Clinical Experiences With Resorbable Ultrasonic-Guided, Angle-Stable Osteosynthesis in the Panfacial Region

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Purpose: In this study we report our experiences with the treatment of midfacial fractures and various other indications in regions with low load bearing (eg, dysmorphias) using the biodegradable Osteosynthesis System (SonicWeld Rx by KLS Martin, Tuttlingen, Germany), comprising biomechanical and histological aspects.

Patients and Methods: Seventy-five patients were included in this study. We describe the application of this system for the treatment of fractures of the zygomamaxillary complex, frontal bone impression fractures, surgical treatment of mukocele in the frontal sinus, isolated fractures of the orbital floor, complex midfacial trauma and bone cap fixation, craniosynostoses, and fixation of a distracted bone fragment.

Results: The pin insertion could be finished with a total failure rate of lower than 5%. In 3 patients, soft tissue swellings in regions with less subcutaneous fat were observed 6 to 8 months postoperatively. No fracture dislocations occurred. Scanning electron micrograph of the experimentally acquired connection between the resorbable plate and 2 pins clearly demonstrates a tight and reliable fusion to bone, both at the cortical as well as at the spongy compartment. Conventional histology leads to corresponding findings as scanning electron micrography, and shows a close fusion between all components.

Conclusion: This retrospective study shows the general feasibility, sufficient mechanical stability, and efficient intraoperative handling of this angle-stable, ultrasonic-guided resorbable Osteosynthesis System (ResorbX and SonicWeld Rx) for a wide variety of indications in craniomaxillofacial surgery.
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J Oral Maxillofac Surg 67:1211-1217, 2009

Osteosynthesis is a well-established technique in craniomaxillofacial surgery. Titanium is used for fixation and stabilization of facial fractures. Removal of the osteosynthesis material may be necessary for screw and plate loosening or palpations under tender skin and discomfort of the patient in the midface.[1,2]

Also, the plates and screws may cause imaging artifacts in computed tomography (CT).[1] Titanium osteosynthesis plates are only necessary for the stabilization of the fracture and during the healing period. After this period the plates and screws can be removed.

Resorbable osteosynthesis materials may avoid these shortcomings of the titanium osteosynthesis material.[3-5] Nevertheless, mechanical stability as well as handling is a limitation of their application in trauma treatment in the face.[3] Therefore, resorbable osteosynthesis materials are primarily recommended for anatomical areas with minor mechanical load.[4,5] The required heat-activating process and the thread-tapping can especially hamper the surgical workflow. Most common raw materials for the fabrication of biodegradable materials are polymers and copolymers of glycolic

Received from the University Hospital of Cranio-Maxillofacial and Oral Surgery, Medical University of Vienna, Vienna, Austria.

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0278-2391/09/6706-0010$36.00/0
doi:10.1016/j.joms.2008.12.033

acid (polyglycolid, PGA), lactic acid (polylactid, PLA), and mixtures of D- and L-lactides (PDLLA).[6-8] The biodegradation of resorbable osteosynthesis depends on 2 main factors: the composition of the material itself and the surrounding tissue. The manufactured combination determines the properties as biomechanical stability and biochemical decomposition of the osteosynthesis plates. Complications that have to be considered with biodegradable materials are soft tissue swelling, foreign body reactions, sterile fistulas, and osteolysis.[9] A crucial criterion for the application of resorbable plates and screws in craniomaxillofacial surgery is their mechanical stability at least for the duration of 10 weeks, during the time of fracture healing.

Fixation of the plates with resorbable screws requires tapping a thread. This makes the application of resorbable plates very difficult, especially in the thin bone of the midface. To avoid this additional step would improve and facilitate the application of a resorbable system. A new application system by welding a special configured resorbable pin though ultrasound may overcome the disadvantages of thread tapping. With the advantage of only a 2-step procedure, without cutting a thread into the bone the resorbable pin is welded in the corticospongy structure of the bone, using an ultrasonic tool. The resorbable plates and pins are commercial products and consist of an amorphous Poly (D-,L-) lactide.

We report on the application of this new resorbable system (SonicWeld Rx by KLS Martin, Tuttlingen, Germany) for the treatment of different fracture types in the midface and craniofacial region. We also describe our experiences with numerous indications in regions with low load bearing (eg, dysmorphias). Our documentation comprises intraoperative handling, mechanical aspects, and an histological examination of the interactions between the material and the bone.

Patients and Methods

PATIENTS

During July 2002 to December 2007, 75 patients were operated on for midface fractures. Their ages ranged from 7 months to 63 years (mean age: 34.5 years; 59 male, 16 female). They were included in this study after having signed informed consent. We describe the application of this system for the following, various indications: fractures of the zygomamaxillary complex, frontal bone impression fractures, surgical treatment of mukocele in the frontal sinus, isolated fractures of the orbital floor, complex midfacial trauma, and bone cap fixation, craniosynostoses, and fixation of a distracted bone fragment (Fig 1).

The patients were treated by 16 surgeons who had different levels of experience and who consider potential effects of a learning curve in the handling of the ultrasonic device. For fracture treatment the SonicWeld Rx system was used.

THE SONICWELD RX OSTEOSYNTHESIS SYSTEM FOR THE FIXATION OF RESORBABLE PLATES (RESORBX)

The application of this system is based on 2 components: the already well-established resorbable plate and mesh system, ResorbX, in combination with a new special configured pin system, SonicWeld Rx. The resorbable material is composed of a fully amorphous polymer, consisting of pure PDLLA (D-lactide [50%] and L-lactide [50%]).[6,8] Therefore, both components (pin and plate) can melt together and weld into the bone. The geometrical design has been optimized according to Finite Element analyses to fulfill the biomechanical requirements for the distinct applications. The pin (which replaces the screw known from other systems) is inserted by means of an ultrasonic handpiece (the so-called sonotrode) in a 2-step procedure (Fig 2). After surgical reposition the plate is adapted by "heat activation" in a water quench. The plate is fixed by "screw" (ie, the pin) using the sonotrode. It welds the pin into the corticospongy microstructure of the bone. At the same time the pin head melts together with the resorbable plate or mesh to provide a stable plate-pin complex. Consequently, no thread drilling in the bone and material is required.

Pins are available in various dimensions, with diameters ranging from 1.6 to 2.4 mm and lengths from 4.0 to 9.0 mm, and are compatible with the established ResorbX system.

Evaluation and follow-up was done by a special documentation form that was filled in for every operation

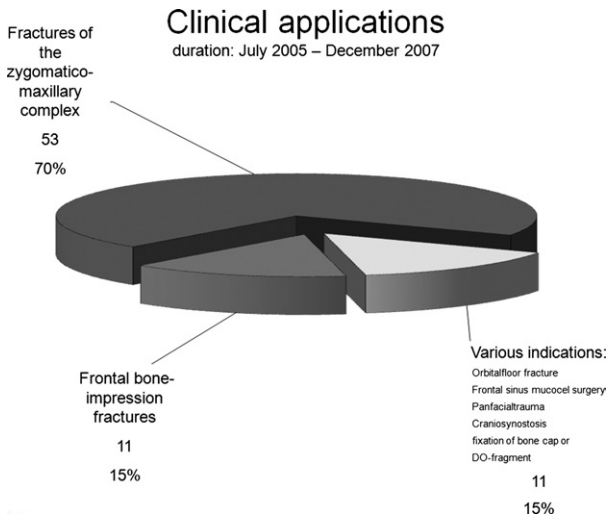

FIGURE 1. Indications for the application of SonicWeld Rx in this study.

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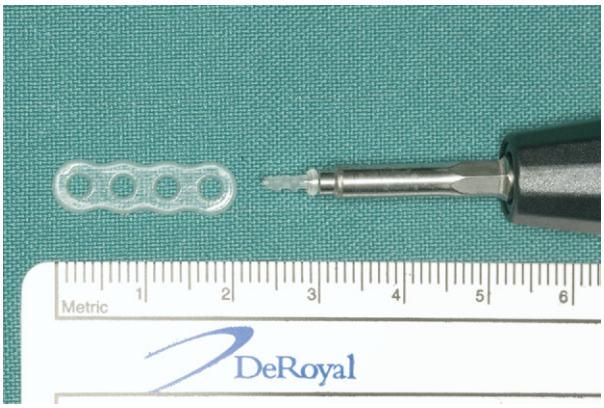

FIGURE 2. Components of the new resorbable osteosynthesis system: ResorbX 4-hole plate (*left*) and a SonicWeld Rx 2.0 pin attached to the sonotrode handpiece (*right*). The head of the pin is specially designed to fit reliably to the ultrasonic handpiece.

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by the surgeon to report on "welding problems" and other potential intraoperative technical shortcomings or complications. Furthermore, the conventional surgical reports are considered in the evaluation.

The postoperative follow-up comprises a period of 30 months (from June 2005 until December 2007), where we thoroughly document clinical findings like swelling and infections. Mechanical stability is assessed on the basis of postoperative native radiographs or computed tomographies (CTs) (depending on the indication). These findings are considered in the evaluation as well as the status of wound healing and the occurrence of soft tissue dehiscencies. Additionally, clinical judgement of this innovative technology is based on scanning electron microscopic analyses and conventional microscopy of tissue samples

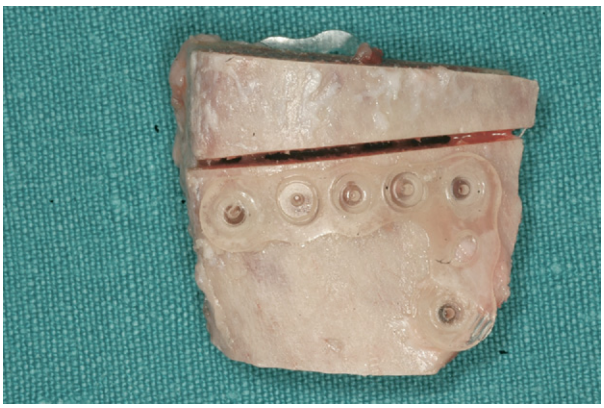

FIGURE 3. Iliac crest bone with ResorbX 7-hole L-plate, fixed with 6 SonicWeld Rx 2.0 pins. On the opposite side a mesh has been attached (not visible). This specimen was used for scanning electron microscopic and histological investigation as described in Figures 5 and 6.

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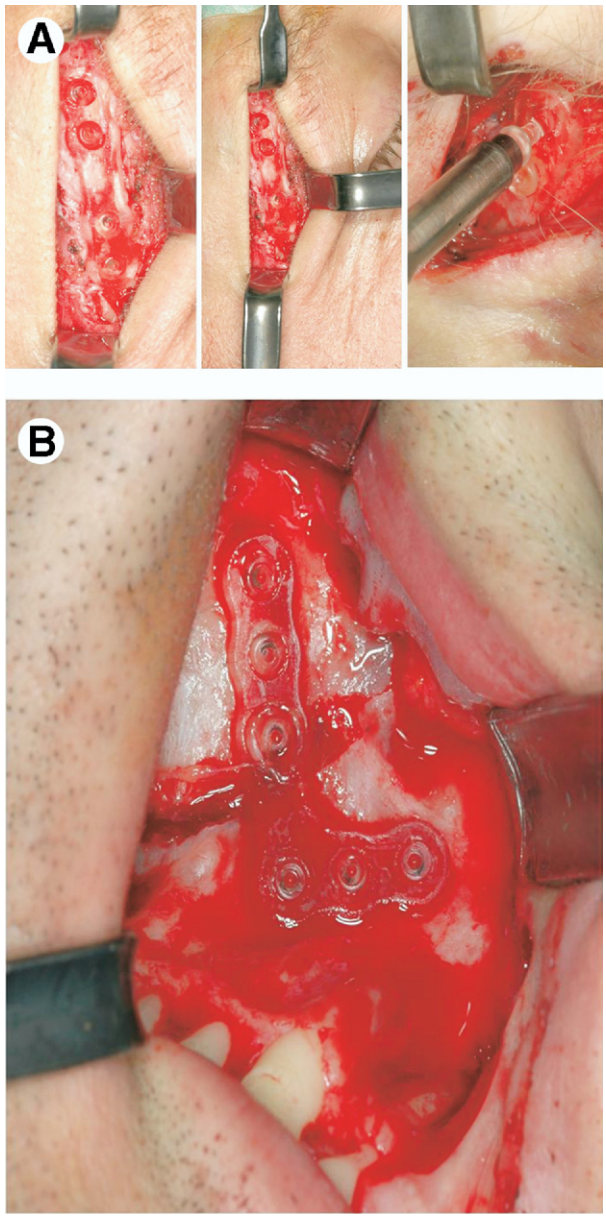

FIGURE 4. *A*, Right-sided zygoma fracture: intraoperative view on the lateral eyebrow after osteosynthesis with SonicWeld Rx pins and a 4-hole ResorbX plate after repositioning at the frontozygomatic suture. *B*, Intraoral view in the same case after surgical treatment with a 7-hole plate.

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(taken from the bone bank) from locations where interactions between human bone and the resorbable materials take place. The bone material had been stored in the bone bank for little more than 1 year; therefore, it could not be used as augmentation material to a patient anymore due to legal regulations. These tissue samples have been prepared in the operating theatre under realistic OR conditions. A 7-hole L-plate was fixed with 6 pins on 1 side of the iliac crest sample, and a mesh piece (4 × 2

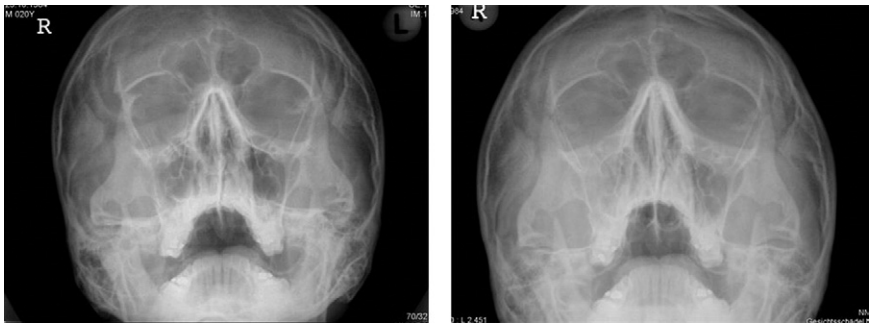

FIGURE 5. Pre- (*left*) and postoperative (*right*) Water's projection of the patient presented in Figure 4.

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holes) with 2 pins on the other side. The specimen was cut directly in the plane of the pin axis for analysis by electron microscopy and conventional histology (Fig 3). To avoid melting artifacts caused by the saw we applied water cooling. For scanning electron microscopy, the specimen was fixed in 2.5% glutaraldehyde (pH = 7.4), dehydrated in a graded ethanol series, critical point dried, and sputter coated. Analysis was accomplished using an scanning electron microscope (JEOL JSM 6310, Tokyo, Japan), setting: 15 kV. For histology, the specimen was fixed in 4.5% formaldehyde, dehydrated in a graded ethanol series, and prepared by a modified cutting grinding technique.[9] The sample was stained with 1% thionine. We used the electron microscope investigation only as an additional illustration of the histology.

Data are presented by means of descriptive statistics.

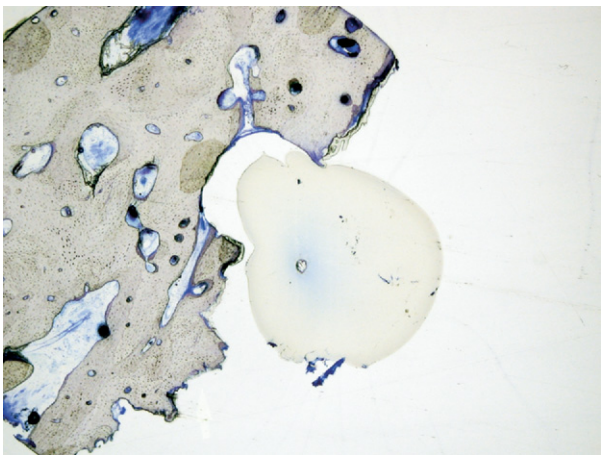

FIGURE 6. Histology 4 months postoperatively shows a bone segment from the paranasal pillar after osteotomy. Material has already been partially resorbed. (Cross-section along the pin axis, magnification ×2.)

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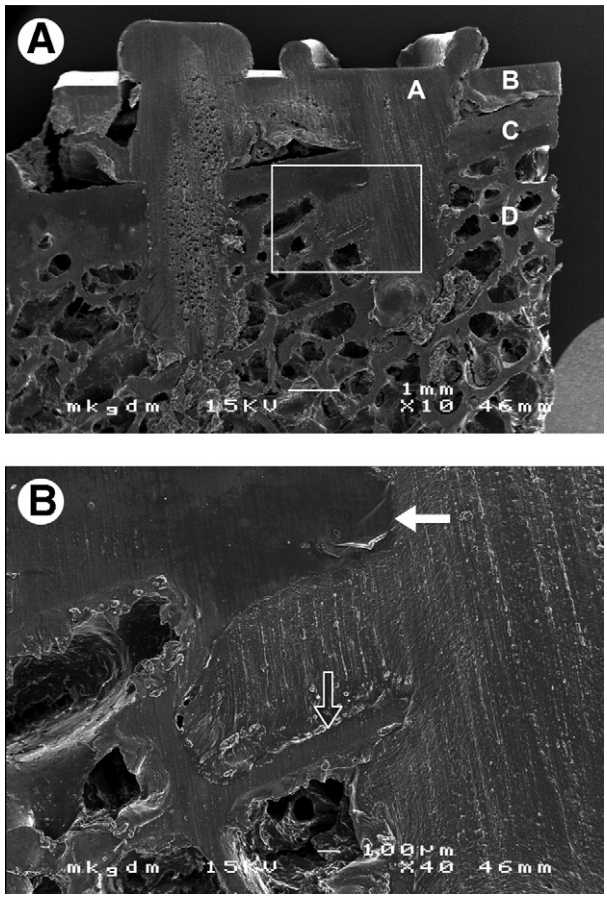

FIGURE 7. Scanning electron microscopy of the pin-mesh complex using the ultrasonic device ("welding into the bone and melting together with the plate"). *A*, SEM image at magnification ×10 clearly demonstrates the tight connection between mesh, pin and bone. A—Melted pin head, B—mesh, C—cortical bone, D—spongious bone. *B*, Detail of part *a*: magnification ×40. Fusion between osteosynthesis material and bone is almost complete at the trabecular (*upper white arrow*) as well as at the spongious site (*lower black arrow*).

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Results

In the course of the operations considered in this study, a total of 588 pins were inserted in a total of 75 patients.

INTRAOPERATIVE HANDLING

The pin insertion could be finished with a total failure rate of lower than 5% (24 pin failures). Besides a small number of "welding problems," other reasons for intraoperative complications were, in 1 case, the application of an improper drill; and in another case, the selection of an improper pin. For the treatment of midfacial fractures this osteosynthesis technique could successfully be used with the typical surgical approaches: transoral, extraoral (Fig 4), and minimally invasive. Sufficient surgical outcome could be verified by Water's projection in all cases of zygoma fractures (Fig 5).

POSTOPERATIVE FOLLOW-UP

In 3 of 75 patients (4.0%) soft tissue swellings in regions with less subcutaneous fat (eg, at the sutura frontozygomatica) were observed 6 to 8 months postoperatively. No fracture dislocations occurred. One patient with a centrolateral midfacial fracture suffered from severe postoperative pain in the paranasal pillar for several months. This patient underwent a second-stage operation to correct the post-traumatic nasal dysmorphia. In the course of this intervention the material, which had already been partially resorbed, was removed (Fig 6).

In 8 patients (10.7%) the resorbable system had to be combined with conventional titanium plates to achieve sufficient reposition results.

SCANNING ELECTRON MICROSCOPY (SEM)

An SEM micrograph of the experimentally acquired connection between the resorbable plate and 2 pins (melting procedure) clearly demonstrates a tight and reliable fusion to bone, both at the cortical as well as at the spongy compartment (welding procedure) (Figs 7, 8).

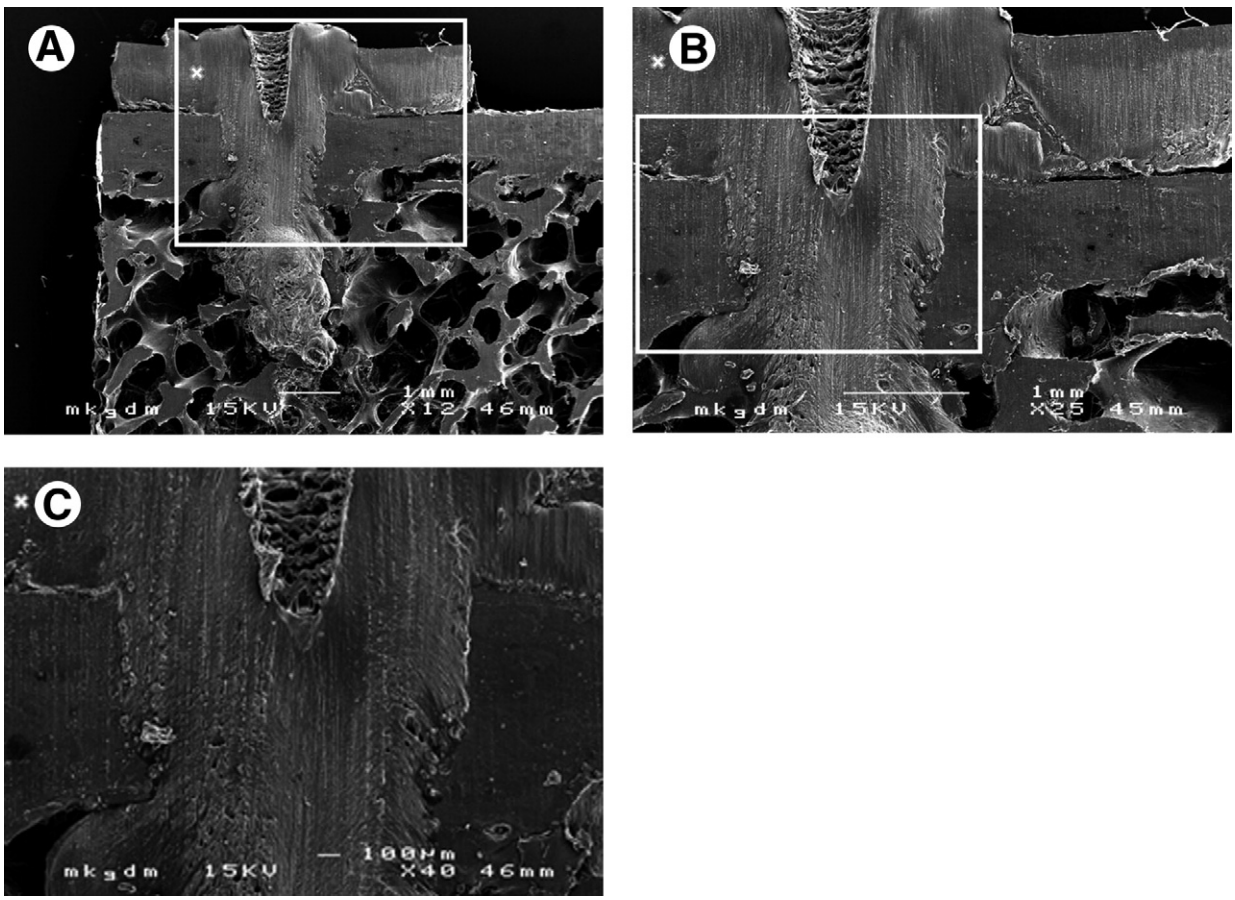

FIGURE 8. Scanning electron microscopy of the pin-plate complex. The melting process between pin head and plate is clearly perceptible. *A*, Magnification ×12 (*white frame*: detail as shown in *B*); *B*, magnification ×25 (*white frame*: detail as shown in *C*); *C*, magnification ×40. The *cross* indicates the melting zone.

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HISTOLOGY

Conventional histology leads to corresponding findings as SEM micrography and shows a close fusion between all components, the tight and stable junction between the material itself and the zone where the material pours into the bony microstructure is proven by the histological examination (Fig 9).

Discussion

Our results show that this resorbable osteosynthesis system with melting and welding procedure of the pin allows for safe intraoperative handling with a low complication rate. These findings correspond with other recent experimental as well as clinical reports.[7,10] The fact that 16 surgeons at different levels of experience participated in the study means that a successful utilization of this technology does not depend on specific skills, respectively, and that only a limited degree of training is required. Even this low intraoperative complication rate could be reduced when the documented reasons (eg, use of the wrong drill) are carefully considered in the future. Within this 2-step workflow it is not necessary to drill a thread into the bone and the plate (tapping procedure) to achieve a stable resorbable osteosynthesis. Consequently, this technology not only contributes to shorter durations of the surgical interventions, but also avoids a possible secondary dislocation caused by the tapping after reposition.

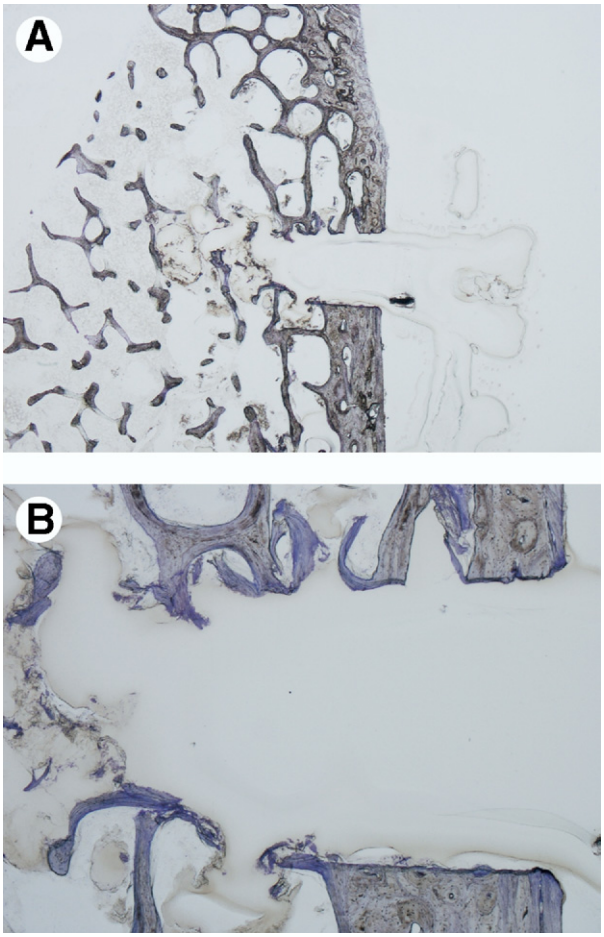

FIGURE 9. Histology proves the successful welding process of the pin at the experimentally acquired osteosynthesis site (1% thionine staining). *A*, Magnification ×1, *B*, magnification ×4.

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Probably the most relevant advantage of resorbable osteosynthesis systems is that there is no second-stage operation necessary to remove the material. Furthermore, we expect that this technique should not hamper the growth process, which is important for the treatment of children, for example, suffering from craniosynosthosis.[6] Of course, this must be investigated and confirmed in further long-time studies. Other known adverse effects of titanium osteosynthesis materials, like temperature-induced paraesthetic pain or interference with imaging modalities, can be avoided with resorbable plates and pins.[11,12]

In accordance with other studies,[7,13] our postoperative follow-up also showed sufficient mechanical stability in all the described indications. Pilling at al[7] quote in their experimental study the following significant advantages of ultrasound-assisted, resorbable pin osteosynthesis: optimum intraoperative handling, reduced insertion time, avoidance of fractures of the fixation elements, and higher 3-dimensional load capacity. The mechanical properties of the presented system are mainly determined by the combined melting-and-welding process, which is an innovative way to achieve a resorbable and more stable osteosynthesis. In this method the principle of angle-stability is realized through a rigid plate-pin complex and is also feasible with angulated pin insertion. Pins can also be inserted outside the predefined holes of plates or meshes, which is especially valuable, for example, at the facial wall of the maxillary sinus, in the course of minimally invasive procedures (eg, endoscopically assisted treatment of frontal bone impression fractures), or in other regions with spatial limitations.

In conclusion, this retrospective study shows the general feasibility, sufficient mechanical stability, and efficient intraoperative handling of this angle-stable, ultrasonic-guided resorbable Osteosynthesis System (ResorbX and SonicWeld Rx) for a wide variety of indications in craniomaxillofacial surgery.

Acknowledgments

We kindly acknowledge technical advice and support by Oliver Scheunemann (Gebrueder Martin GmbH & Co KG, Tuttlingen, Germany) and Frank Reinauer.

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