



Patient-specific 3D printed plates improve stability of Le Fort 1 osteotomies in vitro



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ABSTRACT

Purpose: Selective laser melting used to manufacture patient-specific 3D-printed (PSP) plates is a delicate process, which may introduce weakened areas in the plates, with risk of fracture. This in vitro study's purpose was to test the ability of PSP plates to stabilize Le Fort I osteotomies compared with manually adapted stock plates. The study's objectives were to measure the force needed to compress the osteotomy and evaluate whether the PSP plates would break during compression.

Materials and methods: This controlled in vitro study evaluated the maxillary stability using the clinical data from 7 patients. The virtually planned maxillary reposition was 3D-printed in 2 copies, and the osteotomy gap was fixated by either PSP plates or stock plates. The models were compressed until the Le Fort I osteotomy gap was eliminated. The primary outcome was the force needed to compress the model. The primary predictor variable was a comparison between PSP and stock plates. Secondary outcome measurements were the slope of elastic modulus, yield point, and force needed for 2 mm compression. Statistical testing was performed by Wilcoxon signed-rank test with significance level at $P \leq 0.05$.

Results: The PSP plates performed better than stock plates in all outcome measurements. None of the plates broke during compression despite forces of more than 4000 N. The first point of failure in PSP plates was the first screw cranial to the osteotomy. In comparison, the first point of failure in stock plates was in the plates' bend at the osteotomy.

Conclusion: In this in vitro setup, the Le Fort I osteotomies fixated with PSP plates were more stable than the osteotomies fixated with conventional stock plates. No adverse effects occurred during testing of PSP plates; thus, PSP plates seem to be a safe alternative to stock plates and may even be preferable.

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1. Introduction

Patient-specific 3D-printed (PSP) plates are matched to the patient's unique bony contour, and they are designed to incorporate the virtual surgically planned repositioning of the maxilla. The PSP plates can be used in combination with osteotomy and drill guides to position the maxilla with a high degree of surgical accuracy

without the need for intermaxillary splints (Gander et al., 2015; Heufelder et al., 2017; Stokbro et al., 2018). Despite PSP plates being commercially available for clinical implementation (Gander et al., 2015; Mazzoni et al., 2015; Brunso et al., 2016; Kraeima et al., 2016; Suojanen et al., 2016; Heufelder et al., 2017; Li et al., 2017), no one has evaluated the mechanical properties of PSP plates for orthognathic surgery.

Manufacturing PSP plates is an advanced process involving metal-on-metal apposition at high temperatures. Metal-on-metal apposition can be performed by selective laser melting (SLM), where a laser beam is used to sinter layers of metal powder to bind the metal together in 3D additive manufactured plates. Printed

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metal plates are more rigid than conventional plates, but if not handled correctly, the manufacturing process may introduce areas with reduced resistance to fracture (Liu et al., 2014; Szykiedans and Credo, 2016). Therefore, the authors were concerned as to whether the plates would break in patients with excessive bite force, such as in nightly bruxism.

In vitro testing of plates is usually performed on solid blocks of polyurethane (Lauria et al., 2016) or polyurethane models with thick bony walls (Araujo et al., 2001; Esen et al., 2016); however, this does not reflect the variable anatomical differences encountered in patients with growth deviations of the jaws. Therefore, this study was performed on duplicate sets of models printed from patients' 3D scans to simulate clinical conditions in orthognathic patients. Thereby, the performance could be directly compared between PSP plates and manually adapted stock plates.

The primary purpose of this study was to test the ability of PSP plates to withstand compression, compared to manually adapted stock plates on printed models derived from patients previously treated with inferior maxillary repositioning. The secondary purpose was to evaluate whether PSP plates would break during compression. The authors hypothesized that PSP plates would be more stable, but were unsure whether some of the plates might break under excessive pressure. This study measures the force needed to compress the model segments until the osteotomy gap was eliminated and to describe the first point of failure or breakage in both PSP and stock plates.

2. Material and methods

To test the study hypothesis, the authors implemented a prospective, controlled in vitro study on 3D models printed from patients' virtual surgical plans. These plans were obtained from a published study evaluating the precision of patient-specific plates in inferior maxillary repositioning (Stokbro and Thygesen, 2018; Stokbro et al., 2018). Power calculations were performed based on the first study (force at 2 mm: PSP plates – stock plates = 1413 N) calculated with twice the normal standard deviation for manually bended plates (100 N) (Lauria et al., 2016); with a significance level of 0.05 and power of 80%, the participant number was calculated to 2 sets of models. To adequately test and describe the clinical behavior of the PSP plates, data from 7 participants were enrolled. The participants with the largest osteotomy gaps were selected for inclusion in the study. Participants were treated according to the Declaration of Helsinki (October 2000). The study was exempt from ethical review by the institutional review board.

2.1. Study setup

Two identical 3D models were created from the midface of the 7 orthognathic patients.

The midface from the inferior orbital margin to the enamel–cementum junction of the teeth was recreated from the virtual surgical plan, exported from Dolphin 3D surgery (Dolphin Imaging and Management, Chatsworth, CA). The independent STL models were appended in Autodesk MeshMixer (Autodesk Inc., San Rafael, CA) to fixate the osteotomy gap and planned reposition of the dental segments. A disc was added to the midface to ensure that the right and left side would not move independently, and to calibrate the model height at 46 mm in all models.

The midface models were printed by fused deposition modeling using Stratasys uPrint (Stratasys Ltd., Eden Prairie, MN), with standard print settings: 0.254 mm layer height, sparse filled, high density models and smart support material. Models were printed in acrylonitrile-butadiene-styrene (ABS) material with soluble support material. The midface models were printed in a supine

position to enable plate adaptation with the models still fixed by support material. Thereby, the PSP plates and the conventional plates were adapted to identical clinical situations. After the plates were adapted, the holes were predrilled and the support material dissolved, which created 2 independently moveable parts separated by the osteotomy gap. The PSP plates were mounted and fixated by 5 mm Biomet 2-0 screws (Zimmer Biomet Corp., Warsaw, IN) in the predrilled holes. The conventional plates were mounted and fixated by 5-mm screws, 2.0 Leibinger system (Stryker-Leibinger, Freiburg, Germany) (Fig. 1).

The PSP plates used for testing were manufactured by biomedical designers and engineers at 3D systems (3D systems, Rock Hill, SC). The PSP plates were designed with 11 screw holes: 6 superior and 5 inferior to the osteotomy. The plates were designed with 3 connections across the osteotomy gap, each with a thickness of 1.2 mm and a width of 5.2 mm. The PSP plates were manufactured in Ti64Al4V material by direct metal printing and post-processed by smoothing the surface and countersinking the screwhead to maximize adaptation between plate and screws. The control group was bilaterally fitted with 2 Leibinger 2.0 stock plates (Stryker-Leibinger, Freiburg, Germany), manufactured in grade 2 titanium. The intermediate section, spanning across the osteotomy gap, had a thickness of 1.0 mm and width of 2.4 mm. All plates were manually adapted by the same investigator. Careful measurements and markings were used to avoid the need for repeated or excessive bending of the plates during adaptation. The conventional plates were chosen with the smallest separator in the intermediate section without placing the bend directly in the screw hole.

Compression testing was performed in a Zwick Roell Z050 testing machine (Zwick Roell, Ulm, Germany). The lower compression plate was a fixed plane, and the upper compression plate was secured with a ball joint able to rotate freely, thereby allowing for asymmetrical deformation. Compression was performed with a preload of 50 N, after which compression force and displacement were recorded. Testing was performed by compressing the model 2 mm per minute, while recording the force needed to compress the model. The test was terminated when the plates failed or the osteotomy gap had completely disappeared.

2.1.1. Variables and measurements

The primary outcome measurement was the force needed to compress the model. The primary predictor variable was a comparison between PSP plates and the stock plates. Secondary outcomes were the elastic modulus of the combined setup (model, screws, and plates), along with the force at the yield point and force needed to compress the model 2 mm. Since all measurements were compared on identical sets of models, no other confounding variables were evaluated.

All tests were plotted with the compression in millimeters along the x-axis and force (Newton) needed to compress the model along the y-axis. The yield point was calculated as a 0.2% offset from the E-modulus along the displacement axis; because all models were printed at 46 mm height, this was rounded up to 0.1 mm offset.

2.1.2. Statistical analysis

Analysis of the data was performed by STATA 15.0 (STATA Corp., College Station, TX).

Measurements were treated as non-parametric measurements because of the limited number of observations. All measurements were presented by a median and range. The slope of the elastic modulus was calculated by linear regression of the steepest slope on the graphs. Comparison of outcome was performed using Wilcoxon signed-rank test. The statistical significance level was set at $P \leq 0.05$.

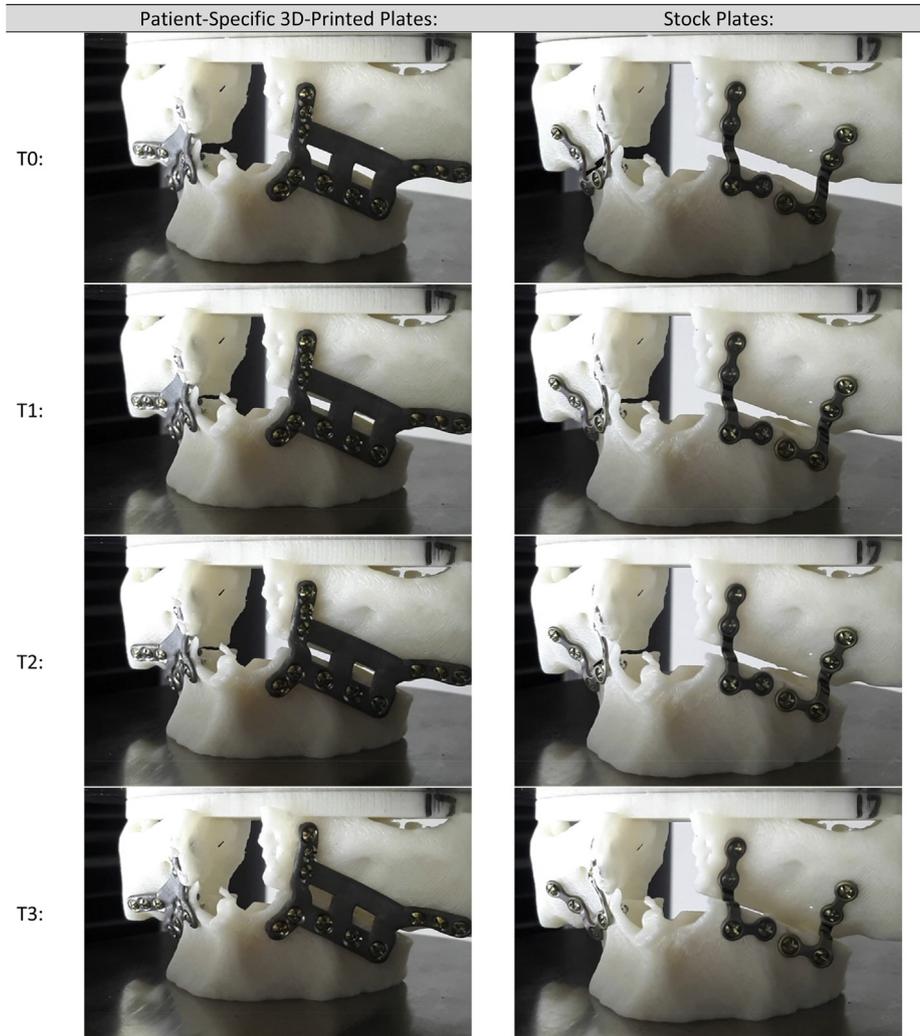


Fig. 1. Phases during test 5. T0: Pretest before load. T1: Preload of 50 N. T2: Yield point; PSP plate 2708 N, stock plate 576 N. T3: Compression with elimination of osteotomy gap: PSP plate 3034 N, stock plate 1071 N.

3. Results

The planned maxillary repositions all included down grafts and advancements of 1.0–6.9 mm (Table 1). Two patients were planned with asymmetric repositioning with more than 1 mm difference between the right and left osteotomy gaps.

Table 1
Descriptive cohort analysis.

Test	Maxillary reposition			Osteotomy gap				Conventional plate size			
	Advance (mm)	Inferior (mm)	Asymmetry	Right		Left		Right		Left	
				Z	P	P	Z	Z	P	P	Z
1	2.9	-2.9		2.5	2.5	2.5	2.5	M	M	M	M
2	3.5	-3.1		3.3	3.4	2.8	2.7	L	L	L	L
3	3.7	-2.5		2.4	2.3	2.5	2.9	M	L	L	M
4	1.0	-3.6		4.4	2.5	2.9	5.1	M	M	M	M
5	6.9	-2.6	Yes	2.2	2.1	1.6	3.2	M	M	L	L
6	1.0	-2.1		1.7	2.6	2.2	1.2	R	M	M	R
7	3.4	-3.1	Yes	0.8	2.0	3.2	2.9	M	L	L	M

Z = zygomatic buttress; P = piriform rim; L = long intermediate section; M = medium intermediate section; R = regular intermediate section.

Overall, the PSP plates performed better than the conventional plates (Fig. 2). In all instances, the PSP plates resisted more force before the osteotomy gap was eliminated and needed more force to compress the models 2 mm (Tables 2 and 3). Likewise, the PSP plates had higher elastic modulus and higher yield points in six of the tests. Despite forces of more than 4000 N, none of the PSP plates broke during compression.

Qualitative analysis of the plates revealed a shift in the first point of failure when PSP plates were tested (Fig. 1). Following the yield point, the first point of failure in stock plates was in the plates' bend closest to the dental segment. The first point of failure in PSP plates was loosening of the screws and/or fracture in the anatomic model. During the preloading of 50 N, the screws would settle and rotate slightly away from the osteotomy (T1). Then, force was applied during the elastic phase of the compression until the yield point (T2). During the elastic phase, the model would be slightly compressed, but without breakage or damage. After the yield point, the models would break at the screw points or the screws would become loose (T3). The first screw cranially to the osteotomy was the first point of failure. The investigators were surprised by how much the osteotomy gap was compressed in some models during the preload of 50 N.

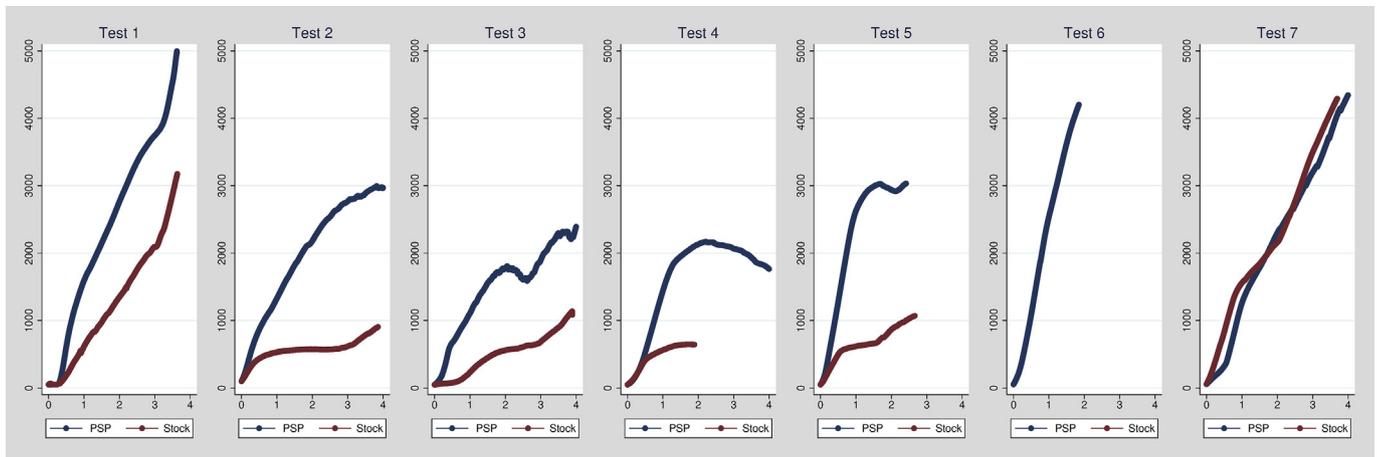


Fig. 2. Compression forces for plate displacement. Force (N) needed to compress the model is measured along the y-axis. Compression (mm) of the osteotomy gap is measured along the x-axis. Each test corresponds to one patient's midface, printed in duplicate model sets, and the osteotomy gap was fixated by either PSP plates or stock plates. In test 6, the osteotomy gap fixated with stock plates was compressed completely during the preload of 50 N. PSP = patient-specific 3D-printed plates. Stock = manually adapted stock plates.

Table 2
Force needed to eliminate the osteotomy gap.

	Median	(Range)	P value ^a
Patient-specific plates	3047	(1171–4966)	
Conventional plates	1133	(50–4292)	
Difference	1318	(146–2002)	0.018

^a Wilcoxon signed-rank test.

The outliers in the conventional test groups showed large variation. In test 6, the conventional plates yielded during the initial preloading, and the osteotomy gap was compressed at 50 N. Likewise, in test 1, the posterior plates yielded during the preload, while the anterior plates still supported the osteotomy gap. In test 7, the osteotomy gap was asymmetrical and the right side was compressed during the preload, prior to the left. The details of each test and additional clinical photos are supplied in [Appendix 1](#), along with photos of each plate's performance during each of the test phases T1 to T3.

4. Discussion

This study primarily tested the ability of PSP plates to withstand compression compared to manually adapted stock plates, on printed models derived from patients previously treated with inferior maxillary repositioning. Secondly, the study evaluated whether PSP plates would break during compression. The study showed that PSP plates were stiffer with higher yield points than conventional plates. The first point of failure in stock plates was in the plates' bend closest to the dental segment. The first point of failure in PSP plates was screw loosening, primarily the first screw in the cranial

part of the model. None of the PSP plates fractured despite compression forces of up to 4000 N.

No other study has evaluated the maximum forces needed to compress and deform PSP plates in orthognathic surgery. A study of orthopedic PSP plates, evaluating 3.5 mm anterior clavicle plates, found two to three times greater mechanical properties of PSP plates compared with stock plates (bending stiffness, bending strength, and bending structural stiffness) (Liu et al., 2014). Although a straight 3.5 orthopedic plate does not correspond to a bent 2.0 orthognathic plate, the mechanical properties of printed plates compared with stock plates seem similar between the two studies. However, it cannot be concluded from this study that PSP plates are more rigid than conventional, stock plates, as the dimensions and design of the plates differed significantly between the plates.

The mechanical properties of conventional stock plates have been tested in vitro and are better understood. Manually adapted stock plates are reported to fail between 534 and 1145 N (8 mm linear advancement) (Araujo et al., 2001), which matched the yield point in this study's control group. In vitro tests with a cleft palate found that 2 L plates bilaterally would yield after compression of more than 210 N (7 mm advancement, 3 mm osteotomy gap) (Esen et al., 2016). Stock plates yield points were also correlated with the degree of maxillary advancement, and an occlusal force of 250 N was above the yield point in 6 and 9 mm linear advancement (Huang et al., 2016). In this study, no correlation was seen between advancement and yield point; however, multiple confounding factors may have masked such a correlation.

There may be several reasons for the increased strength in PSP plates: the printed metal is stiffer, and since the plates do not need manual adaptation, the plates could be printed as a 1-piece, tripod-curved plate with connections twice as wide as the stock plates.

Table 3
Testing difference between patient-specific 3D-printed plates and manually adapted stock plates.

	Patient-specific plates		Stock plates		P value ^a
	Median	(range)	Median	(Range)	
2-mm Displacement (N)	2299	(1779–4318)	637	(559–3205)	0.028
E-modulus (N/mm)	2119	(922–3042)	828	(487–2254)	0.018
Yield point (E + 0.1 mm)	1518	(759–3376)	538	(444–2416)	0.018

N = Newton; E = elastic.

^a Wilcoxon signed-rank test.

Furthermore, the number of screws increased from 16 to 22, and the screws were placed in maximum bone thickness by design. Especially the number of screws and the placement in maximum bone thickness are critical factors because these are considered to be the first points of failure in PSP plates. A screw's pull-out strength increases by 250 N per millimeter of maxillary cortical bone thickness in 2.0 screws (Shelton and Loukota, 1996). To increase stability at the first point of failure, additional fixation could be obtained by either an additional screw or a larger screw diameter cranial to the osteotomy (Nagasao et al., 2007; Shelton and Loukota, 1996).

Screw pull-out strength in orthognathic patients may be greater than in the in-vitro test. In finite element modeling, the elastic modulus of 3D printed ABS is 1.35 GPa (Poisson ratio 0.33) (Huang et al., 2016), while the elastic modulus of bone is 1.85–14.8 GPa (cancellous–cortical, Poisson ratio 0.30) (Erkmen et al., 2009). Because pull-out strength is greater in bone than in ABS, this study may have underestimated the in vivo strength of the PSP plates. Increased pull-out strength should affect only the group fixated by PSP plates because the conventional stock plates yielded in the plates without screw loosening. Increased screw pull-out strength should increase the overall stability in patients in whom the osteotomy gap is fixated by PSP plates. This increased resistance is probably of no clinical importance, because the forces used in the test far exceeded clinical occlusal forces, even in patients with nightly bruxism (8–900 N) (Nishigawa et al., 2001). However, this study evaluated only linear increasing compression and does not represent the physiological complexity of masticatory forces in chewing and bruxism. Therefore, the results should be interpreted with some restriction, as the masticatory forces may lead to different results from the forces applied in this study.

The limitation of this study is the test setup, which combines the strengths and weaknesses of the plates, screws, and model. Therefore, the elastic modulus does not reflect a single material, but the combined setup with interaction among plates, screws, and model. Thus, the results are presented as load force and are not converted into standardized Young's modulus or mechanical stress loads. However, this study setup may represent the dynamics of orthognathic surgery more closely, where the first point of failure is the crucial event. Therefore, we considered it an important observation that the first point of failure shifted from within the plates to the first screws above the osteotomy and at higher yield points.

The strength of this study is the direct comparison between conventional plates and PSP plates under clinically simulated conditions. This study provides qualitative and quantitative analysis of the first point of failure, the yield point, and the pressure needed to deflect the plates 2 mm. This information is clinically useful in evaluating the cost–benefit trade-off of new plates under challenging, clinical conditions. The clinical perspectives of PSP plates should be kept in mind during the clinical decision process in which the individual patient's clinical challenges are considered. The PSP plates should be advantageous when additional support is needed (i.e., inferior repositions, large advancements, or segmental procedures) or in challenging biological conditions (i.e., eggshell-thin maxillary bone). Thus, this study supports clinical implementation of PSP plates in selected patients.

5. Conclusion

In this in vitro setup, the Le Fort I osteotomies fixated with custom-designed PSP plates were more stable than the Le Fort I osteotomies fixated with conventional stock plates. No adverse effects occurred during testing of PSP plates; thus, PSP plates seem to be a safe alternative to stock plates and may even be preferable

due to the possibility of designing increased mechanical strength in the plates.

Conflicts of interest

The authors declare that they have no conflicts of interest in regards to this work.

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This study was supported by grants from the Region of Southern Denmark (16/13511) and the University of Southern Denmark. The patient-specific 3D-printed plates were provided by 3D Systems at a reduced cost, covering the manufacturing expenses of the plates. 3D Systems did not influence the setup, test, analysis, or interpretation of the study in any way. All materials were provided and paid for by the Department of Oral and Maxillofacial Surgery, Odense University Hospital, Denmark.

Ethical approval

This study was exempt from ethical approval due to the retrospective nature of the study without direct involvement or influence on patients.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jcms.2018.12.015>.

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