the patient wore shoes. The radiographs showed that the osteotomy had not moved and that there was no associated damage to the bone. At the operation site, the pin was protruding about 3 mm dorsally, but due to the advanced stage of degradation, the protruding tip of the pin fragmented on contact. The histological examination revealed that it was a giant cell granuloma. The second patient presented at the 3-month follow-up with a small subcutaneous lump with almost the same clinical features as the previously described case. However, as it was not painful and did not limit ambulation, the patient refused to undergo a surgical excision. Both patients had been very active after the first 21 days of relative rest, which may have caused the pin to protrude dorsally as the osteotomy became compacted. At the 1-month follow-up, we found a slight loss of correction in 9 cases (3.2%) due to a lateral tilt of the metatarsal fragment, causing a slight increase in the IM angle when compared with the measurement taken immediately postoperatively. All the patients admitted to not having respected the postoperative protocol with regard to ambulation, although they had all used the prescribed talus postoperative shoe. We did not find any correlation between the size of capital displacement and the loss of correction. At the 3-month follow-up, a new...
radiographic assessment was made. No further loss of correction was observed, and in none of the cases was a second operation necessary.

In the metal screw group, at the 1-year follow-up, there was 1 case (0.6%) of dorsal swelling, redness, and pain of the hallux when shoes were worn. On radiographs, a slight dorsal protrusion of the proximal end of the screw was observed, which probably caused soft-tissue impingement. The screw was then removed with no loss of correction and complete resolution of pain.

Discussion

Since Austin and Leventen\(^1\) first described the chevron osteotomy for the treatment of symptomatic hallux valgus, this procedure has been modified to improve stability by incorporating various internal fixation methods such as K-wires,\(^{19,34,35}\) metal screws,\(^{8,25,29}\) metal plates,\(^{36}\) staples,\(^8\) and, more recently, bioabsorbable pins.\(^{2,6,10,13,20,21,26}\) The use of permanent metal implants is associated with drawbacks such as the potential need for hardware removal and, as a recent issue, the possibility of metal hypersensitivity. The incidence of metal implant removal ranges from 2% to 15%, according to various authors,\(^{22,23}\) and in some cases this can be a complex procedure. The hardware may be concealed within the bone and its removal complicated by stripping of the screw, which has been described to be as high as 7% in the first operation.\(^{29}\) Although most of the reports on metal hypersensitivity are drawn from cases where large orthopaedic implants have been used, as shown in dentistry, even small volumes of metal can cause local and systemic adverse reactions.\(^{31,32}\) By implanting bioabsorbable devices, the potential need to remove the fixation in a second operation is eliminated, which both reduces the cost of treatment and patient discomfort and inconvenience. In the infrequent event that correction is lost over time and further surgery is required, it is easier to perform and less damaging to the bone. Finally, follow-up radiological evaluations are clearer as bioabsorbable materials do not obscure the anatomy and are also compatible with magnetic resonance imaging.

When compared with percutaneous fixation methods, bioabsorbable fixation decreases the risk of bacterial colonization and gives an easier and less disabling postoperative experience for the patient; there are no protruding parts to protect or to keep clean, and the discomfort caused by skin traction is avoided.

Bioabsorbable pins have been shown to provide a good level of stability until bone healing has occurred, gradually transferring stress to the bone as the pin degrades.\(^{12}\) Nevertheless, complications have been reported resulting from their use: osteolysis, sterile sinus formation, foreign body reaction, implant extrusion, loss of mechanical stability, and breakage of the implant.\(^{4,11,27}\) Various studies have shown that the rate of complications is either lower or comparable to traditional fixation methods,\(^{6,13,35}\) depending on the type of bioabsorbable material used. Certain bioabsorbable materials are less prone to infection, rejection, or loss of stability than others. Research has shown that the use of dyes within the chemical composition of implants can increase foreign body reaction rates,\(^6\) and fewer complications are associated with the use of PLLA than polyglycolide (PGA),\(^5\) and likewise with poly-p-dioxanone (PDS) pins compared with PGA pins (3% vs 55%, respectively)\(^{26}\). Copolymers have been created to combine the advantages of the various bioabsorbable materials, balancing stability, rate of absorption, and the risk of foreign body reaction.\(^{28}\) It is reasonable to suppose that with continued research and experimentation, complications associated with the use of bioabsorbable implants should reduce further in the future.

When compared with the literature, the results of the copolymer pin study group are particularly satisfying as it is a much larger cohort than those reported in the literature treated with the same procedure and fixation. At final follow-up, we observed a reduction in mean IM angle of 6.1 degrees and in mean HV angle of 14.8 degrees, which is similar to or better than the reductions reported in other studies. Gill et al\(^{13}\) achieved 5.3 degrees and 14.8 degrees of correction, respectively, in their 70 cases fixed with bioabsorbable pins. Caminear et al\(^6\) reported 11 degrees reduction in IM angle and 13.2 degrees in HV angle when using a copolymer pin fixation, but there were only 18 cases in their study. Barca and Busa\(^2\) reported 5 degrees of IM angle reduction and 14 degrees of HV angle in 35 cases fixed with a PLLA pin, and Deorio and Ware\(^{10}\) reported reductions of 4.3 and 9.5 degrees, respectively, in 41 cases. Compared with the other studies relating to bioabsorbable fixation, we observed a similar or lower rate of complications. Two patients (0.7%) developed giant cell granulomas, of which only 1 required treatment, although as noted above, we are not sure about the second case and must at least maintain a certain level of skepticism. Of the cases, 3.2% (9 patients) did suffer a slight loss of correction, but this was due to excessive loading in the immediate postoperative period and was not related to the use of the bioabsorbable pin. Gill et al\(^{13}\) reported various complications in their cases fixed with a PDS pin, but it should be noted that the pin contained a non-reactive dye: 1 malunion of the osteotomy (1.4%), 7 wound infections (10%), 1 loss of correction, and 6 cases of osteomyelitis (8.6%). In the 18 cases in Caminear et al,\(^6\) the only complication was a granuloma in 1 patient (6.6%). Both Barca and Busa\(^2\) and Deorio and Ware\(^{10}\) reported no complications with the use of absorbable pins, although the former did report a case of avascular necrosis in their 35 case series, but in the authors’ opinion, it was not related to the use of the bioabsorbable pin.

Comparing the 2 study groups, the lack of compression across the osteotomy site with the absorbable pin did not
seem to impair bone healing, as was demonstrated by the comparable clinical and radiographic results. The low rate of complications we observed was very similar for the different fixation methods. According to the clinical measures, the 2 fixation methods again gave similar results, and indeed no statistical difference was observed either in the AOFAS score or in the correction achieved in the HV angle. If the almost identical surgical procedures and operating times are taken into account, the only major difference that this study showed between the 2 fixation methods was from a financial perspective, as the metal screw was 25% cheaper than the bioabsorbable pin.

**Conclusion**

Our study found that bioabsorbable pins were a valid fixation method for chevron osteotomies in the treatment of hallux valgus. The postoperative immobilization was no longer than that with a metal fixation device and allowed a swift return to functional normality. Careful patient and implant selection can help minimize complications, and care must be taken with the surgical technique to ensure success. If these measures are adopted, the risk of complications is low and comparable with the rate observed with the use of other means of fixation.

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