CHAPTER **51**

SELF-REINFORCED POLY-L-LACTIC ACID PIN AND BURIED THREADED KIRSCHNER WIRES IN THE FIXATION OF THE AUSTIN BUNIONECTOMY

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In 1962 Dale Austin began performing a horizontally directed "V" osteotomy for Hallux Valgus and Metatarsus Primus Varus. He originally described the procedure without the use of any type of fixation.[1] More recently it has become common practice to fixate this osteotomy with some type of fixation (Figure 1).

There have been various types of metallic internal fixation described in the literature for osteosynthesis, including kirschner wires, cerclage wires, Herbert screws, and AO screw fixation.[2] Although these devices are effective, there are known disadvantages, which include stress shielding, corrosion, irritation, and inconvenience of removal.[3] These problems have led to the research into absorbable fixation devices.

Since the 1960's, bioabsorbable synthetic materials have been investigated for their use as suture material and internal fracture fixation.[4] Absorbable fixation implants were initially studied for use in maxillofacial surgery.[5] Researchers have been searching for the ideal bioabsorbable material that is rigid, noninflammatory, nonallergenic, and absorbs at a rate sufficient for healing.[6] When the first implants were prepared they could not withstand the forces required for fracture fixation, later melt-molding and extrusion was used to form the pins and rods. Although this method created a stronger material, it was not until a fiber-reinforced composite was introduced that a material capable of withstanding the forces required for fracture fixation was available. This process consists of reinforcing the polymer matrix with suture fibers of the same material.[7,8]

Since the introduction of these self-reinforced materials, these absorbable polymers have been used for fracture fixation. A number of studies have analyzed the use of absorbable material for the fixation of the Austin osteotomy.[2,3,9-15] Most of these studies have used the polyglycolic acid (PGA) or poly-para-dioxanone (PPD) material as their fixation material. In addition, a few studies have compared the absorbable fixation to metallic fixation.[16-18]

In this study, the Austin bunionectomy was performed and fixated using two types of fixation. The first was the self-reinforced poly-lactic acid (SR-PLLA) absorbable pin and the second the buried threaded Kirschner wire (K-wire). Three hyposthesis were developed and investigated. The first was that there would not be any difference in the outcome of the Austin procedure between the two types of fixation. Second, there would not be any inflammatory reactions or sterile sinus formations associated with the use of the PLLA material. Lastly, there would be a decreased number of complications associated with the use of the buried K-wire compared to the percutaneous K-wire in fixating the Austin bunionectomy.

MATERIALS AND METHODS

A retrospective clinical and radiographic review was performed on 37 total patients in which 48 Austin bunionectomies were performed for metatarsus primus adductus with hallux abductovalgus. A minimum of one-year clinical postoperative follow up was required to be included in the study. The 48 feet included in the study were divided into two groups. Group A was fixated with the SR-PLLA pin and included 20 patients with a total of 26 osteotomies. Group B was fixated with a threaded K-wire and included 17 patients with 22 feet. The type of fixation used was dependant on the surgeon that performed the procedure. Those osteotomies fixated with the bioabsorbable pin were performed by either DRG or RMG, and the K-wire fixated osteotomies were performed by WJ. The patients included in the two groups were comparable in both age and gender.

OPERATIVE PROCEDURE

The procedure performed in both groups was an Austin bunionectomy with a first intermetatarsal release (inclusive of an adductor hallucis tenotomy and release of the fibular sesamoidal ligament.) which has been described previously.[19] The only difference in technique between the two groups was the angle between the two osteotomy cuts and the type of fixation used. In group A, the well described 60° osteotomy was used, while the osteotomy used in group B was increased to 90° (Figure 2).

The bioabsorbable fixation utilized in group A consisted of a Bionx 2.0mm SR-PLLA smartpin inserted from dorsal proximal to plantar distal across the plantar osteotomy but not penetrating the plantar cortex into the joint (Figure 3). A 2.0 drill was used to create the hole that was measured with a depth gauge. The appropriate sized implant was inserted using a plunger supplied by Bionx. The pin size ranged from 25-30mm in length. The excess protruding pin was cut flush on the dorsal aspect of the metatarsal using a cautery ring. One bioabsorbable pin was used in each case with the exception of three cases in which a second pin was required to ensure stable fixation of the osteotomy.

A 0.062 threaded K-wire was placed across the osteotomy in the same direction as the absorbable pin for fixation of group B osteotomies (Figure 4). The first metatarsophanlangeal joint was then inspected plantarly for protruding fixation and corrected as necessary. The K-wire was then cut flush on the dorsal metatarsal shaft.

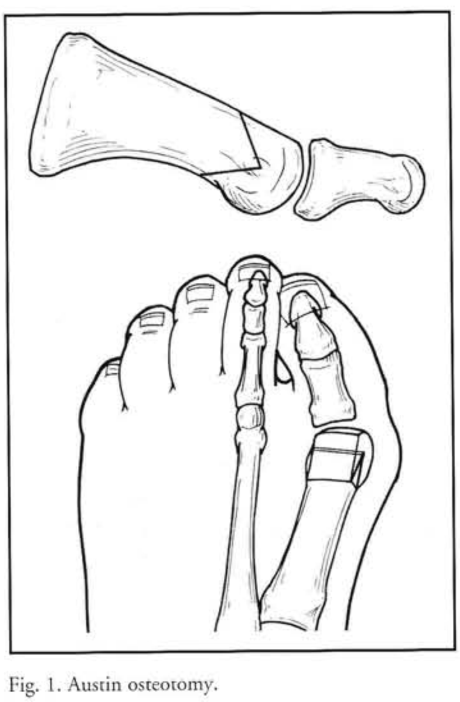

Fig. 1. Austin osteotomy.

One K-wire was used in five cases. 15 cases required a second K-wire, and 1 case required three K-wires to ensure proper stability of the capital fragment.

Postoperatively, both groups of patients were put into a hard soled postoperative shoe and allowed to bear weight immediately. Crutches were provided only to those patients requiring further pain relief initially, but each were encouraged to bear weight.

CLINICAL REVIEW

A total of 37 patient charts were reviewed for postoperative complications which included foreign body reaction, pain in metatarsophalangeal joint, pain over the incision, prominent fixation and infection. Also noted was the removal of any fixation or a required corrective procedure. The average clinical follow up was 20.0 months for group A and 23.4 months for group B.

RADIOGRAPHIC REVIEW

The radiographs of 48 feet were reviewed. The anterior-posterior view of the preoperative and final postoperative radiographs were obtained and several angles were measured and recorded. These angles included the intermetarsal, hallux abductus, proximal articular set and metadductus. Also noted was the tibial sesamoid position and metatarsal protrusion distance. The radiographs were also examined for postoperative osteolysis about the fixation site, malunion or non-union of the osteotomy, and displaced fixation. The average days of radiographic follow up for group B was 71.9 and 233.7 days for group A.

RESULTS

The average age of the patients in group A and B was 49.1 and 45.2 years respectively. Group A totaled 18 females and 2 males while group B consisted of 16 females and 1 male. Both the age and gender of the two groups did not differ significantly. The average follow up for each of the groups was 20.0 and 23.4 months respectively for group A and B. In the chart review there were no foreign body reactions, sinus tract formations or infections in either group. There were a number of notable clinical complications. In group A there was one patient that developed a hallux varus which required a soft tissue release one month post operatively. This procedure successfully corrected the deformity. One other patient developed nerve pain over the incision, which resolved with injection therapy. In group B there were two feet in which prominence of the K-wire was noted. One remained asymptomatic while the other was painful and required removal in the office one year postoperatively

Neither group was noted to have a non-union but each group did have one or two asymptomatic malunions of the capital fragment. Group A consisted of one malunion, while group B included 2 malunions, none of which required further corrective surgery. In neither group were any inflammatory reactions or sterile sinuses noted. 16 of the 26 feet in group A did have a radiolucency at the pin site in the metatarsal on the final radiograph without any surrounding osteolysis (Average of days postoperative).

The final radiographs were taken an average of 233.7 days postoperatively for group A and 71.9 days for group B. The mean preoperative intermetatarsal angle prior to surgery for both group A and group B was 12.4°. The post-operative values were 6.8° for group A and 4.1° for group B. This difference was statistically significant ($P < 0.05$). The average degree of correction of the intermetatarsal angle was 5.6° and 8.3° for group A and B groups, respectively. This was also statistically significant ($P < 0.05$). The average metadductus angle of group A was 14.7° and of group B was 13.5°. The mean hallux abductus angle prior to surgery was 23.3° for group A and 27.2° for group B.

Postoperatively the mean hallux abductus angle measured 9.7° and 8.7°, respectively. The average correction of this angle was 14.6° for group A and 17.5° for group B. The preoperative tibial sesamoid position averaged 5.1 for group A and 5.7 for group B. The postoperative position was corrected to 3.1 and 2.3 for each group, respectively. The difference of the postoperative tbial sesamoid position between the two groups was found to be statistically significant ($P < 0.05$). The average amount of correction of the tibial sesamoid position for each group was 2.0 and 3.4 for group A and B which was also found to be a statistically significant difference. The proximal articular set angle (PASA) was measured preoperatively to be 7.8° for group A and 15.1° for group B. This was a statistically significant difference ($P < 0.05$). Postoperatively, the PASA for group A and B measured 3.8° and 4.6° respectively. The measurements for groups A and B were assessed with a students t-test for equality of the means, with significance being a P value of < 0.05 (Table 1).

DISCUSSION

Since the introduction of the bioabsorbable fixation devices, there have been related adverse soft tissue reactions similar to an inflammatory foreign body reaction. The first material that was used for these implants was the PGA. The foreign body reactions associated with this material usually occurred 2-4 months after implantation. It appeared as a 5-10 mm red, fluctuant swelling in the area of a normally healed incision.[3] This reaction was studied by Bostman et al in 1990 and was found to be a nonspecific foreign body reaction to the liquefied material of the implant.[20]

In the SR-PLLA group, there were no foreign body reactions or sinus tract formation, but 16 of the 26 cases fixated with the SR-PLLA pin had a visible pin site on final

Table 1

RADIOGRAPHIC RESULTS

Measured angle	Group A (SR-PLLA)		Group B (k-wire)	
Mean preop IM	12.4°	(SD = 2.4)	12.4°	(SD = 2.8)
Mean postop IM **	***6.8°***	***(SD = 2.5)***	***4.1°***	***(SD = 2.6)***
Mean corrected IM **	***5.6°***	***(SD = 2.6)***	***8.3°***	***(SD = 3.2)***
Mean preop HA	23.3°	(SD = 6.4)	27.2°	(SD = 9.5)
Mean postop HA	8.7°	(SD = 11.0)	9.7°	(SD = 5.2)
Mean corrected HA	14.6°	(SD = 8.1)	17.5°	(SD = 8.6)
Mean preop TSP	5.1	(SD = 1.3)	5.7	(SD = 1.2)
Mean postop TSP **	***3.1***	***(SD = 1.4)***	***2.3***	***(SD = 0.9)***
Mean corrected TSP **	***2.0***	***(SD = 1.5)***	***3.4***	***(SD = 1.0)***
Mean metatarsus adductus	14.7°	(SD = 4.6)	13.5°	(SD = 4.0)
Mean preop PASA **	***7.8°***	***(SD = 6.9)***	***15.1°***	***(SD = 12.5)***
Mean postop PASA	4.6°	(SD = 7.8)	3.8°	(SD = 7.5)

** statistically significant difference ($P < 0.05$)

radiographic review. This finding in our study agrees with the results in a previous study done by Pihlajamaki et al in which the chevron bunionectomy was fixated with the poly-L-lactide pin. This study showed that the implant was absorbed within two years and the implant channel filled with connective tissue as seen on CT Scan.[15] There were a number of studies done in the 1990's in which the PGA and PPD absorbable pins were used to fixate the Austin bunionectomy.[2,3,9-14,21] Many of these studies associated the PGA material with the development of a sterile sinus tract.[2,3] The SR-PLLA pin has been shown to degrade at a slower rate than both the PGA and PPD materials, therefore maintaining its mechanical strength longer and decreasing the incidence of foreign-body reaction that is associated with the more rapidly depolymerizing copolymer implants.[20]

The theoretical advantage of the bioabsorbable fixation devices has been considered to be its ability to slowly transfer the stress from the implant to the bone as the material degrades, avoiding stress shielding that is often seen with metallic devices.[12,18] Our results did not show any osteolysis surrounding either the K-wire or SR-PLLA pin on final radiographs. There are several advantages to the absorbable fixation. There is no exposed surgical hardware and no need for additional surgery to remove retained hardware. The concern about pin tract infections is eliminated and there is decreased patient concern about retained metallic fixation.[9,12] Studies have also shown that the bioabsorbable fixation devices are as stable as metallic fixation devices.[13,18] This is consistent with our findings in this study in which there were 2 cases of capital fragment malposition in the K-wire group and 1 case in the SR-PLLA group. Since the first postoperative xrays were routinely taken between three and seven days postoperatively, it was impossible to know if the malposition occurred intraoperatively or if there was some postoperative displacement of the capital fragment. It appeared that there was no significant difference in the number of displacements between the two methods of fixation and all of the osteotomies healed without delay.

One disadvantage of the use of the bioabsorbable pins is lack of compression across an osteotomy site. Since this is not a requirement of the fixation used for an Austin osteotomy, the bioabsorbabale implant is a practical method of fixation. The high cost of the absorbable devices has also been considered a disadvantage. Taking into account the possible necessity of removal of metallic fixation, the cost may be less expensive in the long term. Our study showed that only one K-wire required removal, therefore the cost differential may be a relevant factor with the use of the buried K-wire. The radiolucent appearance of the absorbable material on radiograph has also been a noted disadvantage because of the difficulty assessing the placement of the fixation postoperatively. On the other hand, it does allow for the future use of CT and MRI without distortion. The contraindications of the use of the bioabsorbable pins includes, infection at the surgical site, cystic bone formation, osteoporosis, comminution of the bone and a patient history of inflammation to prior absorbable suture materials.[3,9,10,12] Often cystic bone formation and osteoporosis are noted on pre-operative radiographs, therefore in these cases an alternate method of fixation should be considered. In addition, a thorough clinical history should be obtained to rule out any prior reaction to absorbable materials to ensure good results.

This study showed that the use of buried threaded K-wire is a viable option for fixating the Austin bunionectomy. In this group only one foot required removal of the K-wire due to a painful prominence associated with likely migration out of the metatarsal. Duke in 1996 described the use of a buried K-wire in fixating the Austin osteotomy. The K-wire was left just under the skin and after the osteotomy healed the skin was incised and the K-wire removed.[22] The method in which the K-wire is used in this study does not require removal unless it should become prominent due to migration.

Preoperatively, both the SR-PLLA and K-wire groups appeared radiographically similar without statistically significant differences between the radiographic measurements except for the mean PASA, which was statistically significant. The K-wire group had a much larger preoperative mean PASA but postoperatively the two groups appeared much more similar without a statistically significant difference. Postoperatively, the mean intermetarsal angle was found to be statistically different between the two groups. This was most likely attributed to B group laterally transposing the capital fragment more aggressively the A group. The difference between the pre and postoperative mean IM angle for the two groups was also found to be statistically significant which seems to correlate with the statistically siginificant difference found between the postoperative mean IM angles. The preoperative and postoperative changes in the mean IM and HA angles show that there was good reduction of the deformity by utilizing the Austine procedure and that the fixation method did not seem to influence the final outcome.

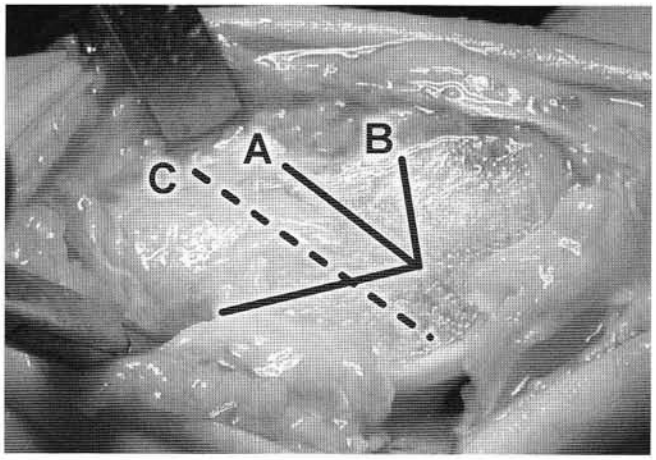

Figure 2. Intra-op photo depicting the two types of osteotomies. A. Austin osteotomy = 60°; B. Distal-L osteotomy = 90°; C. Placement direction of both types of fixation across osteotomy.

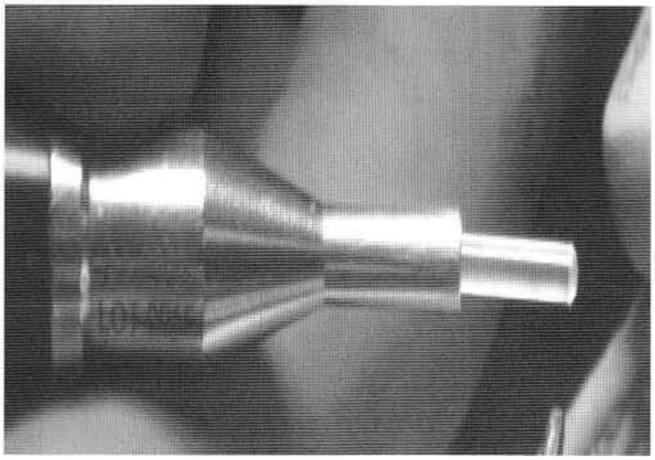

Figure 3. PLLA absorbable pin with inserter device.

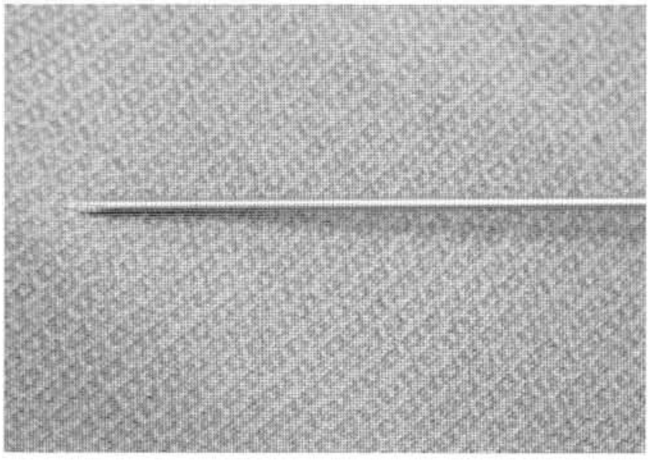

Figure 4. 0.062 threaded K-wire used for fixation of distal osteotomy.

CONCLUSION

In this study two types of fixation methods were used in the fixation of the Austin bunionectomy. To ensure similarity between the two study groups several variables were examined. Both groups were found to be similar in age, sex and the amount of deformity. It was shown that the Austin bunionectomy worked to correct the deformity of both groups despite the type of fixation used. Also described was a technique in which a buried threaded K-wire was used to fixate a bunion osteotomy. This technique negates the previous concern of possible pin tract infection and allows the K-wire to be maintained in the metatarsal without necessity of routine removal. The concerns using bioabsorbable fixation such as inflammatory reaction and sterile sinus formation were evaluated. The SR-PLLA pin used in this study did not support these claims. In fact, there were no inflammatory reactions or sterile sinuses noted in our study. Thus, this study has shown that both methods of fixation of the Austin bunionectomy provide good results with very few complications.

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