

Ultrasound-aided fixation of a biodegradable cranial fixation system: uses in pediatric neurosurgery

Technical note

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Object. Bioresorbable implant systems have been used in neurosurgery for the rigid fixation of cranial and facial bones. A relatively recent advancement has been the fixation of these implants using an ultrasonic device. The experience with such a device in neurosurgical practice has been limited. The authors report on their experience with ultrasound-aided fixation of bioresorbable implants in pediatric neurosurgical practice.

Methods. The study consisted of 2 parts. The retrospective portion consisted of a chart review of pertinent clinical information, complications, and outcomes after the use of a commercially available ultrasound-aided bioresorbable implant system (SonicWeld Rx, KLS Martin L.P.). Follow-up was obtained in all patients via clinical examination or telephone interview. The prospective portion of the study consisted of video analysis of the implantation technique in a routine craniotomy. Implantation times were measured, and delays during treatment were noted.

Results. Over a period of 2 years, 28 consecutive patients underwent placement of these implants for bone fixation during craniotomies or craniofacial reconstructions. The only complication was seen in a child with Crouzon syndrome, who had a wound infection caused by *Serratia* sepsis from a central venous line infection. There were no repeated operations for implant-related swelling, and no cases of premature plate resorption, bone instability, or settling. In vivo, the average time required to implant a resorbable pin with this system was 22 seconds.

Conclusions. The use of a bioresorbable implant system with ultrasound-aided pin fixation in pediatric neurosurgery cases achieved adequate stability with few complications. This system was easy to use and provided rapid fixation of implants. (DOI: 10.3171/2009.2.PEDS08230)

KEY WORDS • ultrasound-aided fixation • biodegradable implants •
craniofacial surgery • pediatric neurosurgery

THE surgical fixation of bones of the skull and the face has evolved over time. One of the first methods of fixation consisted of securing the bone flap to the craniotomy using sutures. A limitation of using sutures alone to secure a bone flap, even in a routine craniotomy, is that the stability provided is weak.⁸ As such, some authors do not recommend simple suture fixation alone for the convex portion of the cranial vault.^{8,13} Compared to suturing, wire fixation confers more stability and rigidity to the bone flap. These methods remain widely used in pediatric neurosurgery.

Metal plates and screws were later developed, providing instantaneous rigid fixation of the bone. This remains a popular method of fixation, particularly in cases in which immediate structural support of these bone frag-

ments is needed (such as skull base and craniofacial surgery). Permanent metal fixation devices, however, carry the risk of intracranial migration with growth as well as skin erosion.¹

Resorbable bone fixation systems were developed in the 1990s and have gained wide use in pediatric cranial and facial surgery.^{4,7} These systems are made from polymers of polylactic or polyglycolic acid that are initially rigid but completely resorb with time through local inflammation and hydrolysis. The polymers are fabricated into various plates or meshes and secured to the skull or facial bone with resorbable fixtures, usually screws or tacks. Such systems have the advantage of immediate rigid fixation without the use of long-term implants.

Rigid fixation of the resorbable systems has been

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achieved using screw- or tack-based methods. Resorbable screws require bone drilling and tapping prior to screw placement, and poor screw purchase can occur if the proper technique is not used.¹⁰ Tack fixation requires that a significant amount of force be applied to the tack to drive it securely into the bone; this can be difficult on a pliant infant skull.

Ultrasound-aided fixation of bioresorbable implants is a recently developed alternative method. A bioresorbable pin is mounted to the tip of a device which then vibrates the pin to ultrasonic speeds. As the vibrating pin is inserted into the hole drilled into the bone, the friction generated at the pin–bone interface causes the pin edges to melt into the bone, effectively welding the 2 surfaces. The commercially available system (SonicWeld Rx, KLS Martin L.P.) consists of D- and L-isomers of polylactic acid.

The use of this system has been reported in 8 infants with craniosynostosis, with good results.³ Advantages of this system compared to screw fixation include reduced application times and increased strength.¹⁰

The purpose of the present study was to evaluate the use of this ultrasound-aided bioresorbable implant system in pediatric neurosurgical practice. Our goal was to examine the implantation technique, clinical results, and complications associated with the use of this system.

Methods

Fixation Method

Briefly, the method of bone fixation involves drilling holes in the cranium using presized, disposable drill bits that are part of the SonicWeld Rx system (Fig. 1). A variety of plates and meshes are available for fixation. We prefer to use 1.0-mm-thick mesh plates that can be molded and shaped in a heated water bath. These plates can be trimmed with a heating pen that comes as part of the set.

The ultrasonic device used to implant the pins consists of a handpiece (Sonotrode) whose tip the resorbable pin is mounted to. This sterile Sonotrode is attached to a base unit that generates the ultrasonic frequency (SonicWeld Rx). The handpiece and the pin are then inserted through the hole in the plate or mesh and into the cranium. The SonicWeld Rx is activated with a foot switch, causing the tip of the Sonotrode to vibrate with the pin. This is then seated into the bone with minimal pressure and melted into the bone edges. After complete pin insertion, the foot pedal is released and gentle pressure on the pin and handpiece is maintained for 1–2 seconds prior to withdrawal of the handpiece. This allows the pin to set in the hole. If the Sonotrode is withdrawn prior to this, the pin can be pulled out with it. In our experience, the purchase on the bone achieved with this method is solid and requires only 2–3 pins on either side of a mesh containing 2 columns of holes.

Study Method

A retrospective review of medical records at the University of Florida at Jacksonville Pediatric Neurosurgery Center was performed. All patients 18 years of age or younger who received the SonicWeld Rx implantation sys-

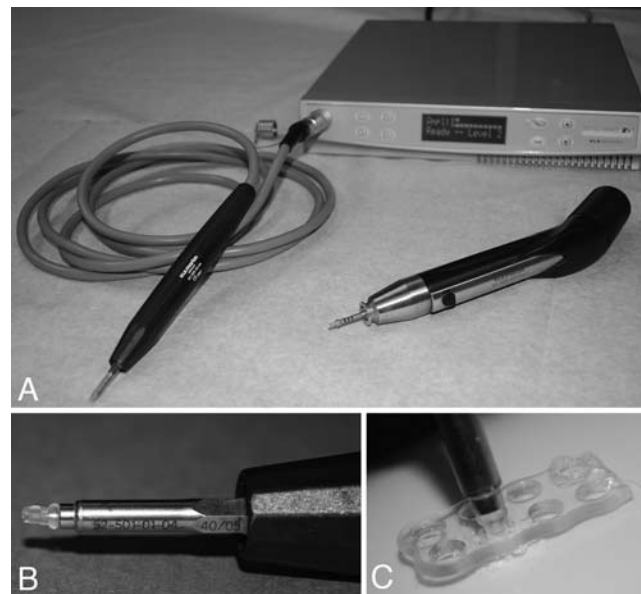


FIG. 1. Photographs of ultrasound-aided implantation equipment. A: The ultrasonic handpiece (Sonotrode) is connected by a cable to the base unit (SonicWeld Rx). The handheld drill with disposable drillbit is to the right of the handpiece. B: The resorbable pin is securely mounted to the tip of the handpiece. C: The pin is shown being welded into place with the handpiece.

tem were included. The follow-up period ended with the last clinical visit or telephone interview. Medical records were supplemented with telephone interviews of the patient's family when necessary. Palpable bone flap settling, cosmetic results, and parent feedback were noted over time, in addition to complications.

Video analysis of the implantation technique was performed. The use of this ultrasound-aided bioresorbable implant system was videotaped during a single frontoparietal craniotomy. The video was then used to examine the process of implant placement for bone fixation. The times to drill and weld each absorbable pin were measured, as were the total times for implantation of each pin. Problems with implantation were also noted.

Results

Over a 2-year period, 28 consecutive patients received ultrasound-aided bioresorbable implants placed during craniotomies or craniofacial procedures. The patients ranged in age from 2 months to 18 years, with a mean of 5.5 years. The median follow-up period was 11.5 months (range 1–22 months); 25 patients had follow-up periods ≥ 6 months. The implants were used in 12 cases of craniosynostosis, 9 tumors, 4 traumatic injuries, and 3 congenital cysts.

Patient Outcomes

A craniotomy infection developed in 1 patient. This patient had Crouzon syndrome, and *Serratia* sepsis first developed from an infected femoral venous catheter the week after craniofacial reconstructive surgery. The craniotomy wound cultures grew *Serratia* a week later. She underwent wound debridement and removal of the re-

sorbable plates, but we were unable to fully remove the pins. The patient became infection free after a course of intravenous antibiotics.

There were no cases of palpable bone flap settling, nor were there returns to the operating room related to device failure or severe subcutaneous swelling caused by the plates. During early postoperative visits, parents often inquired about the prominences related to the plates that were evident once postoperative swelling subsided. The majority of patients (26 out of 28) had cosmetic results deemed acceptable by their parents. However, in 2 cases, raised areas (≤ 5 -mm height) developed in the scalp overlying the implanted plates at 9–10 months postoperatively. Although the swelling resolved spontaneously over a 4-week period, it was significant enough to raise the parents' concern, prompting a clinic visit for reassurance.

Pin Implantation Process

Fifteen 5-mm length pins were implanted in 1 craniotomy. For each pin, the average time to drill a pinhole was 6 seconds, the average weld time was 9 seconds, and the average time to completely implant the pin was 22 seconds.

The bone flap was secured to the craniotomy defect by cutting a 126-mm strip of 2-hole mesh into 3 shorter strips, 4 holes in length. Bone flap replacement took just under 10 minutes. In all but 1 pin solid bone purchase was achieved in the first attempt at fixation. The pin that required reimplantation was pulled out with the Sonotrode before it had time to set.

Some minor problems were observed. In 2 instances the ultrasonic-aided welding device (SonicWeld Rx) was not adequately connected to the generating unit. This resulted in an ~ 30 -second delay for the ultrasonic-aided welding device to complete its start up process. Only in 2 instances did pins that were mounted on the Sonotrode fall, resulting in the wasting of the 2 dropped pins.

Cost Estimates

Cost estimates were obtained from the manufacturer (KLS Martin L.P.). An itemized breakdown of the cost of the disposable items used to fixate a convexity bone flap, including 15 resorbable pins, a single mesh strip divisible into 3 shorter strips, and the drill bit and battery for the drill is displayed in Table 1. The total cost of this was estimated at \$1673.00. At our institution, the implantation instruments (Sonotrode and drill) were provided at no cost as part of a start-up package, a practice that the manufacturer offers to all institutions.

Discussion

We found that ultrasound-aided pin fixation of rigid bioresorbable implants in pediatric cranial surgery provides rigid bone fixation with few complications. Furthermore, the current system allows for pin implantation in only 2 steps, eliminating the need to tap a screw thread or turn the screw, allowing for rapid placement.

In this series of 28 pediatric patients who underwent procedures for various pathological entities, only 1 perioperative craniotomy complication was encountered. This

TABLE 1: Itemized breakdown of the cost of the disposable SonicWeld Rx items used to fixate a convexity bone flap

Item	Quantity	Unit Price (US \$)	Total
mesh strip	1	450.00	450.00
1.6 × 4 mm pins (5-pack)	3	345.00	1035.00
drill bit (1.0 × 4.0) & 4-mm stop	1	120.00	120.00
drill battery	1	68.00	68.00
total cost			1673.00

was seen in a patient with Crouzon syndrome in whom a craniotomy infection developed following *Serratia* sepsis from a femoral central line infection. No cases of palpable bone flap settling were seen, nor were there any device failures. No patients required repeated operations because of device failure or granuloma formation. The appearance of the patients was cosmetically acceptable to the majority of parents, except in 2 cases in which swelling over the plates developed in a delayed fashion 9–10 months postoperatively. The swelling resolved spontaneously ~ 4 weeks after onset.

The implantation of 15 pins in a single craniotomy using the ultrasound-aided method was quick, taking an average of 9 seconds to weld, and an overall average placement time of ~ 20 seconds for each pin. This method was also efficient, with all but 1 pin implanted satisfactorily on the first attempt.

The use of resorbable implant systems for cranial and facial fixation has gained widespread use over the years. A survey of pediatric neurosurgeons identified absorbable plates as the most commonly used method of fixation for closure of cranial defects, and the second most common form of fixation in routine craniotomies, second only to sutures.²

The use of suture alone for bone flap fixation has been shown to be unstable when applied forces of < 25 N during load bearing tests.⁸ Winston and Wang¹² reported an improvement over the technique over simple suture fixation by tightly wedging small fragments of bone or shims between the bone flap and craniotomy margin. This technique provides additional stability to the bone flap and prevents settling. It is difficult, however, to achieve stability of bone fragments using suture fixation when separation or distraction of bone fragments is important, such as for craniofacial reconstruction. This is much more easily achieved with the rigid plating of the bone, which provides for a more stable construct.

Metal plates and screws (stainless steel or titanium) provide rigid fixation and stability; however, in addition to causing artifact in radiographic imaging studies, they can migrate intracranially, cause pain due to their prominence under the skin, and restrict cranial growth.^{1,11}

Resorbable implant systems for cranial fixation were introduced in 1996. Commercially available systems use polymers of polylactic or polyglycolic acid, are fabricated into various plates, meshes, or buttons, and affixed to the bone using screws, tacks, or pins. The material is then degraded initially by local hydrolysis followed by local inflammatory reaction, primarily through phagocytosis. Device-related

complications are rare (< 1%) and these can include device failure secondary to external trauma, delayed foreign body reactions, and granuloma formation.^{4,6} In general, however, bioresorbable implants for cranial fixation are well tolerated and produce good cosmetic results without associated metallic artifacts on radiographic imaging, and eliminate the problems associated with permanent metal implants such as intracranial migration and restriction of bone growth.

One of the limitations of these biodegradable implant systems is the method of fixation of the plates or mesh to the skull. The screw-based fixation requires tapping of the screw threads before insertion because the screws are not self-tapping. This step, particularly if multiple screws are involved, can be quite onerous and result in hand fatigue, as reported by authors of a case series of 1883 patients.⁴ Furthermore, the screw heads can fracture from the shaft if the length of the threaded screw path is inadequate or if the longitudinal axis of the screw is not aligned with the threaded screw path in an orthograde fashion.¹⁰ The hand tapping of the thread can be time consuming, and together with screw placement requires downward pressure, which adds to the difficulty of placement in a pliable infant skull.

Tack fixation was developed as an alternative to screw fixation. Its advantage is that it eliminates the need to cut threads in the bone, reducing the time to fixate the plate. A limitation of this technique is that the tacks require a significant amount of downward pressure to be driven securely into the bone.⁵ This is usually achieved using some form of piston-like device that delivers a sharp blow to the tack head, driving it into the bone. It often takes more than one application of downward force to seat the tack completely. In addition, the head of the tack can fracture from the shaft when struck by the tack applicator if the tack and skull insertion hole are poorly aligned. A cortical "pull-back" has been described in the literature that is implanted by pulling back on the rivet rather than pushing it into the bone, but this is not commercially available.⁵

Ultrasound-aided fixation using resorbable pins is an alternative to screws or tacks in the fixation of bioresorbable plates or meshes. The pin is welded into the bony trabeculae, with minimal pressure. An experiment in sheep skulls revealed several advantages of this system over resorbable screw fixation.¹⁰ The total implantation time for 20 pins using ultrasound-aided fixation was 317 seconds, which is half the time required for placement of the same number of screws. The fixation time for each pin averaged ~ 16 seconds per pin in this laboratory study, which is comparable to the 22-second per pin operative time we measured in vivo. Furthermore, the study on sheep skulls showed that ultrasound-aided pin fixation has significantly increased mechanical stability compared to screw fixation when the pin is subjected to distraction, bending, and lateral shear forces. The reaction in the bone surrounding the implanted pin has been examined histologically.⁹ That study discovered no evidence of thermal-induced damage to the surrounding tissue, and found the pins to be bordered by viable and active osteoblasts. To date, our study has the largest number of patients in whom ultrasound-aided fixation of bioresorbable implants was used, with 28 patients 18 years of age or younger. Eckelt et al.³ in 2007

reported on their experience using the same technique in 8 children for correction of craniosynostosis. In all cases, good pin stability was achieved. One patient required a repeated operation because of device failure, and it was concluded that the mesh used to support the cranial fragments failed because it had been too thin. There were no reported problems with infection or wound healing. Device failure was not seen in any of our 12 cases of craniosynostosis despite our use of the same mesh thickness as reported in Eckelt and colleagues' study. This may be due to differences in the number or technique of placement of the plates and pins. Overall, the low incidence of device-related complications in this previous series compares similarly to our experience.

Study Limitations

There are several limitations to this study. Although our median follow-up period was 11.5 months, and almost 90% of our patients had follow-up times ≥ 6 months, this may not have been enough time for the development and manifestation of delayed foreign body reactions, which have been reported to present up to 2 years after implantation. To date, however, this complication has not been reported in the literature for systems composed of D- and L-poly lactate isomers, such as the one we used. Whether this complication will occur with this system remains to be seen. The cosmetic outcomes were assessed on the basis of clinical examination and parent feedback, not by objective imaging studies or photographs. Although this particular outcome was measured subjectively, both the surgeon and parent were in agreement with the outcome, which is what occurs during routine clinical practice.

The use of ultrasound-aided pin fixation of bioresorbable implants in this study for craniotomies other than craniofacial operations reflects our own practice bias. It is recognized that other forms of bone fixation are adequate. For routine craniotomies, suture fixation is more economical and remains the preferred method of most pediatric neurosurgeons.²

Conclusions

We have shown that our experience with bone fixation of the pediatric skull and face using a bioresorbable implant system with ultrasound-aided pin fixation is safe and effective in a variety of pediatric neurosurgical procedures. Fixation of the bone is rapid, efficient, and stable, providing satisfactory cosmetic results over time.

Disclosure

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References

1. Berryhill WE, Rimell FL, Ness J, Marentette L, Haines SJ: Fate of rigid fixation in pediatric cranial surgery. *Otolaryngol Head Neck Surg* **121**:269–273, 1999
2. Dickerman RD, McConathy WJ, Pearl NA, Stevens QE, Cohen A, Schneider SJ: Pediatric cranial fixation: a survey of pediatric neurosurgeons. *J Craniofac Surg* **13**:769–771, 2002

3. Eckelt U, Nitsche M, Müller A, Pilling E, Pinzer T, Roesner D: Ultrasound aided pin fixation of biodegradable osteosynthetic materials in cranioplasty for infants with craniosynostosis. **J Craniomaxillofac Surg** **35**:218–221, 2007
4. Eppley BL, Morales L, Wood R, Pensler J, Goldstein J, Havlik RJ, et al: Resorbable PLLA-PGA plate and screw fixation in pediatric craniofacial surgery: clinical experience in 1883 patients. **Plast Reconstr Surg** **114**:850–856, 2004
5. Eppley BL, Pietrzak WS: A resorbable rivet system for pediatric craniofacial surgery: biomechanical testing and clinical experience. **J Craniofac Surg** **17**:11–14, 2006
6. Kumar CR, Sood S, Ham S: Complications of bioresorbable fixation systems in pediatric neurosurgery. **Childs Nerv Syst** **21**:205–210, 2005
7. Kurpad SN, Goldstein JA, Cohen AR: Bioresorbable fixation for congenital pediatric craniofacial surgery: a 2-year follow-up. **Pediatr Neurosurg** **33**:306–310, 2000
8. Lerch KD: Reliability of cranial flap fixation techniques: comparative experimental evaluation of suturing, titanium miniplates, and a new rivet-like titanium clamp (CranioFix): technical note. **Neurosurgery** **44**:902–905, 1999
9. Pilling E, Mai R, Theissig F, Stadlinger B, Loukota R, Eckelt U: An experimental in vivo analysis of the resorption to ultrasound activated pins (Sonic Weld) and standard biodegradable screws (ResorbX) in sheep. **Br J Oral Maxillofac Surg** **45**:447–450, 2007
10. Pilling E, Meissner H, Jung R, Koch R, Loukota R, Mai R, et al: An experimental study of the biomechanical stability of ultrasound-activated pinned (SonicWeld Rx+Resorb-X) and screwed fixed (Resorb-X) resorbable materials for osteosynthesis in the treatment of simulated craniosynostosis in sheep. **Br J Oral Maxillofac Surg** **45**:451–456, 2007
11. Sanus GZ, Tanriverdi T, Kacira T, Jackson IT: Effects of rigid fixation on the growing neurocranium of immature rabbits. **J Craniofac Surg** **18**:315–324, 2007
12. Winston KR, Wang MC: Cranial bone fixation in infants and children. **Pediatr Neurosurg** **31**:225–230, 1999
13. Winston KR, Wang MC: Cranial bone fixation: review of the literature and description of a new procedure. **J Neurosurg** **99**:484–488, 2003

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