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Research Paper
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Mechanical properties of three-dimensionally printed titanium plates used in jaw reconstruction: preliminary study

C.-F. Wang[1], Y. Yu[1], W. Bai[2], J.-M. Han[2], W.-B. Zhang[1], X. Peng[1]
[1]Department of Oral and Maxillofacial Surgery, Peking University School and Hospital of Stomatology, Beijing, China;
[2]National Engineering Laboratory for Digital and Material Technology of Stomatology, Department of Dental Materials, Peking University School and Hospital of Stomatology, Beijing, China

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Abstract. The aim of this study was to compare the mechanical properties of three-dimensionally (3D)-printed and conventional surgical plates used for the repair of maxillary or mandibular defects under the same experimental conditions, and to provide experimental evidence for the future application and clinical trial of 3D-printed individualized surgical plates. For the experimental group, two groups of surgical plates with thicknesses of 2.0 mm and 2.5 mm were designed and 3D-printed by electron beam melting, using Ti–6Al–4V as raw material. Conventional commercially available surgical plates with the same thickness were adopted as the control group. A Vickers hardness tester and universal testing machine were used to measure the mechanical properties of the plates (hardness, bending strength, tensile strength, and yield strength). The mechanical properties of 3D-printed surgical plates were significantly better than those of conventional surgical plates of the same thickness ($P < 0.001$). Comparing the surgical plates of different thickness, the 2.5 mm-thick plates had the highest bending strength in the experimental group ($P < 0.001$) and the best hardness ($P < 0.001$), bending strength ($P = 0.001$), tensile strength ($P = 0.001$), and yield strength ($P = 0.001$) in the control group. No statistical difference was found between the two kinds of plates in the experimental group in terms of hardness ($P = 0.060$), tensile strength ($P = 0.096$), and yield strength ($P = 0.496$). The 3D-printed surgical plates have better mechanical properties than the conventional ones.

Key words: three-dimensional printing; bone plates; mandibular reconstruction; mechanical phenomena; hardness; bend strength; tensile strength.

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Maxillary and mandibular defects caused by tumour resection or trauma are common problems in oral and maxillofacial surgery, and often result in significant aesthetic and functional deficits. With the development of digital surgical techniques, the individualized repair of maxillary or mandibular defects has become a popular treatment in clinical practice. Preformed surgical plates are applied in combination with vascularized autogenous bone grafts as the primary tools to repair individual jaw defects. However, the high complexity of this method requires significant amounts of time and effort to perform the preoperative design, print the model of the skull, and manually pre-bend the surgical plates. In addition, some adjustments are usually needed because of the limited accuracy of the preformed surgical plates, which further increases the operation time. To overcome these issues, three-dimensional (3D) printing technology has been used to print individualized surgical plates for maxillary and mandibular reconstruction. Previous studies have shown that the 3D-printed plates can be easily implanted without any preformation step, which may facilitate intraoperative procedures, reduce the operation time, and improve surgical accuracy[1–4].

The reason why 3D-printed surgical plates have not yet found wide application is that 3D printing is a relatively new approach in oral and maxillofacial surgery. Therefore, only a few studies have focused on individualized 3D-printed products, and in particular on the mechanical properties of 3D-printed surgical plates. Before the application of these systems in maxillary or mandibular reconstruction, additional tests are needed to determine whether their mechanical properties meet the requirements of relevant standards and that they provide advantages over the same types of product produced by other techniques that are already in clinical use. The results of these tests will provide an important reference for further studies and future clinical applications.

Materials and methods

A study was conducted to evaluate the mechanical properties of different surgical plates, employing 3D-printed and conventional surgical plates as the experimental group and control group, respectively. The 3D-printed surgical plates were designed by referring to the configuration and dimensions of conventional surgical plates (DePuy Synthes MatrixMANDIBLE reconstruction plates; CP Ti, cast, 04.503), including the plate profile, width, screw locations, and size and pitch of the holes. The plates were then manufactured by electron beam melting (EBM)[5], using titanium alloy (Ti–6Al–4V) as the raw material.

The experimental group included two kinds of plate with a thickness of 2.0 mm and 2.5 mm, which were consistent with those of the plates in the control group. Photographs of the 3D-printed and conventional surgical plates with a thickness of 2.0 mm and 2.5 mm are shown in Figs 1 and 2, respectively.

After computer-aided designing and 3D printing, the two groups of surgical plates were tested to measure their mechanical properties: hardness, bending strength, tensile strength, and yield strength). All tests were conducted in accordance with the GB/T 4340.1-2009/ISO 6507-1:2018, GB/T 4340.4-2009/ISO 6507-4:2018, GB 228.1-2010/ISO 6892-1:2019, and YY/T 0342-2002/ISO 9585:1990 standards[6–9]. The Vickers hardness was measured using a Vickers hardness tester at a load of 9.8 N for 10 seconds. The Vickers hardness was calculated based on the diagonal length of the formed indentation. The bending strength was measured by four-point bending test, while the tensile and yield strengths were evaluated by tensile test using a universal testing machine (Model 5969; Instron, Norwood, MA, USA) at a crosshead speed of 1.00 mm/min at room temperature.

Sample size calculation

This study was identified as a superiority trial. The minimum sample size required for this study was calculated by referring to the test data of tensile strength, yield strength, and Vickers hardness of the Ti–6Al–4V ELI (EBM) and CP Ti (cast)

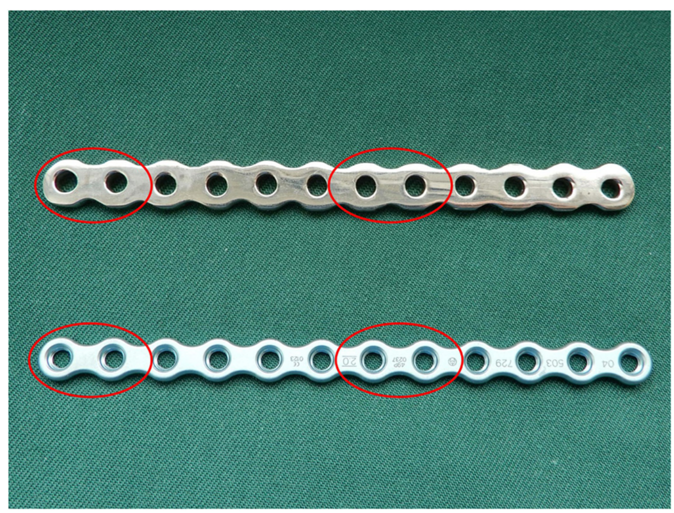

Fig. 1. The 2.0 mm-thickness 3D-printed surgical plate (top) and conventional surgical plate (bottom). Test sites/areas are shown (the sites/areas inside the red circles).

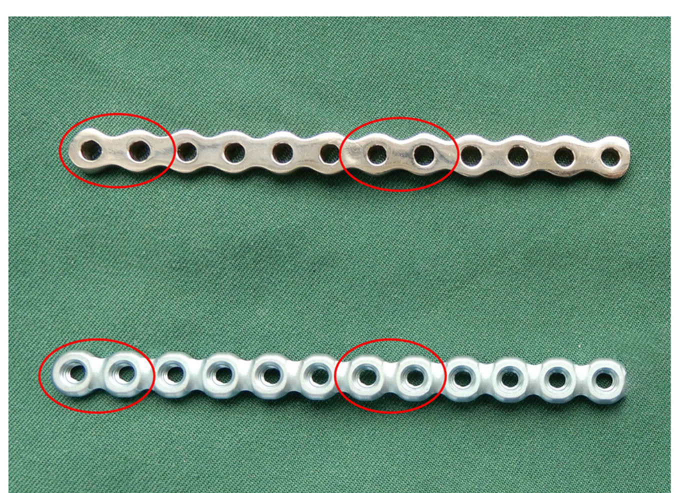

Fig. 2. The 2.5 mm-thickness 3D-printed surgical plate (top) and conventional surgical plate (bottom). Test sites/areas are shown (the sites/areas inside the red circles).

given in an earlier report[10] and using the sample size calculation formula for the superiority trial. The process can now be reformulated with more detail as follows. The calculation formula adopted was $N = \frac{(Z_\alpha + Z_\beta)^2 \sigma^2}{(\delta - \Delta)^2}(Q_1^{-1} + Q_2^{-1})$, where $\alpha = 0.05$, $Z_\alpha = 1.645$, $\beta = 0.10$, $Z_\beta = 1.282$, the standard deviation (σ_1) of tensile strength/yield strength/Vickers hardness of Ti–6Al–4V ELI (EBM) = 26 MPa/28 MPa/2 HV, the standard deviation (σ_2) of tensile strength/yield strength/Vickers hardness of CP Ti (cast) = 27 MPa/32 MPa/13 HV, the σ of tensile strength/yield strength/Vickers hardness = 26.50 MPa/30.07 MPa/9.30 HV, $\delta = \mu_1 - \mu_2$, the mean (μ_1) of tensile strength/yield strength/Vickers hardness of Ti–6Al–4V ELI (EBM) = 775 MPa/735 MPa/369 HV, the mean (μ_2) of tensile strength/yield strength/Vickers hardness of CP Ti (cast) = 555 MPa/463 MPa/185 HV, the δ of tensile strength/yield strength/Vickers hardness = 220 MPa/272 MPa/184 HV, Δ = 170 MPa/170 MPa/170 HV, $Q_1 = 0.5$, $Q_2 = 0.5$. To sum up, the minimum number of samples of the same thickness required for each test in the experimental group and the control group in this study was determined to be eight. Regarding the control group, in consideration of the unavailability of samples in clinical application and the results of the sample size calculation, the minimum sample size was set to eight. The experimental group samples were manufactured by 3D printing technology. On the basis of the minimum sample size requirement, two more samples were manufactured for each test to account for any loss or some other kind of loss unrelated to the test in the testing process such as defective samples; therefore, the number of samples for each test in the experimental group was set to 10. Thirty different sites of each sample were subjected to the Vickers microhardness test to obtain the mean values. Each sample could only be tested once, after which it was discarded.

Statistical analysis

IBM SPSS Statistics version 22.0 software (IBM Corp., Armonk, NY, USA) was used for the statistical analysis. Taking into account the small sample size, a non-parametric testing procedure was applied for independent samples, along with the Mann–Whitney *U*-test.

Results

The hardness of the samples was evaluated by testing at least three randomly chosen sites on each plate in both the experimental group and the control group. Then six plates were randomly selected and an additional site was tested on each plate in the control group. The test sites are shown in Figs 1 and 2, respectively. Thirty sets of hardness data were obtained for each type of plate. The test results are shown in Fig. 3 and summarized in Table 1 (see also **Supplementary Material** Table S1). In the experimental group, the maximum, minimum, and mean hardness of the 2.0 mm-thick plates were 395, 301, and 340.53 HV, respectively, while those of the 2.5 mm-thick plates were 367, 303, and 330.93 HV, respectively. The mean hardness of the 2.0 mm-thick plates was greater than that of the 2.5 mm-thick ones. In the control group, the maximum, minimum, and mean hardness of the 2.0 mm-thick plates were 303, 252, and 270.93 HV, respectively, while those of the 2.5 mm-thick plates were 337, 277, and 295.43 HV, respectively. The 2.5 mm-thick plates had higher mean hardness than the 2.0 mm-thick ones. While no statistical difference was found between the two kinds of plates in the experimental group ($P = 0.060$), in the control group the 2.5 mm-thick plates exhibited better hardness properties ($P < 0.001$). When comparing plates with the same thickness between the two groups, the 2.0 mm- and 2.5 mm-thick plates in the experimental group had significantly higher hardness than the corresponding ones in the control group ($P < 0.001$ in both cases). These results indicate that the 3D-printed surgical plates presented better hardness than their commercial counterparts.

The bending strength was evaluated through a four-point bending test; load–deflection curves were obtained at the same time. Then, the yield load values of two specific points and the distance between the internal and external roll shafts of the detector (this distance was

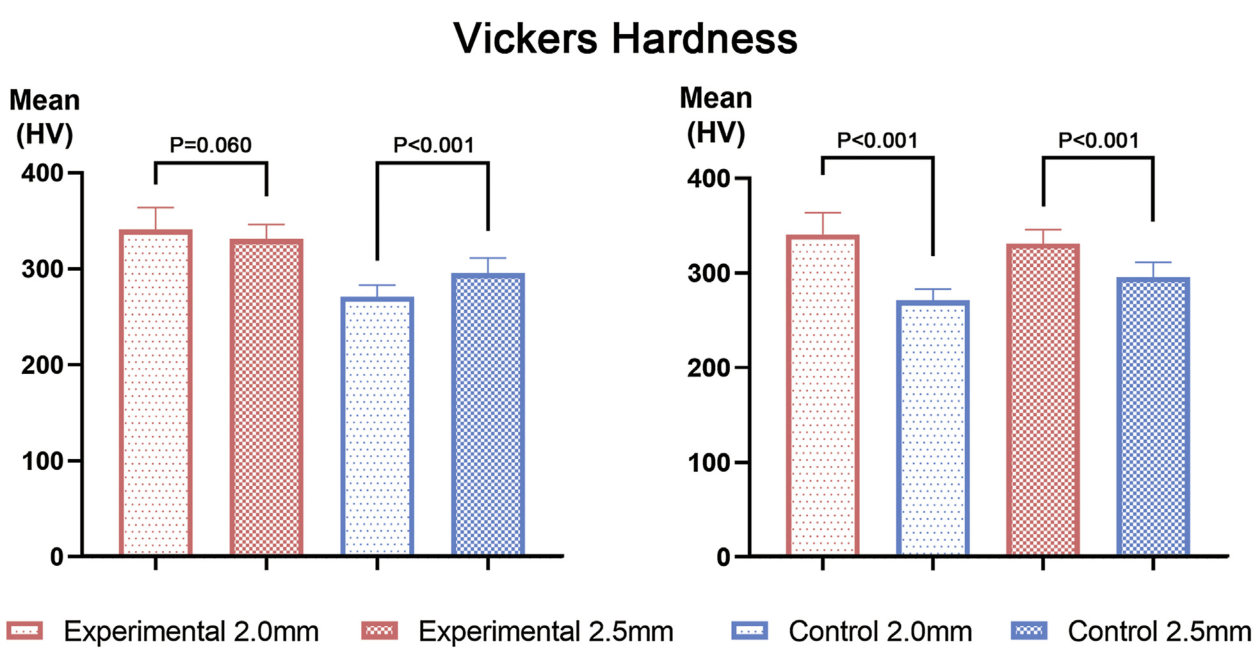

Fig. 3. Analyses of Vickers hardness by Mann–Whitney *U*-test.

Table 1. Testing data—Vickers hardness (HV).

Group	2.0 mm			2.5 mm			*P*-value
	Mean ± SD	Median	IQR	Mean ± SD	Median	IQR	
Experimental	340.53 ± 23.10	338	(325.00–352.25)	330.93 ± 14.97	329	(321.00–337.25)	0.060
Control	270.93 ± 11.93	270	(262.00–278.75)	295.43 ± 15.74	289.50	(284.00–303.75)	<0.001*
P-value	<0.001*			<0.001*			

IQR, interquartile range; SD, standard deviation.
* Statistically significant, $P < 0.05$.

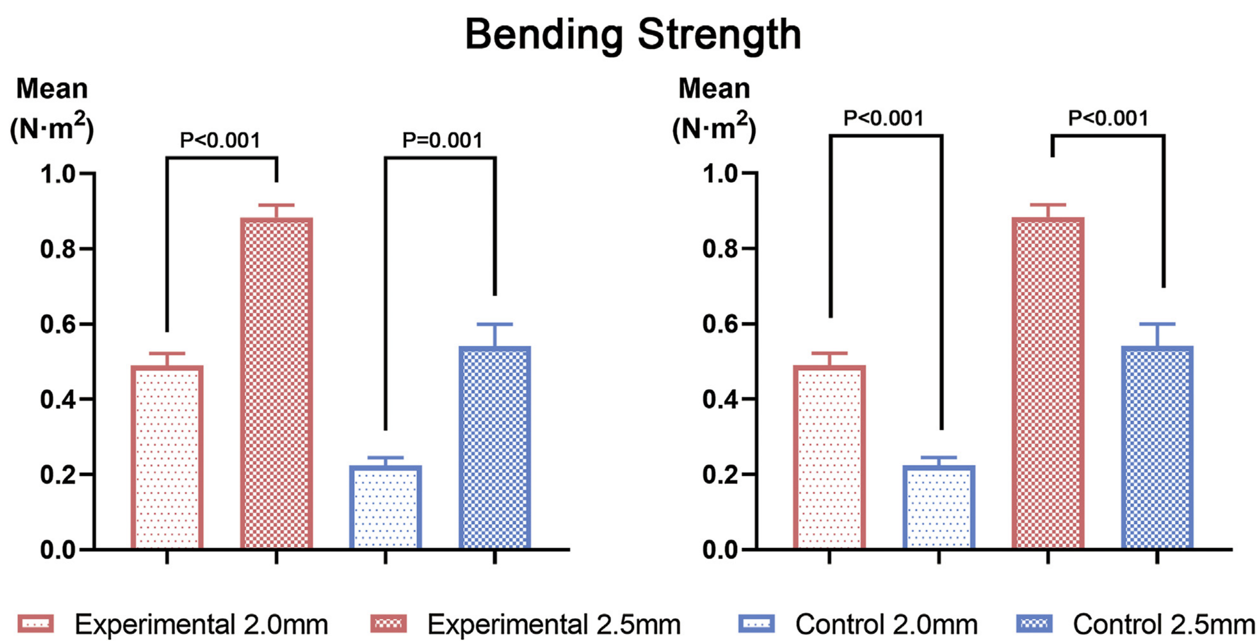

Fig. 4. Analyses of bending strength by Mann–Whitney *U*-test.

Table 2. Testing data—bending strength (Nm^2).

Group	2.0 mm			2.5 mm			*P*-value
	Mean ± SD	Median	IQR	Mean ± SD	Median	IQR	
Experimental	0.4897 ± 0.0323	0.4957	(0.4625–0.5138)	0.8836 ± 0.0331	0.8813	(0.8673–0.9145)	<0.001*
Control	0.2239 ± 0.0205	0.2336	(0.2030–0.2408)	0.5420 ± 0.0577	0.5605	(0.4747–0.5973)	0.001*
P-value	<0.001*			<0.001*			

IQR, interquartile range; SD, standard deviation.
* Statistically significant, $P < 0.05$.

fixed to 0.015 m) were used to calculate the equivalent bending rigidity, which is an indirect measure of the bending strength. The test data are shown in Fig. 4 and summarized in Table 2 (see also **Supplementary Material** Table S2). Compared with the 2.0 mm-thick plates, the 2.5 mm-thick ones had higher bending strength in both the experimental group ($P < 0.001$) and the control group ($P = 0.001$). The comparison of plates with the same thickness between the two groups showed that those in the experimental group had a higher bending strength than those in the control group ($P < 0.001$ in both cases). These results highlight the adequate bending strength of the 3D-printed surgical plates and indicate that the bending strength may have a positive correlation with the thickness.

Tensile tests were used to simultaneously determine the tensile and yield strengths; the data obtained are shown in Figs 5 and 6 and are summarized in Tables 3 and 4, respectively (see also **Supplementary Material** Tables S3 and S4). In the experimental group, no statistically significant difference in tensile strength ($P = 0.096$) or yield strength ($P = 0.496$) was found between the 2.0 mm- and 2.5 mm-thick plates. On the other hand, in the control group the 2.5 mm-thick plates had higher tensile and yield strengths ($P = 0.001$ in both cases). Compared with the 2.0 mm- and 2.5 mm-thick plates in the control group, the corresponding plates in the experimental group exhibited higher tensile and yield strengths ($P < 0.001$ in both cases). Based on the above comparisons, it can be concluded that the 3D-printed surgical plates have relatively high tensile and yield strength.

Discussion

Maxillary or mandibular defects resulting from tumour resection or trauma not only have a strong impact on the patient's appearance, but also lead to physiological speech, chewing, and swallowing dysfunctions, among others. With the development of advanced medical technologies, surgical plates combined

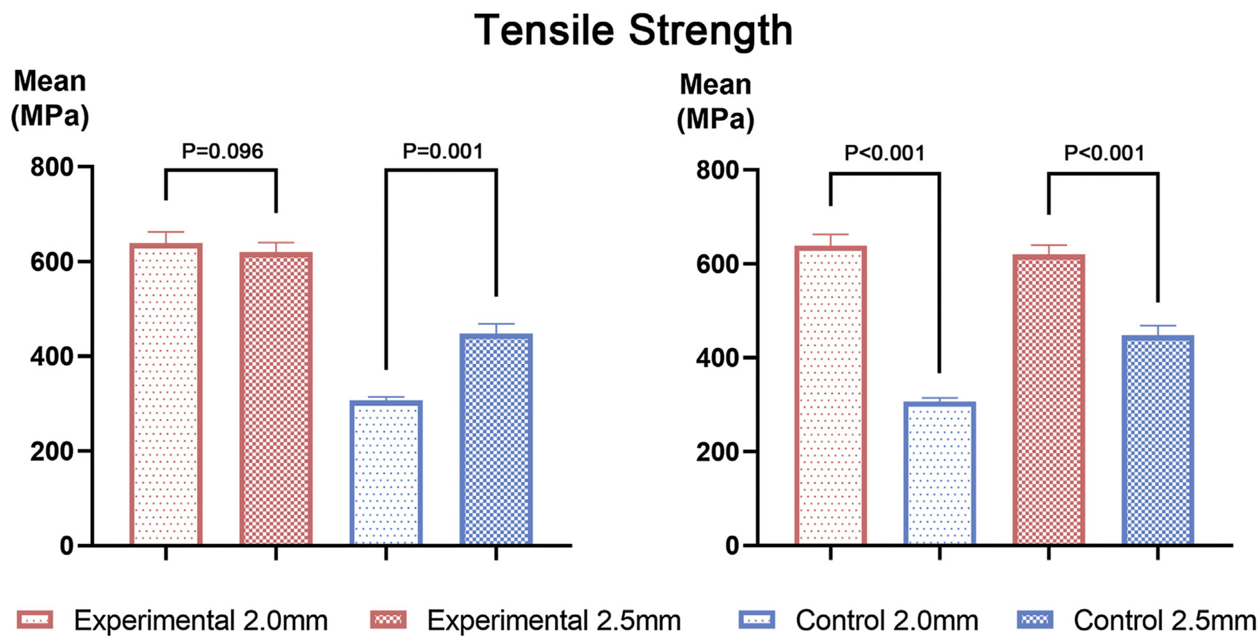

Fig. 5. Analyses of tensile strength by Mann–Whitney *U*-test.

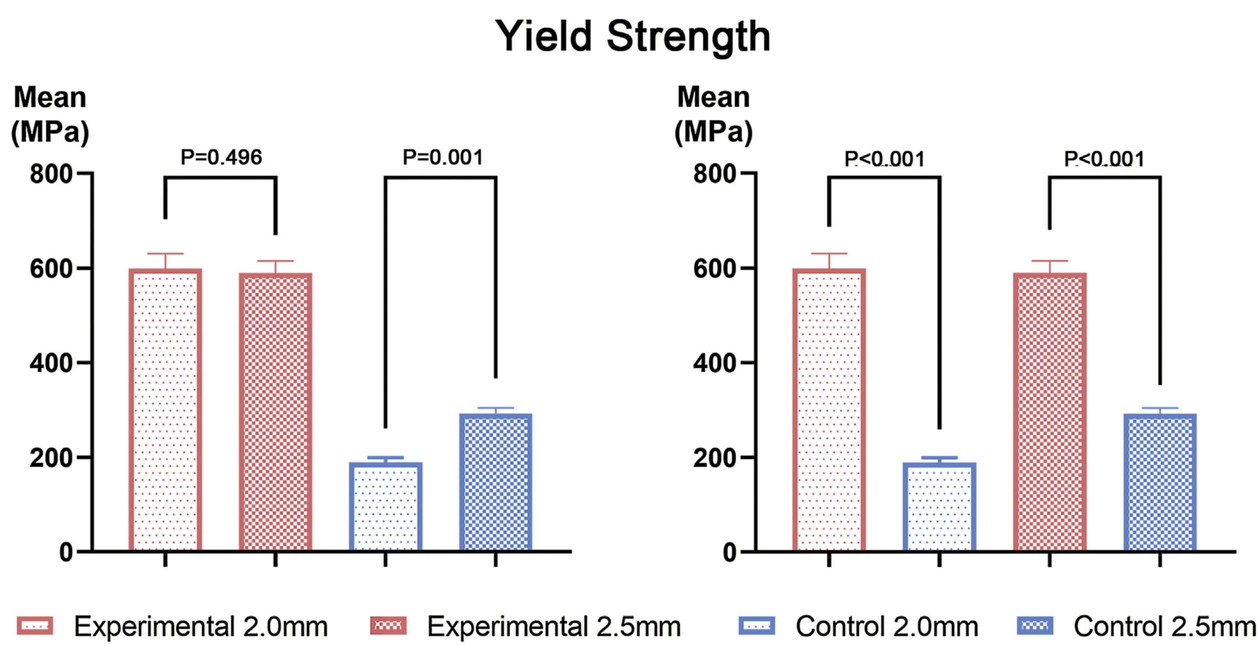

Fig. 6. Analyses of yield strength by Mann–Whitney *U*-test.

Table 3. Testing data—tensile strength (MPa).

Group	2.0 mm			2.5 mm			*P*-value
	Mean ± SD	Median	IQR	Mean ± SD	Median	IQR	
Experimental	639.00 ± 23.96	643.90	(614.47–662.34)	619.93 ± 20.24	627.18	(606.07–632.24)	0.096
Control	306.86 ± 7.05	307.06	(300.13–314.22)	448.10 ± 20.52	448.30	(440.11–464.80)	0.001*
P-value	<0.001*			<0.001*			

IQR, interquartile range; SD, standard deviation.
*Statistically significant, $P < 0.05$.

with vascularized autogenous bone grafts have been applied extensively in maxilla and mandible reconstruction. Conventionally, the surgical plates need to be bent manually to match the contour of the jaw and bone flap before the operation, and should be adjusted according to the actual operating conditions during the surgical procedure. However, the bending procedure for surgical plates is complicated and relies on the experience of the surgeon, which results in a considerable waste of

Table 4. Testing data—yield strength (MPa).

Group	2.0 mm			2.5 mm			*P*-value
	Mean ± SD	Median	IQR	Mean ± SD	Median	IQR	
Experimental	599.65 ± 30.75	602.58	(573.62–630.61)	589.66 ± 25.70	593.17	(587.27–602.50)	0.496
Control	189.37 ± 9.85	187.81	(182.70–191.43)	292.94 ± 11.75	290.73	(282.66–305.85)	0.001*
P-value	<0.001*			<0.001*			

IQR, interquartile range; SD, standard deviation.
* Statistically significant, $P < 0.05$.

manpower and time resources in the preparation and adjustment processes[1,11–13]. Furthermore, in order to achieve the desired contour in some complicated cases, the surgical plates need to be bent repeatedly, eventually leading to stress fatigue, which generates areas of stress concentration, thus accelerating the fracture process of the surgical plates[14–16].

Based on these premises, individualized surgical plates prepared by 3D printing are being explored with the aim of overcoming the drawbacks of conventional surgical plates. This is a type of rapid prototyping technology, also known as additive manufacturing. The approach is based on digital model files and employs adhesive materials such as powdered metal or plastic to build objects via layer-by-layer printing. The 3D-printed individualized surgical plates are customized based on the patient's computed tomography data; hence, plates with a satisfactory and personalized appearance can be obtained according to the specific conditions, making the plates more suitable to match the contour of the reconstructed bone. Moreover, compared to conventional surgical plates, the individualized surgical plates have a smoother surface and higher accuracy, which may contribute to reducing postoperative complications[1,17–20].

Prior to clinical application, a key question is whether the 3D-printed individualized surgical plates possess better mechanical properties than their commercial counterparts. To address this issue, we referred to a similar study reported in the literature[10], and obtained a detailed understanding of the test materials and testing methods. In this previous research, the authors adopted the standard samples recommended by relevant testing standards, manufactured the samples with different manufacturing techniques, tested the mechanical properties, grindability, and corrosion behaviour of the samples, and then drew their conclusions. It appears that previous studies have focused mainly on testing the mechanical properties of standard samples. Although these results are of important research significance, they might not fully reflect the differences that exist between individualized 3D-printed surgical plates and commercial surgical plates under clinical application. Therefore, in order to solve this problem, the samples were designed and manufactured in a shape and with other parameter designs that were consistent, as far as possible, with the surgical plates currently used in clinical practice, and their mechanical properties were then compared. The results from these tests may be more consistent with the clinical application, so as to provide a basis for mechanical properties and an important reference for the development and clinical application of 3D-printed patient-specific surgical plates. Specific experiments and tests were conducted.

In particular, four representative mechanical properties of the 3D-printed surgical plates were focused on: hardness, bending strength, tensile strength, and yield strength. Hardness represents the local resistance of a solid material to the pressure exerted on its surface by a hard object. This is an important index that measures the soft and hard nature of a material. Bending strength reflects the maximum stress that a material can withstand before it breaks or reaches a specified bending moment under the action of a bending load. This parameter reflects the bending resistance of the material. Tensile strength is the critical indicator of the transition from uniform to locally concentrated plastic deformation in a metal, and represents the maximum tensile stress that the metal can withstand. Yield strength is defined as the yield limit where yielding occurs in a metal, i.e. the stress value resisting microplastic deformation. For metal materials without obvious yield, the yield strength is defined as the stress value corresponding to 0.2% residual deformation. If the external force is greater than this limit, the material will be permanently deformed and its shape can no longer be restored.

The experimental results clearly highlighted differences in the mechanical properties of the 3D-printed and conventional surgical plates. Overall, the mechanical properties of all plates met the requirements of relevant national/international and industrial standards[6–9]. Comparing the surgical plates of the same thickness manufactured with the different techniques, the 3D-printed ones were significantly better than the conventional ones in terms of hardness and especially bending, tensile, and yield strength. Among surgical plates of different thicknesses prepared with the same manufacturing technique, the 2.5 mm-thick plates exhibited higher bending strength in the 3D-printed group and greater hardness, bending strength, tensile strength, and yield strength in the conventional group. No statistical difference in hardness, tensile strength, or yield strength was observed between the two kinds of plates in the experimental group, which may indicate that these properties have no direct relationship with the thickness. Moreover, statistically different bending strength values were found both between plates with different thicknesses in the same group and plates with the same thickness in the two different groups.

The conventional surgical plates have been used in clinical application for many years, and their mechanical properties meet the requirements of relevant standards. Considering that this study was a superiority trial, the mechanical properties of conventional surgical plates were taken as normal values, which could provide the corresponding reference data as the control group. Therefore, only by proving the superiority of the test data of 3D-printed surgical plates over the data of conventional surgical plates in regard to mechanical properties can it be accepted that these properties of 3D-printed surgical plates are better and that they are reliable and can be applied in the clinic. In comparison to conventional surgical plates, the 3D-printed ones had higher hardness and could withstand higher pressures, bending loads, and tensile stresses, as reflected by their better mechanical performance. This means that the 3D-printed surgical plates could withstand higher functional loads such as occlusal, masticatory, and muscle forces, providing a more stable fixation for vascularized autogenous bone grafts and stronger mechanical support for the repair of maxilla or mandible defects. Therefore, the differences are of great importance to the clinical application.

In the present study, the test areas of the plates that were chosen were those around the holes and the connections between the holes, as shown in Figs 1 and 2, respectively; the areas inside the red circles were the test areas. Standard testing methods were used for the tests, and the force vector applied in the test processes was perpendicular to the surface of the surgical plates, which might also be a specific stress condition in clinical use and reflected the mechanical properties under vertical load.

Furthermore, finite element analysis and digital design are not only useful to gain a better estimation of the mechanical properties and to optimize the 3D-printed surgical plates, but will also contribute to simulating different magnitudes, directions, and types of loading behaviour and analysing the mechanical properties and stress distribution of the 3D-printed surgical plates under different circumstances. For instance, individualized surgical plates could be manufactured into various shapes and structures or reinforced on some important sites such as the symphysis, parasymphysis, and mandibular angle, to provide greater stability and resistance to fracture based on biomechanical principles and on the specific clinical conditions[21–23].

In recent years, with the help of computer-aided design/computer-aided manufacturing (CAD/CAM), virtual surgical planning, and other digital techniques, 3D-printed patient-specific plates combined with vascularized autogenous bone grafts have been increasingly used in maxilla and mandible reconstruction. Yang et al.[1] conducted a prospective clinical trial to assess the feasibility, safety, and accuracy of 3D-printed patient-specific surgical plates. The 3D-printed plates could be closely adapted to the bone surface without pre-bending. The clinical trial achieved an intraoperative success rate of 100% and had a high reconstruction accuracy, which indicated that 3D-printed patient-specific surgical plates could be effective in head and neck reconstruction and simplify the corresponding surgical procedures. Yang et al.[19] introduced a method for the design of 3D-printed patient-specific surgical plates in mandibular reconstruction. Their study suggested that this novel approach was feasible and time-saving, and likely to promote the wide application of 3D-printed surgical plates, leading to potential advances in mandibular reconstruction. Melville et al.[20] described the use of a patient-specific 3D-printed plate together with a vascularized fibula flap to repair a maxillary defect. The 3D-printed plate corresponded precisely with the surgical defect, and the maxilla and midface were reconstructed to ideal dimensions with no unplanned surgical manipulation and a shorter overall operating time. Rana et al.[24] presented a retrospective multicentre analysis of a novel approach for the reconstruction of mandibular continuity defects using selective laser-melted patient-specific functional implants combined with free fibula flaps; their study demonstrated the accuracy of this approach, whose application could contribute to a better clinical outcome. Based on the results of these clinical studies, it can be concluded that 3D-printed surgical plates could be accurate, effective, and practical tools in maxillary or mandibular reconstruction.

Although the 3D-printed surgical plate has been used for some years in some countries, it is a relatively new technology and has not been used widely in many parts of the world including mainland China, especially in oral and maxillofacial surgery. According to the Standard for Quality Management of Medical Device Clinical Trials of the National Medical Products Administration and National Health Commission of the People's Republic of China[25], before a clinical trial of medical apparatus and instruments, the sponsor must perform tests in preclinical studies to support the clinical trial. Regarding the present study, the testing of mechanical properties not only provides a basis for clinical trials or clinical use and the modification of the surgical plates, but will also help to identify potential deficiencies in the material characteristics allowing improvements to be made before there are any problems in the clinical application.

In this initial phase of the experimental design, a small sample size was adopted to evaluate differences between the two types of plate. The results showed that the 3D-printed plates exhibited satisfactory performance in practical conditions. Further improvements could be achieved in future studies by increasing the sample size to determine the nature of the correlation between the bending strength and thickness of the plates. In addition, finite element analysis will be conducted to test and verify the mechanical properties of the 3D-printed surgical plates as a supplement to the current study.

In conclusion, 3D-printed surgical plates exhibited better mechanical properties than conventional surgical plates and could be applied effectively for maxilla or mandible reconstruction in clinical practice. In the next stage, a clinical trial needs to be performed to verify the validity and feasibility of this technique.

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Competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Ethical approval

Not required.

Patient consent

Not required.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijom.2021.09.008.

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Address:
Xin Peng
Department of Oral and Maxillofacial Surgery
Peking University School and Hospital of Stomatology
22 Zhongguancun South Avenue
Beijing 100081
China
Tel.: +86 10 82195210; Fax: +86 10 62173402
E-mail: pxpengxin@263.net