

# INION<sup>®</sup> compared with titanium osteosynthesis: a prospective investigation of the treatment of mandibular fractures

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## Abstract

We prospectively studied two groups of 30 patients to assess the outcome of treatment of mandibular fractures with the biodegradable INION<sup>®</sup> system compared with osteosynthesis with titanium miniplates. The degree of occlusion, wound healing, and swelling, were noted preoperatively and at 1 week, 6 weeks, and 6 months postoperatively.

All fractures healed uneventfully, both clinically and radiologically, and independently of the osteosynthesis used. We found no long-term disturbance of occlusion, but there were twice as many malocclusions in the INION<sup>®</sup> group at one week. We now use a 3–5 day period of postoperative elastic intermaxillary fixation (IMF) to prevent material deformities. Both groups developed problems with wound healing; with INION<sup>®</sup> adequate soft tissue closure combined with appropriate positioning of the plates prevented this. At 6 months a dense swelling developed in some patients in the INION<sup>®</sup> group as a result of biodegradation of the plates.

INION<sup>®</sup> plates were biocompatible and strong enough to treat mandibular fractures.

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## Introduction

Titanium or steel osteosynthesis was used routinely for treatment of mandibular fractures. However, material-related disadvantages such as corrosion and the spread of titanium into the tissues, thermal paraesthesia, the need to remove the plate, and interference with computed tomograms (CT) led to the search for biocompatible systems of osteosynthesis.<sup>1–3</sup> Resorbable materials were established in maxillofacial surgery, initially in craniofacial surgery<sup>4,5</sup> and then in the treatment of midfacial fractures<sup>6</sup> and ortho-

gnathic surgery.<sup>7,8</sup> Reports of the use of resorbable systems in mandibular fractures have recently been published.<sup>9,10</sup> The suitability of resorbable plates as biodegradable osteosynthesis material for resorption and biocompatibility has been shown.<sup>11</sup> Poly-(DL)-lactide polymers are degraded by hydrolysis in vivo to  $\alpha$ -hydroxiacides and then to water and carbon dioxide.<sup>12</sup> Within the first three days after implantation mechanical stability increased, after which the biomechanical rigidity is similar to that of titanium plates.<sup>13</sup>

The INION<sup>®</sup> system is available in 3 different sizes: 1.5 mm, 2 mm, and 2.5 mm. The screw holes are drilled with conventional drills and tapped. The screws are inserted at right angles to the plate. The wound should be closed accurately to allow an adequate soft tissue cover. The transbuccal approach is difficult with resorbable materials

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and can cause additional scarring. Placement of the plate on the lateral mandibular surface is possible using an angled screwdriver.

## Patients and methods

We used biodegradable INION<sup>®</sup> plates (Striker, Germany) and titanium-miniplates (Martin Medizin-Technik GmbH, Tuttlingen Germany). From March 2005 two groups of 30 patients were evaluated. The assignment of the patients to the two groups was initially planned to be randomised, however on occasion, unavailability of the required plating system did not allow this. The groups were similar: patients in the INION<sup>®</sup> group had a mean age of 24 years (range 15 to 45), and 27 were male and 3 female. In the titanium group the mean age was 32 years (range 15 to 75), and 28 were male and 2 female.

They were examined preoperatively and at 1 week, 6 weeks, and 6 months postoperatively. Radiographs were taken preoperatively, and 1 week and 6 months postoperatively. Patients with fractures of the mandibular body, from one mandibular angle to the other, were included in this study. Four patients in the INION<sup>®</sup> group and 3 in the titanium group had additional fractures of the mandibular neck that were treated with titanium miniplate osteosynthesis outside the protocol.

The patients in the INION<sup>®</sup> group had 37 mandibular fractures (1 symphyseal, 14 parasymphiseal, and 22 of the mandibular angle). Seven patients had double fractures. The mean time between accident and treatment of the fracture was 2.5 days (range 0 to 12). In the titanium group 44 fractures were treated (21 parasymphiseal and 23 mandibular angle). Fourteen patients had double fractures. The mean time between the fracture and the operation was 2.3 days (range 0 to 6).

The displacement of the fractures between the two groups was similar: the INION<sup>®</sup> group had 15 undisplaced, 9 slightly displaced (less than one cortical thickness overlapped), and 13 with displaced fractures (more than one cortical thickness overlap). The titanium group had 19 non-displaced, 17 slightly displaced, and 8 displaced fractures.

Fractures were treated by open internal fixation under general anaesthesia. The miniplates were adapted to the bone and the reduced fracture was fixed by inserting monocortical screws according to Champy's<sup>18</sup> principles. Wounds were closed with non-resorbable sutures. Despite reports, no postoperative intermaxillary fixation (IMF) was used. Osteosynthesis was achieved with 2.0 mm and 2.5 mm INION<sup>®</sup> plates. The plates consisted of L-poly lactide, DL-poly lactide, and trimethylenecarbonate. In the other group, only 2.0 mm titanium miniplates were used.

To standardise disturbances of occlusion, they were assessed with the thinnest occlusion foil. Subjective disturbances of occlusion were evaluated after the patient had been questioned. Analyses of dehiscences were difficult to stan-

Table 1  
Subjective disturbances of occlusion

Time postoperatively (weeks)	INION <sup>®</sup> (n = 30)	Titanium (n = 30)
1	13	7
6	2	4
24	0	0

dardise, so any abnormality of wound healing was classed as a dehiscence.

## Results

All patients were examined at 1 and 6 weeks after operation. Preoperative and postoperative radiographs were taken. At 6 months, there were only 17 patients in the INION<sup>®</sup> group and 21 patients in the titanium group. Of the 13 patients in the INION<sup>®</sup> group who did not attend for 6 month follow up, 5 had the plate removed early because the wound did not heal; 8 patients failed to attend. Of the 9 missing patients from the titanium group, 4 had plates removed early and 5 failed to attend.

All the fractures healed both clinically and radiologically, and independently of the osteosynthetic material used. There were no persisting disturbances of occlusion. The median inpatient treatment time of the patients in the INION<sup>®</sup> group was 7 days (range 1 to 14), and in the titanium group 7 days (range 2 to 17).

Only 29 patients in each group could be evaluated (Tables 1 and 2); one patient was edentulous and another had too few teeth to assess the occlusion.

In the INION<sup>®</sup> group we found 12 objective and 13 subjective disturbances of occlusion after one week, and 12 patients agreed about the subjective and objective problems. All patients were treated with elastic intermaxillary fixation (IMF) for a week, and after 6 weeks only one objective and two subjective malocclusions were recorded. In both patients premature contacts of the teeth were identified and ground in. However, after 6 months all patients had perfect occlusions.

In the titanium group there were 6 objective and 7 subjective malocclusions after a week. These patients were treated with elastic IMF for a week. There were 2 objective and 4 subjective malocclusions after 6 weeks, but no malocclusion could be detected objectively or subjectively at 6 months.

We found 11 dehiscences in the INION<sup>®</sup> group after a week. One patient had a purulent wound infection and one a massive haematoma. Another patient had poor oral hygiene, which did not improve despite continuous encouragement.

Table 2  
Wound dehiscences

Time postoperatively (weeks)	INION <sup>®</sup> (n = 30)	Titanium (n = 30)
1	11	12
6	2	3
24	1	0



Fig. 1. Exposure of a 2.5 mm INION® plate applied to the oblique ridge of the mandible.

After 6 weeks only two patients had dehiscences. The patient who had had a wound infection still had pronounced problems with wound-healing. After 6 months the patient with poor oral hygiene was the only one who had a dehiscence. In general we found that dehiscences with INION® plates depended on the size of the plate and on the method of application: we found 9 dehiscences and 4 exposed osteosynthesis plates with the 2.5 mm INION® plates. The exposed plates were usually situated on the oblique ridge of the mandible (Fig. 1) however one was parasymphyseal. When the 2.0 mm INION® plates were placed on the lateral surface of the mandible there were only 4 dehiscences and no plate exposures.

In the titanium group 12 dehiscences were detected after a week, including three wound infections, and one haematoma. At 6 weeks there was only one wound dehiscence and none after 6 months.

All patients had a soft postoperative swelling a week after operation. After 6 weeks 13 patients in the INION® group and 8 in the titanium group still had a soft swelling. At the final follow up there were 4 dense swellings in the INION® group.

One patient treated with INION® had the plate removed after 3 weeks because it was exposed. Nevertheless, the fracture was already stable and no new osteosynthesis was required. It was necessary to remove 4 exposed INION® plates from the oblique ridge between 3 and 6 months, but this had no effect on the healing of the fracture.

Four titanium miniplates were removed early because of problems with wound healing; the earliest was 2 weeks after operation, and a new osteosynthesis was required. The others were removed between 6 weeks and 4 months postoperatively.

Routine removal of metal plates is normal practice in the department. Nine were removed as inpatients, each of 3 days' duration. A further 11 were removed under local anaesthesia in the outpatient department. Six patients failed to keep their appointments. Complications of the operations were 6 bulky swellings, 5 disturbances of sensation of the lower lip, and 4 wound infections.

## Discussion

The data presented clearly show that the INION® system gives sufficient support to allow bony healing that is on a par with that of titanium miniplates. The stability of self-reinforced poly-L/DL-lactide osteosynthesis materials for bony healing has been shown previously.<sup>10,14</sup> The stability of PLLA- osteosynthesis materials in fractures, which are subject to lower loads in other sites, was shown in 1989.<sup>15</sup> All fractures in our study healed successfully, and there were no clear differences in the duration of inpatient treatment between the two groups.<sup>9</sup> We found twice as many malocclusions in the INION® group after the first week, which is possibly related to the material itself, as the self-reinforced poly-L/DL-lactide osteosynthesis materials gain their final stability after 3 days in place.<sup>13</sup> We agree that postoperative IMF for 3 to 5 days should be used to prevent material deformities. Disturbances of occlusion were treated by elastic IMF for 1 week, and following that there were no differences in occlusal problems between the groups at 6 weeks. No prolongation of the duration of inpatient treatment was necessary because of the IMF.

Another reason for the postoperative disturbances of occlusion could be the postoperative oedema of the temporomandibular joint after reposition of the condylar neck or angle fractures. Both groups developed dehiscences and problems with wound healing, but with increased experience with INION® plates, we found that adequate soft tissue closure prevents problems with healing. Such problems with resorbable osteosynthesis materials are with the position of the plate.<sup>16</sup> Our results showed no more wound healing problems with the use of INION® plates than with titanium plates.<sup>17</sup> In general early removal of the INION® plates was later than early removal of the titanium plates. Inflammation of the tissue caused by the resorbable material, as described by other groups<sup>10,14</sup> does not seem to be a problem when there is adequate soft tissue coverage.

The deformation of INION® plates seems to be higher at the oblique ridge than over the lateral surface of the mandible and, after we changed the position of the plate from the oblique ridge to the lateral surface, we detected fewer malocclusions. The change from 2.5 mm to 2.0 mm INION® plates reduced the rate of dehiscences without changing the biomechanical characteristics. The degradation of the INION® plates seems to be responsible for the higher rate of long-lasting soft tissue swellings. There were dense swellings after 6 months, which were unsightly and slow to shrink.

The disadvantages of biodegradable materials (costs, breakage of screws, more difficult operative handling, and swelling of the plate during degradation<sup>9</sup>) contrast with the potential risks of removing the titanium plates (cost, time, and a relatively high morbidity). In some places titanium plates are removed routinely, in which case these drawbacks cannot be considered. However the question of long-term titanium toxicity should be borne in mind.

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