

Biomechanical and Histological Evaluation of a Newly Designed Bone Plate for Fixation of Mandibular Fractures in Mental Nerveregion

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Abstract: Purpose: The aim of this research was to evaluate both biomechanically and histologically for a new three dimension experimental mandibular miniplate designed for mandibular fractures at mental nerve region. **Materials and methods:** Six sheep were used, via intraoral approach unilateral mandibular fracture was induced using fine surgical bur and fine osteotome. The sheep divided into two groups according to method of fixation either using conventional 3D miniplate or using new designed 3D experimental mandibular plate. Data were recorded and analyzed. Freshly extracted mandibles of another six sheep were obtained for this study. All the mandibles were stripped of their soft tissues and sectioned through the midline. Hemi-mandibles ($n=12$) were divided into two groups of 6 specimens each (group A and group B. These groups were then fixed with two different plating techniques: Group A (study group) the fixation was done by using the newly designed experimental 3D miniplate. Group B (control group) the fixation was done by using conventional six-hole rectangular miniplate. **Results:** Newly designed 3D experimental miniplate offers biomechanically resistance and stability to the displacing forces at the mandibular fracture site at mental nerve region without mental nerve interference.

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1. Introduction:

Mandibular fractures at the level of the symphysis and/or parasymphysis are relatively common and account for approximately 20% of mandibular fractures. Usually second fractures of the mandible, especially at the subcondylar region are often associated with fractures at this region. Also the clinical findings of a widened intragonial distance with resultant malocclusion are often associated with these fractures [1,2].

Fractures of the anterior mandible lack two of the stabilizing factors provided to fractures of the posterior tooth-bearing mandible: (i) the splinting effects of the masseter and internal pterygoid muscles, which form a natural sling, and (ii) the interlocking cusps and fossae of bicuspid and molar teeth [3].

As many techniques of fracture management are founded, the goals have not changed significantly. Proper reduction of the fractures, maintenance of pre-morbid occlusion, and early return to function are the keys to successful management of these fractures. The technique of fracture repair and fixation means depend on the fracture pattern, fracture severity, and patient factors, such as residual dentition, coexistent lacerations, and associated injuries [4].

The surgical treatment modalities have ranged from conservative measures such as closed reduction

and indirect fixation using splints or arch bar to open reduction with direct fixation [5, 6]. Many authors recommend open reduction and fixation for majority of mandibular fractures [7, 8].

In concept of rigid fixation that was promoted by the AO/ASIF, compression, tension, torsion and shearing forces, which develop under functional loading, are neutralized by thick solid plates fixed by bicortical screws. In contrast, the Champy's method of semi-rigid fixation uses an easily bendable monocortical miniplate along an "ideal osteosynthesis line" [9,10]. As masticatory forces produce a natural compression strain along the lower border of the mandible this neutralizes the functional developing forces. Both techniques are associated with disadvantages. Numerous authors have documented low complication rates with monocortical non-compressive miniplate fixation "Champy's technique" [8,11,12]. The miniplate fixation of mandibular fractures is semi rigid fixation so the stability provided by it becomes a point of contention among surgeons based on both experimental and clinical studies [13-15].

These shortcomings of rigid and semi-rigid fixation, led to the development of 3 dimensional (3D) miniplates which consisting of two "4-hole" miniplates interconnected by vertical cross struts. In contrast with compression and reconstruction plates, their stability is

not derived from the thickness of the plate but with the screws monocortically fixed to outer cortical plate, these rectangular plates form a cuboid which possess 3D stability^[16].

The standard profile, malleability as well as strength of 3D plate all facilitating reduction and stabilization at both the superior and inferior borders and giving three dimensional stability which lead to shorting the operative time as stabilization at superior and inferior borders occurred at the same time. Fractures involving the mental nerve area and oblique fractures are considered as a limitation for using 3D miniplates. In addition, there is an excessive hardware material because of the extra vertical bars incorporated for countering the torque forces^[16,17].

In order to overcome the limitations of conventional 3D miniplates in the mental nerve region, this study was conducted to evaluate the surgical accessibility, stability and resistance to mechanical forces as well as histological study the bone healing process of surgically induced mandibular fractures that were fixed by a newly designed experimental surgical 3D miniplate with better adaptability to mental nerve area.

Adequate mechanical properties of the plates used for fixation of fractures are very important to withstand the deforming forces during function. The flexural strength measurement is used to evaluate the bending/fracture resistance and elasticity of a material^[18]. Therefore, it is so important to evaluate the plate resistance to bending forces by measuring the flexural strength as well as the flexural elastic modulus. The modulus of elasticity (stiffness) is an inherent property of a material. It is a measure of the resistance of the material to deformation under load. The higher modulus of elasticity the minimum deformity will be occurred when the material subjected to forces from the surrounding environment^[18,19]. So it important to evaluate the flexural elastic modulus of the investigated plates.

Like soft tissues, bone could heal by primary or secondary intention. The primary bone repair (direct

bone healing) occurs only under conditions of absolute stability or enough rigidity, anatomic reduction and good vascular supply at the fracture site. Secondary bone healing is seen in spontaneous bone healing (without surgical intervention) or healing after non-rigid or semi-rigid fixation^[20-22].

So this study beside the biomechanical evaluation, aimed to examine the healing process of bone at the surgically induced mandibular fractures that were fixed with the newly designed experimental surgical 3D miniplate.

2. Materials and Methods:

Six sheep (all are 1-year old) were be used for this study

The anesthesia for animals was induced with pentobarbitone sodium (20 mg/kg bodyweight) administered through a catheter in the jugular vein. Endotracheal intubation was performed under laryngoscopy with a Rush tube and anaesthesia was maintained in an open circuit with oxygen, nitrous oxide and halothane.

The mandibular bone at the mental nerve area was exposed through intraoral vestibular incision and reflection of mucoperiosteal flap. Careful blunt dissection was done to separate the mental nerve from adjacent soft tissues. A unilateral mandibular fracture was induced using fine surgical bur and fine osteotom.

The animals divided into 2 groups according to means of fixation of the surgically induced fractures.

Group I (study group): The newly designed experimental 3D miniplate (EP) was used for the fixation. This plate was fabricated as 3D miniplate with open one vertical bar at one end and attached to the remaining plate with a joint which allows opening and closing the plate. The plate was inserted with the bar open to pass underneath the mental nerve. The bar, then, closed again to make the plate rectangular in shape. The plate was secured in place using 8 monocortical screws.



Figure1: Intraoperative photograph for mental nerve dissection and plate is opened to pass underneath the nerve (left). after plate closing (right)

Group II (control group): A6×2 Straight 3-dimensional (3D) plate (1 mm profile height, Stryker-Leibinger, Freiburg, Germany) was used for the fixation.

After accurate fixation the wound care was performed then the mucoperiosteal flap was sutured using absorbable suture material. The animals returned to normal diets from second day postoperatively. All animals were followed up of 3 months postoperatively.

One animal was sacrificed from each group at interval of 2 weeks, one month, and three months post-operatively.

Histological Preparation:

After scarification dissection of the mandibles was done then the dissected mandible were sectioned at midline. The hemi-mandibles were subjected to the usual processing for histological study to evaluate the bone healing at the fixated fracture sites in both groups.

The hemi-mandibles of both groups were fixed in 10% buffered formalin. Decalcification was done in 50-50 (v/v) solutions of 40% formic acid and 6.25% sodium citrate. The decalcified solution was changed every other day. One week from the beginning of decalcification, the hemi-mandibles were dissected more from their muscle remnants, and trimmed from the anterior and posterior peripheries. After complete calcification, the specimens were washed, dehydrated, cleared in xylene and embedded in paraffin. Serial sections of 3-5 microns were cut mesio-distally and stained with hematoxylin and eosin.

Biomechanical testing study

Freshly extracted mandibles of another six sheep were obtained for this study. All the mandibles were stripped of their soft tissues and sectioned through the midline. The specimens were kept moist and refrigerated until all investigations had been completed. Hemi-mandibles ($n=12$) were divided into two groups of 6 specimens each (group A and group B), provided that the two halves of every single mandible fall in different groups. These groups were then fixed with two different plating techniques:

(1) The newly designed experimental 3D miniplate (EP) was used for the fixation of Group A.

(2) Conventional six-hole rectangular miniplate, as a control miniplate (CP), was used for the fixation of Group B.

To simulate the parasymphiseal fracture, every single hemi-mandible was sectioned at the parasymphiseal region using a diamond disc. For the two groups, to avoid poor adaptation of the plates after sectioning, the plates were pre-adjusted to the hemimandible before sectioning. After adaptation of plate to the hemimandible, one corresponding hole

was drilled in each segment with a standard drill and the plate screwed to the hemi mandible. The screw was then removed from one side and acute was made at the parasymphiseal region to mimic the parasymphiseal fracture. The cut segments were reduced, leaving a maximum of about 1 mm space between the bone segments, as recommended by Ribeiro-Junior *et al.* [23] This crew was then re-positioned at the pre-drilled site of the mandibular segment. The remaining holes, which had not been drilled prior to the cut, were drilled and the plates screwed to the hemi mandibles on both sides of the cut.

In Group A (include 6 hemimandibles): all hemimandibles were fixed with a newly designed experimental 3D miniplate (EP). The miniplate was secured to the hemimandible at both sides of the cut using 4 monocortical titanium screws.

In Group B (include 6 hemimandibles): The hemimandibles were fixed using the control plate (CP) which was secured to the cut segments then the fixation was done with conventional rectangular 3D miniplate.

Mechanical testing

At room temperatures, all specimens were submitted to flexural forces in a universal testing machine (model 3365, Instron, High Wycombe, UK) to determine the resistance to bending and the flexural elastic modulus of the investigated plates. For flexural tests, the flexural strength is measured through some calculations depending on force applied, specimen dimensions and distance between supporting points. In our study, the aim was not to measure the flexural strength of the investigated plates but to measure the bending resistance of each plate when submitted to a pre-determined load.

Testing procedures were the same for Group I and Group II. The hemimandible with the fixed plate was mounted to the three-point bending parts of the universal testing machine where the supporting points were 5 mm away from the edge of the fixed plate and the loading point exactly at the middle of the upper surface of the plate. A pre-determined load of 1 kN was used to load the investigated plates at a cross-head speed of 1mm/min. Before initiating the loading, the vertical distance between the mid-point of the fixed plate and the bottom surface of the test assembly was measured (in mm). Then the specimen was loaded until the pre-determined load (1 kN) is reached. At this point, the test was stopped and the bending that took place in the plate was measured. This was done by measuring the vertical distance between the mid-point of the plate and the bottom surface of the test assembly after loading and subtracting this value from that measured before loading. The difference is the

bending (in mm) that took place in the plate. After all specimens were tested, the results of the two groups were tabulated and compared.

Flexural modulus was determined from the slope of the linear region of the load-deflection curve. Data acquisition was done using the software (Bluehill LE testing software, Instron Ltd).

Statistical analysis:

The statistical significance of differences between the two groups was evaluated using the Mann–Whitney U-test. For comparisons of the subgroups, the Kruskal–Wallis H-test followed by Bonferroni correction was used. P-values equal to or less than 0.05 ($P \leq 0.05$) were accepted as statistically significant. Linear regression and correlation analysis were performed to investigate the correlation between the flexural elastic modulus and bending of the examined plates.

3. Results:

Clinical results:

Wound healing in all animals showed primary healing uneventfully achieved in all animals after one week postoperatively in both groups. All animals return to normal diets from third days postoperatively. The body weight average in group I was 24.0 without significant difference when compared with the average of preoperative body weight 23.6 as p value was 0.235. In Group II, the body weight average was 24.5 without significant difference when compared with the average of preoperative body weight 24.1 as p value was 0.224. When comparing the postoperative bodyweight average in both groups there is no significant difference as P value was 0.152.

Histological Results:

Histological examination of the fracture gap, two weeks post-operative, showed that it completely filled with connective tissue in group I. Where in group II, the connective characterized by mesenchymal

condensation together with an obvious increase in the vascularity which seemed to form center of ossification. A Few small bone trabeculae scattered in the fibro-vascular tissue were observed in both groups. Figure (2).

One month post-operatively, revealed that the fracture gap of both groups was filled with condensed connective tissue that demonstrated numerous immature bone trabeculae which were larger in group I than that in group II. These woven bone trabeculae had disordered collagen fibers and large number of osteocytes. Numerous plump-shaped osteoblasts were arranged around the woven bone trabeculae that indicated active bone formation Figure (3).

Three months post-operative, the fracture gap of both groups was almost filled with newly formed lamellar bone with remnant fibrous tissue and wide vascular areas. The newly formed bone showed numerous vertically oriented osteons that had many Volkmann's canals. Moreover, in group II reversal line separated between the newly formed bone and the remodeled one could be observed Figure (4).

Biomechanical results

The values of three-point bending test and flexural elastic modulus of examined specimens of both groups are presented in Table 1. Linear regression and correlation analysis revealed a strong negative correlation between the bending resulted in the investigated plates after loading with 1 kN and the corresponding flexural elastic moduli, Figure (5).

For both plates and tested mechanical parameters, it was clear that the values of the examined specimens were close to each other which were confirmed with the small values of standard deviations.

Upon comparing the results, there was no statistically significant difference between the two groups neither in the 3-point bending ($p = 0.0613$) nor in the flexural elastic modulus values ($p = 0.0724$).

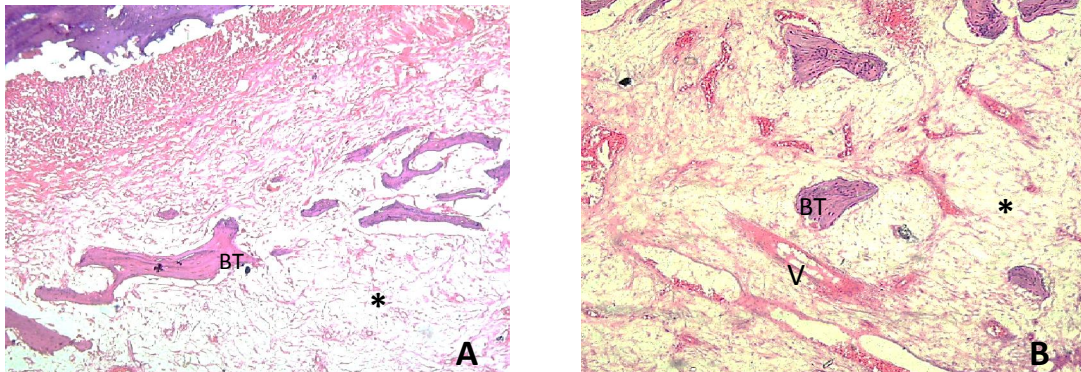


Figure (2): (A) a photomicrograph of group I, two-week post-operative displays fibro-vascular tissue (*) with few scattered small bone trabeculae (BT). (B) a photomicrograph of group II, two-week post-operative displays fibro-vascular tissue (*) with increased vascularity (V) together with few scattered small bone trabeculae (BT). (H & E X 100).

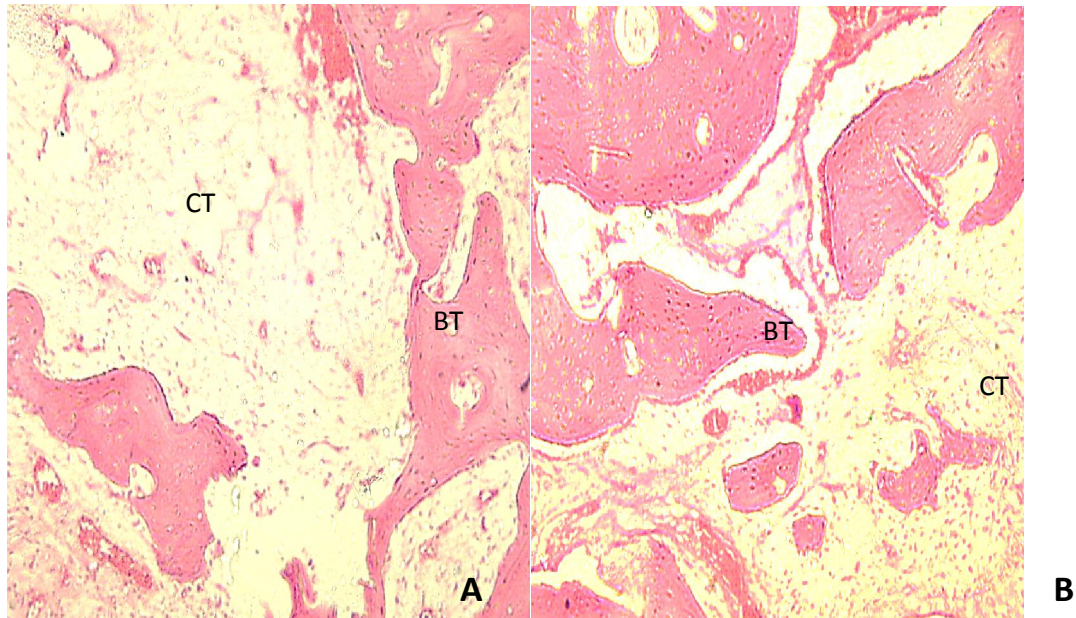


Figure (3): (A) a photomicrograph of the group I, one month post-operative showed that the fracture gap was filled with dense connective tissue (CT) with numerous woven bone trabeculae (BT). (B) a photomicrograph of the group II, one month post-operative displayed that the fracture gap was filled with large woven bone trabeculae (BT) with denser connective tissue (CT). These bone trabeculae have disordered collagen fibers and large number of osteocytes (H & E stain x 100).

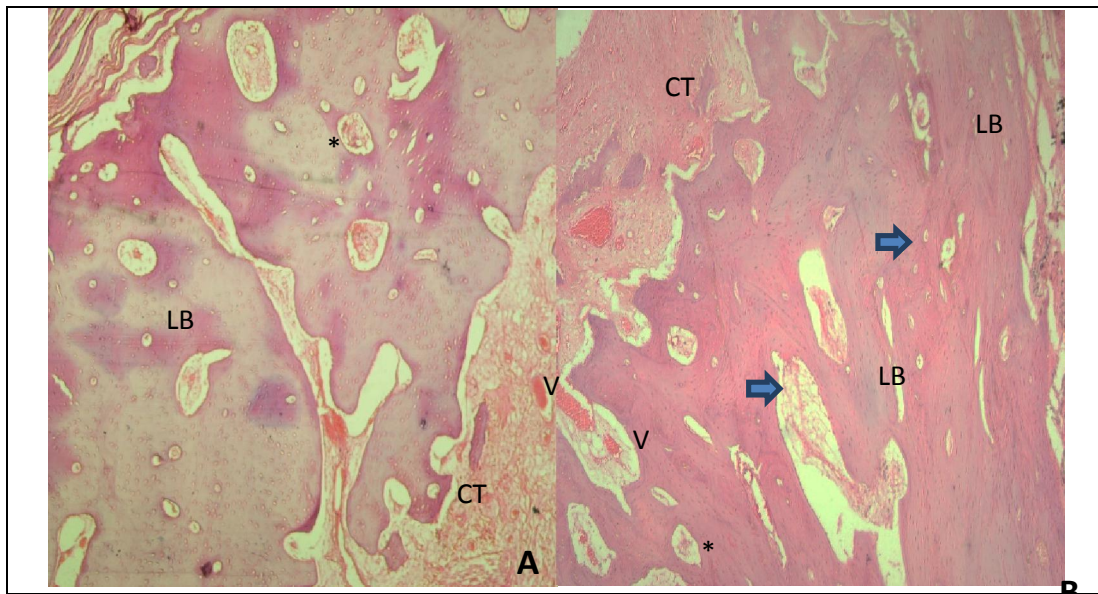


Figure (4): (A) & (B) photomicrographs of the both groups, three months post-operative revealed that the fracture gap was almost filled with newly formed lamellar bone (LB) with remnant of connective tissue (CT) and wide vascular areas (V). The newly formed bone showed numerous vertically oriented osteons (*) that had many Volkmann's canals (small arrow). Moreover in group II (B) reversal line (arrows) separated between the newly formed bone and the remodeled one that could be observed. (H & E X 100).

Table 1: presenting results of three-point bending test and flexural elastic modulus in both groups

Specimen	Three-point bending test		Flexural elastic modulus	
	Group I	Group II	Group I	Group II
1	61.7	8	76.5	76.5
2	63.3	7	69.9	69.9
3	59.9	6.5	70.9	70.9
4	61.1	8	74.6	74.6
5	64.8	9	75.8	75.8
6	58.6	7	72.7	72.7
Mean	61.6	7.6	73.4	73.4
SD	2.2	0.92	2.7	2.7
p-value	0.0613		0.0724	

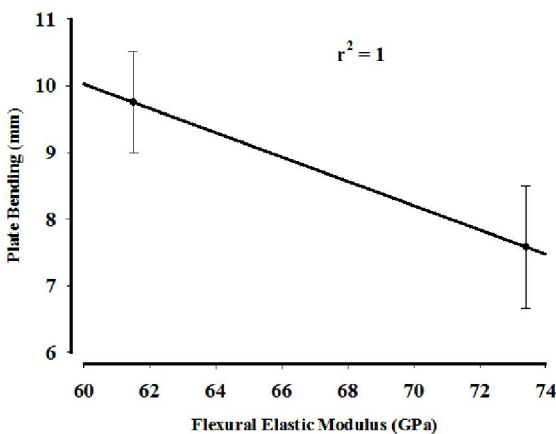


Figure (5): showing a negative strong correlation between the bending that took place in the investigated plates and the corresponding flexural elastic moduli.

4. Discussion

The technical application, economic aspects as well as the surgical approach must be considered when evaluating any methods of osteosynthesis. Adequate knowledge of biomechanics and static and dynamic forces acting in the region being restored are important factors for successful management⁸.

Mandibular fractures were treated either with closed reduction and a course of prolonged maxillomandibular fixation or open reduction and internal fixation using wire osteosynthesis, then titanium hardware including lag screws and plates²⁴.

The superior mandibular border was a tension zone, while the inferior border was compression zone so when miniplates placed long ideal lines of osteosynthesis were thought to provide optimal fixation and stability. As these plates are small and the screws are monocortical, they simplified surgery and reduced surgical morbidity.^[9, 10]

Farm and et al^[25] in 1992 developed the concept of 3D miniplates. Their shape provides a geometrically

stable configuration for support. Since the stability achieved by the geometric shape, these plates surpass the standard miniplates. The basic form is quadrangular with 2 × 2 holes square plate and 3 × 2 or 4 × 2 holes rectangular plate. The 3D miniplate itself was inaccurate name as the plate was not 3-dimensional, but it produces stability that can resist the 3-dimensional forces acting at the fracture site during function.

The 3D miniplate can be used as an easy alternative to conventional Champys miniplates. But some restriction for it uses were founded especially in cases with oblique fractures and fractures involving the mental nerve area.^[26]

The current study aimed to evaluate, histologically and biomechanically, the newly designed experimental 3D miniplate in the fixation of surgically induced mandibular parasymphseal fracture in sheep in attempt to overcome the limitation of conventional 3D miniplate at this area. The study assessed whether the adaptability of the newly designed plate as well as the stability of a mandibular parasymphseal fractures were improved and comparing with the conventional 3D miniplates at the mental nerve area.

The clinical results in this study revealed that, uneventfully primary wound healing was achieved in all animals after one week postoperatively in both groups. All animals return to normal diets from third days postoperatively. The body weight average in group I was 24.0 without significant difference when compared with the average of preoperative body weight 23.6 as *p* value was 0.235. In Group II, the body weight average was 24.5 without significant difference when compared with the average of preoperative body weight 24.1 as *p* value was 0.224. When comparing the postoperative body weight average in both groups there is no significant difference as *P* value was 0.152. This can be

explained, as the early return of animals in both groups to normal diet may be indicator for good fracture stability.

In regarding to histological results, the current study used cheep due to their similarities to human in bone structure and regeneration together with reminiscent response to different mechanical properties. In addition, we utilized conservative extra-alveolar device that allowed the use of many screws to ensure that the device was rigidly fixed to the bone so that the original setting and good control of the (3D) plate. Our results showed that this new 3D miniplate estimate new bone formation similar to that of the conventional 3D miniplate technique, especially in one and three month post operatively. Whereas the new bone formation one week post-operative in new 3D miniplate in crease in the vascularity which seemed to form center of ossification than that of the conventional the new 3D miniplate.

In regarding the biomechanical results, this study was to design a new 3D miniplate that would overcome the limitation of the conventional 3D miniplate techniques at the mental nerve area. Our results showed that this new 3D miniplate provided biomechanical stability similar to the stability of the conventional 3D miniplate technique.

Upon comparing the results, there was no statistically significant difference between the two groups (Group I fixed with EP and Group II fixed with CP) neither in the 3-point bending ($p = 0.0613$) nor in the flexural elastic modulus values ($p = 0.0724$).

In conclusion, although it is difficult to extrapolate the results of this in vitro study to actual patient care, the findings demonstrate that this newly designed 3D miniplate offers resistance and stability to the displacing forces at the fracture site similar to conventional 3D miniplates. This new design 3D miniplate could be useful in the treatment anterior mandibular fractures involving the mental nerve to produce 3D fracture stability without mental nerve interference. Further prospective clinical studies are required to determine the effectiveness of this new plate design.

Conflict

This paper has no conflict of interest.
No fund.

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