

## Treatment of mandible fractures using resorbable plates with a mean of 3 weeks maxillomandibular fixation: a prospective study

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**Purpose.** In this study, a 2.5-mm resorbable plating system (Inion CPS, Tampere Finland) was assessed for the fixation of mandibular fractures with 3 weeks of maxillomandibular fixation.

**Patients and Methods.** Fifty mandibular fractures in 34 patients (32 males, 2 females) with a mean of 20.8 days of maxillomandibular fixation (MMF) were included in this study. The 2.5-mm resorbable plates were adapted along Champy's line of ideal osteosynthesis and secured with four 8 × 2.5 mm monocortical resorbable screws. All patients were followed for a minimum of 6 weeks with an average long-term follow-up of 10 months. The incidence of soft tissue infection, nonunion, malunion, malocclusion, osteomyelitis, nerve injury, and tooth damage was prospectively assessed.

**Results.** Primary bone healing was achieved in 100% of cases. Ten minor complications (20%) were observed: 5 soft tissue infections (10%), 4 plate dehiscences (8%), and 1 malocclusion (2%). No evidence of malunion, nonunion, osteomyelitis, plate fracture, or iatrogenic dental or nerve injury was noted; no readmission or reoperation was necessary.

**Conclusion.** The Inion 2.5-mm resorbable plating system along Champy's line of ideal osteosynthesis plus 3 weeks of MMF is a viable option for the treatment of mandible fractures. (Oral Surg Oral Med Oral Pathol Oral Radiol 2013;115:25-28)

Treatment of the mandible fracture is basic to the treatment of maxillofacial trauma. Successful treatment of mandible fractures results in an anatomic bony union with restoration of normal occlusion and function.

These fractures are commonly treated with closed reduction and maxillomandibular fixation (MMF) or open reduction with either rigid or nonrigid fixation. Titanium plates have been the gold standard for internal fixation of mandible fractures for the past 3 decades.<sup>1</sup>

Resorbable plating systems have been used for midface, craniofacial, and pediatric cases. Resorb-

able plates and screws represent the next frontier in craniomaxillofacial treatment. Only the Inion System is approved by the Food and Drug Administration for mandibular fixation with an appropriate period of MMF.

The purpose of this study was to determine the efficacy of the Inion Biodegradable Fixation System (Inion CPS) in the treatment of mandible fractures in conjunction with 3 weeks of MMF. This is only the second such Inion resorbable mandible clinical trial in the United States.<sup>2</sup>

### MATERIAL AND METHODS

This study is a prospective clinical trial conducted at Kings County Hospital Center in Brooklyn, New York, from 2008 to 2010, consisting of 50 mandibular fractures treated in 34 patients (Table I). The study included 32 males and 2 females, with mean age of 27 years, who consented to the procedure as per SUNY Brooklyn internal review board protocol.

### Statement of Clinical Relevance

Resorbable plating systems represent the next frontier in craniomaxillofacial treatment. Resorbable plates and screws have been used for midface, craniofacial, and pediatric cases. Only the Inion System is approved by the Food and Drug Administration for mandible fixation with an appropriate period of maxillomandibular fixation.

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**Table I.** Fifty mandible fractures in 34 patients treated with Inion 2.5-mm resorbable plates and screws with a mean of 20.8 days of MMF

Patient	Fracture location	Days of MMF	Patient	Fracture location	Days of MMF
1	Right angle, left P/S	16	18	Left body, right P/S	17
2	Right P/S	15	19	Right angle, left P/S	22
3	Left angle	21	20	Right angle, left P/S	15
4	Left angle	23	21	Right body, left P/S	21
5	Right P/S, left angle	16	22	Left angle	21
6	Left body	21	23	Left angle	23
7	Right body	15	24	Left P/S	23
8	Left angle	5	25	Symphysis	23
9	Left angle	6	26	Left angle	12
10	Right P/S, left angle	20	27	Left angle	24
11	Left angle, right P/S	15	28	Right angle	39
12	Right angle	18	29	Left angle, right P/S	30
13	Right angle	25	30	Right angle	22
14	Left angle, right body	22	31	Left angle, right P/S	30
15	Right B, left body	22	32	Right angle, left body	30
16	Right angle, left body	21	33	Right angle, left P/S	24
17	Left angle, right P/S	19	34	Right body	8

B, body; MMF, maxillomandibular fixation; P/S, parasymphysis.

The fractures treated included 24 angle fractures, 16 parasymphysis fractures, 9 body fractures, and 1 symphysis. Exclusion criteria included infected or comminuted fractures, condylar fractures, tumors or pathologic fractures, previous osteomyelitis, patients unable to tolerate MMF (poorly controlled asthma, epilepsy, psychiatric disorders, and alcohol or drug abuse), and immunocompromised patients.

All fractures were treated under general anesthesia via nasotracheal intubation 6 to 72 hours from the time of injury. Maxillary and mandibular arch bars, Ivy loops, or perialveolar screws were used to reestablish preinjury occlusion in MMF. All fractures were treated transorally with mucosal incision. Extraction of teeth in the line of fracture was performed if indicated (fractured teeth, periodontally involved teeth, nonrestorable, grossly carious teeth, teeth interfering with reduction of fracture, or occlusion). Patients were placed in ideal occlusion, MMF was applied, and fractures were reduced. All patients received a 48-hour perioperative course of intravenous antibiotics and then prescribed a 7-day course of oral antibiotics (clindamycin or penicillin) and chlorhexidine rinses upon discharge.

A 2.5-mm Inion resorbable plate was adapted along Champy's line of ideal osteosynthesis (Figure 1) after being immersed in a sterile water bath at 55°C for 15 seconds. A four-hole extend plate was secured with four 8 × 2.5 mm Inion resorbable monocortical screws (Figures 2–4) using a drill–tap–screw sequence. Care was taken to place the screws lateral to the roots and above the neurovascular bundle at the angle, with a minimum of two screws in the proximal and distal segments of the fracture. The area was irrigated and closed with resorbable sutures.



Fig. 1. Champy's line of ideal osteosynthesis.

The patients were placed in MMF for an intended period of 3 weeks and instructed to be on a soft diet for 3 weeks thereafter. Because of suboptimal patient compliance and follow-up, the mean period of MMF was 20.1 days, with a range of 5 to 39 days and a medium of 21 days. Arch bars, Ivy loops, and perialveolar screws were removed after 6 weeks. Patients were followed for at least 6 weeks with biweekly panoramic x-rays (Figure 5).

Patients were followed and observed for complications: soft tissue infection, plate dehiscence, nonunion or malunion of fractures, osteomyelitis, malocclusion, dental injury, and iatrogenic nerve injury.

## RESULTS

Ten minor complications (20%) were noted (Table II): 5 soft tissue infections treated with wound care and oral

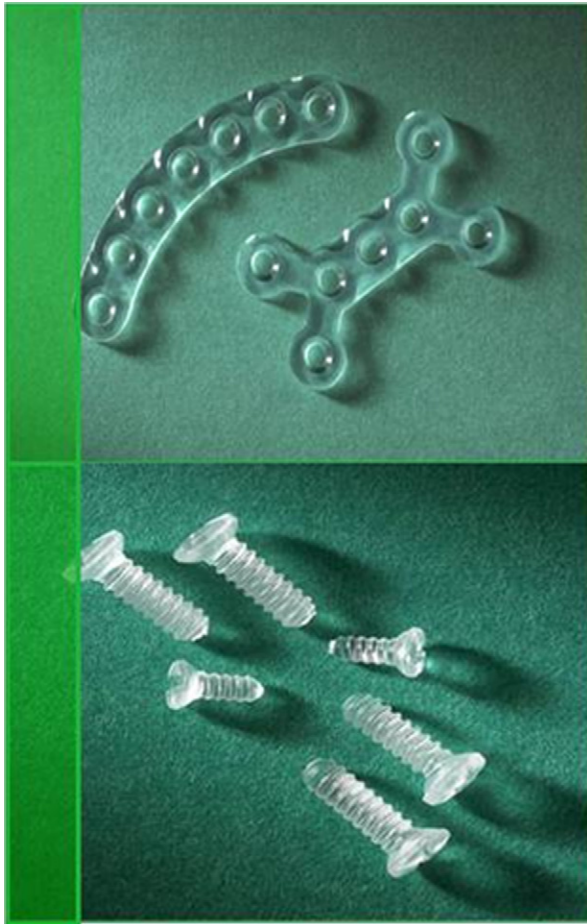


Fig. 2. Inion CPS plates and screws.

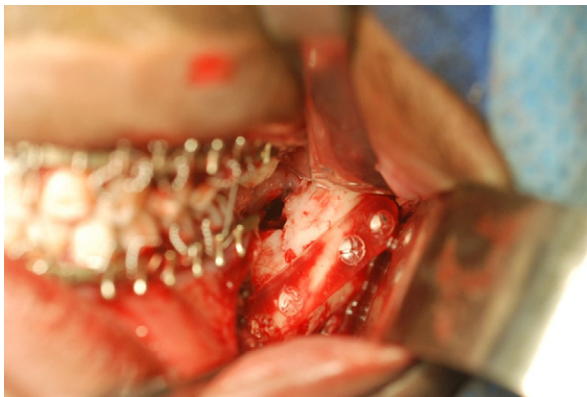


Fig. 3. Transoral open reduction internal fixation of mandibular angle fracture with 2.5-mm Inion CPS resorbable plate and screws.

antibiotics, 4 plate dehiscences with 2 plates removed in the clinic under local anesthesia, and 1 minor malocclusion corrected with occlusal adjustment. The 9 soft tissue infections and plate dehiscences were evenly distributed among the fracture sites: 3 angle, 3 body,

Fig. 4. Transoral open reduction and internal fixation of mandibular symphysis fracture with Inion 2.5-mm resorbable plate and screws.



Fig. 5. Postoperative panoramic view of open reduction and internal fixation of left mandibular angle fracture and right parasymphysis fracture with 2.5-mm Inion resorbable plates. Note resorbable screw holes. No radiopaque marker for the plate or screws.

**Table II.** Complications

Complications	Results	
	Number (%)	
Soft tissue infection	5	(10)
Plate dehiscence	4	(8)
Malocclusion	1	(2)
Malunion, nonunion, osteomyelitis	0	(0)
Dental injuries, nerve injuries	0	(0)
Late complications	0	(0)
Total	10	(20)
Readmissions/reoperations	0	(0)
Healed fractures	50	(100)

and 3 parasymphysis. Bone healing of all 50 fractures was achieved (100%) with satisfactory alignment of fracture segments, reproducible preinjury occlusion and temporomandibular joint function, and satisfactory esthetics as determined clinically and radiographically. No reoperation or readmission was necessary. No long-term complications such as foreign body reaction or

fistula formation were noted with an average long-term follow up of 10 months.

## DISCUSSION

Treatment of mandible fractures with titanium plates has been well studied in our institution.<sup>3-6</sup> Transoral locking miniplate fixation of mandible fractures with 1 week MMF is our current treatment protocol, with a 100% bone healing and overall complication rate of 9.4% (3). This study (2004-08) recorded 15 minor complications in 159 fractures including 11 soft tissue infections or wound dehiscence (6.8%), 2 hardware removal (1.3%), and 2 malocclusions (1.3%). There was 1 readmission for intravenous antibiotics (0.6%) and no reoperations. This protocol allows the patient to achieve mandibular function faster than those patients treated with closed techniques.

Titanium plating systems have some disadvantages, including palpability, thermal sensitivity, image interference, transcranial migration in pediatric cases,<sup>7</sup> growth inhibition when placed across growth sutures, and the need for secondary hardware removal surgery.<sup>8</sup>

The ideal fixation system will stabilize the fracture until the bone is completely healed, remaining biocompatible, and then resorb completely in a minimum amount of time.

The advantages of the resorbable plating system are no thermal sensitivity, no long-term palpability, no image interference, no growth inhibition, and no need for secondary hardware removal surgery.

The Inion resorbable plates and screws consist of an amorphous injection-molded copolymer of L-lactide/D-lactide/trimethylene carbonate. These plates resorb slowly, maintaining 70% of their strength at 9 to 14 weeks, and lose their strength steadily thereafter. There is a 42% bulk resorption at 40 weeks and then complete resorption by 2 to 4 years.<sup>9</sup> The mechanism of plate and screw resorption is hydrolysis of the long polymer chains into shorter water-soluble fragments and then metabolism via Krebs cycle and excretion as CO<sub>2</sub> and water.<sup>10</sup>

The list price of the Inion CPS four-hole extended 2.5-mm resorbable plate and four 8 × 2.5 mm resorbable screws is approximately \$800. This is 23% more costly than the list price of a typical titanium four-hole, 2.0-mm locking miniplate with four 2.0 × 8 mm locking screws at approximately \$650. However, this is less than a fraction of the cost of secondary hardware removal surgery and anesthesia, if indicated.

The Inion CPS Biodegradable Fixation System is a viable treatment for open reduction internal fixation of noncomminuted, noninfected mandible fractures with successful healing in 100% of cases. We found the complication rate of 20% to be higher than our previously published complication rate of 9.4% with titanium layered metal prototyping. This can be attributed to a steep learning curve, width and thickness of the plate, and transoral technique on Champy's line at the angle not transbuccal at the inferior border as in Laughlin's resorbable study.<sup>2</sup> Case selection is key and Inion should only be used as a load-sharing plate in a semi-rigid technique after anatomic reduction. It is not meant as a load-bearing heavier plate with bicortical screws, as seen in rigid fixation.

This clinical trial must be considered a preliminary study. Long-term follow-up studies with larger cohort groups are under consideration.

## REFERENCES

1. Champy M, Loddé JH, Must D, Jaeger JH, Muster D. Mandibular osteosynthesis by miniature screwed plates via buccal approach. *J Maxillofac Surg* 1978;6:14-21.
2. Laughlin RM, Block MS, Wilk R, Malloy RB, Kent JN. Resorbable plates for the fixation of mandibular fractures: a prospective study. *J Oral Maxillofac Surg* 2007;65:89-96.
3. Lazow SK, Tarlo I. Mandible fracture: transoral 2.0mm locking miniplate plus 1 week maxillomandibular fixation. *Atlas Oral Maxillofacial Surg Clin N Am* 2009;17:27-34.
4. Bolourian R, Lazow S, Berger J. Transoral 2.0-mm miniplate fixation of mandible fractures plus 2 weeks' maxillomandibular fixation: a prospective study. *J Oral Maxillofac Surg* 2002;60:167-70.
5. Chritah A, Lazow SK, Berger JR. Transoral 2.0-mm locking miniplate fixation of mandibular fractures plus 1 week of maxillomandibular fixation: a prospective study. *J Oral Maxillofac Surg* 2005;63:1737-41.
6. Lazow SK. The mandible fracture: a treatment protocol. *Commentary/update. J Cranio Maxillofac Trauma* 1997;3:38-45.
7. Cohen SR, Holmes RE, Amis P, Fitchner H, Shusterman EM. Tacks: a new technique for craniofacial fixation. *J Craniofac Surg* 2001;12:596-602.
8. Schmidt BL, Perrott DH, Mahan D, Kearns G. The removal of plates and screws after Lefort I osteotomy. *J Oral Maxillofac Surg* 1998;56:184-8.
9. Inion data on file. White paper. Enhancing Biocompatibility Second Generation Biodegradable Implants. 2005.
10. Inion data on file. White paper. Versatility and Suitability of Biodegradable Materials in Cranio-maxillofacial Surgery. 2005.

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