

Treatment of Malar and Midfacial Fractures With Osteoconductive Forged Unsintered Hydroxyapatite and Poly-L-Lactide Composite Internal Fixation Devices

Constantin Landes, MD, DMD, PhD, FEBOMFS,* Alexander Ballon, MD, DMD,†
 Sharam Ghanaati, MD, DMD,‡ Andreas Tran, MD,§ and
 Robert Sader, MD, DMD, PhD, FEBOMFS||

Purpose: To evaluate the internal fixation of malar and midfacial fractures, long-term results, and biocompatibility of osteoconductive internal fixation devices composed of a forged composite of unsintered hydroxyapatite and poly-L-lactide (F-u-HA/PLLA).

Materials and Methods: From January 2006 to June 2010, 29 patients (24 males and 5 females; age 33 ± 15 years) were included in the present prospective study. The fracture type was malar in 24 patients, midfacial in 5, isolated orbital floor blowout in 2, and frontal sinus, cranial base in 2 patients. The fractures were fixed with internal fixation devices; these were plates and screws composed of F-u-HA/PLLA. The 24 patients with malar fractures were treated with a single 4-hole L-plate or a straight plate at the infrazygomatic crest.

Results: All fractures with internal fixation using devices composed of F-u-HA/PLLA healed well. All malar and midfacial fractures had satisfactory long-term stability. The follow-up examinations at 12 to 67 months after surgery showed that most patients had no complaints, although 2 patients (15%) had a foreign body reaction that was treated by implant removal, with complete symptom resolution. At 5 years after fracture fixation, 2 patients had ultrasound and 2 had radiographic evidence of residual material. An exemplar biopsy showed direct bone growth into the material.

Conclusions: In patients with malar and midfacial fractures, hardware composed of the F-u-HA/PLLA composite provided reliable and satisfactory internal fixation, intraoperative handling, long-term stability, and biocompatibility. Direct bone growth into the material could be histopathologically exemplified, in contrast to previous polymer fixations that were resorbed and surrounded by a connective tissue layer. This finding indicates that long-term F-u-HA/PLLA residual material will be included into the remodeled bone, which was confirmed on long-term follow-up radiographs.

© 2014 American Association of Oral and Maxillofacial Surgeons

J Oral Maxillofac Surg ■:1-11, 2014

Resorbable internal rigid fixation avoids the necessity of metal internal fixation devices.^{1,2} The development of resorbable fixation devices has focused on

resorption after successful bone fixation and fracture reossification and can include incremental bone loading to the healing callus without foreign body

Received from the Department of Oral-Craniofacial and Plastic Facial Surgery, Goethe University, Hospital Frankfurt am Main, Frankfurt am Main, Germany.

*Professor.

†Consultant.

‡Consultant; and Institute of Pathology, Laboratory for Regenerative Pathology and Interface Research, Johannes Gutenberg University, Mainz, Germany.

§Research Fellow.

||Professor and Chair.

Address correspondence and reprint requests to Dr Landes: Mund-, Kiefer- und Plastische Gesichtschirurgie, Klinikum J. W. Goethe-Universität Frankfurt, Theodor-Stern-Kai 7, Frankfurt am Main 60590, Germany; e-mail: constantinlandes@gmail.com
 Received August 5 2013

Accepted February 17 2014

© 2014 American Association of Oral and Maxillofacial Surgeons
 0278-2391/14/00238-9\$36.00/0

<http://dx.doi.org/10.1016/j.joms.2014.02.027>

reactions.^{1,3} Third-generation resorbable internal fixation devices were developed to be osteoconductive and could have bone bonding capacity.⁴

First-generation, highly crystalline polylactide fixation devices were associated with long-term foreign body reactions, molecular weight stability, and minimal disintegration.^{5,6} Subsequent developments included bioabsorbable fixation devices using noncalcined, unsintered hydroxyapatite (u-HA) particles (size 0.2 to 20 μm ; average 3.0; calcium/phosphorus ratio 1.69) that contained carbonate ions uniformly distributed in the poly-L-lactide (PLLA) matrix (viscosity-averaged molecular weight 400 kDa). The PLLA matrix contained 20-50% HA by weight ($\pm 10\%$) and was reinforced into a composite by forging (compression molding). Raw blocks were machined to create internal fixation devices that had high mechanical strength, were absorbable, and had bioactivity, bone bonding capacity, and osteoconductivity.⁴

Forged composites of u-HA and PLLA (F-u-HA/PLLA) have greater strength than similar materials used previously, with a bending strength of 270 MPa (greater than the bending strength of cortical bone), modulus of 12 GPa (almost similar to cortical bone), and impact strength of 166 kJ/m² (twofold greater than that of polycarbonate). With a u-HA content of 30-50%, an immediate change in the molecular weight will occur with immersion in phosphate buffer. The bending strength decreased, together with the viscosity average molecular weight, and was retained at 200 MPa for 24 weeks (in phosphate buffer), the period usually necessary for bone union.⁴ A high u-HA content permits immediate hydrolysis throughout the implant and avoids the time gap to hydrolysis that occurs with pure crystalline PLLA.⁴ In addition, HA crystals will be deposited on the implant surfaces after 3 to 6 days of immersion, suggesting that this material could have bone bonding capacity. Miniscrews, plates, and other bone fixation devices can be produced from this material. The 3-dimensional shape of the fixations used within this evaluation was similar between the F-u-HA/PLLA when compared to titanium devices.

The purpose of the present study was to evaluate the results of using internal fixation devices made of F-u-HA/PLLA in the treatment of malar and midfacial fractures.⁷ The applied composite contained u-HA particles at 30% by weight for miniscrews and 40% by weight for plates; with this u-HA content, the strength was greater than the devices made from PLLA only.⁸ Special attention was given to operative feasibility, postoperative bony union, biocompatibility at long-term follow-up, bone formation noted on the radiographs, and eventual long-term residual material absorbed into the healing callus.

Materials and Methods

PATIENTS

Patients from our outpatient clinic who presented with malar and midfacial fractures were included in the present prospective study after approval by the in-house ethical board committee (ethics approval no. 227/06). Blinding the patients regarding the used fixation, whether titanium or F-u-HA/PLLA was considered unethical, because this would have included not demonstrating postoperative radiographs to the patients in which the titanium or F-u-HA/PLLA fixation devices can be clearly differentiated. Keeping the surgeon unaware of the devices used was impossible. Finally, the local ethical board committee did not approve keeping the patients unaware of the devices used.

The patients were included in the present study after the study protocol had been explained orally and the patients had signed the detailed study information form in German that informed about the possible risks of instability and foreign body reactions. In addition, the patients were included only when the fixation devices were available for the operation. Patients were excluded if they had fractures other than malar or midfacial fractures; had highly complex midfacial fractures that included very small fragments that could not be stabilized with the fixation devices because the smallest available screw diameter was 2 mm; had limited compliance because of alcohol dependency or metabolic disease; or were unwilling to participate.

A total of 44 patients were included from January 2006 to June 2010; 15 patients were withdrawn from the study because of incomplete documentation ($n = 3$) or an intraoperative change to a titanium fixation device because of surgeon preference ($n = 12$). The remaining 29 patients included in the present study mostly were young adult males who had experienced trauma from a fight or sports accident that had caused a malar fracture (Table 1, Figs 1, 2). All patients had undergone preoperative and postoperative ophthalmologic examinations, including an assessment of diplopia and visual impairment.

SURGERY

Surgery was performed 1 to 5 days after the trauma by 1 of 6 experienced surgeons. After total anesthesia had been induced and orotracheal or nasotracheal intubation established, a transoral vestibular marginal incision was made for the malar fractures, and the anterior maxillary wall and infrazygomatic crest were exposed. The infraorbital nerve was exposed transorally, and a transconjunctival incision was made, with inspection of the orbital floor.

Table 1. CLINICAL CHARACTERISTICS

Characteristic	Value
Population	
Recruited	44
Included	29
Excluded	15
Gender	
Male	24
Female	5
Age (yr)	
Mean \pm standard deviation	33 \pm 15
Range	13-70
History of injury	
Fight	13
Sports accident	7
Traffic accident	4
Fall	3
Work accident	2
Fracture type*	
Right malar	12
Left malar	12
Frontal sinus, cranial base, and nasoethmoid	2
Orbital floor	2
Le Fort I	2
Le Fort II	3
Preoperative ophthalmologic findings	
Good vision, no diplopia	28
Orbital hematoma	4
Diplopia and enophthalmos	1
Local moderate swelling and tenderness	1

Data reported as n or mean \pm standard deviation and range.

* Two patients had a combined malar and Le Fort fracture, 2 patients had frontal sinus, cranial base, and malar fractures.

Landes et al. Osteoconductive Osteosynthesis in Malar Fractures. *J Oral Maxillofac Surg* 2014.

After evaluation of the displaced malar bone, the fracture was reduced with a single hook inserted from the transoral or transbuccal approach through

a small stab incision and fixed with an F-u-HA/PLLA L-plate (Osteotrans Mx, 1-mm strength, and 6- \times 2-mm screws, Takiron, Osaka, Japan) at the infrazygomatic crest.⁹ In severely displaced fractures, fixation was performed with an additional infraorbital plate and lateral supraorbital fixation. For associated fissural orbital floor fractures, polydioxanone foil was inserted after transconjunctival exposure and dissection of the orbital periosteum.

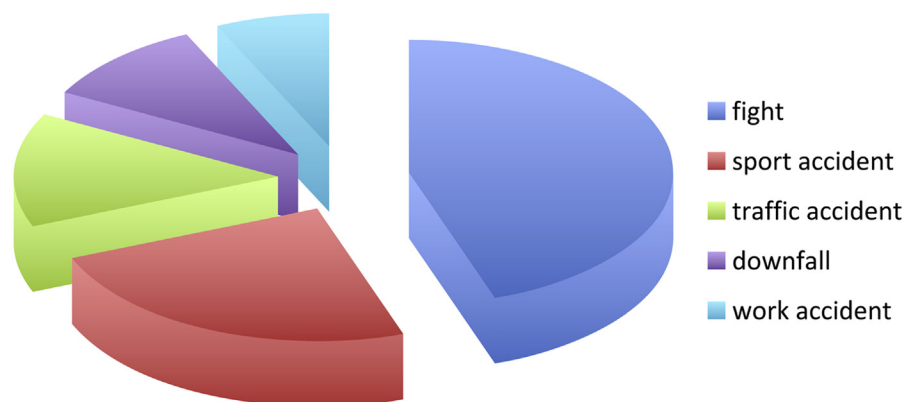
Frontal sinus wall fractures were inspected through the lacerated skin and a Killian incision, repositioned with a Gillies hook, and fixed. Median frontal sinus silicone tube drainage to the lower nasal passage was positioned in the frontal sinus and retained for 6 weeks.

Extended defect orbital floor blowout fractures were inspected from a transconjunctival exposure, all orbital soft tissues were repositioned, and F-u-HA/PLLA mesh was positioned and screwed to the bone with 6-mm screws.

Le Fort fractures were treated with nasotracheal intubation and bilateral exposure of the anterior maxillary walls and orbital floors. The midface was repositioned using Rowe pliers and fixed paranasally and at the infrazygomatic crest with 4-hole L-plates.

Le Fort II, dislocated malar, and frontal sinus fractures received F-u-HA/PLLA fixation, which were implanted also in areas of thin overlying tissue such as the infraorbital rim, glabella, or lateral orbital frontozygomatic suture.

The plates were cold bent to the bone at room temperature, and no hot water basin was necessary such as was the case with earlier resorbable fixation devices. The F-u-HA/PLLA devices were, just as were the earlier implants, brittle, necessitating careful screw turning and limiting the cold bending of the plates to 40° angulation or less at the plate surface and not the side face. Although more extensive contouring could be performed with a heating basin, this

**FIGURE 1.** Clinical history of patients with malar and midfacial fractures treated using osteoconductive implants.

Landes et al. Osteoconductive Osteosynthesis in Malar Fractures. *J Oral Maxillofac Surg* 2014.

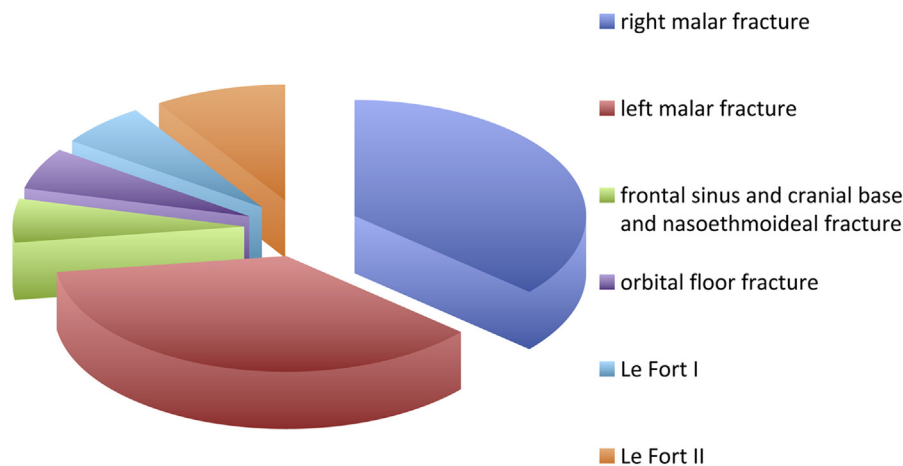


FIGURE 2. Fracture types of patients with malar and midfacial fractures treated using osteoconductive implants.

Landes et al. Osteoconductive Osteosynthesis in Malar Fractures. *J Oral Maxillofac Surg* 2014.

was not used in the present study. All screws were 6 or 8 mm long and had a diameter of 2 mm. Intraoperative prophylactic antibiotics were given to all patients (cefuroxime; Cephasaar, St Ingbert, Germany).

FOLLOW-UP EXAMINATION

Follow-up examinations were performed in the outpatient clinic at 1, 2, and 4 weeks and 1, 3, and 5 years. Independent outpatient clinicians who had not been involved in the surgery performed the follow-up

examinations. Subjective infraorbital light touch sensitivity was examined by local stroking with a 4-0 polypropylene suture (Prolene, Ethicon GmbH, Nordestedt, Germany) to evaluate the myelinated A alpha fibers. A standardized assessment of diplopia was performed by the same examiners and included a guided analysis of the primary eye position and guided movements, finger tracking, and analysis of the secondary position. Tertiary position movements also were evaluated, and patients provided subjective feedback.

Table 2. OSTEOCONDUCTIVE IMPLANTS IN 29 PATIENTS

Implant	Malar Fracture		Midfacial Fracture		Isolated Orbital Floor Blowout Fracture		Frontal Sinus, Cranial Base Fracture	
	Patients (n)	Implants × Patients	Patients (n)	Implants × Patients	Patients	Implants × Patients	Patients	Implants × Patients
Patients (n)	24		5		2		2	
Fixation hardware								
L-plate	15	15 × 1	5	2 × 2 1 × 3 2 × 4				
Straight plate	9	7 × 1 2 × 2	1	1 × 2			2	1 × 1 1 × 4
Orbital floor mesh					2	2 × 1		
6-mm Screws	22	19 × 4 2 × 8 1 × 12	5	1 × 8 1 × 12 1 × 15 2 × 16	2	2 × 1	2	1 × 4 1 × 14
8-mm Screws	2	2 × 4						
Polydioxanone foil	13	13 × 1	2	2 × 1			1	1 × 1
Polydioxanone thread	1	1 × 1						

Data regarding the number of implants reported as the number of patients × number of implants/patient.

Landes et al. Osteoconductive Osteosynthesis in Malar Fractures. *J Oral Maxillofac Surg* 2014.

Clinical soft tissue asymmetry that was perceived on the frontal examination was scored as “local swelling” when the affected side appeared more voluminous and the radiographs showed no residual displacement. This examination was performed also in the supraorbital area of the patients who had a frontal sinus fracture.

The projection of the zygoma was assessed by inspecting the malar projection and exocanthion landmark and comparative palpation of the zygion landmark from anteriorly and cranially. In patients with Le Fort fractures, occlusion was evaluated using occlusion foil (40 μ m; Dr Jean Bausch KG, Cologne, Germany).

DIAGNOSTIC IMAGING

Preoperative and postoperative computed tomography (CT) or radiography with Water projections was performed, and the patients were discharged from the hospital 3 to 5 days after surgery. An independent research fellow assessed the images for symmetric projections of the fractured zygomatic bones. An experienced consultant cross-checked 30% of the images for the intraindividual and interindividual reliability assessment. Regular radiographs were taken up to 1 year after surgery; later radiographs were taken when persistent problems were encountered by history taking or clinical examination. Additional radiographs for documentation of inclusion of the F-u-HA/PLLA material into reparative bone formation was judged unethical.

Good repositioning was ascertained when the fragments were aligned without steps in their linear continuity. When a step of up to 2 mm had occurred at a single fracture line (infraorbital rim or infrazygomatic crest), repositioning was considered fair; displacements greater than 3 mm were scored as insufficient.

STATISTICAL ANALYSIS

Data analysis and descriptive statistics were performed using a spreadsheet program (Microsoft Excel, Microsoft, Redmond, WA).

Results

For all 29 patients, all fractures with internal fixation with devices of F-u-HA/PLLA healed well. Most patients (24 patients) had had malar fractures that were treated with a single 4-hole L-plate or a straight plate at the infrazygomatic crest (Table 2). The plate type was selected intraoperatively according to the fracture pattern and location (Table 2, Fig 3).

The Le Fort midfacial fractures were treated primarily using 4-hole L-plates (15 plates in 5 fractures) and 6-mm screws (Table 2, Fig 4). The 2 orbital floor blowout fractures were fixed with orbital floor mesh (1 mm strength) screwed to the infraorbital rim with a single

6-mm screw (Table 2, Fig 5). Frontal sinus fractures received straight plates with 6-mm screws according to the individual fracture pattern and location.

Although all patients were available for immediate postoperative follow-up examination, approximately one half of the patients were lost to follow-up after 30 days postoperatively (Table 3). When interviewed by telephone, most of the patients who had not returned for follow-up stated they did “not see the point” of returning because they had no complaints.

All malar and midfacial fractures had successful long-term stability, and no nonunions occurred. All patients had palpable implants after surgery. Two patients also experienced foreign body reactions, with local redness and swelling at 15 and 33 months after fracture fixation. Solid bony union was noted at the surgery to remove the plates, and their symptoms subsided after curettage. The foreign body reaction did not inhibit bony union.¹ All other implant sites healed without complications.

At 5 years after fracture fixation, 2 patients each had ultrasound and radiographic evidence of residual material. However, because of its osteoconductive capacity, this material might have been incorporated into local bone, similar to 1 patient with HA-based bone replacement material with new bone formation found at bone biopsy (Fig 6). The biopsy material was explanted at a secondary operation for scar correction, with informed patient consent and institutional review board approval (clearance given July 29, 2005).

Most postoperative Water protections and CT scans showed good bony alignment. Only 1 patient had fair alignment. No insufficient fragment retention was observed, and no excess bone formation was encountered. On the long-term follow-up CT images, residual material could be seen in the remodeled earlier fracture site (Fig 5).

Within 30 days after surgery, most patients had no complaints, although several patients had slight local swelling (Table 3). The follow-up examination at 1 to 12 months after surgery showed that most patients had no complaints. Only 4 of 15 patients had varied complaints. One patient required an osteoplastic sinus operation (Table 3). However, from the localization on the contralateral side and the absence of intraoperative findings on the operated side, it would seem unlikely that the implant had been the cause of the symptoms. One patient had subjective temporary diplopia that subsequently resolved.

The follow-up examination at 12 to 67 months after surgery showed that most patients had no complaints; 2 patients (15%) had a foreign body reaction that was treated by implant removal, with complete resolution of symptoms (Table 3). All other patients had no complaints, and the implant was not palpable in most patients (Table 3). Finally, 2 patients had infraorbital

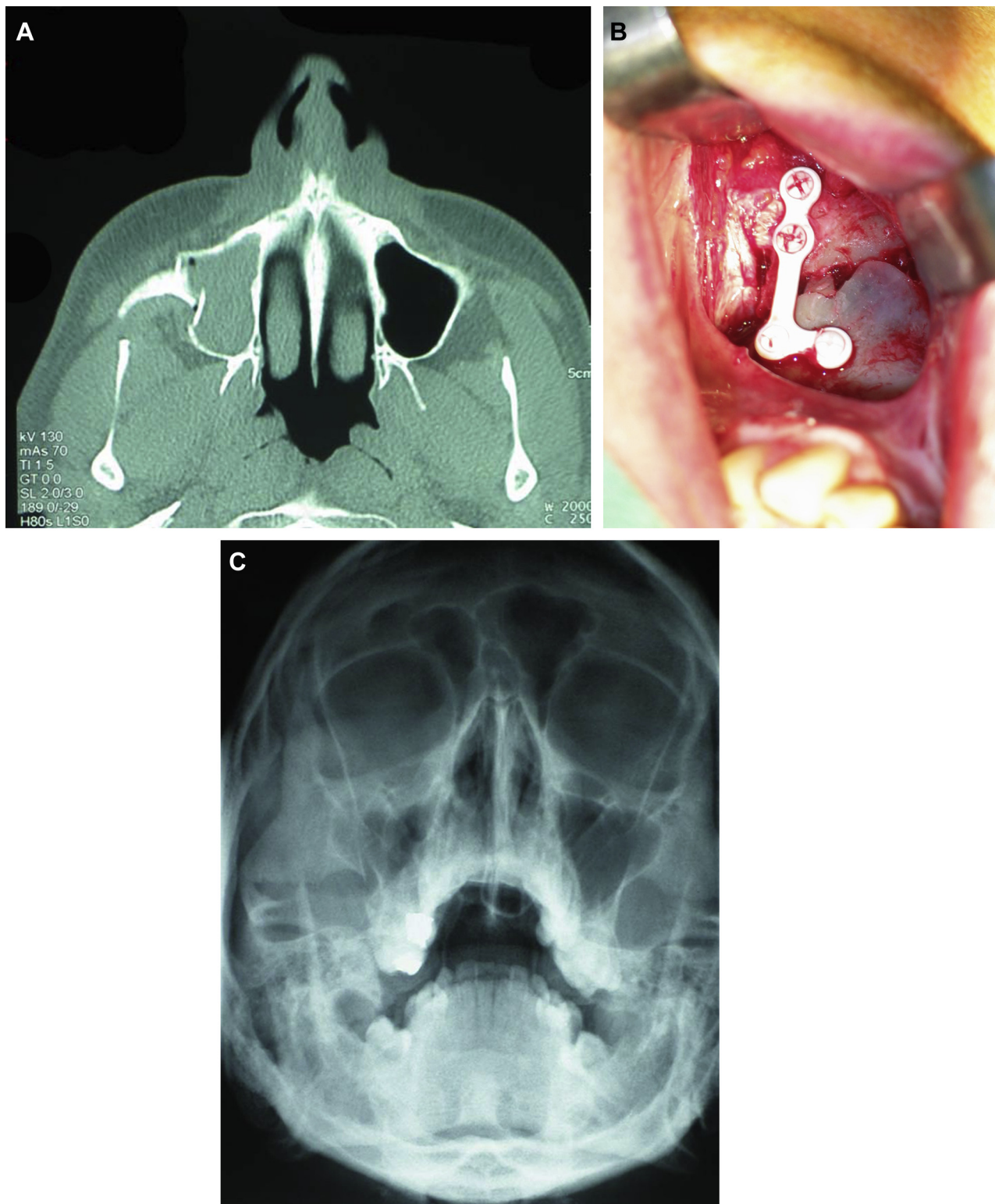


FIGURE 3. An 18-year-old male patient with a right malar fracture from a sports injury. A, Computed tomography scan of the right malar fracture. B, Intraoperative appearance after fracture reduction using a transoral vestibular margin incision and internal fixation with a 4-hole L-plate with 6-mm screws. C, Water projection radiograph at 1 day postoperatively showing satisfactory reduction and fixation.

Landes et al. Osteoconductive Osteosynthesis in Malar Fractures. J Oral Maxillofac Surg 2014.

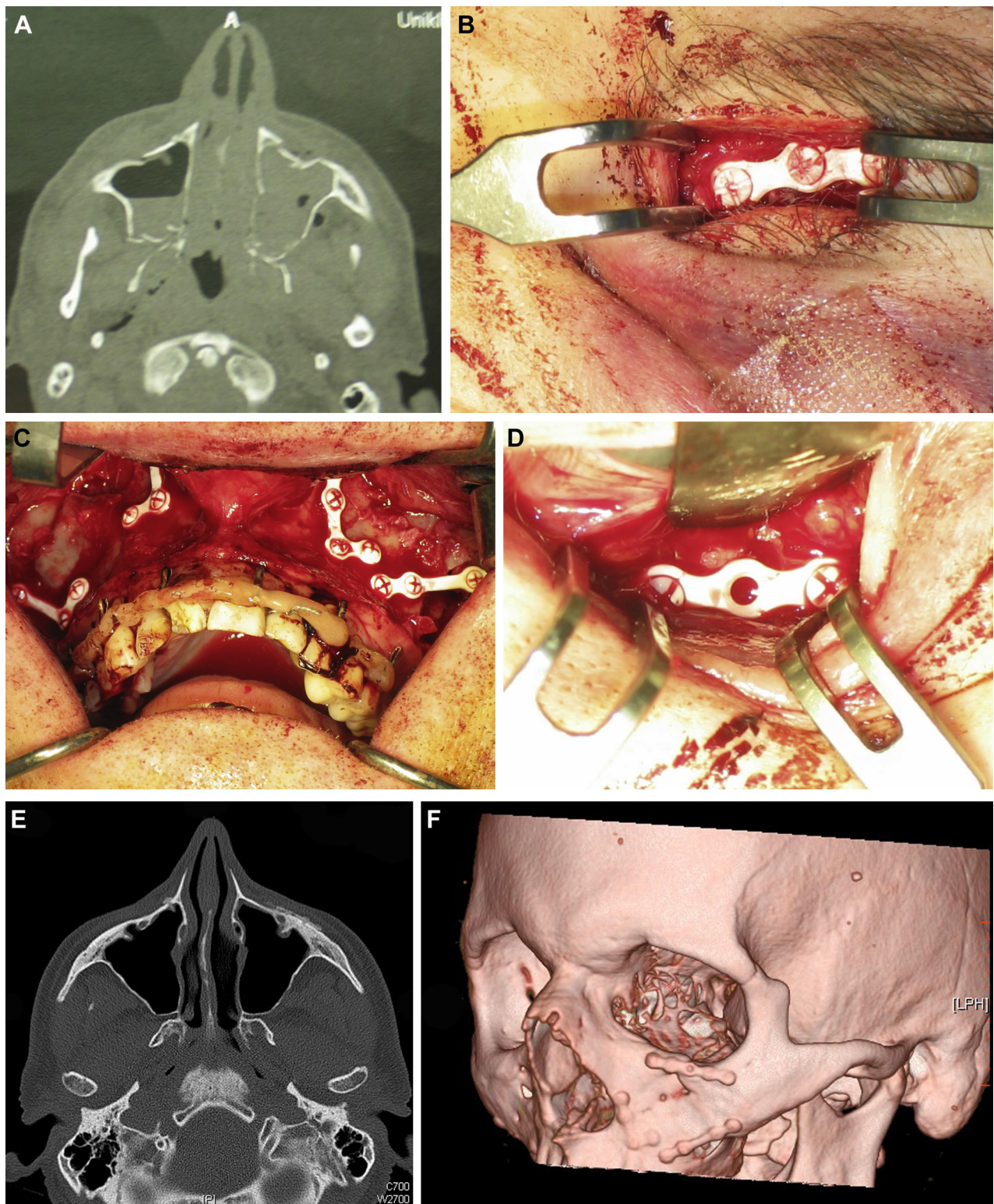


FIGURE 4. A 56-year-old male patient with a Le Fort II and right malar fracture from a sports injury. A, Preoperative computed tomography scan. B, Laterosupraorbital internal fixation. C, Transoral internal fixation. D, Infraorbital (transconjunctival) internal fixation. E, F, Computed tomography scan with 3-dimensional reconstruction 53 months after surgery showing bone integration of the implants.

Landes et al. Osteoconductive Osteosynthesis in Malar Fractures. *J Oral Maxillofac Surg* 2014.

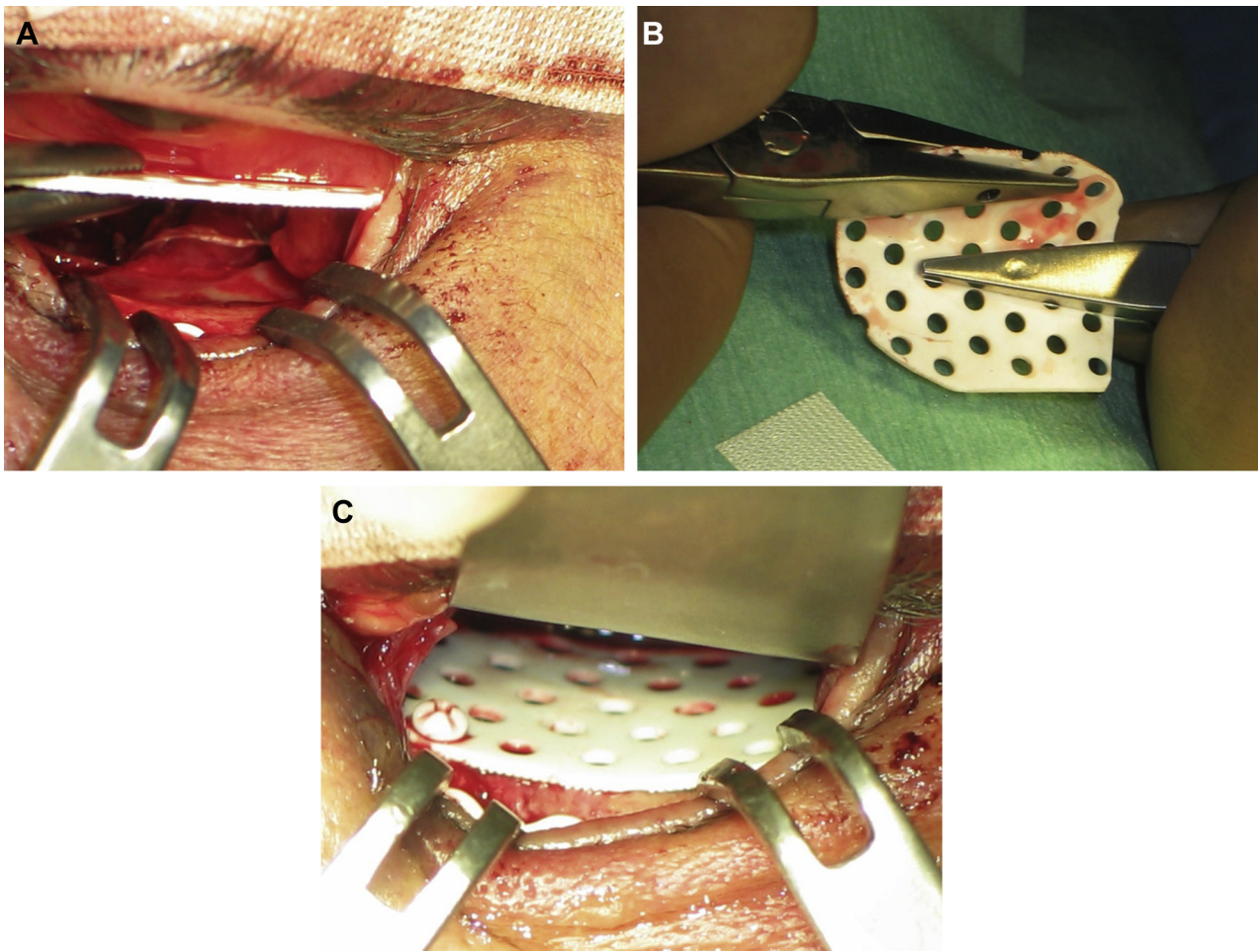


FIGURE 5. A 47-year-old male with a right orbital floor blowout from a fight. A, Internal fixation with unsintered hydroxyapatite and poly-L-lactide (F-u-HA-PLLA) mesh. B, Contouring the mesh with bending forceps. C, The contoured mesh fixed with a single medial 6-mm screw.

Landes et al. Osteoconductive Osteosynthesis in Malar Fractures. *J Oral Maxillofac Surg* 2014.

hyposensitivity that had resolved by 5 days and 46 months after surgery.

Discussion

The present study has shown that internal fixation of malar and midfacial fractures with F-u-HA/PLLA implants will result in satisfactory bony alignment and infrequent residual complaints (Table 3).

Resorbable internal fixation devices will avoid the long-term foreign body reactions to metals and other disadvantages of titanium internal fixation devices, such as stress shielding, palpability, migration, loosening, heat and cold irritability, infection, chronic pain, and secondary operations for metal removal. Titanium implants also can interfere with dental implants and prostheses, local bone augmentation, and diagnostic and therapeutic radiation. Also, local tissue inflammation can occur because of metallosis from titanium.¹⁰⁻¹⁵

Ideal resorbable osteofixation devices can progressively weaken and cause loading of the healing bone

in physiologic increments before the implant has disintegrated completely.¹⁵⁻¹⁷ However, the first assays with highly crystalline poly-L-lactide and polyglycolic acid showed long-term foreign body reactions and insufficient stability.^{5,6,18,19} During the past 20 years, copolymers have been developed for resorbable osteofixation such as poly(L-lactide-co-glycolide) and used successfully for midfacial fractures.²⁰⁻²³ The disadvantages of these second-generation resorbable implants have included the necessity of an intraoperative heating basin to enable adequate contouring and adaptation of the implant to bone. In addition, the implant material was voluminous and was neither osteoconductive nor osteoinductive.

The composite material F-u-HA/PLLA used in the present study was machined on a mold to attain high mechanical strength during osseous union; however, in laboratory and animal studies, it was totally absorbable and bioactive in bone bonding and osteoconductivity.^{4,23} The present study could be generalizable, because it included a typical distribution of fracture

Table 3. CLINICAL RESULTS

Characteristic	Follow-Up		
	1-30 Days	1-12 mo	12-67 mo
Patients (n)	29 (100)	15 (52)	13 (45)
Follow-up	4 ± 5 days	7 ± 4 mo	53 ± 10 mo
Missing data or withdrawn		14 (48)	16 (55)
Radiographic or ultrasound findings			
Satisfactory reduction and alignment	28 (96)	15 (100)	13 (100)
No residual material	0 (0)	0 (0)	9 (69)
Clinical findings			
Implant palpable	27 (93)	15 (100)	4 (31)
Ophthalmologic findings			
Good vision, no diplopia	27	15 (100)	13 (100)
Diplopia, enophthalmos	1	0 (0)	0 (0)
Missing data	1	0 (0)	0 (0)
Complaints			
None	20 (69)	11 (73)	11 (85)
Slight local swelling	6 (21)	0 (0)	0 (0)
Persistent swelling	0 (0)	1 (7)	0 (0)
Local moderate swelling and tenderness	1 (3)	0 (0)	0 (0)
Diplopia	1 (3)	1 (7)	0 (0)
Impaired mouth opening at 30 mm	0 (0)	1 (7)	0 (0)
Chronic pain and sinus mucosal hyperplasia	0 (0)	1 (7)	0 (0)
Plate infection and removal	0 (0)	0 (0)	2 (15)
Missing data	1 (3)	0 (0)	0 (0)
Osteolysis noted on radiographs	0 (0)	0 (0)	0 (0)

Data presented as n (%), mean ± standard deviation, or n.

Landes et al. Osteoconductive Osteosynthesis in Malar Fractures. *J Oral Maxillofac Surg* 2014.

types in appropriately compliant patients at a general maxillofacial trauma center within a reasonable period.

A highly granular approach, including, for example, only noncomminuted malar fractures, would have had very limited clinical transferability, because the use in moderately comminuted malar fractures or orbital floor fractures and Le Fort fractures would each have required a separate study. The collective we have presented represents a typical distribution of fracture pat-

terns in appropriately compliant patients at an average maxillofacial trauma center during a feasible period.

The HA included in the composite material in the present study might not completely resorb or dissolve. The u-HA cubes might become integrated into bone, which occurred in the patient who had undergone bone biopsy (Fig 6). Moreover, this could be concluded from the available long-term follow-up CT scans. In contrast to the previous resorbable materials, which were designed for total resorption and disintegration,^{20,22,24-26} the present composite material was designed to become integrated into, and replaced by, bone.^{4,23} The F-u-HA/PLLA is subject to hydrolysis in the body, similar to other resorbable polymers, and unbound u-HA molecules will be released within 2.5 years after implantation.²³ In a rabbit femur model, uniform hydrolysis occurred throughout the PLLA layers in the F-u-HA/PLLA matrix, and a steady release of small amounts of PLLA debris during PLLA degradation did not provoke adverse tissue responses.²³ The F-u-HA/PLLA composite included u-HA cubes (average side length 5.8 to 7.3 μm). A thin PLLA film was present between the u-HA particles and might permit invasion of water molecules for homogeneous hydrolysis, the first step in PLLA degradation.²³

The present study confirmed successful clinical stabilization of midfacial fractures and long-term biocompatibility. In the 2 patients with a foreign body reaction, implant removal and the follow-up findings were uncomplicated. Occasional inflammatory reactions can occur with all resorbable or bioabsorbable materials, and local resorption can occur with foreign body giant cells.^{2,25,26} This also could have occurred in the present patients and remains a short-term risk when the PLLA is resorbed from the composite material as the u-HA is replaced slowly by bone, similar to nanocrystalline HA embedded in silica matrix.²⁷ The biopsy performed in 1 patient in the present study confirmed the presence of the PLLA matrix and u-HA granules in the process of bioabsorption (Fig 6). In contrast to earlier copolymer biopsies, no connective tissue layer separated the regenerating bone from the material, supporting the inclusion of F-u-HA/PLLA into the regenerating bone, instead of earlier resorption as a foreign body.²⁵ Therefore, the residual palpable prominence found on long-term follow-up examinations that also might be visible on diagnostic imaging (Fig 5) might have been newly formed bone that had integrated and partly replaced the F-u-HA/PLLA implant material.

The greatest tissue foreign body reaction can occur during degradation of the PLLA polymer chains within 2 years after implantation. In earlier studies of the same material in smaller groups and with shorter follow-up periods, successful reossification of the osteotomy gaps was noted after Le Fort I osteotomy in

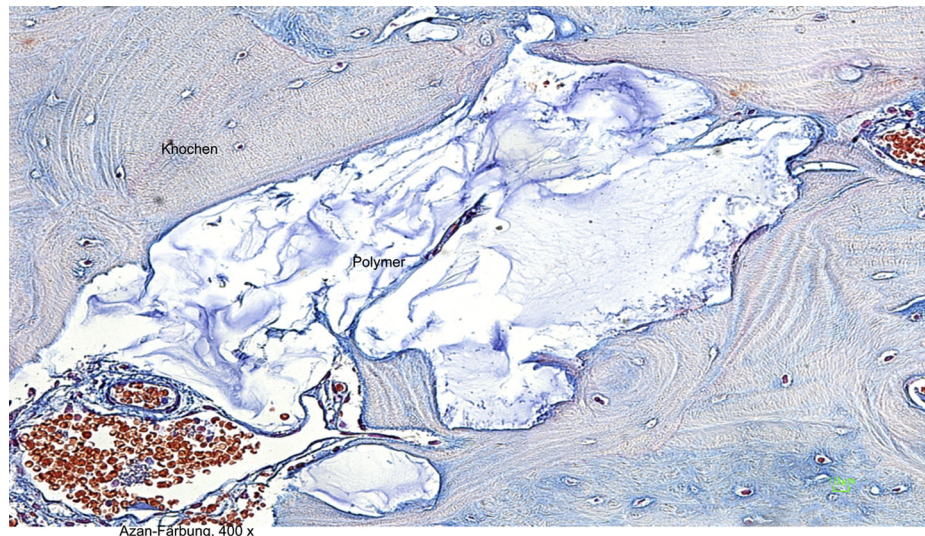


FIGURE 6. Histologic findings of unsintered hydroxyapatite and poly-L-lactide (F-u-HA/PLLA) internal fixation plate and screw at the infraorbital region after 28 months showing new bone formation at the composite polymer site (Heidenhain azan stain, original magnification $\times 400$). Unlike previous polymer fixations that resorb and were surrounded by a connective tissue layer, direct contact between bone formation and material occurs. This indicates long-term F-u-HA/PLLA residual material were included into the remodeled bone, which was confirmed on the long-term follow-up radiographs.

Landes et al. Osteoconductive Osteosynthesis in Malar Fractures. *J Oral Maxillofac Surg* 2014.

CT measurements of bone diastasis.²⁸ In addition, F-u-HA/PLLA used in sternal osteotomies caused earlier sternal fusion, and osteogenesis promotion by the material was suggested by the observed increased cortical bone density at 1 year after surgery.²⁹ A lower frequency of complications might result after sternal closure using F-u-HA/PLLA pins.³⁰ More confirmatory clinical data are required, and a prospective clinical study by us of mandible fractures is to be published.

A weakness of the present study could have been the intraoperative change from planned F-u-HA/PLLA internal fixation to titanium in 12 patients excluded from the study. Another study showed that switching to titanium can occur in studies of resorbable and bioabsorbable osteofixation implants.³¹ Switching might be more likely during fixation of mandibular fractures than for bilateral sagittal split osteotomies.³¹ The cause of switching implant choice was unknown; however, a possible factor might have been the individual learning curve to acquire the skills needed to use the biodegradable system. In a retrospective review, no switching occurred during isolated Le Fort I osteotomies, although the biodegradable system seemed more difficult to apply in the midface. The main reason for switching might have been the anticipation of inadequate stability, and this factor might have been related to the material, inexperience, lack of confidence in the system, or impatience of the surgeon.³¹

The high frequency of patients lost to follow-up was typical for studies of craniofacial trauma. In a previous long-term outcome study of mandibular condyle fractures, only 88% patients reappeared after 6 weeks,

although remuneration (\$100) was offered for attending the follow-up examinations.³² The frequency of follow-up visits was greater in the present study (52%) than in the previous study (32%) at 1 year or at 2 years (present study 45%, previous study 14%).³² In another study, only 28 of 136 patients returned for the follow-up examination at 3 years.^{33,34} Therefore, the low frequency of follow-up has been typical for clinical follow-up studies of maxillofacial trauma patients. Contributing factors could have included high geographic mobility and the unavailability of patients.

In conclusion, the present 5-year prospective follow-up study of midfacial fractures showed successful treatment with resorbable implants composed of composite F-u-HA/PLLA. Intraoperative handling of these implants was good, and a heating basin was not needed because bending at room temperature was feasible for up to 40° of angulation. All patients had successful fracture stabilization and reossification, with a low incidence of mild foreign body reactions. The long-term presence of the implant material could be caused by the osteoconductive properties of the composite material, similar to other HA-based bone replacement materials that are slowly transformed to bone. More biomechanically adapted implant designs will be created for specific applications, such as has been started with preshaped L-plates for Le Fort I osteotomies.³⁵ Future developments in resorbable implants could also include silk fibroin and bacterial cellulose, which might enable local delivery of drugs such as bone morphogenetic protein.^{36,37}

References

- Böstman OM, Pihlajamäki HK: Adverse tissue reactions to bio-absorbable fixation devices. *Clin Orthop Relat Res* 371:216, 2000
- Landes CA, Ballon A, Roth C: In-patient versus in vitro degradation of P(L/DL)LA and PLGA. *J Biomed Mater Res B Appl Biomater* 76:403, 2006
- Landes CA, Seitz O, Rieger J, et al: First experiences with a new resorbable osteosynthesis material of high strength retention force and small size [abstract O.063]. *J Craniomaxillofac Surg* 34(suppl 1):18, 2006
- Shikinami Y, Okuno M: Bioresorbable devices made of forged composites of hydroxyapatite (HA) particles and poly-L-lactide (PLLA): Part I. Basic characteristics. *Biomaterials* 20:859, 1999
- Bergsma EJ, Rozema FR, Bos RR, de Bruijn WC: Foreign body reactions to resorbable poly(L-lactide) bone plates and screws used for the fixation of unstable zygomatic fractures. *J Oral Maxillofac Surg* 51:666, 1993
- Suuronen R, Pohjonen T, Hietanen J, Lindqvist C: A 5-year in vitro and in vivo study of the biodegradation of polylactide plates. *J Oral Maxillofac Surg* 56:604, 1998
- Knepil GJ, Loukota RA: Outcomes of prophylactic antibiotics following surgery for zygomatic bone fractures. *J Craniomaxillofac Surg* 38:131, 2010
- Shikinami Y, Okuno M: Bioresorbable devices made of forged composites of hydroxyapatite (HA) particles and poly-L-lactide (PLLA): Part II: Practical properties of miniscrews and mini-plates. *Biomaterials* 22:3197, 2001
- Rasse M: Spezielle Traumatologie, in Hausamen JE, Machtens E, Reuther JE et al (eds): *Mund-, Kiefer- und Gesichtschirurgie* (ed 4). Berlin, Springer-Verlag, 2012, pp 239–283
- Fiala TG, Novelline RA, Yaremchuk MJ: Comparison of CT imaging artifacts from craniomaxillofacial internal fixation devices. *Plast Reconstr Surg* 92:1227, 1993
- Fiala TG, Paige KT, Davis TL, et al: Comparison of artifact from craniomaxillofacial internal fixation devices: Magnetic resonance imaging. *Plast Reconstr Surg* 93:725, 1994
- Katou F, Andoh N, Motegi K, Nagura H: Immuno-inflammatory responses in the tissue adjacent to titanium miniplates used in the treatment of mandibular fractures. *J Craniomaxillofac Surg* 24:155, 1996
- Jorgenson DS, Mayer MH, Ellenbogen RG, et al: Detection of titanium in human tissues after craniofacial surgery. *Plast Reconstr Surg* 99:976, 1997
- Chaushu G, Manor Y, Shoshani Y, Taicher S: Risk factors contributing to symptomatic plate removal in maxillofacial trauma patients. *Plast Reconstr Surg* 105:521, 2000
- Pietrzak WS, Eppley BL: Resorbable polymer fixation for craniomaxillofacial surgery: Development and engineering paradigms. *J Craniofac Surg* 11:575, 2000
- Wiltfang J, Merten HA, Schultze-Mosgau S, et al: Biodegradable miniplates (LactoSor): Long-term results in infant minipigs and clinical results. *J Craniofac Surg* 11:239, 2000
- Weingart D, Bublit R, Michilli R, Class D: Resorbable osteosynthesis material in craniostylosis [in German]. *Mund Kiefer Gesichtschir* 5:198, 2001
- Bos RR, Rozema FR, Boering G, et al: Degradation of and tissue reaction to biodegradable poly(L-lactide) for use as internal fixation of fractures: A study in rats. *Biomaterials* 12:32, 1991
- Törmälä P, Vasenius J, Vainionpää S, et al: Ultra-high-strength absorbable self-reinforced polyglycolide (SR-PGA) composite rods for internal fixation of bone fractures: In vitro and in vivo study. *J Biomed Mater Res* 25:1, 1991
- Eppley BL, Reilly M: Degradation characteristics of PLLA-PGA bone fixation devices. *J Craniofac Surg* 8:116, 1997
- Eppley BL: Zygomaticomaxillary fracture repair with resorbable plates and screws. *J Craniofac Surg* 11:377, 2000
- Enislidis G, Pichorner S, Lambert F, et al: Fixation of zygomatic fractures with a new biodegradable copolymer osteosynthesis system: Preliminary results. *Int J Oral Maxillofac Surg* 27:352, 1998
- Shikinami Y, Matsusue Y, Nakamura T: The complete process of bioresorption and bone replacement using devices made of forged composites of raw hydroxyapatite particles/poly L-lactide (F-u-HA/PLLA). *Biomaterials* 26:5542, 2005
- Landes CA, Ballon A: Indications and limitations in resorbable P(L70/30DL)LA osteosyntheses of displaced mandibular fractures in 4.5-year follow-up. *Plast Reconstr Surg* 117:577, 2006
- Landes CA, Ballon A, Roth C: Maxillary and mandibular osteosyntheses with PLGA and P(L/DL)LA implants: A 5-year inpatient biocompatibility and degradation experience. *Plast Reconstr Surg* 117:2347, 2006
- Landes CA, Kriener S, Menzer M, Kovács AF: Resorbable plate osteosynthesis of dislocated or pathological mandibular fractures: A prospective clinical trial of two amorphous L-/DL-lactide copolymer 2-mm miniplate systems. *Plast Reconstr Surg* 111:601, 2003
- Ghanaati S, Barbeck M, Willershausen I, et al: Nanocrystalline hydroxyapatite bone substitute leads to sufficient bone tissue formation already after 3 months: Histological and histomorphometrical analysis 3 and 6 months following human sinus cavity augmentation. *Clin Implant Dent Relat Res* 15:883, 2013
- Ueki K, Miyazaki M, Okabe K, et al: Assessment of bone healing after Le Fort I osteotomy with 3-dimensional computed tomography. *J Craniomaxillofac Surg* 39:237, 2011
- Tsunekawa T, Usui A, Oshima H, et al: A bioresorbable osteosynthesis device can induce an earlier sternal fusion after median sternotomy. *Interact Cardiovasc Thorac Surg* 15:377, 2012
- Hamaji M, Sakaguchi Y, Matsuda M, Kono S: Reinforced closure of the sternum with absorbable pins for high-risk patients. *Interact Cardiovasc Thorac Surg* 9:559, 2009
- van Bakelen NB, Buijs GJ, Jansma J, et al: Decision-making considerations in application of biodegradable fixation systems in maxillofacial surgery—A retrospective cohort study. *J Craniomaxillofac Surg Epub* 2013 Jul 5; <http://dx.doi.org/10.1016/j.jcms.2013.05.032>
- Throckmorton GS, Ellis E III, Hayasaki H: Masticatory motion after surgical or nonsurgical treatment for unilateral fractures of the mandibular condylar process. *J Oral Maxillofac Surg* 62:127, 2004
- Palmieri C, Ellis E III, Throckmorton G: Mandibular motion after closed and open treatment of unilateral mandibular condylar process fractures. *J Oral Maxillofac Surg* 57:764, 1999
- Landes CA, Lipphardt R: Prospective evaluation of a pragmatic treatment rationale: Open reduction and internal fixation of displaced and dislocated condyle and condylar head fractures and closed reduction of non-displaced, non-dislocated fractures. Part I: Condyle and subcondylar fractures. *Int J Oral Maxillofac Surg* 34:859, 2005
- Landes CA, Ballon A, Tran A, et al: Segmental stability in orthognathic surgery: Hydroxyapatite/poly-L-lactide osteoconductive composite versus titanium miniplate osteosyntheses. *J Craniomaxillofac Surg Epub* 2014 Jan 21; <http://dx.doi.org/10.1016/j.jcms.2014.01.013>
- Lee JM, Kim JH, Lee OJ, Park CH: The fixation effect of a silk fibroin-bacterial cellulose composite plate in segmental defects of the zygomatic arch: An experimental study. *JAMA Otolaryngol Head Neck Surg* 139:629, 2013
- Wenk E, Wandrey AJ, Merkle HP, Meinel L: Silk fibroin spheres as a platform for controlled drug delivery. *J Control Release* 132:26, 2008