Journal of Cranio-Maxillo-Facial Surgery (2010) **38**, 517–521

doi:10.1016/j.jcms.2010.02.013, available online at http://www.sciencedirect.com

Pullout strength of a biodegradable free form osteosynthesis plate

Siegfried JANK, MD, DMD, Associate Prof.[1], Petteri VÄÄNÄNEN, PhD (Medical Engineering)[2], Frank R. KLOSS, MD, DMD[2], Janne T. NURMI, DVM, PhD[3], Juha-Pekka NUUTINEN, PhD (Eng)[4], Sanna JAKONEN, MSc (Eng)[5], Harri HAPPONEN, MSc (Eng)[5]

[1] *Medical University of Innsbruck, Department of Oral-, Cranio- and Maxillofacial Surgery, Innsbruck, Austria;* [2] *Department of Physics, Faculty of Natural and Environmental Sciences, University of Kuopio, Kuopio, Finland;* [3] *Department of Clinical Veterinary Sciences, Faculty of Veterinary Medicine, University of Helsinki, Helsinki, Finland;* [4] *Institute of Biomaterials, Tampere University of Technology, Tampere, Finland;* [5] *Inion Oy, Tampere, Finland*

SUMMARY. **The Inion® Free Form Plate is a newly designed biodegradable plate. After drilling through the plate and tapping, a biodegradable screw can be inserted, followed by removal of the screw head. As an alternative a countersink screw can be used. Aim of the study was to compare the mechanical properties of the 1.4 mm Free Form Plate with the 2.0 mm conventional shaped plate. Mechanical testing of the plate pull-out strength was conducted for the Inion® Free Form Plate fixed with an Inion OTPS™ 2.0 × 20 mm Screw. In addition, the failure mode was reported. Overlapping confidence levels were found with regard to the yield load, first peak load and maximum load, when comparing the Free Form Plate and the conventional 4-hole plate. The Free Form Plate fixed with a screw with head and countersink showed the highest stability at maximum load. The results of the mechanical stability testing showed no significant differences between the tested plates. The main failure mode was a failure of the screw shaft. The results of the current investigation imply that the 1.4 mm Free Form Plate could be used as an alternative to the 2.0 mm conventional shaped plate. © 2010 European Association for Cranio-Maxillo-Facial Surgery**

Keywords: **biodegradable materials, osteosynthesis, mechanical testings, pullout strength, polylactide**

INTRODUCTION

Biodegradable osteosynthesis materials are well-established in maxillofacial surgery (*Tams* et al., 2001; *Yerit* et al., 2005a, b), being well-documented by numerous publications in the last decade (*Haers* et al., 1998; *Bahr* et al., 1999; *Kallela*, 1999a, b; *Enislidis* et al., 2005; *Eckelt* et al., 2007). They have been used for craniofacial and pediatric fractures (*Shetty* et al., 1997; *Gosain* et al., 1998; *Yerit* et al., 2005a, b), midfacial fractures (*Bahr* et al., 1999; *Bell* and *Kindsfater*, 2006), mandibular fractures (*Tormala* et al., 1987; *Bos et al.*, 1989; *Gerlach*, 1993; *Tams* et al., 1999, 2001; *Hasirci* et al., 2000; *Wiltfang* et al., 2000; *Yerit* et al., 2002; *Ylikontiola* et al., 2003; *Bell* and *Kindsfater*, 2006; *Rasse* et al., 2007) and orthognathic surgery (*Suuronen* et al., 1992a, b, 1997; *Maurer* et al., 2002). Many patients still undergo the removal of titanium plates because of temperature sensitivity, palpation of the plates or the unacceptability of an incorporated foreign-body. The advantage of biodegradable materials is the degradation of the material over a period of 12–24 months. Until now, biodegradable materials have had to be thicker than titanium to achieve the same mechanical stability (*Ferguson* et al., 1996a, b; *Maurer* et al., 2001; *Leinonen* et al., 2003). This has resulted in surgeons' and patients' complaints regarding the bulkiness of the material especially in the first six postoperative months. Therefore, research on biodegradable osteosynthesis materials should focus on the reduction of the materials size when compared to titanium plates. When considering the Inion® System, the 2.0 mm biodegradable plates are indicated for use in the midface (*Wood*, 2005). The stability of the 2.0 mm system is comparable with conventional 1.5 mm titanium systems (*Wood*, 2005). Recently, a new plate design has been introduced: The Inion® Free Form Plate (Fig. 1) is a plate which has a thickness of 1.4 mm. The plate has no prefabricated holes, only pilot holes to guide the drill. It is also possible to drill through the plate in a position without a pilot hole. After drilling there are two ways of inserting a screw: 1. Inserting a conventional screw with a countersink and 2. Inserting a screw after tapping the hole and then cutting off the screws head.

The 1.4 mm Free Form Plate was designed to achieve the same mechanical stability as the 2.0 mm conventional plates. The aim of the study was to evaluate the mechanical pullout strength of the 1.4 mm Free Form Plate when compared to the 2.0 mm conventional plate.

MATERIAL AND METHODS

Two different sizes of the Inion® Free Form Plate are manufactured. One of which is 65 mm and the other

100 mm long. The width of the plates is 20 mm and the thickness 1.4 mm. The diameter of the pilot holes is 1 mm. The distance between the adjacent pilot holes is 6.5 mm and the displacement between the pilot hole columns is 3.25 mm (Fig. 1). The manufacturing process consists of extrusion, compression molding and laser cutting. The plates are designed to allow for them to be cut and shaped to the desired form during use. Only the pilot holes which are going to be used are drilled and tapped for screws (holes can also be drilled and tapped at other positions on the plate if needed). Countersinks for the screw heads can be created on the surface of the plate or, alternatively, the screw heads can be removed after screw insertion.

In this study, two different types of fixation for the Inion® Free Form Plate were created and tested. The first fixation of the plate was created by drilling and tapping the pilot hole and cutting off the screw head on the surface of the plate after screw insertion. The second fixation of the plate was created by drilling the pilot hole and creating a countersink for the screw head on the surface of the plate. In these cases of countersink fixation the screw head was not cut and the plate was not tapped. The mechanical testing of plate pullout strength was conducted using the plate secured with an Inion OTPS™ 2.0 × 20 mm Screw.

The testing was generally conducted by following the guidelines of the FDA draft: *Guidance Document for Testing Biodegradable Polymer Implant Devices* and ISO 15814, ASTM F543 and ASTM F1839-standards.

After water bath treatment (one minute at 70 °C) the test sample plate was created by cutting the Inion® Free Form Plate to an approximate size of 20 mm × 20 mm. The pilot hole, located in the middle of the test sample, was drilled and tapped or drilled and countersunk for the screw. The appropriate hole was also drilled and tapped in an underlying foam block (20 mm × 40 mm × 45 mm). Finally the test sample was fixed to the foam block and test jig by one Inion OTPS™ Screw as shown in Figs. 2 and 3. When the hole in the test sample plate was tapped, the screw head was cut off after insertion on the surface of the plate by cutting forceps. When the countersink was created on the plate, the screw head was not cut off after insertion (Fig. 2).

Water bath treatment (1 min at 55 °C) was conducted for the Inion OTPS™ 2.0 mm System extended 4 Hole Plates, according to the manufacturers' guidelines for the product line. The appropriate hole was drilled and tapped in the foam block (20 mm × 40 mm × 45 mm) through the hole of the plate. Finally the plate was fixed to the foam block and test jig by one Inion OTPS™ Screw as shown in Fig. 2. The screw head was not cut off after insertion and a countersink was not created on the plate.

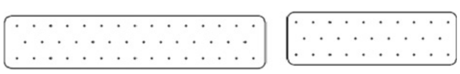

Fig. 1 – The Inion® Free Form Plate, 20 × 100 mm, on the left and the Inion® Free Form Plate, 20 × 65 mm, on the right. Notice that pictures are not in real scale.

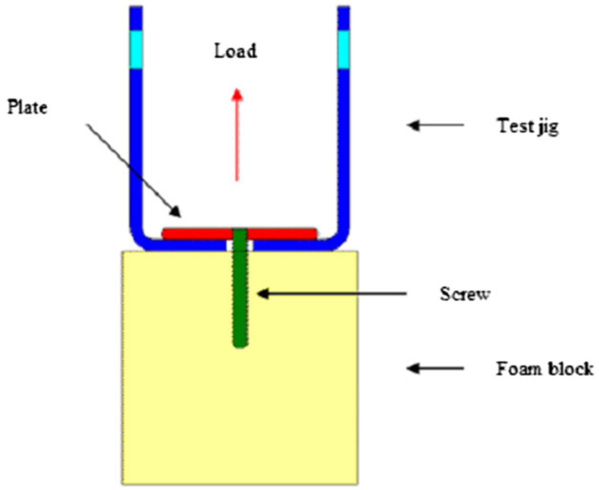

Fig. 2 – The schematic drawing of the test setup of the Inion® Free Form Plate test sample fixed with screw, foam block and test jigs. The direction of the load is shown with a red arrow.

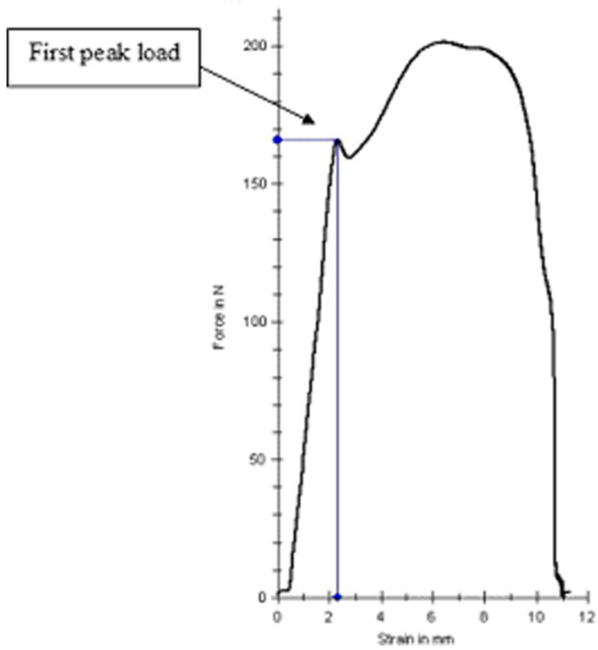

Fig. 3 – Determination of the first peak load from the stress–strain curve.

The test setup (i.e., test jig) decreases the effective length (i.e., the part of the screw which is inside the foam block) of the screw threads approximately 1.5 mm in comparison to the clinical situation (Fig. 2).

Prior to testing the sample plate, the screw attached to the foam block and the test jig were all conditioned in ionized water at 37 °C for 24 h.

The plate pullout testing was performed in water at 37 °C. The foam blocks were connected to the material testing machine by specially designed test jigs. Once connected the plate was loaded (pullup) with a constant speed of 5 mm/min until failure of the fixation. The yield load (N), first peak load (N), maximum load (N),