Uriel Zapata[1]
Mechanical Engineering Department,
EAFIT University,
Medellin 050022, Colombia
e-mail: uzapata@eafit.edu.co

Ikuya Watanabe
Department of Dental and Biomedical
Materials Science,
Nagasaki University Graduate School of
Biomedical Science,
Nagasaki 852-8588, Japan

Lynne A. Opperman
Baylor College of Dentistry,
Texas A&M University,
Dallas, TX 75246

Paul C. Dechow
Baylor College of Dentistry,
Texas A&M University,
Dallas, TX 75246

Timothy Mulone
Craniotech ACR Devices,
Dallas, TX 75214

Mohammed E. Elsalanty
College of Dental Medicine,
Georgia Regents University,
Augusta, GA 30912

In Vitro Mechanical Evaluation of Mandibular Bone Transport Devices

Bone transport distraction osteogenesis (BTDO) is a surgical procedure that has been used over the last 30 years for the correction of segmental defects produced mainly by trauma and oncological resections. Application of BTDO has several clinical advantages over traditional surgical techniques. Over the past few years, several BTDO devices have been introduced to reconstruct mandibular bone defects. Based on the location and outline of the defect, each device requires a uniquely shaped reconstruction plate. To date, no biomechanical evaluations of mandibular BTDO devices have been reported in the literature. The present study evaluated the mechanical behavior of three different shaped prototypes of a novel mandibular bone transport reconstruction plate and its transport unit for the reconstruction of segmental bone defects of the mandible by using numerical models complemented with mechanical laboratory tests to characterize strength, fatigue, and stability. The strength test evaluated device failures under extreme loads and was complemented with optimization procedures to improve the biomechanical behavior of the devices. The responses of the prototypes were characterized to improve their design and identify weak and strong regions in order to avoid posterior device failure in clinical applications. Combinations of the numerical and mechanical laboratory results were used to compare and validate the models. In addition, the results remark the importance of reducing the number of animals used in experimental tests by increasing computational and in vitro trials. [DOI: 10.1115/1.4026561]

Keywords: bending test, finite element, tension test, bone distraction, medical device

Introduction

Craniofacial alterations following head and neck oncologic surgery, trauma, and injuries from accidents or combat exceeds 160,000 cases per year [1,2], and resulting deformities are personally devastating and expensive to repair. Particularly, morphological alterations of the mandible, resulting mainly from cancer resection, can cause bony deficits, which require reconstruction by bridging the defect. The most basic option involves the positioning of a reconstruction plate [3]. Other methods require positioning a bone graft in the defect, which not only requires a second surgical site but also increases infection risk [4,5]. In addition, a novel surgical procedure called mandibular bone transport distraction osteogenesis has been used because it presents fewer complications, minimum tissue morbidity, and less complexity than the current surgical procedures [6]. In BTDO, a vital bone transport segment is separated from the edge of the bony defect and then moved incrementally across the gap to a docking site where it fuses with the native bone, creating new regenerate bone within the gap by using the body's natural fracture healing capabilities [7].

The application of the BTDO surgical technique has produced extended conceptualization and design of new BTDO devices to be used in human subjects [8,9]. However, most of these new BTDO devices have been produced without biomechanical evaluation, resulting in risk of device failure or lack of optimization of the size of the device [10]. At this point, the most common development process for new BTDO devices includes conceptualization, design, manufacture, and trials on patients [11]. For instance, clinical tests involving assessing device failure risk under normal physiological performance have been conducted [10,12]. In an attempt to obtain a first approximation of biomechanical evaluation and avoid device failure, several researchers have used animal models for the development process of the devices [13–15]. Nevertheless, biomechanical evaluation of the BTDO device is essential for optimizing the devices before it is to be used in humans.

Generally, the conceptualization-design process of BTDO devices has two possible outcomes, one physical and the other conceptual. The physical outcome, called a prototype, may be tested mechanically either by isolating the device within the laboratory or complemented with surrounding tissues using a process of biomechanical testing [16]. The conceptual outcome, known as the analytical model, is based on the design drawings and can be evaluated completely by using engineering frameworks and computer models.

Mechanical tests evaluate the working characteristics of the device by testing its geometry, material response to loading, and functional features [17,18]. On the other hand, the biomechanical test is intended to measure strain and deformation patterns on synthetic, dry, or fresh [19] mandibles complemented with BTDO devices using three different options: strain gauges [14,20,21], holography interferometry [22], and photoelasticity [23]. Although dry mandibles do not have the presence of cartilage and fibrous tissues, they are an accurate model that includes the most important bone features that help to describe the biomechanical behavior of the complex [22].

The analytical evaluation procedures comprise static rigid-body analysis [24–26] and deformable body analysis [27]. In the first procedure, the loading pattern can be estimated by assuming static equilibrium of the mandible-device complex under muscular and bite loads that are represented by vectors and supports that can be

[1]Corresponding author.
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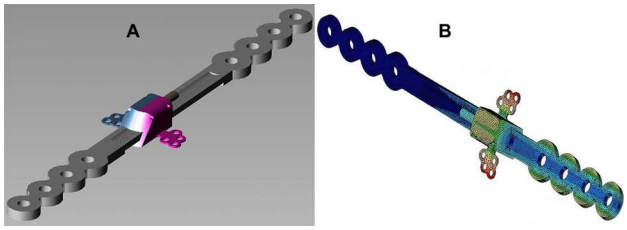

Fig. 1 (*a*) Basic configuration of the BTRP device. (*b*) Finite element model of the BTRP device.

defined as the upper dentition and temporal bones. The second procedure usually uses either the finite element method (FEM) or the boundary element method to obtain stresses, reactions, and strains in the mandible-device complex [28–30]. Overall, the three-dimensional FEM is the most widely used numerical tool to evaluate stress and strain distribution in the mandible during distraction processes [30–34]. In conclusion, mechanical, biomechanical, and analytical evaluation processes should be used together to characterize a device obtained from a conceptual-design process. Particularly, every new BTDO device must be tested under these three methodologies to evaluate strength, stability, and fatigue [11] before being used in patients.

Strength is associated with both the manufacturing process and the nature of the material used to create the device, and its measure can be obtained by testing isolated devices and material specimens independently. Because most of the material properties of the BTDO devices may be assumed to be homogeneous and isotropic, meaning mechanical properties are the same in any direction or at any plane section, three material-dependent properties can be defined in every case: the elastic modulus (E), the shear modulus (G), and the Poisson's ratio (υ). These material properties can be obtained by performing a uniaxial standard tensile test upon standard test specimens [35]. Additionally, testing the device by using a universal testing machine can discern weak points on the device.

Stability tests encompass both local and global stability. Local stability of the BTDO device evaluates the elastic behavior of the isolated device under simulated physiological load with different numbers and positions of the screws used for fixation. Global stability is the biomechanical evaluation of a combination of BTDO device and mandible under equivalent physiological loads [21]. In this case, several variables can be considered: The size of the bone defect, the effect of the level of force, different device orientations, and even the effect of different methods of fixation.

The purpose of this investigation is to evaluate the biomechanical behavior of three prototypes of a novel BTDO device using FEM and compare their results with mechanical testing experiments to assess critical mechanical conditions under normal physiological parameters. This combination of FEM and bench testing can allow the development of a validated model that can be used for further tests, minimizing the number of animals needed for subsequent in vivo testing.

Materials and Methods

Novel BTDO Device Conceptual-Design Description. The bone transport reconstruction plate (BTRP) is a set of three novel devices for the reconstruction of segmental bone defects on the mandible using BTDO. BTRPs are intraoral devices with a screw activation system, which are able to apply unidirectional and bidirectional distraction vectors [9,36,37]. Their designs are considered novel because they are made of two independent components that can be attached together to accomplish dual function during reconstruction of segmental bone defects of the mandible. The first component of the device resembles the traditional plates used to stabilize the mandible after full-thickness bony resections [3]. The second component is a shielded transport unit, which can be mounted to the plate at any time during or postsurgery, and glides on the plate to transport the vital bony disk (Fig. 1). The plate functions as both a track upon which a transport unit can be moved and a plate that spans the mandibular bone defect providing stability between two bone segments. The two ends of the plate can be stabilized to the mandibular cortical bone by titanium screws. The transport unit shield is composed of two symmetric halves attached by two 1.7 mm mini-screws, which enclose the main activation screw. The shape of the transport unit shield has two main characteristics: Its cross section shape allows it to span most of the plate cross section to provide stability during the transport process, and the front has a sloped, smooth shape to permit penetration of the soft tissue during the activation process, allowing free movement of the device The transport unit is activated by clockwise rotation of the end of the activation screw, either by an activation cable that reaches the skin or by a key that is fitted to the activation screw when activation is required. Every complete revolution of the activation cable produces one longitudinal millimeter of transport unit displacement by moving a screw upon a threaded groove present on the surface of the transport track.

Three complementary versions of the BTRP device for application on the mandible were conceived to increase versatility (Fig. 2). The first version of the series is a straight device (BTRP-01) used for the reconstruction of small segmental defects on the body or ramus of the mandible. The second device is an L-shaped device (BTRP-02) used for the reconstruction of large segmental bone defects on the body of the mandible. The last device of the series (BTRP-03) is a curved device for the reconstruction of the mandibular symphysis. All the BTRP devices are made of the biocompatible titanium alloy Ti6Al4V (6% aluminum, 4% vanadium with extra low interstitial (ELI) elements).

Analytical BTDO Devices Evaluation. Three-dimensional geometric models of the mandibular bone reconstruction plates (BTRP-01, BTRP-02, and BTRP-03) were built by using SolidWorks software (Dassault systems S.A., MA). The geometries were then used to create FEMs, which include material mechanical properties, three-dimensional solid elements, boundary conditions at the screw holes, and a functionally distributed bite load in

Fig. 2 Three bone transport reconstruction plate prototypes. (*a*) BTRP-01 straight device recommended for the mandibular ramus. (*b*) BTRP-02 L shaped device suggested for the mandibular body. (*c*) BTRP-03 curved device advised for the mandibular symphysis.

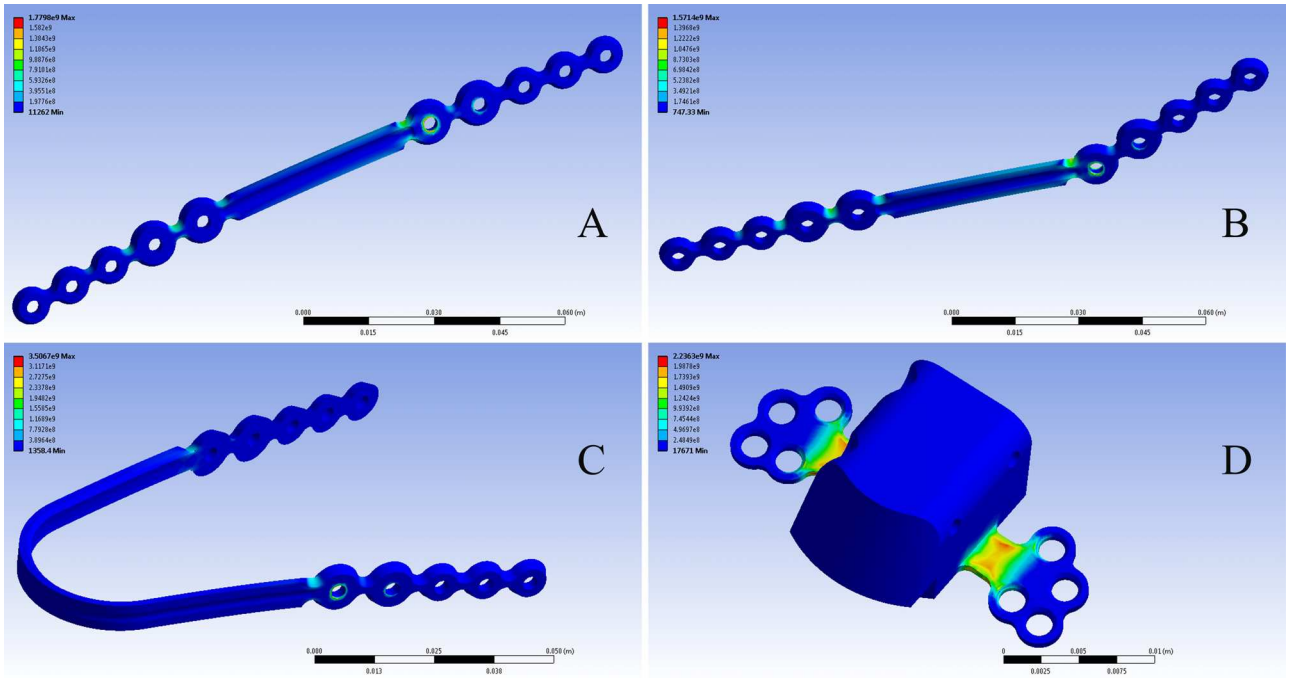

Fig. 3 Finite element models of the three BTRP devices series including von Mises stress distributions. (*a*) Straight BTRP-01 affected by 50 N load, (*b*) L shaped BTRP-02 affected by 50 N load, and (*c*) curve-shaped BTRP-03 affected by 200 N load. (*d*) Transport disk unit affected by a 200 N load effect.

every case (Fig. 3). The numerical models were evaluated using ANSYS FEM software (ANSYS Inc. Canonsburg, PA) to obtain deformations and strains, which were then compared with the mechanical results obtained in the laboratory.

Loads simulating maximum bite force were derived from unilateral [38,39] and incisal [40,41] clenching tasks. Several authors reported bite force reduction of between 38% and 79% after unilateral and bilateral osteotomies [39,42,43]. Therefore, a reduction of 55% in bite force one month after surgery was assumed, so the unilateral force was calculated to be 200 N and the incisal load to be 100 N. Each described physiological load was uniformly spread downward resembling bite force applied on the models of each of the BTRP devices.

A titanium alloy Ti6Al4V ELI (6% aluminum, 4% vanadium with ELI elements) was selected based on its biocompatibility characteristics, excellent corrosion resistance, fatigue properties, and its high strength-weight ratio [44]. An isotropic, homogeneous, and elastic behavior was assumed for this alloy known as grade 23. Elastic material properties were used in all the numerical models as reported for the American Society for Testing and Materials; elastic modulus ($E = 114$ GPa), Poisson's ratio ($\upsilon = 0.342$), fatigue strength (600 MPa > 1,000,000 cycles), and tensile strength elastic limit ($\sigma_Y = 795$ MPa) [44]. All devices used in these tests were manufactured by Craniotech ACR Devices, LLC.

The analytical models were fixed on the left portion of the device resembling screws attaching the device to the posterior mandibular segment. The devices were tested for one to five different screw configurations. In addition, the transport unit was tested by modeling four screws on each end of the BTRP and applying an incisal load of 200 N.

Mechanical BTDO Device Evaluation. Although tension tests are used to characterize the material behavior under axial stretch loading, four similar straight BTRP specimens were subjected to tension loading to determine their weakest points, and these results were compared with a control tension test of a standard titanium reconstruction plate (Stryker Leibinger GmbH & Co. Freiburg, Germany) by using a universal testing machine (Instron, 5567 series, Instron Co., Norwood, MA). Each specimen was grasped by two crosshead grips and subjected to a controlled, gradually increasing tensile axial load (Fig. 4(*a*)). Axial load was applied by the machine, with a rate of 1 mm/min, resulting in the gradual elongation and ultimate fracture of the tested samples. The amount of tensile force applied was recorded, and the specimen deformation was monitored to generate load-deformation curves for each specimen.

Local stability of the transport unit of the device was evaluated by applying incremental vertical loads and varying the number, lengths, and orientation of the cortical screws. The bone transport unit was fixed to the anterior segment of a cadaver pig mandible using titanium screws at the same anatomical orientation as it would be fixed at during the bone transport surgery procedure (Fig. 4(*b*)). The transport unit was tested on a mechanical frame

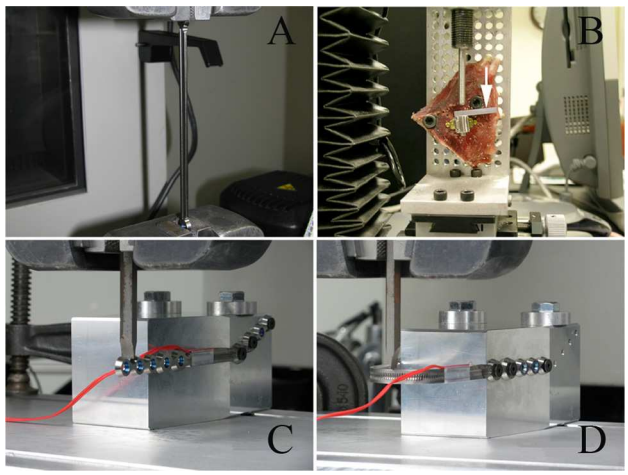

Fig. 4 Mechanical evaluation of BTRP devices series. (*a*) Tension test of straight devices, (*b*) local stability test of shielded transport units, (*c*) bending test of L-shaped devices, and (*d*) bending test of a curved devices.

(650R series, TestResources co, Shakopee, MN) by applying a vertical load in the same direction as the soft tissue's resistance to the movement of the unit during the activation period of the distraction process. The test group consisted of five groups of three specimens, each of which were compared. In the first group, the transport unit was stabilized on each side by three 5 mm long screws vertically inserted into the bone. In the second group, the unit was stabilized by three 7–9 mm long screws vertically inserted on each side. In the third group, the unit was stabilized by three 7–9 mm long screws. The foremost screws (towards the loading transducer) were inserted at a 45 deg angle in order to maximize their resistance to extrusion. In the fourth group, the transport unit was stabilized by four 7 mm screws on each side. In all four groups, the load was centrally applied to the transport unit itself. In the fifth group, four 7 mm screws on either side stabilized the unit, and the load was eccentrically applied (Table 1). The degree of local stability was represented by the maximum load that the transport unit could resist before failure.

Bending strength tests were performed on both BTRP-02 and BTRP-03 plate prototypes. In the first case, the devices were supported using three screws at one end in a cantilever beam configuration. The load was applied as a concentrated force at the opposite end of the device from the screws using a universal testing machine (Instron, 5567 series, Instron Co., Norwood, MA), and the vertical deformation was measured at the same location (Fig. 4(*c*)). In the second case, the specimens were supported at both ends using six screws in a double supported curved beam configuration, a vertical element was attached to the same universal testing machine to slowly load the devices at the middle of the span of each device, and vertical deformation was recorded at that point (Fig. 4(*d*)). To avoid the influence of the strain rate on the mechanical characteristics of the devices tested, the speed was the same in all cases. A rate of 1 mm/min was used in the universal testing machine to test all the BTRP devices, and load-deflection graphs were developed to establish their mechanical characteristics to resist deformation under controlled load.

Strain gauges (UFLG-02-11-1L, Tokyo Sokki Kenkyujo Co., Japan) were attached to the upper surface of the BTRP-02 and BTRP-03 devices during bending tests. The areas for load placement were defined based on preliminary FEMs. Strains were recorded by using both software and hardware sensor interfaces (KYOWA PCD-300A, Ver. 01.07, Soltec Co., San Fernando, CA). Strain is defined as $\varepsilon = dL/L$ [45]. Strain is unitless, and it is given in microstrain ($\mu\varepsilon = 1/1{,}000{,}000$).

Table 1 Local stability test of the transport unit considering different number of cortical screws, lengths, screw orientation, and two load test directions

	Screw					
Group	Number	Length	Orientation	Load direction	Specimen number	Load (N)
1	6	5 mm	Vertical	Central	1	155
					2	160
					3	343
2	6	7–9 mm	Vertical	Central	4	220
					5	225
					6	220
3	6	7–9 mm	45 deg angle*	Central	7	265
					8	270
					9	270
4	8	7 mm	Vertical	Central	10	200
					11	205
					12	227
5	8	7 mm	Vertical	Eccentric	13	295
					14	265
					15	285

Note: The four foremost are inclined.

Results

Analytical Results. BTRP-01 and BTRP-02 reconstruction plates were tested under both incisal and mandibular load magnitudes, but the models exceeded the material elastic limit when one screw was placed in the first hole closest to the defect, and the vertical force was directed over the last hole on the opposite side of the plate. A maximum load magnitude of 50 N was reapplied to the BTRP-01 device to test the local stability of the plate under several combinations of screws position and number. The results were as expected for the experiment that simulates a simple longitudinal bending of the device. Stresses were greatest inferiorly and superiorly on the straight middle portion of the beam (Fig. 3(*a*)). In the same way, stresses increased on the BTRP-02 device toward the posterior region of fixation at the junction between the straight middle portion and curved regions designed for screw placement, creating a stress concentration at this junction (Fig. 3(*b*)). Complementarily, the BTRP-03 device tested in a bending test with 200 N of force produced a similar strain concentration pattern at the junction between the plate and the screw placement area (Fig. 3(*c*)). In addition, the transport disk unit FEM loaded with 200 N showed a critical stress condition at the union between the screw platform support and the body of the case (Fig. 3(*d*)). Maximum vertical deformation at the anterior end of the devices evaluated in the bending test was reported as follows: 5.08 mm for BTRP-01, 4.53 mm for BTRP-02, and 1.70 mm for BTRP-03. In addition, principal elastic strain measured in the FEM at the flat upper part of the devices were 2100–2200, 1977–2048, and 2260–2436 $\mu\varepsilon$, respectively.

Mechanical Results. The axial test of the transport unit reported the following results: In the first group, the unit resisted an average central load of 219.3 N of vertical loading before the initial stages of screw pullout (Table 1). In the second group, the load was 221.6 N, whereas in the third group, resistance increased to 268.3 N. In all three groups, extrusion happened in the foremost screw. In the last two groups with the stemmed, four-screw plate on either side of the unit (group 5), the average central load was 210.6 N; while the average eccentric load was 281.6 N. Failure in those two groups occurred mainly due to plate bending at its neck while the screws remained intact.

The maximum tension load or ultimate tension load for BTRP-01 devices under tension test was 7458.2 N on average (Fig. 5(*a*)), which represents an ultimate tension strength of 1202.9 MPa considering 6.2 mm^2 of area at the failed cross section. In addition, all of the BTRP-01 devices failed in the minimum cross section at the union between the first and the second hole. Maximum deformation at the anterior part of the BTRP-02 and BTRP-03 devices examined in two-point bending tests was recorded for the universal testing machine as 2.4 mm averaged and 4.7 mm averaged, respectively (Figs. 5(*b*) and 5(*c*)).

Strain measurements on the BTRP-02 devices under a two point bending test with 50 N of load were 1912 $\mu\varepsilon$ on average (Fig. 6(*a*)). In addition, strain recorded on the BTRP-03 devices under a two point bending test with 200 N load were 1807 $\mu\varepsilon$ on average (Fig. 6(*b*)). Finally, the transport unit axial compression test showed insignificant statistical differences between the five groups (by nonparametric Kruskal–Wallis test).

Discussion

Mechanical Evaluation. The BTRP series devices were mechanically examined using tension loads and two-point bending tests. Except for the BTRP-03, the described mechanical situations are not related directly with the physiological conditions during the bone transport process. This situation is desired in

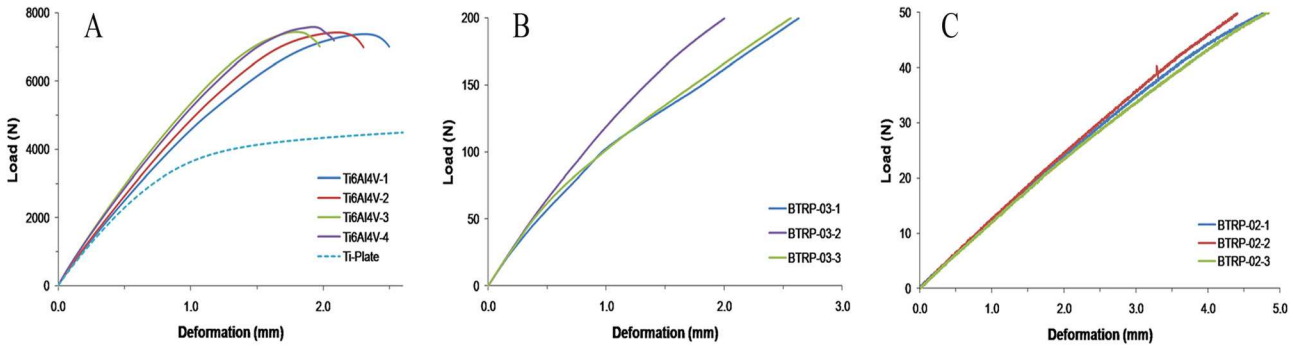

Fig. 5 Mechanical deformation of the BTRP devices series tested in the laboratory. (*a*) Deformation of straight MTRP devices and a standard titanium plate tested under tension load in N, (*b*) deformation of L-shaped BTRP-02 devices tested under vertical load in a bending test, and (*c*) deformation of a curved BTRP-03 device under vertical load in a bending test.

order to obtain the most unfavorable mechanical condition to identify the critical device points. In the case of the BTRP-01 under tension load until it failed, the main goal was to know the weakest point within the device's cross section. In fact, all of the devices tested failed on the bridge between the two first screw holes. Surprisingly, the measured ultimate tension strength was higher than the same property previously reported as 860 MPa for this titanium alloy [44]. This condition could be produced by the difference between the cross section of the BTRP-01 device and the test specimens usually used for this test or the speed used for the universal testing machine during the test.

The BTRP-02 devices were tested using a two-point bending test with a 50 N load applied at the anterior part of the device. In this case, the objective was to identify the critical condition not only at the straight part of the device but also within the region containing the screw holes. Although one end of the body of the transport device was fixed with three screws, the elastic limit was overtaken because the vertical deformation was similar to the inelastic deformation from the FEM and the strain recorded shows a slope change, which should be related with the elastic limit. The BTRP-03 devices were evaluated using a three-point bending test with a 200 N load applied at the center of the span. An extra support substantially changed the mechanical device capacity producing less deformation for more load with practically the same strains (Figs. 5 and 6). This extensive characteristic, called stiffness, is the biomechanical basic feature of the BTRP series device. Stiffness is the resistance offered by BTRP devices to deformation under operational or equivalent physiological loads: shear forces, torsion, and bending moments [46]. Although stiffness is directly related with BTRP devices, it depends on the material properties, the shape, and the boundary conditions. In our case, the device with specific screw distribution was loaded with an equivalent force, and the principal strain was registered in the FEM to be compared with the strain gauge registers [47].

The aim of the transport unit evaluation was to compare the holding strengths of different mini-screws fixed at different positions. Based on the preliminary data, the leading edge of the transport unit was modified so that it has both vertical and lateral slopes to disperse the force of soft tissue resistance, and the number of screw holes was increased to four on each side. This design disperses the tissue resistance force and aligns four screws, instead of two, at the leading edge of the plate to provide more stability. In addition, the optimum direction of screw insertion was found to be when screws were angulated forwards and outwards. This direction provided the maximum resistance to extrusion force and prevented caving in of the transport unit over the plate, which can increase the frictional resistance to the advancement of the transport unit.

Analytical Evaluation. The selection of the biomaterial to be used for the device manufacturing is an important step within the conceptual-design process. The material selection must consider the same requirements as for any device under mechanical stress, but it must additionally include its interaction with the living tissues, which allow it to remain functional during its expected attachment period. Titanium and its alloys are able to support not only the basic mechanical requirements, but it is also able to interact with live tissues without degradation, corrosion, or unfavorable tissue reaction. Although we chose Ti6Al4V ELI (grade 23), it is possible to use Ti6Al4V (grade 5). However, grade 23 has 0.13 less oxygen content, improving ductility, fracture toughness, slightly reducing strength, and favorably affecting corrosion level in internal BTRP devices [44].

The multibody evaluation of the BTRP series device evaluating every device component independently has several advantages at

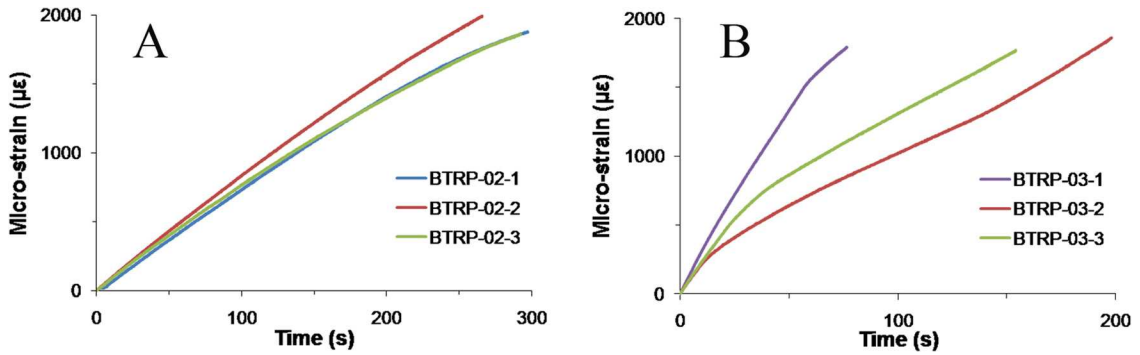

Fig. 6 Microstrain ($\mu\varepsilon$ = m/m*(1/1,000,000)) measures recorded at the strain gauges positioned on the BTRP devices. (*a*) Microstrain recorded on three BTRP-02 L-shaped devices tested on a bending test with a 50 N load. (*b*) Microstrain recorded on three BTRP-03 curved devices during a bending test with maximum applied load of 200 N.

this conceptualization-design stage. It is possible to know the real contribution of every device component to the overall device performance. In the same way, it is possible to optimize each component independently by affecting geometrical characteristics that will not affect the assembly. In addition, because of the novel design of a two-component device, it is possible to mechanically evaluate the reconstruction plate for the first surgical stage and include the activation system within a second evaluation step to test the overall effect of bone transport. Finally, not only is it possible to detect precisely where the mechanical weak points are but also to assemble all the components together to evaluate the mechanical characteristics of the complete device system.

Although the physiological loads were initially obtained and reduced, it is important to clarify that they were reconsidered because the devices were tested under extreme conditions, and in some cases the tests exceeded the material elastic limit. BTRP-01 devices were tested under tension load until device mechanical collapse was reached. BTRP-02 devices were tested in atypical behavior with two-point bending tests under a 50 N load effect reaching the elastic limit without collapse. In addition, BTRP-03 devices were tested using two-point bending tests with a 200 N load effect. These changes are not suggesting a weak device behavior; instead, it is a load adaptation test.

The analytical evaluation of different amounts and positions of cortical screws on the BTRP device series suggest that the device should always have a screw in the first hole position and if possible in the second hole. Although the minimum number of screws on each side of the device is two to provide a system that is sufficiently stable, clinically a minimum of three screws are advised for the accomplishment of planed distraction vectors, faster bone healing processes, and adequate bone formation in BTDO surgical processes [48,49]. The body of the transport device can be fixed bicortically with two screws proximal to each side of the osteotomy and one distally at each end of the device, assuming good osseointegration of the screws to guarantee an adequate interlocking between the plate and the mandibular bone surface. Also, the bone thickness must be sufficient, and the screws must have the same length and diameter. Although several authors have questioned whether the characteristics obtained in the laboratory do not always result in the best clinical outcome [50], our results initially suggest that the BTRP system is stronger and more stable under the described mechanical conditions due to the similarities between analytical and mechanical evaluations. Finally, it is important to mention that the fatigue effect was considered by reducing the material elastic limit [51].

Validation and Optimization. Validation of the results obtained from the analytical process was performed by comparing strain and vertical deformation patterns of the FEM with strain-deformation patterns obtained from the bending test mechanical evaluation. Strain patterns obtained using the FEMs resemble the strain values recorded using the strain gauges during the mechanical test. In fact, strains were in a range of 1977–2048 $\mu\varepsilon$ for the BTRP-02 devices and 2260–2436 $\mu\varepsilon$ for the BTRP-03 devices. These values have a high correspondence with the strain values recorded during the bending mechanical tests (Fig. 6). In the same way, vertical deformation at the anterior part of the devices was obtained from the analytical models. The maximum vertical deformation of the BTRP-02 device analytical model was 4.53 mm and from the BTRP-03 device models was 1.70 mm, which are similar to the 2.4 mm and 4.7 mm obtained, respectively, from the universal testing machine (Fig. 5).

The validation of the FEMs confirms that not only does the numerical model resemble the prototypes but also that the results are similar to those obtained in controlled tests in the laboratory. In turn, validation processes allow small modifications of the devices during an optimization process. Optimization is a method based on the shape and the mechanical characteristics of the prototype that allows for the redesign process of the biomedical device in order to provide more mechanical strength with a minimum increase in material volume without affecting the device function. BTRP-02 was shaped modified on the critical cross section at the union between the straight part of the device and the first screw hole by filling this space to avoid stress concentration (Fig. 7(a')). In the same way, the transport unit was complemented with extra

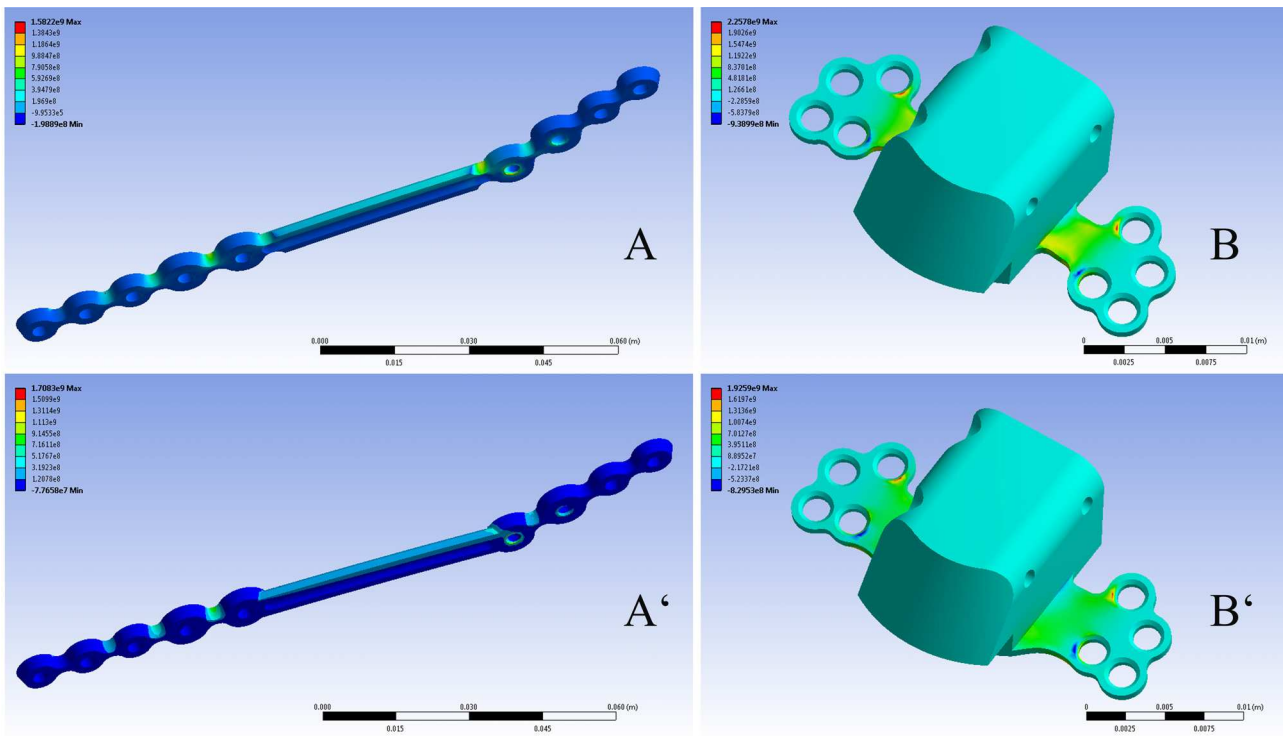

Fig. 7 Principal stress patterns after optimization process applied to BTRP-02 device and its transport unit case

material at the union between the case and the screw platform (Fig. 7(*b′*)). Biomechanical comparison between the standard device and the optimized model shows an interesting stress reduction in the new device with a consequent increase in mechanical strength without affecting clinical function.

It is important to clarify the limitation of our results. Firstly, acquiring the mechanical properties of the device material was not the main goal of the present study. Secondly, several of the tests were conducted with only one side of the device fixed to the support and does not account for variations in the screw stability holding the rod to the support. Although clinical and experimental studies have been centered on the mechanisms of bone formation and effects of rate, latency, and consolidation duration, biomechanical studies have become an important and efficient way to evaluate the short-term effects of distraction [32]. Several technical and mechanical problems will need to be solved before the mandibular bone transport technique will be widely applicable in humans [7].

Conclusion

This study marks the first effort using a combined mechanical and analytical evaluation of mandibular bone transport devices towards the biomechanical evaluation of the device-mandible complex. Although both mechanical evaluation tests and analytical methods are complementary methodologies to first test strength, stiffness, and stability responses of new biomedical devices, experimental evaluation of new devices using animal models has been mainly used during the last decades with a high cost of animal lives [52–55]. The Institutional Animal Care and Use Review Boards (IACUCs) should recommend both preliminary mechanical lab tests and numerical models of medical devices during the conceptual-design process to reduce the number of animals used in experimental tests. In addition, mechanical evaluation and analytical models of medical devices can complementarily consider geometrical and material variables that will allow their redesign and optimization before animal testing.

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References

[1] American Cancer Society, 2012, "Cancer Facts and Figures," http://www.cancer.org
[2] Bell, R. B., 2007, "The Role of Oral and Maxillofacial Surgery in the Trauma Care Center," J. Oral Maxillofac. Surg., **65**(12), pp. 2544–2553.
[3] Klotch, D. W., Gal, T. J., and Gal, R. L., 1999, "Assessment of Plate Use for Mandibular Reconstruction: Has Changing Technology Made a Difference?," Otolaryngol. Head Neck Surg., **121**(4), pp. 388–392.
[4] Herford, A. S., 2004, "Use of a Plate-Guided Distraction Device for Transport Distraction Osteogenesis of the Mandible," J. Oral Maxillofac. Surg., **62**(4), pp. 412–420.
[5] Castaño, F. J., Troulis, M. J., Glowacki, J., Kaban, L. B., and Yates, K. E., 2001, "Proliferation of Masseter Myocytes After Distraction Osteogenesis of the Porcine Mandible," J. Oral Maxillofac. Surg., **59**(3), pp. 302–307.
[6] Cope, J. B., Samchukov, M. L., and Cherkashin, A. M., 1999, "Mandibular Distraction Osteogenesis: A Historic Perspective and Future Directions," Am. J. Orthod. Dentofacial Orthop., **115**(4), pp. 448–460.
[7] Costantino, P. D., Shybut, G., Friedman, C. D., Pelzer, H. J., Masini, M., Shindo, M. L., and Sisson, G. A., Sr., 1990, "Segmental Mandibular Regeneration by Distraction Osteogenesis. An Experimental Study," Arch. Otolaryngol. Head Neck Surg., **116**(5), pp. 535–545.
[8] van Sickels, J. E., and Reddy, L. V., 2008, "Distractor Design and Options," Atlas Oral Maxillofac. Surg. Clin. North Am., **16**(2), pp. 159–167.
[9] Zapata, U., Elsalanty, M. E., Dechow, P. C., and Opperman, L. A., 2010, "Biomechanical Configurations of Mandibular Transport Distraction Osteogenesis Devices," Tissue Eng. Part B: Rev., **16**(3), pp. 273–283.
[10] Uckan, S., Veziroglu, F., and Arman, A., 2006, "Unexpected Breakage of Mandibular Midline Distraction Device: Case Report," Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod., **102**(6), pp. e21–e25.
[11] Panjabi, M. M., 1988, "Biomechanical Evaluation of Spinal Fixation Devices: I. A Conceptual Framework," Spine, **13**(10), pp. 1129–1134.
[12] Alkan, A., Ozer, M., Bas, B., Bayram, M., Celebi, N., Inal, S., and Ozden, B., 2007, "Mandibular Symphyseal Distraction Osteogenesis: Review of Three Techniques," Int. J. Oral Maxillofac. Surg., **36**(2), pp. 111–117.
[13] Djasim, U. M., Wolvius, E. B., van Neck, J. W., van Wamel, A., Weinans, H., and van der Wal, K. G. H., 2008, "Single Versus Triple Daily Activation of the Distractor: No Significant Effects of Frequency of Distraction on Bone Regenerate Quantity and Architecture," J. Craniomaxillofac. Surg., **36**(3), pp. 143–151.
[14] Wu, Z., Liu, Y., Singare, S., and Li, D., 2007, "Animal Model for Evaluation of Strain Gauge in Mandibular Distraction Osteogenesis in Rabbits," Br. J. Oral Maxillofac. Surg., **45**(8), pp. 633–636.
[15] Djasim, U. M., Wolvius, E. B., van Neck, J. W., Weinans, H., and van der Wal, K. G. H., 2007, "Recommendations for Optimal Distraction Protocols for Various Animal Models on the Basis of a Systematic Review of the Literature," Int. J. Oral Maxillofac. Surg., **36**(10), pp. 877–883.
[16] Haug, R. H., Nuveen, E. J., Barber, J. E., and Storoe, W., 1998, "An In Vitro Evaluation of Distractors Used for Osteogenesis," Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod., **86**(6), pp. 648–659.
[17] Burstein, F. D., Lukas, S., and Forsthoffer, D., 2008, "Measurement of Torque During Mandibular Distraction," J. Craniofac. Surg., **19**(3), pp. 644–647.
[18] Cheung, L. K., Zhang, Q., Wong, M. C. M., and Wong, L. L. S., 2003, "Stability Consideration for Internal Maxillary Distractors," J. Craniomaxillofac. Surg., **31**(3), pp. 142–148.
[19] Meyer, C., Martin, E., Kahn, J. L., and Zink, S., 2007, "Development and Biomechanical Testing of a New Osteosynthesis Plate (TCP®) Designed to Stabilize Mandibular Condyle Fractures," J. Craniomaxillofac. Surg., **35**(2), pp. 84–90.
[20] Ryoyama, D., Sawaki, Y., and Ueda, M., 2004, "Experimental Study of Mechanical Analysis in Mandibular Lengthening: Application of Strain Gauge Measurement," Int. J. Oral Maxillofac. Surg., **33**(3), pp. 294–300.
[21] Cope, J. B., Yamashita, J., Healy, S., Dechow, P. C., and Harper, R. P., 2000, "Force Level and Strain Patterns During Bilateral Mandibular Osteodistraction," J. Oral Maxillofac. Surg., **58**(2), pp. 171–178.
[22] Campos, T. N., Adachi, L. K., Chorres, J. E., Campos, A. C., Muramatsu, M., and Gioso, M. A., 2006, "Holographic Interferometry Method for Assessment of Static Load Stress Distribution in Dog Mandible," Braz. Dent. J., **17**(4), pp. 279–284.
[23] Meyer, C., Kahn, J. L., Boutemi, P., and Wilk, A., 2002, "Photoelastic Analysis of Bone Deformation in the Region of the Mandibular Condyle During Mastication," J. Craniomaxillofac. Surg., **30**(3), pp. 160–169.
[24] Osborn, J. W., and Baragar, F. A., 1985, "Predicted Pattern of Human Muscle Activity During Clenching Derived From a Computer Assisted Model: Symmetric Vertical Bite Forces," J. Biomech., **18**(8), pp. 599–612.
[25] Barbenel, J. C., 1972, "Biomechanics of the Temporomandibular Joint: A Theoretical Study," J. Biomech., **5**(3), pp. 251–256.
[26] Nickel, J. C., Yao, P., Spalding, P. M., and Iwasaki, L. R., 2002, "Validated Numerical Modeling of the Effects of Combined Orthodontic and Orthognathic Surgical Treatment on TMJ Loads and Muscle Forces," Am. J. Orthod. Dentofacial Orthop., **121**(1), pp. 73–83.
[27] Lovald, S. T., Wagner, J. D., and Baack, B., 2009, "Biomechanical Optimization of Bone Plates Used in Rigid Fixation of Mandibular Fractures," J. Oral Maxillofac. Surg., **67**(5), pp. 973–985.
[28] Korioth, T. W. P., and Versluis, A., 1997, "Modeling the Mechanical Behavior of the Jaws and Their Related Structures by Finite Element (FE) Analysis," Crit. Rev. Oral Biol. Med., **8**(1), pp. 90–104.
[29] Rohrle, O., and Pullan, A. J., 2007, "Three-Dimensional Finite Element Modelling of Muscle Forces During Mastication," J. Biomech., **40**(15), pp. 3363–3372.
[30] Cattaneo, P. M., Kofod, T., Dalstra, M., and Melsen, B., 2005, "Using the Finite Element Method to Model the Biomechanics of the Asymmetric Mandible Before, During and After Skeletal Correction by Distraction Osteogenesis," Comput. Methods Biomech. Biomed. Eng., **8**(3), pp. 157–165.
[31] Boccaccio, A., Pappalettere, C., and Kelly, D. J., 2007, "The Influence of Expansion Rates on Mandibular Distraction Osteogenesis: A Computational Analysis," Ann. Biomed. Eng., **35**(11), pp. 1940–1960.
[32] Kofod, T., Cattaneo, P. M., Dalstra, M., and Melsen, B., 2005, "Three-Dimensional Finite Element Analysis of the Mandible and Temporomandibular Joint During Vertical Ramus Elongation by Distraction Osteogenesis," J. Craniofac. Surg., **16**(4), pp. 586–593.
[33] Savoldelli, C., Bouchard, P. O., Manière-Ezvan, A., Bettega, G., and Tillier, Y., 2012, "Comparison of Stress Distribution in the Temporomandibular Joint During Jaw Closing Before and After Symphyseal Distraction: A Finite Element Study," Int. J. Oral Maxillofac. Surg., **41**(12), pp. 1474–1482.
[34] Reina-Romo, E., Gómez-Benito, M., Sampietro-Fuentes, A., Domínguez, J., and García-Aznar, J., 2011, "Three-Dimensional Simulation of Mandibular Distraction Osteogenesis: Mechanobiological Analysis," Ann. Biomed. Eng., **39**(1), pp. 35–43.

[35] Cordey, J., and Gautier, E., 1999, "Strain Gauges Used in the Mechanical Testing of Bones. Part I: Theoretical and Technical Aspects," Injury, **30**(Suppl. 1), pp. 7–13.
[36] Rubio-Bueno, P., Padrón, A., Villa, E., and Díaz-González, F. J., 2000, "Distraction Osteogenesis of the Ascending Ramus for Mandibular Hypoplasia Using Extraoral or Intraoral Devices: A Report of 8 Cases," J. Oral Maxillofac. Surg., **58**(6), pp. 593–599.
[37] Ortakoglu, K., Karacay, S., Sencimen, M., Akin, E., Ozyigit, A. H., and Bengi, O., 2007, "Distraction Osteogenesis in a Severe Mandibular Deficiency," Head Face Med., **3**(1), p. 7.
[38] van der Bilt, A., Tekamp, A., van der Glas, H., and Abbink, J., 2008, "Bite Force and Electromyograpy During Maximum Unilateral and Bilateral Clenching," Eur. J. Oral Sci., **116**(3), pp. 217–222.
[39] Throckmorton, G. S., Buschang, P. H., and Ellis, E., III, 1996, "Improvement of Maximum Occlusal Forces After Orthognathic Surgery," J. Oral Maxillofac. Surg., **54**(9), pp. 1080–1086.
[40] Hylander, W. L., 1978, "Incisal Bite Force Direction in Humans and the Functional Significance of Mammalian Mandibular Translation," Am. J. Phys. Anthropol., **48**(1), pp. 1–7.
[41] Paphangkorakit, J., and Osborn, J. W., 1998, "Effects on Human Maximum Bite Force of Biting on a Softer or Harder Object," Arch. Oral Biol., **43**(11), pp. 833–839.
[42] Harada, K., Watanabe, M., Ohkura, K., and Enomoto, S., 2000, "Measure of Bite Force and Occlusal Contact Area Before and After Bilateral Sagittal Split Ramus Osteotomy of the Mandible Using a New Pressure-Sensitive Device: A Preliminary Report," J. Oral Maxillofac. Surg., **58**(4), pp. 370–373.
[43] Nagai, I., Tanaka, N., Noguchi, M., Suda, Y., Sonoda, T., and Kohama, G., 2001, "Changes in Occlusal State of Patients With Mandibular Prognathism After Orthognathic Surgery: A Pilot Study," Br. J. Oral Maxillofac. Surg., **39**(6), pp. 429–433.
[44] Boyer, R., Welsch, G., and Collings, E., 2007, Ma*terial Properies Handbook: Titanium Alloys*, ASM International, Materials Park, OH.
[45] Cordey, J., and Gautier, E., 1999, "Strain Gauges Used in the Mechanical Testing of Bones. Part II: 'In Vitro' and 'In Vivo' Technique," Injury, **30**(Suppl. 1), pp. 14–20.
[46] Robinson, R. C., O'Neal, P. J., and Robinson, G. H., 2001, "Mandibular Distraction Force: Laboratory Data and Clinical Correlation," J. Oral Maxillofac. Surg., **59**(5), pp. 539–544.
[47] de Las Casas, E. B., de Almeida, A. F., Cimini, C. A., Jr., Gomes, P. D. T. V., Cornacchia, T. P. M., and Saffar, J. M. E., 2007, "Determination of Tangential and Normal Components of Oral Forces," J. Appl. Oral Sci., **15**(1), pp. 70–76.
[48] Komuro, Y., Takato, T., Harii, K., and Yonemara, Y., 1994, "The Histologic Analysis of Distraction Osteogenesis of the Mandible in Rabbits," Plast. Reconstr. Surg., **94**(1), pp. 152–159.
[49] McCarthy, J. G., Stelnicki, E. J., Mehrara, B. J., and Longaker, M. T., 2001, "Distraction Osteogenesis of the Craniofacial Skeleton," Plast. Reconstr. Surg., **107**(7), pp. 1812–1827.
[50] Haug, R. H., Barber, J. E., and Punjabi, A. P., 1999, "An In Vitro Comparison of the Effect of Number and Pattern of Positional Screws on Load Resistance," J. Oral Maxillofac. Surg., **57**(3), pp. 300–308.
[51] Hibbeller, R. C., 2010, *Mechanics of Materials*, Prentice Hall, Englewood Cliffs, NJ.
[52] Zeng, R. S., Zhang, P., and Wang, C., 2008, "Osteotomy With Titanium-Nickel Shape Memory Alloy Distracter for Repairing Mandibular Defects in Dogs," J. Clin. Rehab. Tissue Eng. Res., **12**(2), pp. 217–220.
[53] Zhou, H. Z., Hu, M., Hu, K. J., Yao, J., and Liu, Y. P., 2006, "Transport Distraction Osteogenesis Using Nitinol Spring: An Exploration in Canine Mandible," J. Craniofac. Surg., **17**(5), pp. 943–949.
[54] Zheng, X. H., Tian, W. D., Long, J., Jing, W., and Li, S. W., 2005, "Mandibular Distraction Osteogenesis: An Experimental Study in Goats," J. Sichuan Univ. (Med. Sci. Ed.), **36**(3), pp. 386–389.
[55] Eski, M., Nisanci, M., Cil, Y., Sengezer, M., and Ozcan, A., 2005, "A Custom-Made Distraction Device for Experimental Mandibular Distraction Osteogenesis," J. Craniofac. Surg., **16**(4), pp. 675–683.