



Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Novel multi-axial alveolar distractor — Part I: Design, manufacture, and mechanical/functional tests

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ARTICLE INFO

Article history:

Paper received 18 October 2018

Accepted 13 February 2019

Available online 20 February 2019

Keywords:

Distractor

Multi-axial

Bone regeneration

Ball-and-socket joint

ABSTRACT

Purpose: This study developed a novel multi-axial alveolar distractor and evaluated its safety and effectiveness by performing various mechanical tests and finite element (FE) analysis.

Materials and methods: A ball-and-socket joint with a high degree of freedom was proposed as the design concept to make the distractor produce a cone trajectory motion range of up to 60° with respect to the transport screw (central axis). This device was manufactured with Ti6Al4V alloy. Mechanical functional tests included four-point bending resistance testing of the base bone plate, pull-out testing of the multi-axial alveolar distractor, welding strength testing between the base bone plate and ball-and-socket joint mechanism, and torque strength testing of the ball-and-socket joint. These tests were performed to ensure the effectiveness and safety of the multi-axial alveolar distractor. The base bone plate FE analysis of four-point bending resistance and pull-out testing of the multi-axial alveolar distractor were performed to confirm the results obtained from the experimental testing.

Results: The bending strength for the four-point bending test and the maximum force for pull-out testing were 530.88 N mm and 716.33 N, respectively. Substantial equivalence FE simulations also found that large deformations for four-point bending and pull-out testing were smaller than those for the commercial alveolar distractor, indicating that our new distractor is as safe and effective as the commercially available device. The maximum debonding torque resistance for ball-and-socket joint mechanism welding strength was 3481.1 N mm, meaning it is unable to fall off during a surgical operation. No damage was found at the welding edge. The maximum average resistance force in the ball-and-socket joint was 30.26 N without rotation, allowing it to resist distraction forces during bone regeneration — an important safety consideration.

Conclusion: The alveolar distractor designed using a ball-and-socket joint concept can achieve multi-axial distraction with various angle adjustments in 3D space. Thorough mechanical/functional tests confirm the effectiveness and safety of our new multi-axial alveolar distractor.

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1. Introduction

Alveolar distraction osteogenesis (ADO) has become one of the principle surgical techniques used in preimplant surgery to increase the height of the alveolar ridge where rehabilitation with dental implants is required (Raghoobar et al., 2000; Horiuchi et al., 2002; Maurette O'Brien et al., 2004; Block and Baughman, 2005;

Kunkel et al., 2005). ADO offers the advantages of decreased bone resorption, lower rate of infection, no donor site morbidity (Rachmiel et al., 2001; Urbani, 2001; Horiuchi et al., 2002), and soft tissue gain (gingiva) (Raghoobar et al., 2000; Horiuchi et al., 2002; Jensen et al., 2002).

Although several different types of distraction device have been discussed in the literature, optimal vector control regeneration in the distraction remains a critical issue for proper reconstruction during the distraction process (Raghoobar et al., 2000; Watzek et al., 2000; Riccardi et al., 2006). The difficulty in controlling 3D (3-dimensional) movements during transport osteogenesis has

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been widely reported due to the curved limitations of the alveolar ridges, soft tissue pulls, inappropriate device positioning, or poor device trajectory (Hollier et al., 2000; Garcia et al., 2002). Determining the correct distraction vector with a precise evaluation of the planned movement, and to maintain the desired direction of the vector during the alveolar distraction process, are deemed important issues for ADO application (Grayson et al., 1997; Gaggl et al., 2000a,b).

Despite a distractor having adjustable angulation intraoperatively, according to preoperative plans being proposed for achieving buccal–lingual (2-dimensional) vector control (Hariri et al., 2013), a good distractor should be able to be placed in accordance with anatomical limitations such as sinus/cavity, thin cortex bone region, and alveolar nerve. Distraction should provide angular flexibility (tongue/cheek, near/telecentric, occlusal direction, etc.), which can meet both the alveolar bone distractor positioning requirements and the prosthesis occlusion direction. Therefore, multidirectional distraction options with accurate control are considered desirable (Aronson, 1994; Chin and Toth, 1996).

The aim of this study was to develop a novel alveolar distractor that can achieve multi-axial distraction with different angle adjustments in 3D space. The functional tests were performed using various mechanical tests to evaluate the safety and effectiveness of the proposed alveolar distractor, with the expectation of improving on current clinical alveolar distractors.

2. Materials and methods

2.1. Design concept for the multi-axial alveolar distractor

Vector control combined with a high-degree-of-freedom (DOF) ball-and-socket joint were proposed as the design concept to allow the distractor to produce a cone trajectory motion range of up to 60° with respect to the transport screw (central axis). The alveolar distractor consists of an extra-osseous system with a ball-and-socket joint mechanism welded to the base bone plate, which can be adjusted intraoperatively according to the preoperative plan in order to achieve vector control (Fig. 1(a)). The distractor can be angled up to 60° towards the buccal/lingual and mesial/distal sides. The ball-and-socket joint can be relocked by tightening the hex nut after vector adjustment. The base bone plate consists of optional screw holes next to the ball-and-socket joint mechanism for fixing onto the residual bone, in order to achieve safety anchorage. The transport segment, which is completely mobile after osteotomy, is fixed with a transport plate. The transport segment movement vector is achieved by turning the transport screw in the clockwise direction. Each full clockwise rotation is equal to a 0.25 mm distraction distance and the maximum distraction distance is allowed 13 mm distraction height. The turning direction is guided by an arrow marked on the activating key. All components of this alveolar distractor were designed using a CAD system (PTC creo 2.0, PTC Inc., Needham, MA, USA) and manufactured using Ti6Al4V alloy by an ISO13485 quality management systems company (HUANG LIANG Biomedical Technology Co., Ltd., Luzhu Dist., Kaohsiung City, Taiwan) (Fig. 1(b)).

2.2. Functional tests of the multi-axial alveolar distractor using in vitro mechanical testing

To ensure the effectiveness and safety of the proposed multi-axial alveolar distractor, functional tests included: (a) four-point bending resistance testing of the base bone plate; (b) pull-out testing of the multi-axial alveolar distractor; (c) welding strength testing between the base bone plate and the ball-and-socket joint mechanism; and (d) torque strength testing of the ball-and-socket joint.

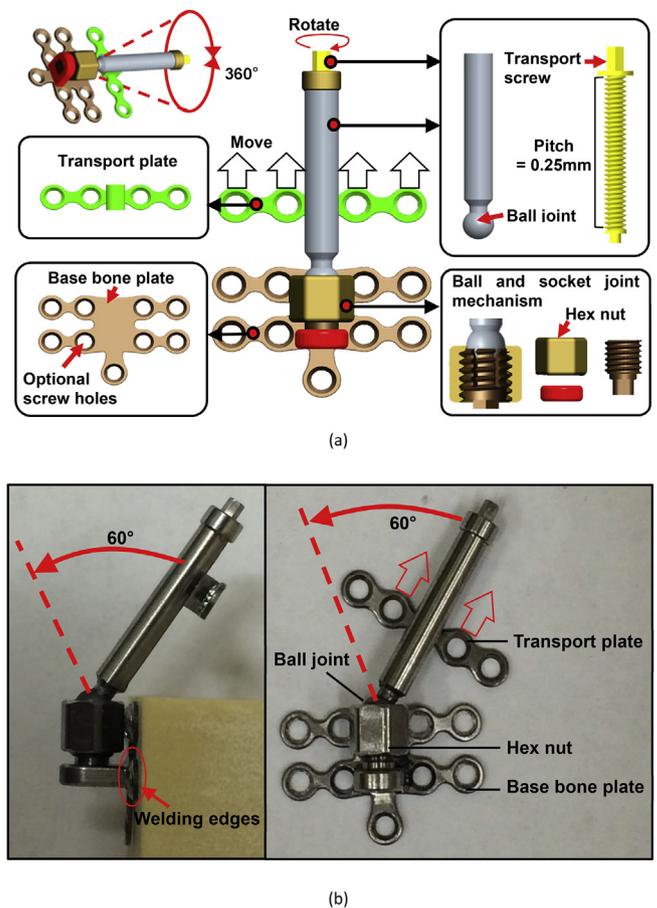


Fig. 1. (a) Illustration of the multi-axial alveolar distractor, showing various components within the distractor, including the base bone plate, transport plate, transport screw, and ball-and-socket joint mechanism; (b) the alveolar distractor was manufactured using Ti6Al4V alloy by an ISO13485 quality management systems company.

2.2.1. Four-point bending resistance testing of the base bone plate

A single-cycle, four-point bending resistance test was carried out according to the ASTM F-382 standard testing method in order to determine the intrinsic, structural properties of the multi-axial alveolar distractor base bone plate. The base bone plate was placed in the fixture and positioned so that the loading rollers were in contact with the bone plate surface. Rigid extension segments were used to effectively lengthen the bone plate so that it could undergo the four-point bending test in accordance with the ASTM F-382 method. The center span (a) and loading span (h), defined as the distance between the two loading rollers and the distance between the loading roller and the nearest support, respectively, were 12.5 mm and 8 mm (Fig. 2). Three distractors were arranged to perform the four-point bending test, which was designed to drive an axial load onto the loading rollers at a cross-head speed of 0.05 mm/s, using a universal testing machine (HT-2402EC, Hung Ta Instrument Co., LTD, Taiwan), until the fracture point. The fracture point was determined either by an obvious fracture or by the load dropping suddenly to 30% of its maximum value, which usually indicates that the test component has been destroyed. The average bending strength, bending stiffness, and corresponding standard deviations were calculated according to the ASTM F-382 testing method.

2.2.2. Pull-out testing of the multi-axial alveolar distractor

Three multi-axial alveolar distractors were fixed on the custom-made Sawbone (3 mm central slot; Block 50 PCF/40 mm thick;

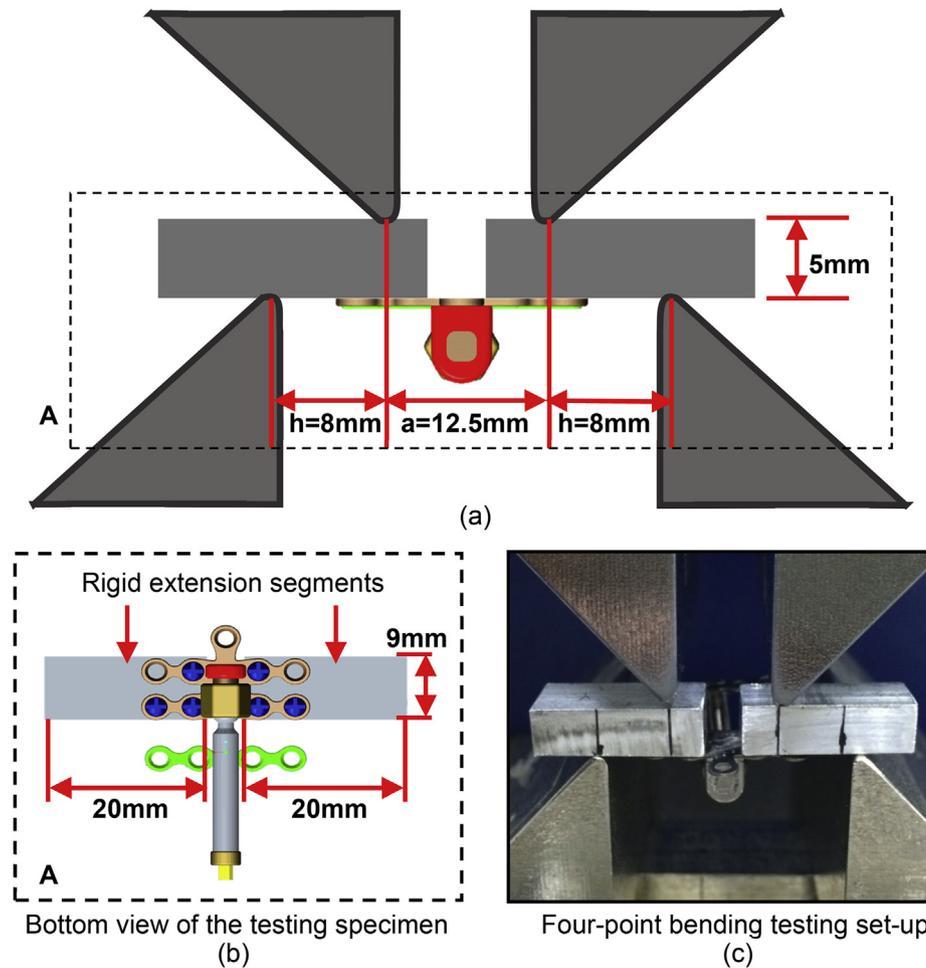


Fig. 2. Four-point bending testing of the multi-axial alveolar distractor in accordance with the ASTM F-382 method: (a) frontal view; (b) bottom view; and (c) picture of the testing set-up.

Pacific Research Laboratories Inc., Vashon Island, WA, USA), which was the alternative standard material for bone biomechanical testing, using six fixation screws (6 mm in length and 1.5 mm in diameter; Ti cortex screw, Synthes GmbH, Oberdorf, Switzerland), and clamped tightly onto the testing machine to perform the pull-out testing. A custom L-shaped loading device was inserted into the Sawbone slot to pull the distractor out using a driving upward force at a speed of 0.02 mm/s (Fig. 3). The maximum pull-out force and fracture pattern for each Sawbone were recorded, and the average pull-out force value and standard deviation were calculated.

2.2.3. Welding strength testing between the base bone plate and ball-and-socket joint mechanism

To avoid the ball-and-socket joint mechanism debonding from the distractor base plate during the operating process, three distractors were fixed onto the Sawbone and clamped onto the testing machine to perform the welding strength test. A custom-made wrench with a semicircular recess in its head was fitted to the base of the ball-and-socket joint mechanism. A downward axial load with 0.02 mm/s speed and 70 mm distance from the ball-and-socket joint mechanism base component was applied to the custom-made wrench arm until the base component debonded/fractured or the load dropped to 30% of its maximum. The torque was calculated using the maximum load multiplied by 70 mm (the moment arm) to evaluate the welding strength between the base bone plate and the ball-and-socket joint mechanism (Fig. 4(a)).

2.2.4. Ball-and-socket joint torque strength testing

This test was required to avoid ball-and-socket joint rotation during multi-axial alveolar bone distractor use. The distractor base plates were fixed onto the Sawbone. The ball-and-socket joint was locked using a torque of 630 N mm, i.e. an axial force of 9 N multiplied by the 70 mm moment arm on the hexagonal wrench, with the transport screw axial direction maintained parallel to the Sawbone surface. Three distractors were arranged to perform torque strength testing, using an axial load at a speed of 0.02 mm/s applied on the transport plate, with 18 mm distance to the center of the ball-and-socket joint (the maximum traveling length of the transport plate), using a custom jig (Fig. 5(a)). To evaluate the torque resistance of the ball-and-socket joint, the maximum forces were recorded when the load dropped to 30% of the maximum load.

2.3. Finite element analysis of the base bone plate of the distractor

In order to confirm the results obtained from four-point bending resistance and pull-out testing of the multi-axial alveolar distractor, base bone plate finite element (FE) models for our new multi-axial distractor and a commercially available two-dimensional alveolar distractor (straight plate, distraction length 12 mm, Synthes GmbH, Oberdorf, Switzerland) were constructed and meshed with quadratic 10-node tetrahedral structural solid elements. The total numbers of elements and nodes for the new multi-axial distractor

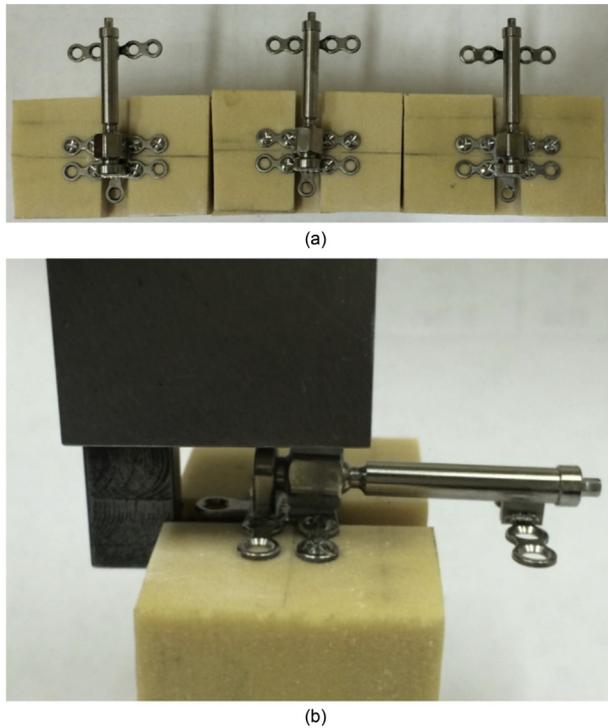


Fig. 3. Pull-out testing of the multi-axial alveolar distractor: (a) three multi-axial alveolar distractors were fixed on the custom-made Sawbone; (b) the custom-made Sawbone with a 3 mm central slot and a custom, L-shaped loading device was inserted into the Sawbone slot to pull the distractor out using an upwards driving force.

were 137 568 and 20 411, respectively, and 141 842 and 211 551 for the commercially available two-dimensional alveolar distractor model.

All elastic modulus and Poisson's ratio values for Ti_6Al_4V were applied as 110 000 MPa and 0.34, in line with the relevant literature (Wu et al., 2017). The boundary conditions applied for four-point bending resistance and pull-out testing were the same as the experimental conditions. The loading conditions applied were 300 N at the loading rollers as the compressive force, in accordance with the experimental conditions for four-point bending resistance testing, and 600 N upward force at the middle position of the base plate for the pull-out testing. FE analysis was carried out to calculate large deformations of the base plate of the alveolar distractors.

3. Results

The four-point bending resistance test results for the base bone plate showed that all distractor base plates deformed obviously (Fig. 6) after testing, with the bending strength and bending stiffness values measured as 530.88 ± 67.34 N mm and 15.53 ± 8.60 N/mm (average value \pm standard deviation), respectively. The pull-out test results for the multi-axial alveolar distractor showed that the average maximum pull-out force was 716.33 N. The destruction pattern for the test sample indicated that the Sawbone fractured unilaterally, and was pulled out together with the fixation screw (Fig. 7). The average maximum load in the welding strength testing was 49.73 N, and the maximum resistant torque, obtained by multiplying by 70 mm (the moment arm), was 3481.1 N mm. Magnification images (37.5 times) at the welding edges between the base plate and the ball-and-socket joint mechanism were found to show no damage when assessed using a non-contact video measurement system (SVP-2010, ARCS Co., Ltd., Taichung, Taiwan) with a color CCD camera (Fig. 8). The maximum average resistance

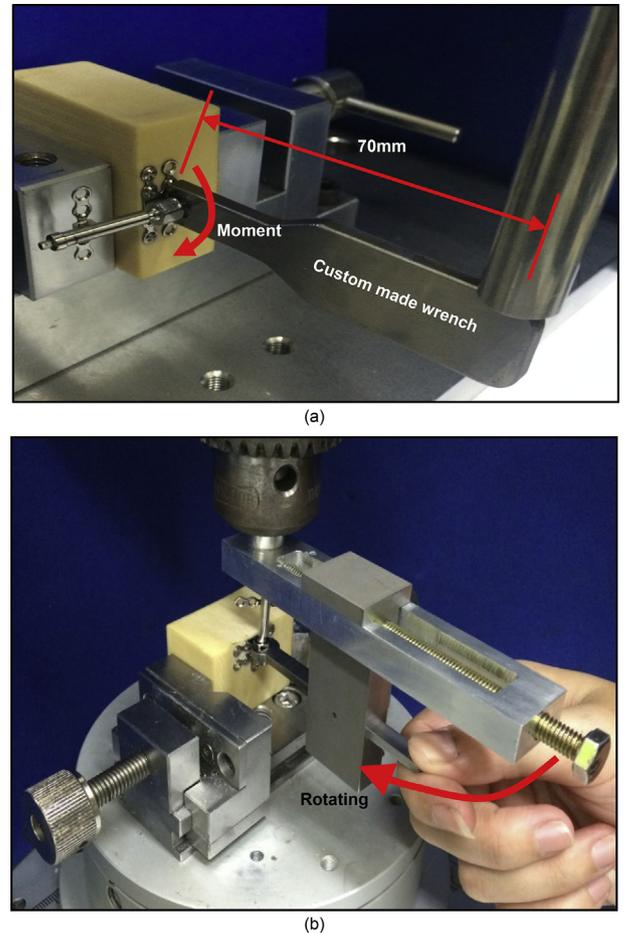


Fig. 4. (a) Welding strength testing between the base bone plate and ball-and-socket joint mechanism. A downward axial load and 70 mm distance to the ball-and-socket joint mechanism base component was applied to the custom-made wrench arm until the base component debonding/fractured or the load dropped to 30% of the maximum load. (b) The maximum torque of the wrench during the operating process was measured by each tester rotating the hex nut of the ball-and-socket joint using a custom-made wrench, until the maximum wrench torque was obtained according to the tester's ability.

force in the torque strength testing of the ball-and-socket joint was 30.26 N. The FE simulated results from large deformations for the multi-axial/commercially available two-dimensional distractors were 7.04 mm/9.44 mm and 1.98 mm/2.62 mm for four-point bending and pull-out testing, respectively. The corresponding total deformations for various load conditions are shown in Figs. 9 and 10.

4. Discussion

Alveolar distraction osteogenesis is intended for bone lengthening of the alveolar ridge in the mandible and the maxilla where gradual bone distraction is required, including cases of deficiency in bone height as a result of trauma, resorption after dental extraction, periodontal disease, and tumor resection (Synthes GmbH, 2015). Our new multi-axial alveolar distractor can be expected to perform at least as well as the commercially available devices, because the design characteristics of the proposed medical device do not raise any new safety or effectiveness questions, according to FDA's premarket notification. Four-point bending testing for the metallic bone plate is the standard testing method for measuring performance-related mechanical characteristics determined to be

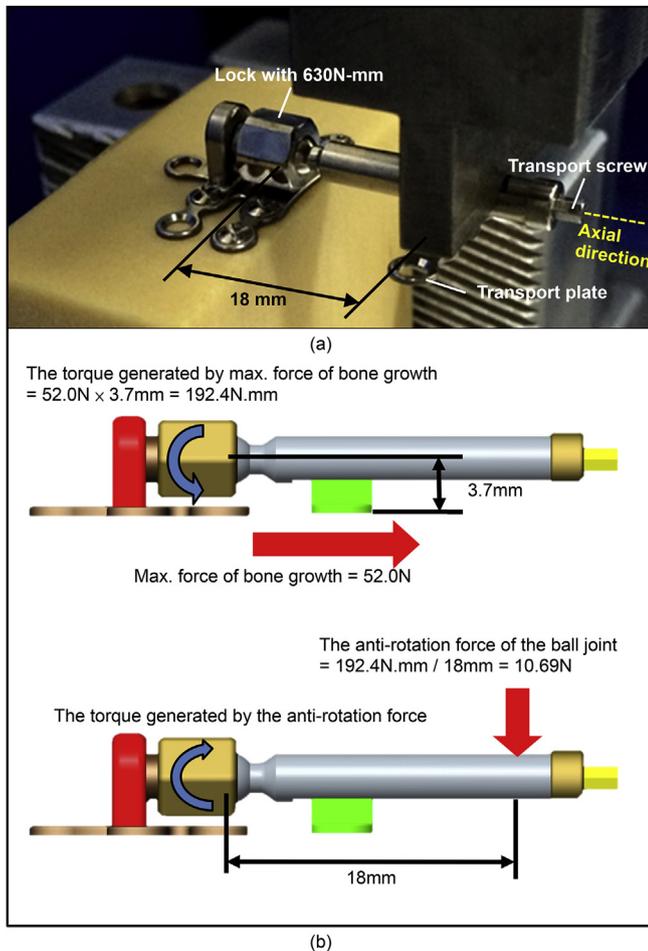


Fig. 5. (a) Ball-and-socket joint torque strength testing. The ball-and-socket joint was locked to 630 N mm and an axial load with 0.02 mm/s speed applied to the transport plate with an 18 mm distance to the ball-and-socket joint center, using a custom jig to record the torque resistance of the ball-and-socket joint. (b) Under the equivalent moment principle, the resistant force to avoid ball-and-socket joint rotation was estimated at 10.69 N.

important for the in vivo performance of bone plates. Therefore, four-point bending resistance testing, based on the ASTM F-382 standard, was performed to provide a comprehensive reference for bone plates used in skeletal system surgical internal fixation (ASTM International, 2017). However, our multi-axial distractor mechanism includes not only the bone plate structure, but also the transport screw, ball-and-socket joint, and fixation screw. Pull-out testing, welding strength testing between the base bone plate and ball-and-socket joint mechanism, and torque strength testing of the ball-and-socket joint were performed to ensure the mechanical/functional safety of the multi-axial distractor. The FE analysis results found that large deformations for four-point bending and pull-out FE simulations for the new multi-axial alveolar distractor were smaller than those for the commercially available Synthes alveolar distractor (approved by the FDA). These results indicated that our proposed device is as safe and effective as the Synthes device.

To ensure whether the ball-and-socket joint mechanism–base bone plate welding strength was sufficient to resist the surgical operating process, three male and female testers (average age 23 years) were used to measure the maximum torque of the wrench during the operating process. The ball-and-socket joint mechanism, welded onto the base bone plate of the multi-axial alveolar



Fig. 6. The results for deformation of the base plate of the multi-alveolar distractor after the four-point bending resistance test.

distractor, was rotated by each tester using a custom-made wrench applied to the hex nut until the maximum wrench torque was obtained, in order to measure the tester's ability (Fig. 4(b)). The average maximum wrench torque values for males and females were 1149.8 N mm and 851.2 N mm, respectively. These values were less than the welding strength between the base bone plate and ball-and-socket joint mechanism in the experimental testing (3481.1 N mm) and indicated that the ball-and-socket joint mechanism was safe for use. These results also indicated that the ball and socket mechanism cannot fall off during a surgical operation, with no damage found at the welding edge.

According to the literature, the average bone regeneration distractor force for pig mandible after osteotomy was about 52 N (Kessler et al., 2005). The torque resistance of the ball-and-socket joint worked out as 192.4 N mm using average distractor force multiplied by the moment arm ($52\text{ N} \times 3.7\text{ mm}$) when applied to our device (Fig. 5(b)). Under the equivalent moment principle, the resistance force to avoid ball-and-socket joint rotation was estimated at 10.69 N when the moment arm was taken to be at the end of the transport screw (18 mm). The maximum average resistance force in the torque strength testing of the ball-and-socket joint mechanism was calculated as 30.26 N, which was 2.83 times the resistance force to avoid ball-and-socket joint rotation. This result confirmed that, for safety consideration, the ball-and-socket joint does not rotate and can resist the distraction force during bone regeneration.

One of the major advantages of this newly designed multi-axial distractor is to provide a high-degree-of-freedom cone trajectory motion, with a range of up to 60° as a result of its ball-and-socket joint structure. This overcomes the limitation of the current commercially available alveolar distractors, which can only be adjusted in one or two linear directions. In clinical practice, the vector adjustment joint is covered in a soft tissue flap to reduce local mucosal tissue irritation, and only the transport screw is exposed transmucosally for distraction. Therefore, the vector should be determined during the operation. In cases where the vector must be changed during the distraction phase, a small mucosal incision is necessary to expose the joint for facilitating adjustment. Compared with the commercially available distractors, the proposed distractor provides the most flexible vector control adjustability as a result of its ball-and-joint design. In combination

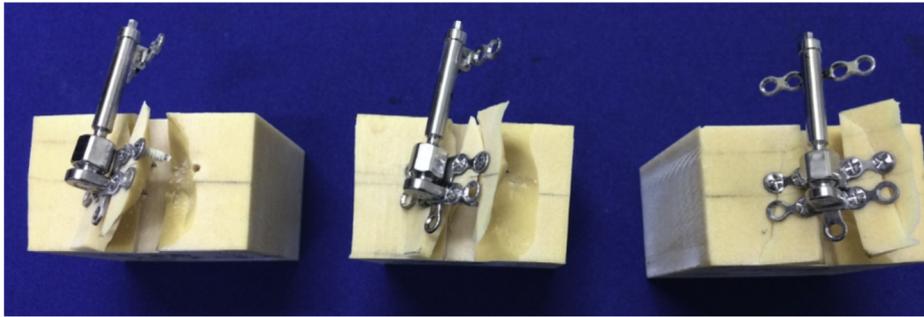


Fig. 7. The pull-out test results for the multi-axial alveolar distractor showed that the testing sample was fractured and pulled out together with the fixation screw.

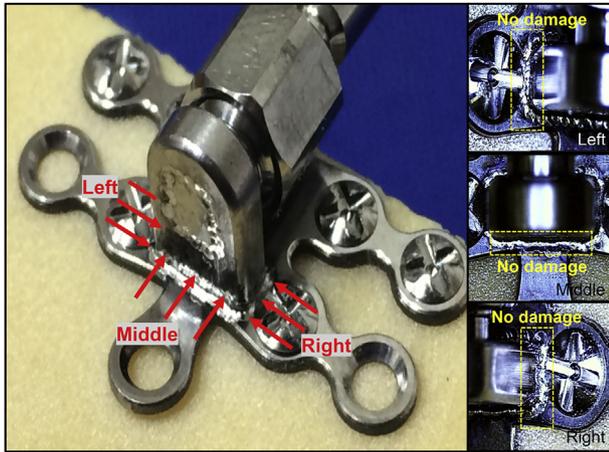


Fig. 8. Welding edges between the base plate and ball-and-socket joint mechanism were found to have no damage, according to a non-contact video measurement system after welding strength testing.

with computer-assisted planning, an ideal vector could be set preoperatively to prevent the need to change during distraction.

The ball-and-joint design is slightly larger than the commonly used hinge-type distractors due to the mechanical requirement for the ball-and-joint structure. Although the increased joint size may interfere with flap closure, leading to further dehiscence, this can be overcome by changing the flap design and by adequate periosteum release. Furthermore, the multi-axial vector allows surgeons to have more freedom in choosing the best location for facilitating tension-free wound closure.

This study is currently only in the functional/mechanical testing phase. To confirm the effectiveness of the device's future applications, it is expected that feasibility and operability testing of this new multi-axial alveolar distractor will occur through in vivo animal experiments. Bone osteogenesis and regeneration situations (growth vector and rate) need to be tracked regularly as a reference for future multi-axial alveolar distractor improvements and clinical applications.

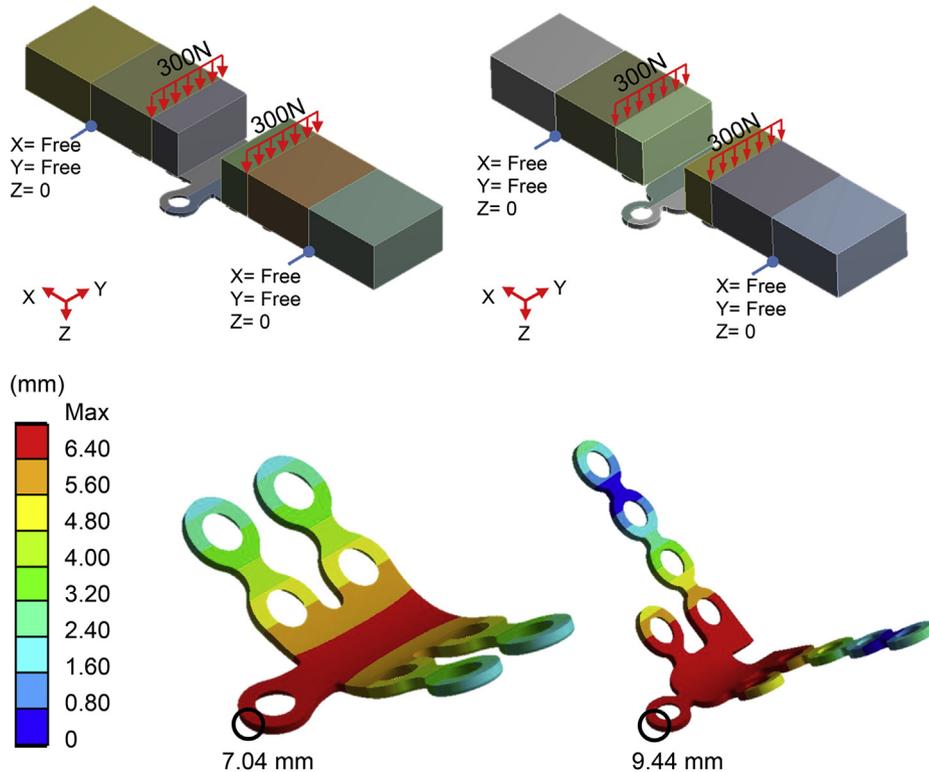


Fig. 9. The FE simulated results from large deformations for the multi-axial and commercial two-dimensional distractors under four-point bending testing were 7.04 mm and 9.44 mm, respectively.

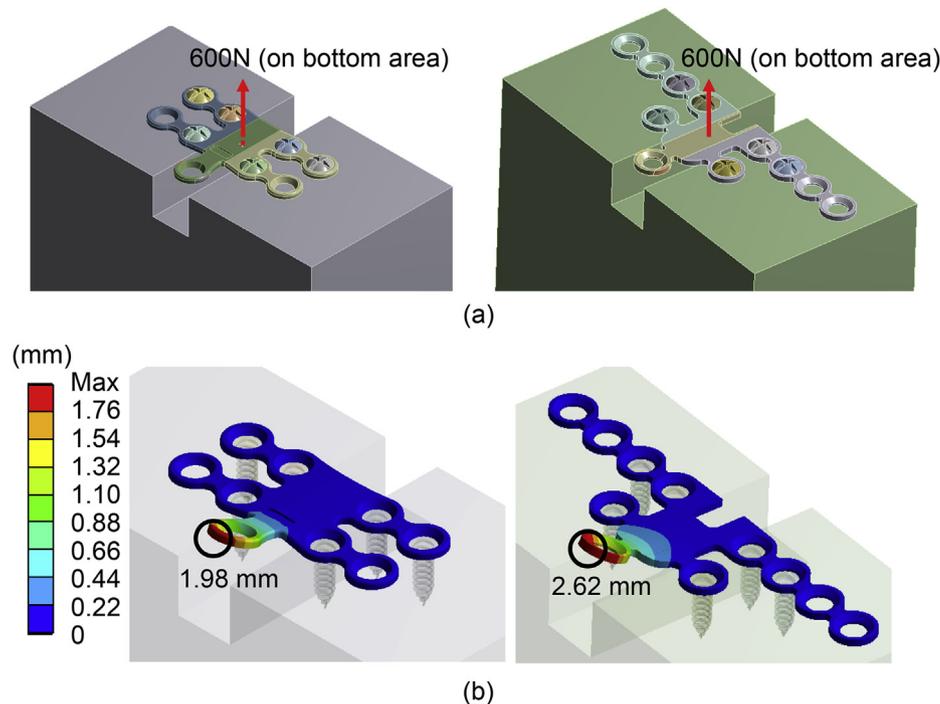


Fig. 10. The FE simulated results from large deformations for the multi-axial and commercial two-dimensional distractors under pull-out testing were 1.98 mm and 2.62 mm, respectively.

5. Conclusion

Our new multi-axial, ball-and-socket joint, alveolar distractor, with its high-degree-of-freedom design concept, can achieve multi-axial distraction with different angle adjustments in 3D space. Extensive mechanical/functional test results, including four-point bending resistance testing of the base bone plate, pull-out testing of the multi-axial alveolar distractor, welding strength testing between the base bone plate and ball-and-socket joint mechanism, and torque strength testing of the ball-and-socket joint, confirmed the effectiveness and safety of our new multi-axial alveolar distractor. Considerations regarding adequate flap design and periosteum release were required to avoid interference with flap closure, which can lead to further dehiscence, due to the increased joint size of the multi-axial alveolar distractor.

Ethical statement

Ethical approval was not required.

Funding

No funding was available.

Conflicts of interest

None declared.

Contributions

YS Lin, CH Wu, and CL Lin conceived and designed the experiments; YS Lin and CH Wu performed the experiments and analyzed the data; CH Wu and CL Lin wrote the manuscript; and all authors read and approved the final version of the manuscript.

Source of support

This study was supported in part by MOST projects 106-2622-8-010-002-TB1 and 106-2321-B-010-014 of the Ministry of Science and Technology, Taiwan.

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