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Inion biodegradable plates: The first century

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Abstract

I have used the Inion biodegradable plate system to treat patients with facial fractures who presented to Arrowe Park Hospital, Wirral between May 2003 and November 2004. I have inserted 100 miniplates (68 mandible, 15 maxilla, 12 zygomatic bone, 3 nose, and 2 thyroid cartilage). All the fractures healed.

Keywords: Inion biodegradable plates; Facial fractures

Introduction

An ideal miniplate in the treatment of facial fractures must have adequate strength and versatility. It should be non-toxic to allow bony healing, not interfere with imaging, function while the bone heals, and resorb once the task has been accomplished.[1] At present most oral and maxillofacial surgeons use titanium plates, including reconstruction plates, compression plates, miniplates, and microplates for the fixation of bony fragments, which in some cases avoids the need for intermaxillary fixation.[2] Titanium miniplates do not satisfy all the ideal criteria. In orthopaedic surgery it has been reported that fixation by rigid metallic plates deprives bone of normal stress patterns and prevents the rapid formation of callus.[3] Avoidance of stress with the use of miniplates in the treatment of facial fractures is a theoretical consideration as there is no research on the subject. Bulky titanium plates can cause discomfort, thermal sensitivity, and local macroscopic and microscopic destruction of hard and soft tissue near the plate.[4–6] In oral and maxillofacial surgery biodegradable materials were first used in animal studies,[1,7] and later in humans for fixation in the treatment of fractures and in orthognathic surgery.[8–10] Biodegradable plates have been made of lactic (PLA) and glycolic (PGA) acid polymers that degrade by diffusion-controlled hydration, the products of which are taken up by macrophages and finally eliminated through Kreb's cycle.[11] PGA is rapidly resorbed while PLA is hydrophobic and can take up to 5 years to disappear completely.[11] The recent blending of these polymers with trimethylene carbonate to increase their flexibility has allowed the development of a biocompatible, bioresorbable material suitable for the use in the treatment of facial fractures.[11,12] They were restricted in their initial application because of poor mechanical properties, but with the development of highly orientated fibres in the longitudinal axis of the polyester, which improved the tensile and flexural modulus of elasticity, their use in the treatment of facial fracture was possible.[9] I now report the result of my first 100 miniplates in the treatment of facial fractures with the Inion biodegradable fixation system, the mini plates being made from highly orientated fibres of polymers of PGA and PLA.

Inion biodegradable plating system

The Inion plates are categorised by diameter of screws (1.5 mm, 2.0 mm, 2.5 mm). They are manufactured to constant width and thickness in varying lengths with some variations in shape. The plates are activated by immersion in a water bath at 55 °C and can be moulded easily to the desired shape. The screws are available in varying lengths,

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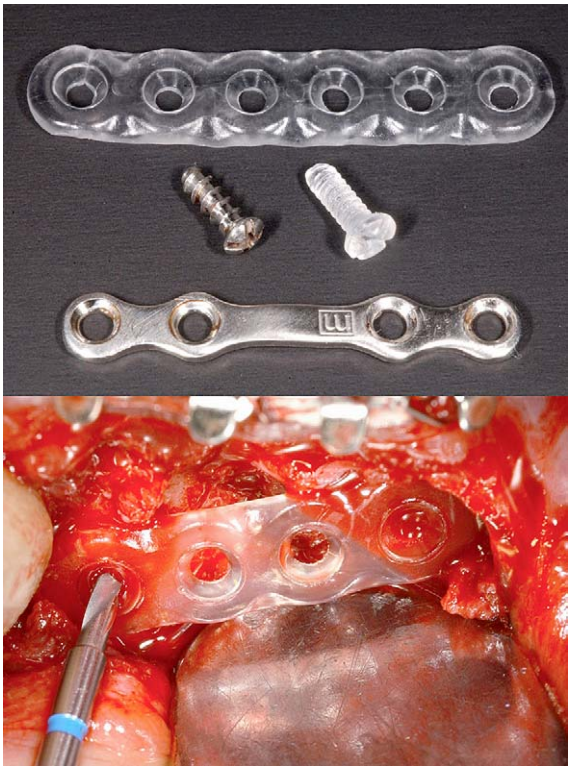

Fig. 1. Biodegradable and titanium plates and screws to compare their size and the insertion of a biodegradable plate.

with a fine thread to provide maximum engagement and they are inserted with a universal screwdriver. Five screws are in each sterile package while the plates are individually packed.

Before being used a plate is softened in a water bath and then it is contoured to the desired shape of the site where it is to be inserted. A screw hole of the correct size is drilled in the bone and then tapped (Fig. 1). The drill and tap are colour coded and are designed for single use.

Intermaxillary fixation is recommended for at least 3 days when the plate is used in the mandible while the plate becomes rigid and gains strength similar to that of a metal plate.

The material cost of using this system is less than for titanium.

Method

For fractures of the zygomatic bone that required stabilisation the 1.5 mm plates were used and the 2.0 mm plates for maxillary fractures without intermaxillary fixation.

In the mandible 2.5 mm and later 2.0 mm plates were used, augmented with intermaxillary fixation for varying periods. All mandibular fractures were initially fixed with rigid elastic intermaxillary fixation using Erich arch bars at the time of operation and later changed to light elastic traction. Stabilisation of fractures at the mandibular angle was initially by placement of 2.5 mm plates on the external oblique ridge whenever possible, but later when 2.0 mm plates were used plates were inserted by a transbuccal approach. Parasymphyseal fractures were treated initially with two plates but later with a single plate when the mandibular arch bar provided suitable stability. I changed the size of the plates for mandibular fractures to 2.0 mm when exposure of the plate and other complications became apparent with the 2.5 mm plate.

A single patient with a fracture of the thyroid bone was treated with two 1.5 mm four-hole miniplates with eight 4.0 mm screws.

Results

All but one fracture healed by bony union to the planned occlusion and every patient was satisfied with the result.

All the maxillary, nasal, and thyroid cartilage plates remain asymptomatic at the site of insertion and appear to be degrading without complications.

One patient who had been treated with four plates to stabilise a fractured right zygomatic bone returned some 4 months later with inflammation of the infraorbital area, which was thought to be caused by a failure to remove the degradation products. No surgical treatment was undertaken and the inflammation resolved completely with a course of antibiotics.

Problems have arisen in the treatment of mandibular fractures. The 2.5 and 2.0 mm plates are thicker than comparable titanium plates. Nineteen of the 2.5 mm plates have been removed as a result of exposure or infection of the plate. The mean time to removal was 108 days (range 38–205). Most of the plates were removed by grasping them with forceps and lifting them free without the need for a local anaesthetic.

The high rate of exposure of the 2.5 mm plates was thought to result from the size of the plate, the blood supply, or leakage of saliva. Fractures of the mandible were later treated with 2.0 mm orthognathic plates inserted by a transbuccal approach for angular and parasympyseal fractures with an arch bar (acting as a superior plate) and a single plate placed above the lower border. Only a single plate was exposed and lost after 251 days but an asymptomatic discharging sinus has appeared at the site of some plates which to date has been left without treatment.

All but six mandibular fractures had intermaxillary fixation applied (median 14 days, range 7–28).

One patient with a fractured mandible (in whom no intermaxillary fixation was used) required a further operation as a result of fracture of the miniplate 3 weeks after insertion. I inserted a titanium reconstruction plate and the fracture then healed uneventfully. This patient had received radiotherapy for the treatment of a breast carcinoma 15 years previously and had a pencil-thin mandible from continual wearing of a denture.

One tooth was extracted because the root was damaged by placing a screw hole partly within it.

All the patients to date remain free of symptoms and I hope that the miniplates will continue to biodegrade without complications.

Discussion

Insertion of biodegradable plates is quite different from insertion of titanium plates. The miniplate can be shaped easily by digital pressure once it becomes malleable after immersion in the water bath. Care must be taken not to over-tighten the screw to avoid fracturing the head. Should it happen a replacement can be inserted easily by drilling through the fractured screw, tapping a new hole and inserting another screw. The transbuccal approach is difficult, as there is no way of holding the plate in position while a screw is inserted. The use of the 1.5 mm plates is the most difficult as the nurse who mounts the screws on the screwdriver can easily destroy the slot in the screw by repeated attempts. The need to tap and then insert a screw requires great manual dexterity by the surgeon and until mastered will take longer than the insertion of a titanium plate. The surgeon may become frustrated so that the technique is abandoned but it should be resisted as the technique can be mastered.

These plates are radiolucent and do not interfere with computed tomographic or magnetic resonance imaging and they allow a clear postoperative view of the fracture site on plain radiographs.

The fractures have been sufficiently stable to allow bony healing clinically indistinguishable from those treated with metal miniplates. It remains to be seen if any further problems arise from their use until all the plates have biodegraded.

Particularly with the reported success of fixation of osteotomies with biodegradable plates[13] it would be difficult to argue against the routine use of biodegradable plates for fractures of the maxilla.

The use of the 2.5 mm plates in the treatment of mandibular fractures has not been so successful. It was disappointing to have to experience exposure of the plate so soon after insertion of the 2.5 mm plates as I rarely encountered the problem so soon when I used titanium plates. The incidence of exposure and removal of titanium plates is reported to range from 10% to 16% over a 2 year period and clearly it is much earlier when using biodegradable plates.[2] The exposure rate may not be much different from titanium over the whole cycle but this will be reported when all the plates have biodegraded.

A different technique with 2.0 mm orthognathic plates was used in an attempt to overcome the exposure of plates. Early exposure was virtually eliminated but later many patients returned with an asymptomatic discharging sinus adjacent to the plate which was thought to be from a collection of biodegradable products taking the line of least resistance and discharging to the surface. Some of these plates have been removed while others have been left in place and the patient kept under review. It is too early to report whether these sinuses close without the need to remove the plate.

When using titanium miniplates the size of plate and the number of screws used are of little consequence as the material is inert. However, with biodegradable plates and screws it is important to use only what is required so as to minimise the amount of breakdown products.

I used intermaxillary fixation to facilitate reduction of the fracture and application of the plate. It is difficult to insert a plate by hand while holding the reduced fracture in the correct occlusion. The manufacturer advises the application of light elastic IMF for 3 days to enable the plate to attain maximum strength. It is our aim not only to establish bony healing of the fracture but also restoration of the original occlusion and so it is difficult to argue against intermaxillary fixation. Rigid IMF was applied in every case (mean 14 days, range 7–21) and then light elastic traction (mean 14 days, range 7–28). This regimen resulted in bony union of all the fractures with the occlusion as it was before the fracture.

The Inion system has been successful in the maxilla but further work in the treatment of mandibular fractures is advisable. The new generation of miniplates that involves its incorporation into bone rather than its degradation may be the answer in the mandible; we must await the research. Nevertheless these plates are successful in the treatment of some facial fractures particularly in the maxilla.

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