CHAPTER **44**

THE USE OF THE ALLOFIX® ALLOGRAFT BONE SCREW IN HALLUX VALGUS REPAIR

Mickey D. Stapp, D.P.M.
Robb A. Mothershed, D.P.M.

INTRODUCTION

An osteotomy performed for a hallux valgus repair is most often stabilized with the use of internal fixation devices. There are many options of internal fixation available to the podiatric surgeon. Historically, osteotomies of the first metatarsal have been fixated with stainless steel wire, smooth and threaded K-wires, Steinmann pins, staples, absorbable pins, A-O type cortical and cancellous screws, cannulated screws, absorbable screws, allograft cortical bone pins, and allograft bone screws.

Regardless of the internal fixation device chosen, the goals of internal fixation remain the same. Atraumatic operative techniques should be followed; accurate anatomic reduction should be strived for; rigid internal compression should be applied; and soft-tissue damage should be avoided.[1] Rigid internal fixation is the basis for the successful application of osteotomies in correction of the hallux valgus deformity. The fixation should provide stability of the osseous structures to allow for earlier range of motion and return to function of the surgical site. The fixation device should be inert and stabilize the osseous structures until the bone itself is healed through primary bone healing and able to withstand load forces.

Of the fixation devices described, a lag screw, whether it be made of metal, absorbable material, or allograft bone, provides the most efficient rigid internal fixation or static interfragmental compression. An external fixator, historically not used for fixation of first metatarsal osteotomies in hallux valgus repair, can also achieve interfragmental compression. Cerclage wire, K-wires, Steinmann pins, staples, absorbable pins, and allograft bone pins provide a splintage-type of fixation, but do not produce rigid internal compression fixation and cannot be expected to produce primary bone healing.[2] In this paper, lag screws, constructed of various materials, will be compared and contrasted with emphasis placed on the allograft bone screw.

METALLIC SCREWS

A screw providing rigid internal fixation should be non-reactive to the bone, surrounding soft tissues, or the body as a whole. Many materials have been used and proven relatively inert. The traditional surgical stainless steel screw is a chromium nickel molybdenum steel alloy and has proven to be very strong, yet with few reported reactions. Patients with a nickel allergy can react to the small nickel content with the Swiss-developed surgical stainless steel. Lag screws composed of titanium are more inert without possessing the nickel allergen.

Metallic screws have the potential for stress shielding, producing stress osteopenia of the surrounding bone. Since the elasticity of metal does not change as the bone heals, the stress-related remodeling does not occur unless the metallic implant is removed. This may result in weakened neighboring bone with loosening of the fixation devices. Fixation devices have also been reported to undergo corrosion in the body. Titanium appears to have less potential for corrosion than surgical stainless steel.

A common disadvantage to metallic screws is the necessity for removal. While the practice of removing metal internal fixation devices varies widely with surgeon preference, patient preference, clinical situation, and general school of thought, it is widely accepted in the podiatric profession to not routinely remove metallic implants unless they produce a foreign body reaction, become loosened or broken, or cause discomfort. The AO/ASIF school recommends eventual removal of fixation to restore normal biomechanical forces on the bone. If this school of thought is followed, the elimination of a second procedure for removal of fixation, would be an obvious economical and psychological benefit for an absorbable type of internal fixation device.

ABSORBABLE SCREWS

Absorbable screws, while apparently providing less interfragmentary compression, do provide less stress shielding to the surrounding osseous structures than traditional metallic screws. It is the elasticity of the absorbable screw, similar to the elasticity of bone, that reduces the stress shielding of bone and the secondary osteopenia associated with more rigid fixation. This implant elasticity gradually weakens as the bone gains strength. This is clinically advantageous for faster healing of an osteotomy and/or arthrodesis site. Since the absorbable screws eventually absorb as the stress is transferred to the bone, the potential need for removal is eliminated.[3]

While absorbable screws provide adequate strength for many podiatric applications, they can produce a unique non-infectious foreign body reaction that may require aspiration or surgical drainage. Reactions have been seen with some absorbable implants approximately up to four years after surgery. Absorbable screws of polyglycolide (PGA) and poly-L-lactide (PLLA), also have the disadvantage of being radiolucent. The surgeon must rely more on metallic temporary fixation intraoperatively and skill and experience in placement of fixation devices in the postoperative radiographic assessment.[3]

ALLOGRAFT BONE SCREWS

Allograft bone has been used successfully for many years in podiatric surgery. A common example is the allograft bone graft utilized in the anterior calcaneus in the Evans calcaneal osteotomy. Allograft bone is recovered from a deceased donor whose legal next of kin has given permission for the bone to be donated. The bone is recovered utilizing sterile procedures and the processing and packaging is performed under aseptic conditions.[4]

Donors of allograft bone undergo extensive screening and testing prior to donation. The donor's medical/social history is screened for conditions that would contraindicate the donation of tissues. Such contraindications include the presence of infectious diseases, diseases of unknown etiology, malignant diseases, neurological degenerative diseases, and exposure to toxic substances. Further donor suitability is determined based on infectious disease testing, available medical records, behavioral risk assessment, autopsy or coroner reports, and procurement test results. Donor blood samples taken at the time of recovery include Hepatitis B surface antigen, Hepatitis B core antibody, Hepatitis C antibody, HIV-1 antibody, HIV-2 antibody, HTLV-1 antibody, and syphilis. Blood and tissues collected at the time of recovery are also tested for aerobic and anaerobic organisms.[5]

Although there have been two case reports of HIV transmission with *unprocessed* tissues,[6,7] there has never been a confirmed report of transmission of HIV, hepatitis B, or hepatitis C from *processed* tissues.[8] The Musculoskeletal Transplant Foundation has screened and tested more than 9,000 donors and processed more than 500,000 tissues, and there has never been a confirmed case of transmission of a bacterial or viral disease.[9]

Allograft bone pins have been available for several years and have been utilized in digital surgery and in fixation of osteotomies for hallux valgus repair. Because of the design, that of a pin, interfragmental compression is not achieved with the use of these pins. Splintage is achieved with this design but not rigid internal compression fixation.

The design and development of the allograft bone screw has been ongoing and will continue to undergo change, modifications, and improvements with time. The rationale for the development of the allograft lag screw was similar to the rationale for developing the absorbable screw. A device needed to be developed which would be inert, provide stability until primary bone healing had been achieved, and would be incorporated into the bone eliminating the potential for removal of the implant. Musculoskeletal Transplant Foundation has developed the Allofix® bone screw.(Fig. 1) This

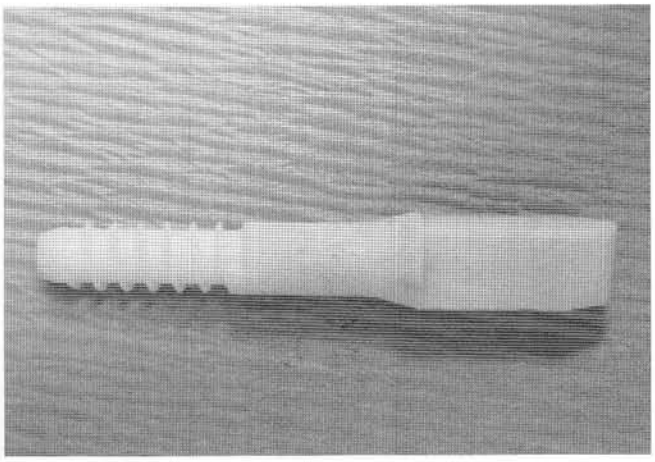

Figure. 1. The Allofix® bone screw.

allograft screw provides interfragmentary compression for primary bone healing, produces no noted foreign reaction, and is incorporated within the host bone, eliminating the need for future removal.

It can be theorized that the elasticity of allograft bone screws is less than that of metal screws and nearly equal to the elasticity of natural bone. Therefore, the elasticity of the allograft bone screw diminishes as the host bone incorporates the graft bone, transferring load to the host bone. This reduces the stress shielding and secondary stress osteopenia that may be seen in more rigid metallic fixation.

The allograft bone screws are available in 3.5 mm diameter and 14mm, 16mm and 18mm lengths. These correspond to several of the more common lengths necessary for fixation of the first metatarsal. The screws are harvested from the cortex of freeze-dried femur, humerus, and tibia. The bone screws will expand approximately 3% to 5% in diameter when placed in solution, therefore it is important to reconstitute the screws for a short period of time before implantation, otherwise the expansion may make the insertion of the screw more difficult.

The instrumentation used for insertion of these allograft bone screws is fashioned after AO/ASIF instrumentation. The drills, countersink, tap, and screw driver are compatible with the quick release handle in the AO/ASIF sets. The technique for insertion of the 3.5 mm allograft screws is the same for the AO/ASIF 3.5 mm cortical screw. A thread hole is created with a 2.9 mm drill. Over drilling of the near cortex only is accomplished with a 3.6 mm drill. Countersinking is performed with the supplied 3.5 mm countersink. The hole is measured for screw length with the depth gauge. The thread holes are cut with the supplied 3.5 mm tap. The screw is then inserted with the specially designed screw driver.(Fig. 2)

The allograft screw is designed as a cortical screw with pitch thread patterns similar to the AO/ASIF cortical screw, but the allograft screw has a smooth shank similar to a cancellous screw. The head of the screw offers a lower profile and smaller head than the traditional AO/ASIF screw. There is a square peg of allograft bone attached to and continuous with the head of the screw. The square peg has beveled edges at the top of the peg.(Fig. 3) The square peg is used to insert the screw with the special screw driver. There is no hexagonal or cruciate pattern cut into the head of the screw for insertion in the traditional manner. The beveled edge of the square peg is also designed so that if too much torque is applied while inserting the screw, the specially designed screw driver will slip off of the square peg and therefore prevent breaking or splintering the allograft screw.

Intraoperatively, the osteotomy of the first metatarsal is performed the same as would be performed if traditional AO/ASIF screws were to be used. The osteotomy is temporarily fixated with K-wires and the planned screw placement is predrilled with a .045" or .062" K-wire. Using the previously described sequence, the screw is inserted across the osteotomy. It is recommended that one screw be placed in complete sequence before beginning instrumentation for a second screw, if a second screw is to be used. This allows placement of a metal second screw if a problem is encountered in placing the first screw.

Once the screws are in place, bone resection and remodeling are performed before the square peg is cut from the head of the screw. This will

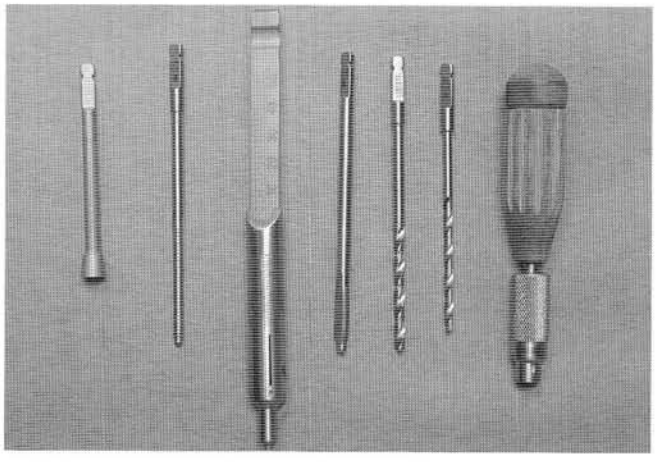

Figure. 2. Instrumentation for the 3.5mm allograft bone screw.

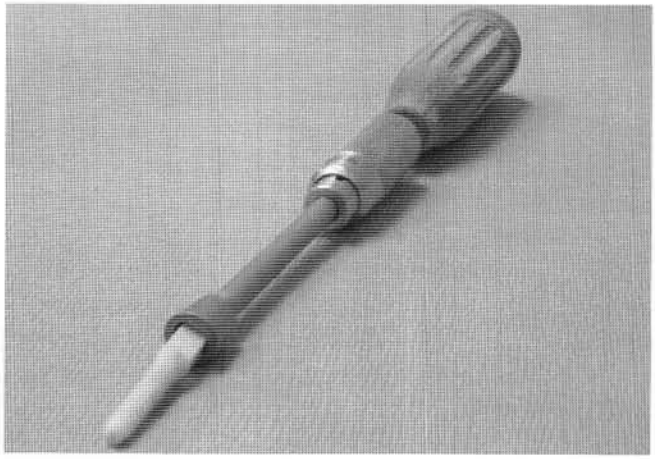

Figure. 3. Note the special screw driver design and beveled top of the insertional square peg of the allograft bone screw.

enable the surgeon to check for tightness of the screw(s) after all bone remodeling is performed. The peg is then cut with power instrumentation flush with the head of the screw. The head of the screw can then be reshaped, and any prominent areas reduced, utilizing a power burr. Care should be taken not to reduce the head of the screw flush with the bone since the undersurface of the head provides the compression of the near cortex against the threads purchasing the far cortex.

Applications of the allograft bone screw in first metatarsal osteotomies include distal metatarsal osteotomies such as the Austin bunionectomy, long dorsal "V" or Kalish type bunionectomy, and Reverdin type procedures. Mid-shaft osteotomies, such as the Scarf procedure, and base osteotomies, are also applications for the allograft bone screw. With the current length of screws, some applications may require a longer screw than available. Osteotomies of the first metatarsal in which allograft cortical screws are placed in a dorsal to plantar direction are ideal for the currently available size, and length.(Figs. 4 - 6)

CONCLUSION

The allograft bone screw offers several advantages over previously available fixation devices for hallux valgus repair. The screw provides rigid internal fixation, remains strong enough for the duration of bone healing, then gradually is incorporated into the host bone transferring normal stress to the healing bone. By becoming incorportated into the host bone, the need for removal is prevented. The allograft screw has an additional advantage over the PGA and PLLA absorbable screws, in that the screws can be identified on radiographs and are not likely to cause any local tissue reaction.

Use of these allograft bone screws has been very limited. The authors' experience has also been limited but has been favorable. No difference has been noted in bilateral cases in which one foot was fixated with stainless steel screws and the contralateral foot was fixated with the allograft screws. No intraoperative complications, such as breakage of the screw, failure to purchase and provide compression, or stress fracture of the surrounding host bone, have been noted in the authors' experience. No postoperative complications, such as failure to maintain rigidity and compression, breakage of the screw, loosening of the fixation device, painful or prominent screw, or soft tissue reaction, have been noted. The screws have provided an alternative means of fixation without the possible need for removal, and have provided the same compression and stability as the stainless steel screws, even in patients who are 60 to 70 years of age.

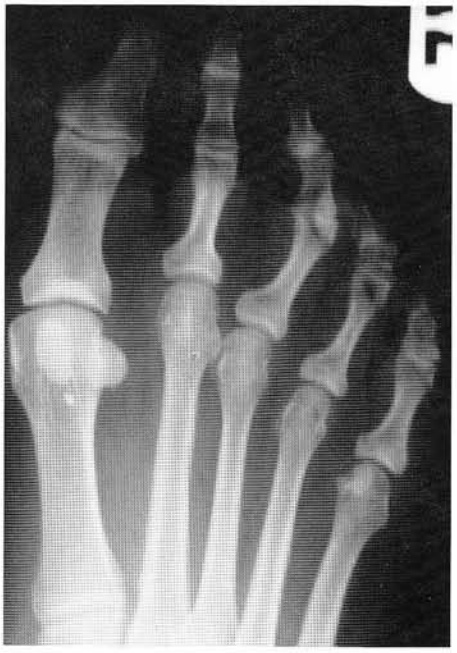

Figure. 4A. Preoperative AP radiograph of hallux valgus deformity.

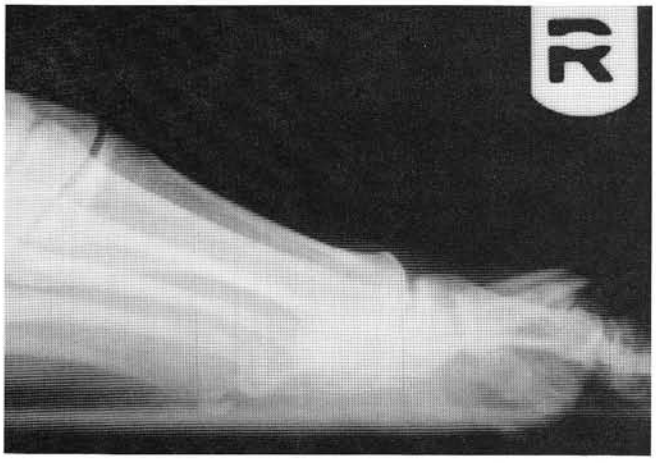

Figure 4B. Preoperative lateral view.

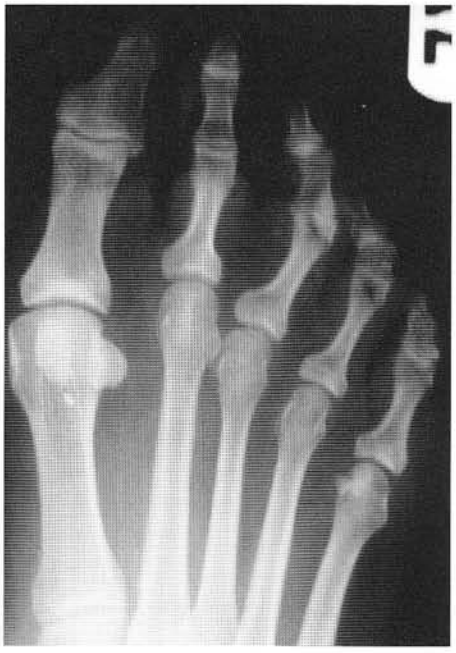

Figure. 5A. Immediate postoperative AP radiograph showing correction of hallux valgus deformity with use of the allograft bone screw. Note the radiodensity of the bone screw.

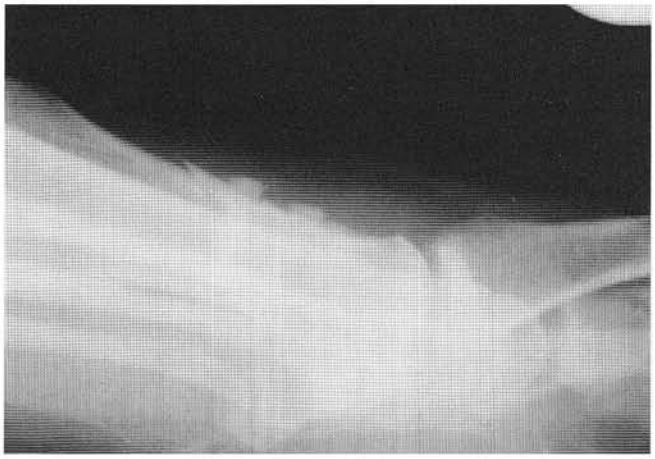

Figure 5B. Immediate posoperative lateral view.

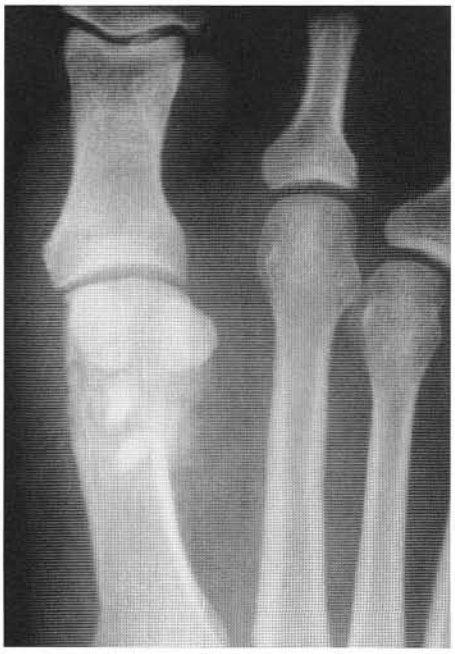

Figure. 6A. Two months postoperative AP radiograph showing correction of hallux valgus deformity with use of the allograft bone screw.

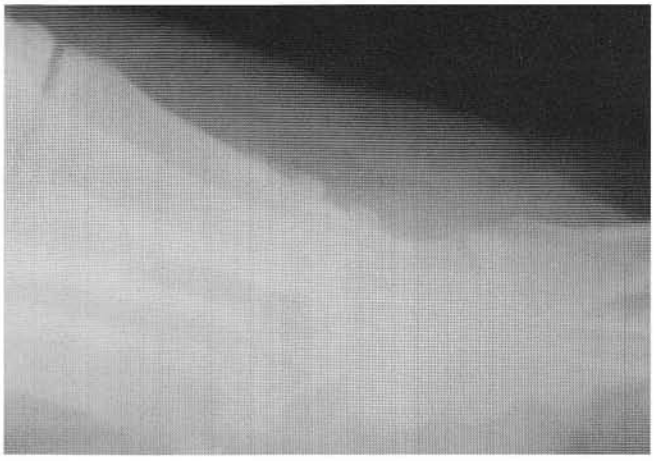

Figure 6B. Lateral view, two months postoperative.

REFERENCES

1. Muller M, Allgower M, Schneider R, Willenegger H: *Manual of Internal Fixation.* New York, Springer-Verlag, pp. 1-426, 1991.
2. Corey SV, Ruch JR: Principles of Internal Fixation. In McGlamry ED, Banks AS, Downey MS (eds) *Comprehensive Textbook of Foot Surgery,* 2nd ed. Baltimore, Williams and Wilkins, pp 119-158, 1992.
3. Cicchinelli LD, Gonzalez San Juan M, Aycart Testa J: Absorbable Screw Fixation. In Camasta CA, Vickers NS, Carter SR (eds) *Reconstructive Surgery of the Foot and Leg: Update '95,* Podiatry Institute Publishing, Tucker, GA, pp 58-65, 1995.
4. Mahan KT: Bone Graft Materials and Perioperative Management. In Camasta CA, Vickers NS, Carter SR (eds) *Reconstructive Surgery of the Foot and Leg: Update '95,* Podiatry Institute Publishing, Tucker, GA, pp 69-71, 1995.
5. Package Insert, Allofix Bone Screw. Musculoskeletal Transplant Foundation. Edison, NJ, 1999.
6. Simonds RJ, Holmberg SD, Hurwitz RL, Coleman TR, Bottenfield S, Conley LJ et al:Transmission of Human Immunodeficiency virus Type 1 from a seronegative organ and tissue donor. *N Eng J Med* 326:726-732, 1992.
7. Centers for Disease Control: Transmission of HIV through bone transplantation: Case report and public health recommendations. *Morbidity Mortality Weekly Report* 39:597-599, 1988.
8. Asselmeier MA, Caspari RB, Bottenfield S: A review of Allograft processing and sterilization techniques and their role in transmission fo the Human Immunodeficiency Virus. *Am J Sports Med* 21:170-175, 1993.
9. Musculoskeletal Transplant Foundation Data. Edison, New Jersey.