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A new system of resorbable rigid three-dimensional fixation using ultrasounds (Sonic Weld Rx + Sonic Pins Rx) adopted in craniofacial traumatology: the author's experience

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Aim. **In the last 30 years further advancements in treating craniofacial traumas were achieved by the introduction of new osteosynthesis systems as the resorbable materials. Initially plates and screws were made out of polylactic acid (PLLA), polyglycolic acid (PGA) and polydioxanone (PDS); recently they are made out of polylactic D-lactide and L-lactide (PLDLA, each 50%). A groundbreaking innovation occurred with the introduction of a new fixation technique using ultrasonic system (Sonic Weld Rx System) coupled with resorbable plates (Resorb Xs) and pins (Sonic Pins Rx). The aim of this was to analyze the advantages offered by this new system.**

Methods. **Since November 2006 until October 2008, at the Department of Maxillofacial Surgery of the University of Catanzaro (Italy), 26 patients with craniomaxillofacial traumas underwent surgery with the new Resorb-X SF system. Three patients had fractures of the frontal sinus wall, and in one case the fracture was associated with an midface fracture; 23 patients had only orbital-zygomatic-maxillary fracture, which in three cases were bilateral.**

Outcomes. **The authors noticed a 40% reduction of intraoperative timing. The technique used provides an excellent three-dimensional mechanical stability among plate, pins and bone; no thermal bone damage has ever been observed. The authors assessed the plates and screws resorption by ultrasonography, which took on average between 8 to 12 months.**

Conclusion. **The experience here reported enables to validate this system to manage fractures of the middle third of the face also in pediatric patients. As for its use in jaw fractures in pediatric patients, it cannot be validated except for single-sided fractures, compound fractures, mesh fractures or undisplaced fractures.**

KEY WORDS: Facial nerve injuries - Ultrasonography, interventional - Fracture fixation, internal.

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Craniomaxillofacial traumas have become more and more common in the last decades; most of them are the consequences of road, work and home accidents but are also due to fights, which are increasing in our statistics and concerns especially all non-EU citizens.

Over the years several methods were used to manage the fractures of the facial skeleton, starting from the orthopedic method – which is still suitable for the management of some fractures in pediatric patients not showing serious functional restrictions – to the surgery and surgical orthopedics treatments.[1, 2]

Surgery has evolved very quickly from rigid external to rigid internal fixation using Kirschner wires and pins, which were very common in surgical orthopedics. Then, the method using metal plates and screws gained ground: it became very reliable presenting few complications, so becoming the most diffused technique nowadays.

However, these advancements did not only have an effect on fixation techniques but they also changed the material of plates and screws. In 1907, Lambotte used an aluminium plate held by two screws to stabilize a maxillary fracture; steel plates and screws were used later on and were replaced then by titanium ones. The real breakthrough is the poly-L, D-lactide acid (PLDLA) resorbable system.[3-6]

A important innovation took place with the introduction of a new fixation technique using ultrasonic system (Sonic Weld Rx System) together with

Figure 1.—Battery-operated drill.

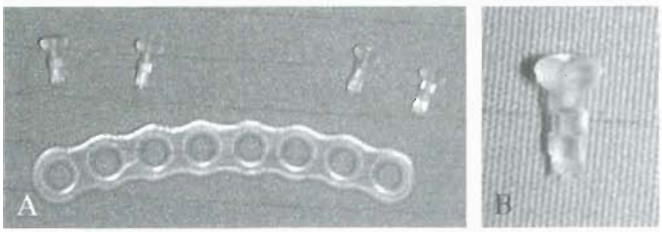

Figure 2.—A) Plate and pins; B) Pin.

resorbable plates (Resorb Xs) and pins (Sonic Pins Rx). The aim of this study was to analyze the advantages offered by this new system.

Materials and methods

Since November 2006 until October 2008, at the Department of Maxillofacial Surgery of the University of Catanzaro (Italy) 123 patients underwent surgery for craniomaxillofacial traumas. In 26 patients, 10 females and 16 males aged between 5 and 18 – most of them in pubertal age –the new technique with resorbable fixation using ultrasonic system (Sonic Weld Rx System) was adopted. This system consists of a battery-operated drill to drill the hole that will host the pin

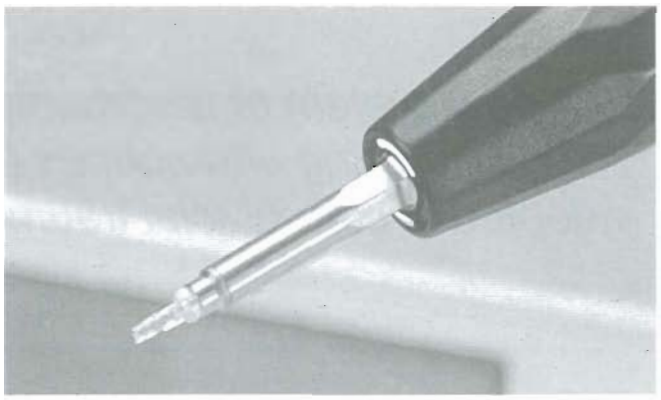

Figure 3.—Sonotrode with the pin.

Figure 4.—A 6-year-old boy with road trauma.

(Figure 1); it works at low revs and high torque and thus it does not need a continuous watering by sterile solution since it does not give rise to thermal bone necrosis. Plates and pins are made out of 100% amorphous PLDLA, which is extremely biocompatible (Figure 2A, B). The PLDLA complex polymer chains absorb the water contained in the surrounding biological fluids. By hydrolysis its long chains are broken down into ever shorter structures until the human metabolism transforms them into carbon dioxide and water, which are discharged naturally and no residues are left. Plates are thinner than the ones already used and pins do not have their conventional thread. They

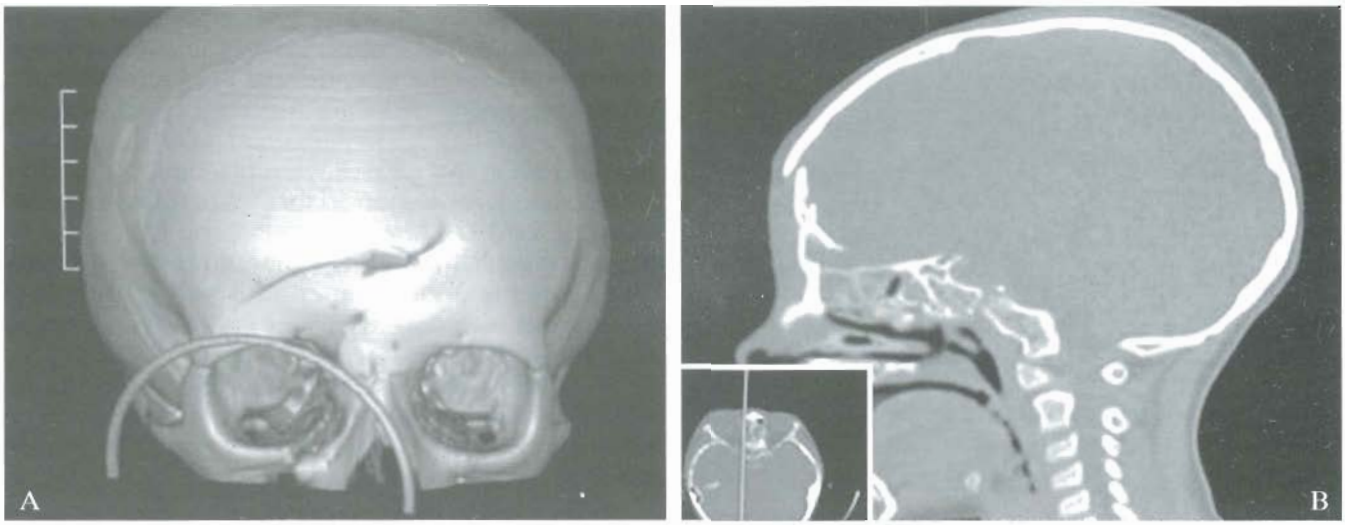

Figure 5.—Preoperative computed tomagraphic scan demonstrating frontal and orbital-zygomatic-maxillary fractures. CT 3D (A), sagittal view scan (B).

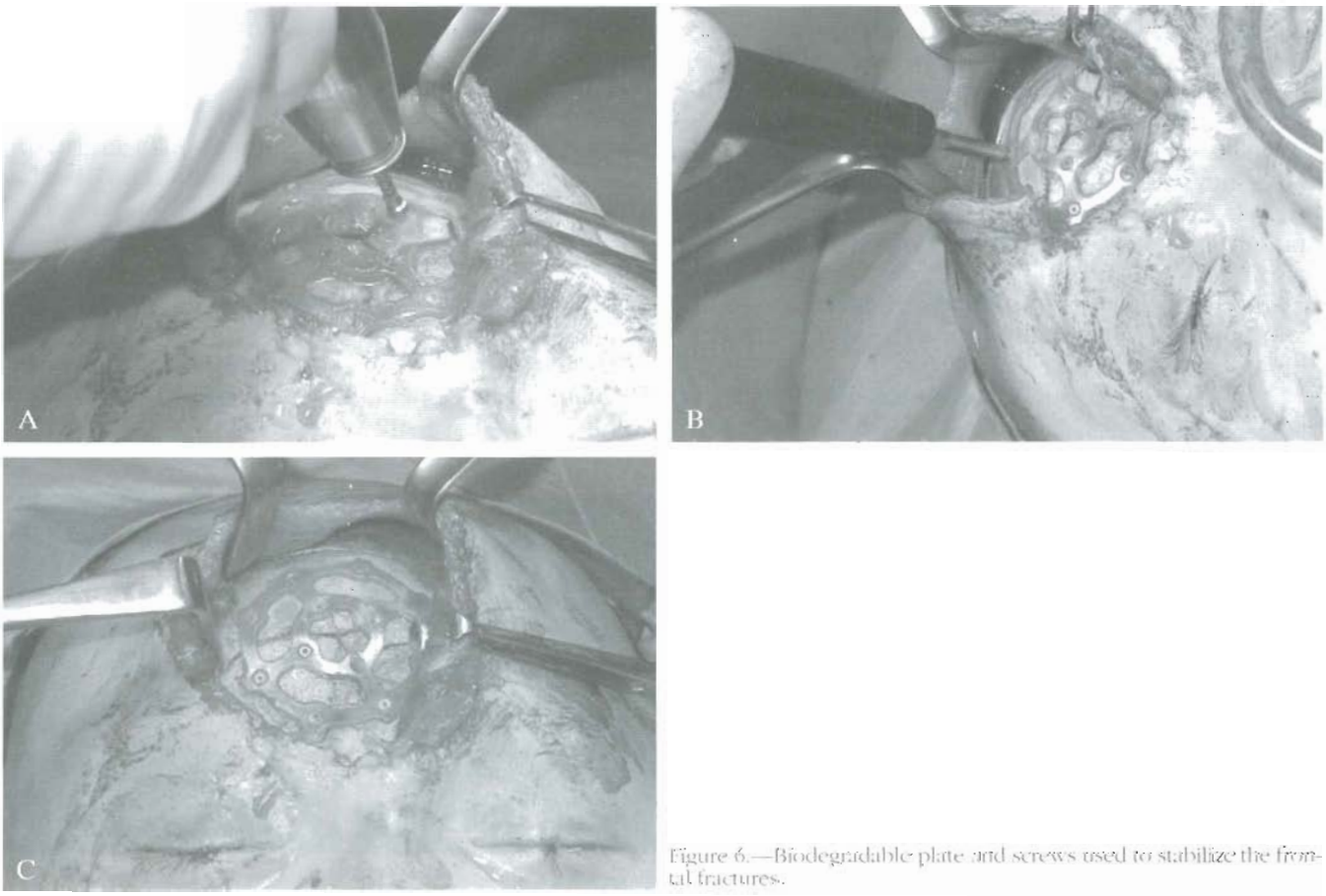

Figure 6.—Biodegradable plate and screws used to stabilize the frontal fractures.

Figure 7.—Biodegradable plate and screws used to stabilize OZM fractures.

are vibrated by means of exact ultrasonic frequencies that liquefy them and make them penetrate into bone trabeculae, which would be beyond the reach of conventional screws for osteosynthesis. This occurs because the sonotrode ultrasonic vibrations cause the pin to melt and flow into the predrilled hole very smoothly; moreover, pins heads melt with the plate that has been placed achieving a perfect anchorage and creating a single three-dimensional architecture (pin, plate, and bone) (Figure 3). The pins can be placed in the same hole also under difficult anatomical conditions, for example it can be implanted at an angle (maximum angle: 40°).

Three patients presented a comminuted fracture of the frontal sinus wall, which did not affect the posterior wall and whose fragments had sunk in and down. In just one case the fracture was associated with an orbital-zygomatic-maxillary fracture (COMZ) (Figure 4); the remaining 23 patients had only COMZ fracture, which in three cases were bilateral.

Road accidents accounted for 57% of fractures, sports traumas for 15%, home accidents for 12%, occupational accidents for 8% and fights and batteries for 8%.

All patients underwent clinical and instrumental assessment including OPT and a CT of facial bones (Figure 5A, B).

The three patients with a fracture of the frontal sinus wall had the bone fragments reduced and stabilized by using a 1-mm-thick, 55-mm-Ø resorbable mesh fixed by pins (Figure 6A-C).

Midface fractures were reduced and their fragments osteosynthesized by using 1-mm-thick resorbable plates with 6 holes for the zygomatic-maxillary buttress and with four holes for the frontal-zygomatic buttress always fixed by pins (Figure 7). An equine collagen membrane has been placed in all patients to cover osteosynthesis.

Clinical and instrumental (ultrasonography) follow-up was performed 1, 3, 6,12 and 24 months after surgery . Clinical and instrumental (CT) follow-up was performed 6, 12 and 24 months after surgery (Figures 8A-C, 9).

Results

By using this system, the authors noticed a 40% decrease of intraoperative period compared to all the

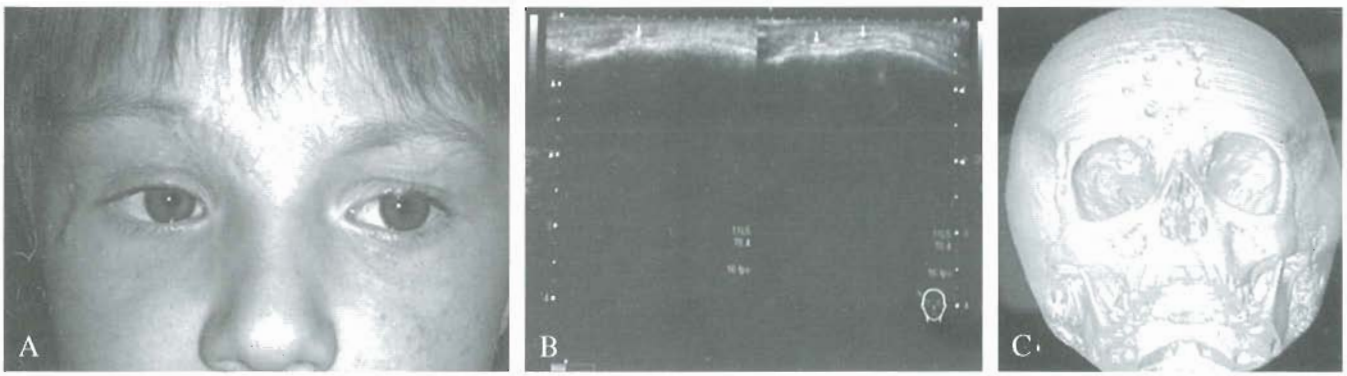

Figure 8.—Clinical (A), ultrasonography (B) and CT (C) follow-up 6 months after surgery.

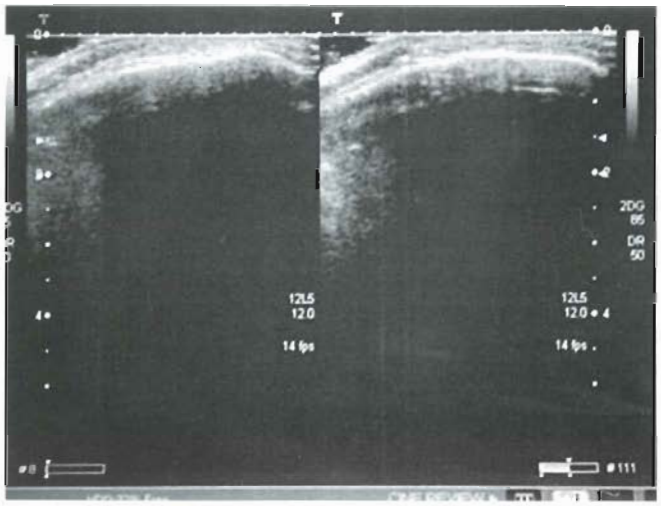

Figure 9.—Ultrasonography follow-up 12 mounths after surgery (completed resorption).

other resorbable fixation systems. It is easy to implant and pins can be placed in the same hole also under difficult anatomical conditions (maximum angle: 40°); it provides an excellent three-dimensional mechanical stability among plate, pins and bone and no thermal bone damage has ever been observed. Moreover, it delivers all advantages commonly offered by resorbable materials, *i.e.* no further surgery needed to remove plates and pins and no interference with bone growth. As for plates and screws resorption, it was assessed by ultrasonography. Table I points out that for 22 cases out of 26 the resorption timing was about 12-14 months, while for 4 it was longer. For all patients, after 1 month after the surgery, there was not any evidences of resorption to the ultrasound, which was only manifest after 6-12 months after the surgery.

Only 4 patients — 2 of them presenting COMZ frac-

TABLE I.—*Resorption timing.*

N.	Sex	Age	Fracture	Follow-up to 1 month	Follow-up to 3 months	Follow-up to 6 months	Follow-up to 12 months	Follow-up to 24 months	Complications
1	M	8	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
2	M	15	COMZ fracture bilateral	– – –	– –/+	–/+ +	+ + +		
3	M	12	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
4	M	13	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
5	F	10	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
6	M	16	COMZ fracture bilateral	– – –	– –/+	– –/+	+ + +		*
7	F	18	COMZ fracture	– – –	– –/+	– –/+	–/+ +	+ + +	
8	F	17	Frontal sinus fracture	– – –	– –/+	–/+ +	–/+ +	+ + +	
9	F	15	COMZ fracture	– – –	– –/+	–/+ +	+ + +		*
10	F	14	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
11	M	12	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
12	M	16	COMZ fracture bilateral	– – –	– –/+		+ + +		*
13	F	17	COMZ fracture	– – –	– –/+	– –/+	–/+ +	+ + +	*
14	F	14	Frontal sinus fracture	– – –	– –/+	–/+ +	+ + +		
15	M	12	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
16	M	8	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
17	M	5	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
18	M	11	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
19	M	7	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
20	F	18	COMZ fracture	– – –	– –/+	– –/+	–/+ +	+ + +	
21	M	6	Frontal sinus fracture + COMZ fracture	– – –	– –/+	–/+ +	+ + +		
22	M	18	COMZ fracture	– – –	– –/+	– –/+	+ + +		
23	M	12	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
24	F	14	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
25	F	13	COMZ fracture	– – –	– –/+	–/+ +	+ + +		
26	M	11	COMZ fracture	– – –	– –/+	–/+ +	+ + +		

– – – no resorption; – –/+ during resorption; –/++ uncompleted resorption; +++ completed resorption; *adverse reaction like inflammation due to a foreign body.

ture on both sides — had adverse postoperative reactions like an inflammation due to a foreign body, just controlled with medical treatment.

The authors notice no dehiscence of the surgical flaps or exposure of the plaque.

Discussion

The need to find resorbable materials originated from some disadvantages and complications caused by metal plates and screws, such as the contingent plate exposure, foreign-body reaction, and their interference with bone growth above all in pediatric patients: these conditions urged a second surgery to be carried out in order to remove them.[3, 7, 8] It is also important to remind the metal artefacts presence in radiographic images (*e.g.* CT and RMN). Thus, new resorbable materials were engineered in order to redress these problems: they should also guarantee the same advantages offered by titanium osteosynthesis. The first resorbable materials to be adopted were poly-alpha-oxyacids, namely PLLA (poly-L-lactide), polyglycolide (PGA) and polydioxanone (PDS).[9, 10] The main feature of alpha-oxyacids is that their carboxyl group and their R-OH are linked to the same carbon atom; monomers are linked by ester bonds and produce poly-(alpha-hydroxy acid), which in a physiological environments biodegradates and gives rise to low-molecular-weight intermediate substances of cellular metabolism because of a the progressive chain scissoring.

In the 1970s resorbable systems were first used in maxillofacial surgery by Cutright [11-14] in pediatric and adult patients to manage fractures of the middle third of the face. However, data from literature show that this resorbable system has several limits, such as low mechanical stability, poor manageability; it is time-consuming, and screws breakages are quite frequent.[15-17] For these reasons new plates and screws made out of resorbable materials as well as a new technique for their fixation using ultrasonic system were developed: they provide a simpler, faster and more reliable method.[15, 18] Its use is intended not only for traumatology, but also for the treatment of dysmorphic syndromes or malformations, as well as for postoncologic reconstruction of facial skeleton.[18]

The new biodegradable fixation system (Sonic Weld Rx System) paved the way to new scenarios for craniomaxillofacial traumatology, dysmorphic disorders, malformations and postoncologic reconstructions of the facial skeleton.[15, 16, 18] The achieved outcomes are satisfying: it is time-saving, less costly, and ostesosynthesis of craniofacial bones is firmer. We are going to validate it for the management of mandibular fractures in adult patients.

Conclusions

The experience here reported suggests to validate this system to manage the fractures of the middle third of the face in pediatric patients. As for its use to manage jaw fractures in pediatric patients it cannot be validate yet, except for single-sided fractures, compound fractures, mesh fractures or undisplaced fractures.

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