

INTERNAL FIXATION IN A HALLUX VALGUS SURGICAL PROCEDURE WITH RESORBABLE PINS

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INTRODUCTION

For the Austin bunionectomy, internal fixation was originally considered not to be necessary. Today, fixation as an aid for stability is generally favored (1-3). Fixation is usually performed using small fragment tension screws, allowing immediate full load (4). The use of biodegradable pins is a viable option, however, several complications such as sterile abscess and foreign body reactions are connected to this type of fixation.

A new fixation technique, the SonicPin pin is fixated in the cancellous bone by ultrasonic melting to overcome these potential complications. Polylactide polymers are biodegradable materials that have often been used in resorbable pins fixed in press-fit techniques, plates and screws (2, 5). They have been shown to maintain their baseline mechanical strength for about 30 weeks, and it takes about 1.5 to 2 years until complete resorption (6, 7). The SonicPin takes advantage of the excellent biodegradable and biocompatible properties of polylactide resomers (8, 9) as well as of an ultrasound fixation procedure (also known as BoneWelding), which melts the pin tip at the interface between the implant and the host bone. The polymer, liquefied by ultrasonic energy, flows into the cavities of the cancellous bone structure, cools down immediately and solidifies, resulting in a stable fixation due to interdigitation (Figure 1). Thus, the SonicPin is well suited to serve as a plug to achieve immobilization of bone fragments until healing of the osteotomy site occurs.

Several studies have assessed the biomechanical properties of polylactide pins fixed by BoneWelding. Biomechanical testing of the quasi-static push-out strength and fatigue performance of polylactide pins bonded to a bone surrogate material using the BoneWelding process demonstrated significantly superior mechanical performance of the bonded pins to conventional bone screws, even in extremely porous host material (10). The comparison of polylactide screws to polylactide pins fixed with ultrasonic energy revealed higher 3-dimensional load capacity of the latter system (11). Another study addressing the same

comparison observed up to 11.5 times higher values of the pins fixed by ultrasonic energy compared to screws for tensile strength and stiffness as well as side bending stiffness (12). Another biomechanical study, however, showed that titanium screws showed superior resistance to shear forces compared to polylactide pins fixed with ultrasonic energy (13).

Biodegradable polylactide pins, fixed by ultrasonic melting, have been clinically used in combination with biodegradable plates for fixation of bone fragments when repairing craniosynostoses in 8 pediatric patients, and it proved to be advantageous over conventional fixation due to reduction of surgery time by half and dispensability of a second operation for plate removal (14). Furthermore, there are 2 recent reports on the clinical use of polylactide pins fixed by ultrasonic melting in craniotomies and craniofacial reconstructions (28 patients), as well as for treating fractures of the zygomaxillary complex, frontal bone impression fractures, mukocoele in the frontal sinus, isolated fractures of the orbital floor, complex midfacial trauma as well as performing bone cap fixation, craniosynostoses and fixation of a distracted bone fragment (75 patients) (15, 16). The authors conclude that this fixation method is generally feasible, shows sufficient mechanical stability, and allows efficient intraoperative handling for a wide variety of indications in craniomaxillofacial surgery (16).

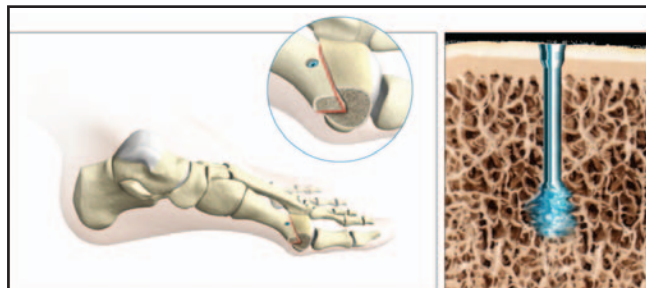


Figure 1. Austin/Chevron osteotomy with lateral shift and fixation (left). Fixation principle of the SonicPin. During insertion into a predrilled hole, the tip of the pin is melted by ultrasound, resulting in interdigitation of the SonicPin with the surrounding cancellous bone (right), (Stryker Product Information SonicPin, Literature Number: 90-17100).

SYSTEM DESCRIPTION

The Stryker SonicPin System consists of a bioresorbable implant pin made of a PLDLLA copolymer in a ratio of 70:30(L/LD) (Figure 2) and an ultrasonic unit (generator and sonotrode) (Figure 3). Pins are implanted using ultrasonic energy generated by an ultrasonic unit, allowing the pin to adapt to the previously drilled hole utilizing the microstructure of the bone for enhance retention. Its intended use is the correction of hallux valgus deformity.

SURGICAL TECHNIQUE

The Austin bunionectomy is performed in the traditional way as a V-shaped osteotomy in the distal metaphyseal area of the first metatarsal. A 0.031 inch smooth Kirschner wire (K-wire) is used both for temporary fixation of the osteotomy and as guide wire for the respective cannulated drill bit (Figure 4). The wire penetrates the cartilage in the metatarsal head area and can be identified by exposing the joint (Figure 5). The wire is then retracted until it is not visible anymore. This will determine the length of the SonicPin, which is available either in 22 mm or 26 mm lengths. The depth gauge is used to identify the correct length (Figure 6).

The cannulated drill bit is introduced over the K-wire (Figure 7). Care must be taken not to bend the wire, which is a sign of a misdirected drill.

Once the 2-step drill is completely introduced onto the drill stop, both the drill and the wire can be removed. The

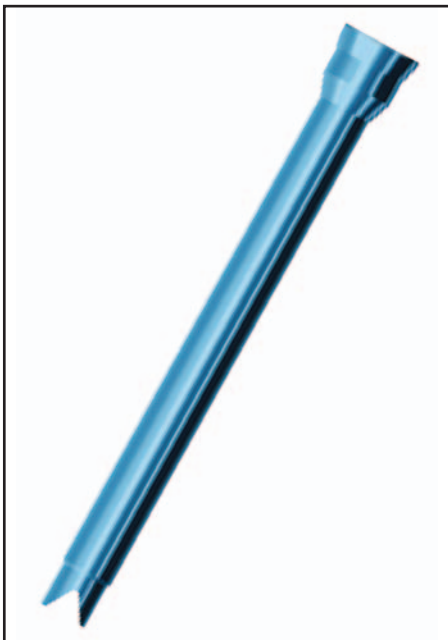


Figure 2. The Sonic pin (0.087 inches x 0.87 and 0.087 x 1.02 inches).

drill must not penetrate the plantar cortex. The reduction of the osteotomy can be secured by an extra K-wire or manually. The sonotrode is threaded to the head of the SonicPin and the system is inserted. The SonicPin is inserted as deep as determined by the drill, so about 0.25 inches of the SonicPin will remain out of the bone. This is the amount of material that will melt into the bone (Figure 8).

Once the SonicPin sits in the drill hole, the ultrasonic energy is activated by continuously pressing the foot pedal for a maximum duration of 5 seconds. The pin has to be advanced into the bone with an axial force until it is flush with the bone. The axial force is critical, as shear forces may cause melting of the head. The Sonotrode can be detached after a tone from the machine (after about 3 seconds) indicates that the cooling process is finished (Figure 9).

In rare situations, prominent parts of the head may be trimmed off with an oval burr. The osteotomy is then stable. The post surgical protocol is the same as after screw fixation. Full weightbearing in a surgical shoe is allowed immediately after surgery.

STUDY DESIGN

The SPEED study was a prospective open-arm cohort evaluation to assess the safety and performance of the SonicPin in maintaining alignment and fixation of the Austin/Chevron osteotomy procedure for hallux valgus correction. The trial was not conducted blinded to study treatment. SPEED24 included an additional follow-up at 24 months after the initial procedure.

The inclusion criteria for the SPEED24 trial were patients who signed the informed consent for SPEED study, completed 12 months follow-up in the SPEED study,

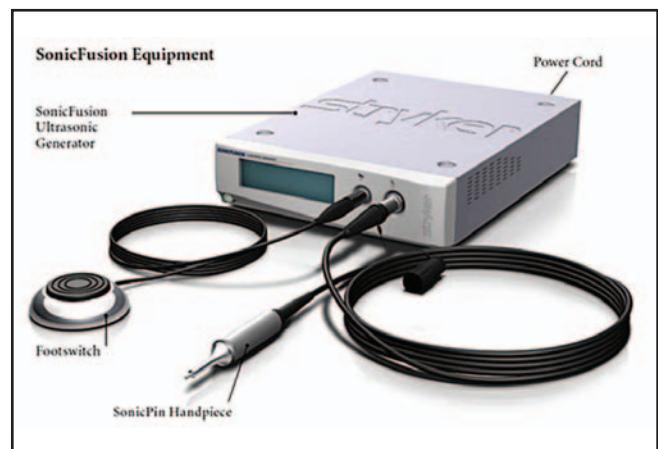


Figure 3. Ultrasonic unit.

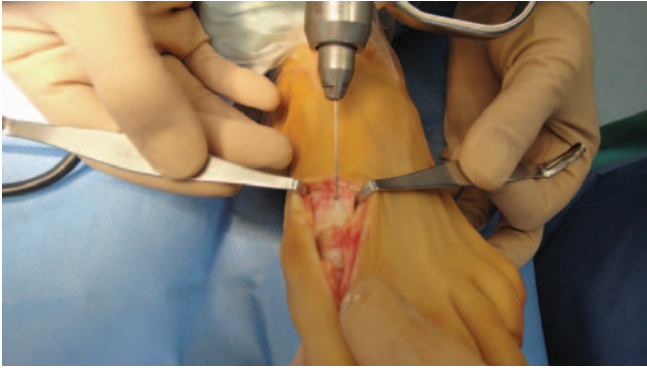


Figure 4. 0.031 inch Kirschner wire is used for temporary fixation.



Figure 5. Wire penetrates the plantar cartilage.

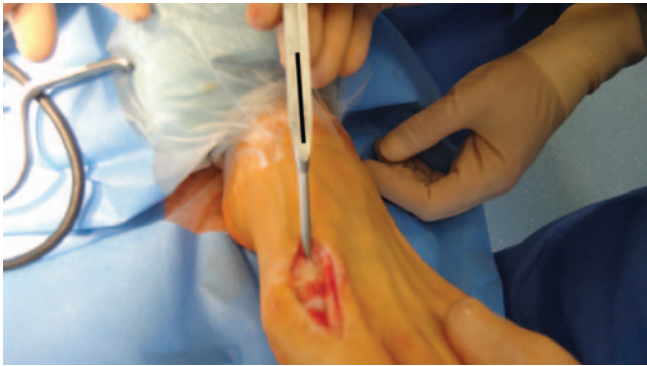


Figure 6. Correct length is determined by using the depth gauge.



Figure 7. Cannulated drill bit is inserted over the Kirschner wire.



Figure 8. SonicPin System is inserted into the drill hole.



Figure 9. Sonic system is detached and the SonicPin is in place being flush with the bone.

underwent hallux valgus correction with use of the SonicPin to maintain alignment in an Austin/Chevron osteotomy, were between 18 and 80 years of age, and were able to communicate meaningfully and to comply with the study protocol.

According to the visit schedule, magnetic resonance image (MRI) examinations were performed with medial/lateral and anterior/posterior views 24 months post-operatively (Table 1). The findings were focused on bone healing, maintenance of correction, foreign body reaction, and pin resorption. Figures 10-12 show the MRI findings after 6, 12, and 24 months of a representative patient.

ADVERSE EVENTS AND COMPLICATIONS

All kinds of complaints, surgical site-related and nonsurgical site-related adverse events, and serious adverse events (SAEs) as well as serious adverse device effects were assessed. Severity was graded as mild, moderate, or severe and defined as not related, possibly related, probably related, or definitely related to the study device, respectively.

One SAE was documented in Subject 12. The patient (3.4%) died of a complication from gastric surgery. The SAE was not device related. One SAE (3.4%) was also reported in

Table 1

SUMMARY OF THE 24 MONTH MAGNETIC RESONANCE IMAGE FINDINGS

Question	3 MONTHS (SPEED)		12 MONTHS (SPEED)		24 MONTHS (SPEED24)	
	Yes	No	Yes	No	Yes	No
Normal healing appearance (callus formation)?	96.7 %	3,3 %	100 %	0 %	100 %	0 %
Valgus correction maintained?	100 %	0 %	100 %	0 %	96.7 %	3.3 %
Any sign of foreign body reaction?	0 %	100 %	0%	100%	0 %	100 %

Table 2

RESULTS OF MRI FINDINGS. THE DATA FOR 3 MONTHS AND 12 MONTHS FOLLOW-UP WERE EXTRACTED FROM THE FINAL REPORT OF THE SPEED STUDY

Question	3 MONTHS (SPEED)		12 MONTHS (SPEED)		24 MONTHS (SPEED24)	
	Yes	No	Yes	No	Yes	No
Did the subject develop any adverse events since the last visit?	3.3 %	96.7 %	10 %	90 %	6.9 %	93.1 %
Has there been any change in medication since the last visit?	0 %	100 %	0 %	100 %	3.4 %	96.6 %
Any sign of foreign body reaction?	0 %	100 %	0%	100%	3.4 %	96.6 %

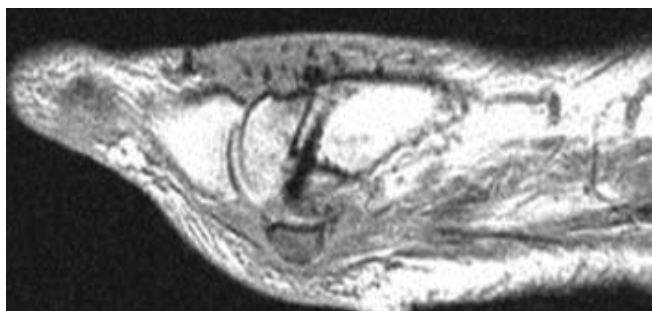


Figure 10. Magnetic resonance image after 3 months.

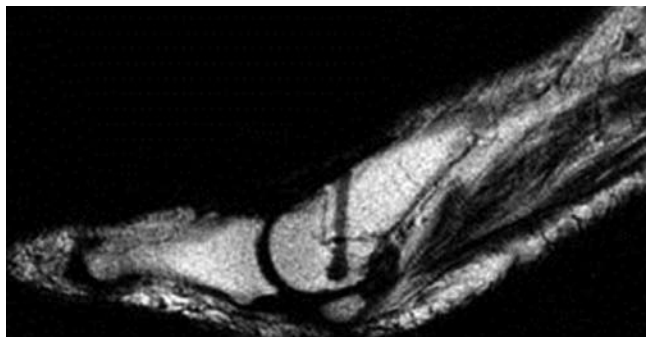


Figure 11. Magnetic resonance image after 12 months.

Subject 10. This patient with hallux rigidus underwent a joint preserving procedure with a Youngswick osteotomy. At 12 months, the osteotomy was healed completely but the patient suffered from arthritic plantar pain in the first metatarsophalangeal joint. This condition had to be treated with an arthrodesis of the respective joint. The adverse event was not device related.

Figures 13-15 show the status of subject 10 at 3 months, 12 months, and 24 months follow-up, respectively.

RESULTS

The outcome at follow-up visits are summarized in Table 2. Non-device related adverse events were observed on 6.9% of 29 patients (Subject 10 and Subject 12), the percentages on the field change in medication and additional procedures correspond to the arthrodesis performed on Subject 10.

DISCUSSION

Given the high incidence of hallux valgus, the Austin/Chevron osteotomy is a frequently performed procedure in foot and ankle surgery (17). Fixation is used routinely and achieved mainly with small tension screws (4). Screws, however, have a limited range of application due to the screw head geometry, threads and often necessitate a second surgery for removal (8, 10, 18). Polylactides as biodegradable materials have been used in the form of screws and press-fit pins. Their biomechanical stability could be greatly enhanced by fixing the polylactide pins by liquidation of their tips using ultrasonic energy, resulting in an interdigitation of the pin tips with the cancellous bone structures (10).

Until now, there has been limited clinical experience with biodegradable polylactide implants fixed by ultrasonic melting. Eckelt et al reported on the successful use of resorbable pins inserted with the aid of ultrasound in cranioplasty for 8 infants ages 12 months to 4 years with craniosynostosis (14). They observed a considerably shortened application time compared to screw fixation with increased stability (14). Aldana et al reported on the use of ultrasound-aided bone fixation with polylactide pins in 28 patients during craniotomies or craniofacial reconstructions (15). They achieved adequate stability with few complications and concluded that the system was easy to use and provided rapid fixation of implants (15). Reichwein et al reported on the application of the ultrasound-aided fixation of polylactide pins in 75 patients who were treated for fractures of the zygomaxillary complex, frontal bone impression fractures, mukocoele in the frontal sinus, isolated

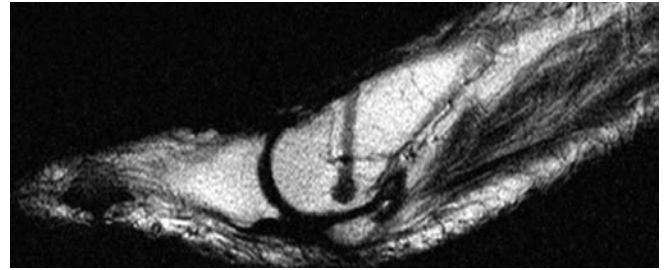


Figure 12. Magnetic resonance image after 24 months.

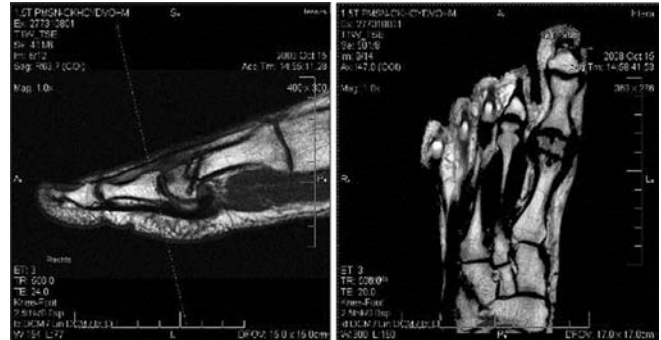


Figure 13. Patient 10, 3 months postoperative lateral magnetic resonance image (left). Patient 10, 3 months postoperative antero-posterior magnetic resonance image (right).

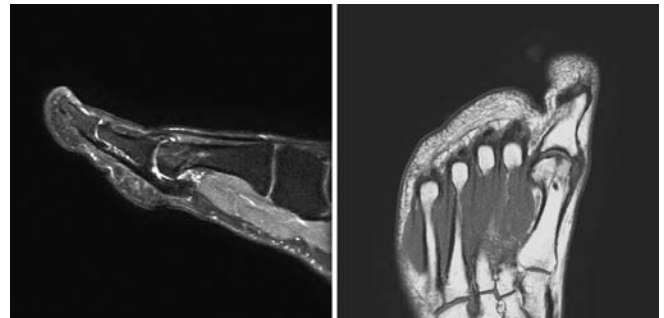


Figure 14. Patient 10, 12 months postoperative lateral magnetic resonance image (left). Patient 10, 12 months postoperative antero-posterior magnetic resonance image (right).

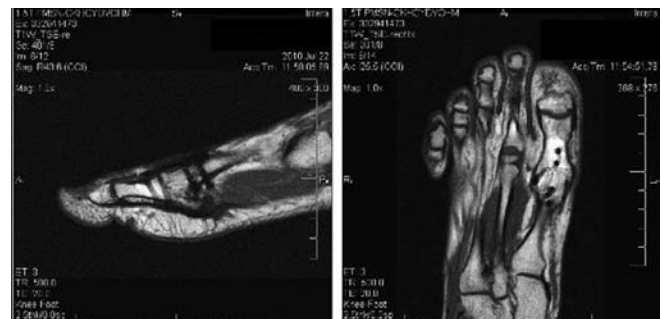


Figure 15. Patient 10, 24 months postoperative lateral magnetic resonance image (left). Patient 10, 24 months postoperative antero-posterior magnetic resonance image after first metatarsophalangeal joint fusion with VariAx locking plate system (right).

fractures of the orbital floor, complex midfacial trauma and bone cap fixation, craniosynostoses, and fixation of a distracted bone fragment (16). They concluded that this fixation system showed general feasibility, sufficient mechanical stability, and efficient intra-operative handling for a wide variety of indications in craniomaxillofacial surgery (16).

This study was designed to assess the safety and performance of the use of SonicPin for the fixation of Austin/Chevron osteotomies following 24 months after the surgical procedure. Generally, the results seen in this study were similar to the standard fixation of Austin osteotomies with K-wires or screws. The SonicPin maintained the alignment and fixation of the osteotomy in 96.7% of the cases. The mixture of the Polyactids PLDLA (70:30 L/LD) causes a slow resorption with a minimal decrease of the PH-value. This seems to be the reason for the absence of foreign body or any inflammatory reactions.

There are no special precautions needed when using the SonicPin compared to standard fixation techniques, and considering that the SonicPin reduces the operation time, and avoids the potential need for future hardware removal, the risk-benefit ratio is clearly favorable for the SonicPin. Future studies should include a larger sample size and compare the SonicPin to standard fixation of an Austin osteotomy with K-wires or cannulated screws in a blinded and randomized manner in order to balance known and unknown factors that can influence the outcome. Furthermore, future studies could be expanded to include other fracture or osteotomy related indications.

In summary, fixation of an Austin/Chevron osteotomy with a SonicPin for treatment of hallux valgus can be considered to be safe and clinically effective when used as intended by the manufacturer, based on the low complication rate and based on the fact that it maintained effectively the alignment of an Austin/Chevron osteotomy after 24 months of the intervention in most of the cases reported in this study.

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