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Fixation properties of a biodegradable “free-form” osteosynthesis plate

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The Inion FreedomPlate, a “free-form” osteosynthesis plate, is a biodegradable plate with just pilot holes for drilling. The construction of the plate allows the surgeon a placement of screws in optimal position. The screw heads can either be countersunk into the plate or cut off. Furthermore, the plate can be cut and contoured to match the bone. The aim of this study was to determine the mechanical properties of the Inion FreedomPlate compared to a conventional biodegradable plate. Acrylic pipes were fixed together with plates and screws. Tensile and cantilever bending tests were performed to measure the fixation properties. In the tensile test, the samples were loaded with a constant speed of 5 mm/min until failure of fixation. The yield load, maximum failure load, and initial stiffness were recorded, and the failure mode was visually determined. In the cantilever bending test, the samples were loaded with a constant speed of 50 mm/min (with a moment arm of 45 mm) until failure of fixation. The yield bending moment and initial stiffness were recorded, and the failure mode was determined. The results of the study show that the new free-form plate provides at least as strong fixation as the tested conventional biodegradable plate. No clinically relevant difference was found between free-form plates fixed with into-the-plate countersunk screws and those fixed with screws without heads. **(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2008;106:477-82)**

The use of biodegradable plates and screws is a well-known alternative to titanium in the osteosynthesis of maxillofacial fractures.[1-4] The applications of biodegradable plates and screws are described in the literature relating to their use in the midface and the craniofacial area, for mandibular fractures, and in orthognathic surgery.[1-23] Further, the loss of stability after a period of about 6 months leads to the indication of biodegradables in pediatric fractures.[3,4,22,24] The design of the plates and screws is similar to titanium, but usually thicker to achieve the same stability. Plate thickness is criticized by some surgeons who complain that the plates are too bulky compared to titanium miniplates. Overly bulky plates (e.g., with thickness of 3 mm) and protruding screw heads of the first-generation biodegradable systems have been reported to increase the risk of postoperative tissue reactions.[25] Accordingly, thinner plates and low-profile screws are now preferred.

Recently, a new type of a biodegradable plating system was designed (Inion FreedomPlate, Inion Oy, Tampere, Finland). These plates have some essential

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Table I. The study groups

Study group	*Plate*	*Screw*
1	Inion FreedomPlate, 20 × 65 mm*	Inion CPS 2.0 × 10.0-mm screw, screw head countersunk into the plate
2	Inion FreedomPlate, 20 × 65 mm*	Inion CPS 2.0 × 10.0-mm screw, without screw head
3	Inion CPS 2.0-mm Extended 4-Hole Plate	Inion CPS 2.0 × 10.0-mm screw, with standard screw fixation, ready-made countersunk screw holes on the plate

*Cut to the size of the Inion CPS 2.0-mm Extended 4-Hole Plate.

differences compared to conventional metal and biodegradable plates. After heating in a warm water bath, the "free-form" plate can be cut to the desired size and shape, and easily contoured to match with the contours of the bone surface. The plate does not have ready-made screw holes, only several pilot holes allowing fluid flow through the plate, and freedom to drill holes through the desired pilot holes in the desired direction (angulation) for optimal screw position in relation to fracture line(s) and bone quantity/quality. The plate is 1.4 mm thick. For low-profile seating of the screw head, the screw heads can either be countersunk into the plate or alternatively the screw heads can be cut off along the plate surface after screw insertion. Screw head removal is possible when threads are created with a bone tap instrument through the plate. By tapping through the plate, a kind of "locking plate" is created. According to the manufacturer, the thickness of the plate is enough to provide adequate portion of threaded material for interlock between the plate and the tight-threaded screws to provide sufficient fixation strength of the plate.

The aim of this study was to investigate the mechanical properties of the Inion FreedomPlate fixed with countersunk screws and with screws without screw heads compared to the corresponding properties of the previously clinically used Inion CPS 2.0-mm plate fixed with conventional screw fixation.[26]

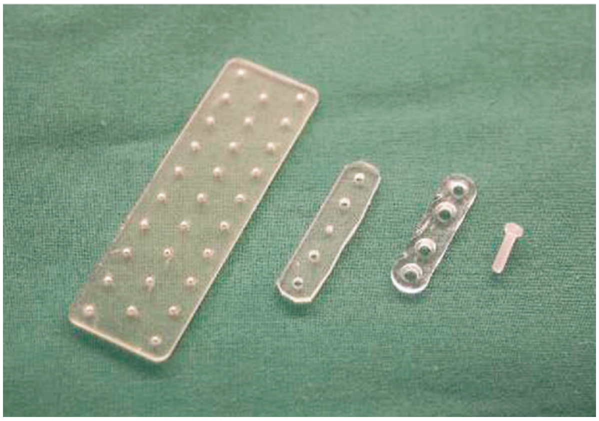

Fig. 1. The implants used in the study (*from left to right*): The Inion FreedomPlate (20 × 65 mm), the Inion FreedomPlate cut to the size of the control plate, the Inion CPS 2.0 mm Extended 4-Hole Plate (control), and the Inion CPS 2.0-mm screw cut to the length of 10 mm.

MATERIALS AND METHODS

The study groups were (1) Inion FreedomPlate fixed with countersunk screws, (2) Inion FreedomPlate fixed with screws without screw heads, and (3) Inion CPS 2.0-mm Extended 4-Hole Plate with standard screw fixation (Table I, Figs. 1 and 2). According to the instructions for use of the manufacturer, the plates were immersed into a warm water bath (70°C and 55°C for the Inion FreedomPlate and Inion CPS plate, respectively) for 1 minute prior to use.

Directly after the water bath treatment, the Inion FreedomPlate was cut to the size of the Inion CPS 2.0-mm Extended 4-Hole Plate and all plates were contoured to match the shape of the acrylic pipe simulating bone in this study. The acrylic pipes had an outer diameter of 13 mm and an inner diameter of 9 mm. Two pipes were connected together with a plate and screws to simulate plate fixation of a standard, transverse osteotomy. A 1-mm gap was left between the pipe ends for worst-case scenario conditions (corresponding to a situation where a tight contact between or perfect alignment of bone fragments is not achieved). Also for worst-case scenario, all plates were fixed to the pipes with the smallest diameter screw available to be used with the Inion FreedomPlate, i.e., the Inion CPS 2.0-mm screw. The screws were cut short enough (i.e., maximum 10-mm long) to guarantee monocortical fixation in the used test set-up. Each plate was fixed with 4 screws (2 on both sides of the osteotomy line). In group 1, each screw hole was drilled through a pilot hole of the plate and the underlying acrylic pipe; a countersink instrument was used to prepare the hole entrance on the plate for low-profile seating of the screw head. Further, threads were created to the hole manually with a bone tap instrument, and finally a screw was inserted into the threaded hole in the pipe. In group 2, threaded drill holes were created in the same way but without countersinking. Without coun-

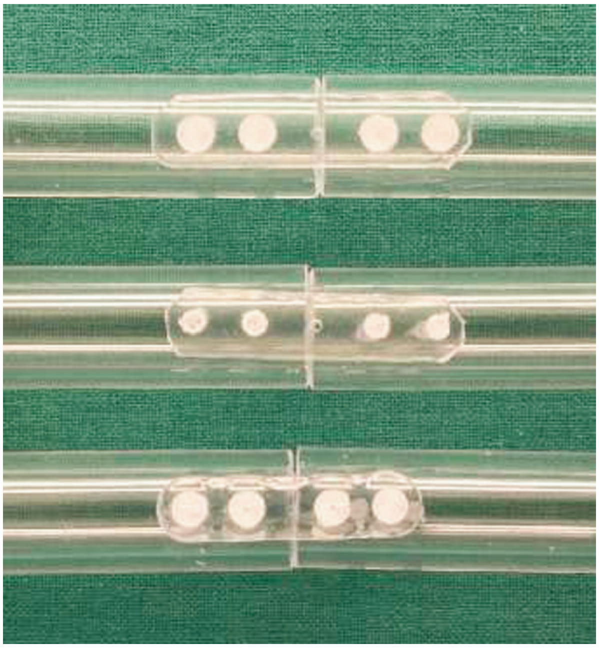

Fig. 2. The Inion FreedomPlate (cut to the size of the control plate) fixed with countersunk screws (*top*), with screws without screw heads (*middle*), and the Inion CPS 2.0 mm Extended 4-Hole Plate with conventional screw fixation (*bottom*).

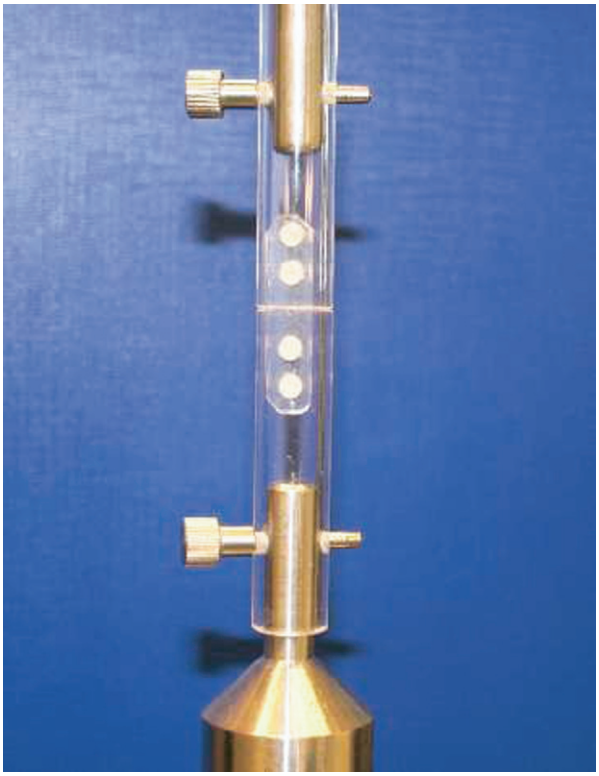

Fig. 3. The test set-up for the tensile test. Please note that the actual tests were carried out in water at 37°C.

tersinking, the tapping created threads also to the plate enabling interlocking between the screw and the plate. After screw insertion, the head of the screw was cut off along the surface of the plate. In group 3, holes were drilled to the acrylic pipe through the ready-made countersunk screw holes of the plate, threads were created to the acrylic pipe with a bone tap instrument, and finally a screw was inserted into the threaded hole in a standard fashion. After insertion of all screws, the samples were immersed into containers filled with ionized water and preconditioned at 37°C for 24 hours prior to testing.

The testing was carried out in water at 37°C. Half of the samples in each group were tested with a tensile test ($n = 4$), and the other half were tested in a cantilever bending test. In both tests, the acrylic pipes were connected to the materials testing machine (Z020/TH2A 2000 materials test system, Zwick Gmbh & Co, Ulm, Germany) with jigs specially designed for the test (Figs. 3 and 4). In the tensile test, the samples were loaded in a direction parallel to the long axis of the acrylic pipe with a constant speed of 5 mm/min until failure of fixation. The yield load (N), maximum failure load (N), and initial stiffness (N/mm) were recorded, and the failure mode was visually determined. In the cantilever bending test, one end of the acrylic pipe was

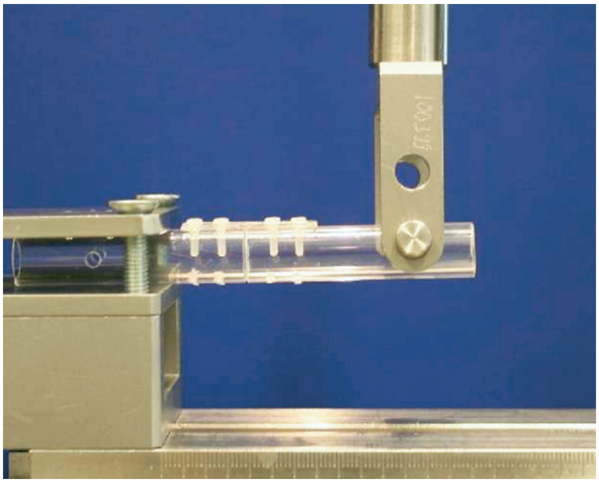

Fig. 4. The test set-up for the cantilever bending test. Please note that the actual tests were carried out in water at 37°C.

rigidly fixed and the samples were loaded (bent upwards) from the other end of the pipe (length of the moment arm was 45 mm) with a constant speed of 50 mm/min until failure of fixation. The yield bending

Table II. The tensile test results

Parameter	Study group	Mean	SD	95% confidence limits
Yield load, N	1	91	16	76–107
	2	88	14	74–102
	3	98	9	90–107
Maximum failure load, N	1	130	17	113–148
	2	110	10	100–120
	3	114	3	111–117
Initial stiffness, N/mm	1*	131	7	124–138
	2	112	23	90–135
	3	93	8	85–100

*$P < .001$ between groups 1 and 3.

moment (Nmm) and initial stiffness (N/mm) were recorded, and the failure mode was visually determined.

Difference between the groups was determined using a *t* test. A *P* value less than .05 was considered statistically significant. In addition, 95% confidence limits were determined for each quantitative parameter.

RESULTS

In the tensile test, the mean yield loads (± SD) were 91 ± 16 N, 88 ± 14 N, and 98 ± 9 N for groups 1, 2, and 3, respectively (Table II). The mean maximum failure loads were 130 ± 17 N, 110 ± 10 N, and 114 ± 3 N. The mean initial stiffness values were 131 ± 7 N/mm, 112 ± 23 N/mm, and 93 ± 8 N/mm. In groups 1 and 2, all fixations failed by screw breakage. In group 3, one of the samples broke by screw breakage and the rest by plate breakage.

In the cantilever bending test, the mean yield bending moment values were 119 ± 6 Nmm, 98 ± 11 Nmm, and 71 ± 6 Nmm for groups 1, 2 and 3, respectively (Table III). The mean initial stiffness values were 0.12 ± 0.01 N/mm, 0.12 ± 0.02 N/mm, and 0.09 ± 0.01 N/mm. All fixations failed by plate bending.

DISCUSSION

The results of this study show that the Inion FreedomPlate provides at least as strong fixation as the tested conventional biodegradable plate. In the tensile test, the tested plates were found to provide similar fixation properties. The only statistically significant difference was found between the mean initial stiffness values of the Inion FreedomPlate (when fixed with countersunk screws) and those of the Inion CPS 2.0-mm plate. The Inion FreedomPlate was found to provide significantly higher mean initial stiffness than the previously successfully clinically used plate.[26] In the cantilever bending test, the Inion FreedomPlate provided significantly higher mean yield bending moment and mean initial stiffness values than the tested conventional biodegradable plate. Based on these results, the Inion FreedomPlate provides an adequate alternative to fixation with a conventional biodegradable plate.

In the current investigation, a comparable size piece of the Inion FreedomPlate was tested against the conventional Inion CPS 2.0-mm Extended 4-Hole Plate. Clinically, even higher stability of the Inion FreedomPlate can be postulated, because the plate could be cut to ideal size and shape for each fracture/bone. After contouring/adaptation to the bone, this ideal plate should lead to an increased 3-dimensional stability compared to the conventional prefabricated biodegradable plates. This 3-dimensional stability is also supported by the fact that the screws could be placed in the desired position (e.g., no large empty screw holes need to be left overlying the fracture gap) and direction (even off-axially) instead of screw placement in often less optimal or unsatisfying position through ready-made screw holes of a conventional plate. In addition, compared to conventional biodegradable plates, the Inion FreedomPlate is easier to adapt to the bone because of the independence of the placement of the screw holes. Further, the principle of drilling and tapping the screw holes in an independent position leads to the possibility of using screws with different diameters in one plate (2.0 to 3.1 mm). In this study, the 2.0-mm screws were used for worst-case scenario. Even higher fixation strength may be achieved when larger diameter screws are used. This assumption is supported at least by the fact that all samples in the tensile tests failed by screw breakage. On the other hand, the results of the cantilever bending test would most likely not be affected by increased screw diameter because all samples failed by plate bending, not by screw breakage.

Another interesting finding of this study was that when the Inion FreedomPlate is used, the screw heads can be cut off after screw insertion without any clinically relevant effect on the initial fixation properties. No significant difference was found between plates fixed with into-the-plate countersunk screws versus

Table III. The cantilever bending test results

Parameter	Study group	Mean	SD	95% confidence limits
Yield bending moment, Nmm	1*	119	6	113–125
	2†	98	11	88–109
	3	71	6	65–76
Initial stiffness, N/mm	1‡	0.12	0.01	0.11–0.13
	2§	0.12	0.02	0.10–0.14
	3	0.09	0.01	0.08–0.09

*$P < .0001$ between groups 1 and 3.
†$P < .05$ between groups 1 and 2, $P < .01$ between groups 2 and 3.
‡$P < 0.01$ between groups 1 and 3.
§$P < .05$ between groups 2 and 3.

plates fixed with screws without screw heads in the tensile test. Although fixation with countersunk screw heads provided significantly higher mean yield bending moment than fixation without screw heads in the cantilever bending test, the mean yield bending moment of the plates fixed without screw heads was still significantly higher than that of the conventional, previously clinically used conventional biodegradable plates.[26] In addition, the fact that the samples of the cantilever bending test all failed by plate bending, not by failure of the plate-screw interlock, indicates that at least the initial fixation strength between the Inion FreedomPlate and its screws is adequate even if the screw heads are cut off. However, further studies are needed to investigate how the plate-screw interlock is retained postoperatively during bone healing when the implants start to degrade.

To achieve a sufficient stability, the first biodegradable plates and screws were designed to have a higher thickness than corresponding titanium plates to achieve the same stability.[14,17-20,27-33] The thickness of the plates resulted in complaints of many surgeons concerning the bulkiness of the material. The concept of cutting off the screw heads after screw insertion is tempting because it provides a lower profile of the plate compared to conventional biodegradable osteosynthesis systems where the inserted screws always lead to increased thickness of the plate-screw system. As secondary removal of implants is sometimes needed and must therefore be possible (e.g., during a revision procedure), screw heads of metal screws could not even theoretically be removed after screw insertion. However, when biodegradable implants are used, screw heads are not needed to be able to remove the implants later as the material can simply be drilled out (if it has not degraded by the time of second surgery).

In conclusion, the new free-form plate was found to provide at least as strong fixation as the tested conventional biodegradable plate. No clinically relevant difference was found in the initial fixation properties of free-form plates fixed with into-the-plate countersunk screws and those fixed with screws without heads.

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