Int. J. Oral Maxillofac. Surg. 2014; 43: 32–39
http://dx.doi.org/10.1016/j.ijom.2013.06.007, available online at http://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Research Paper
Trauma

Comparison and validation of finite element analysis with a servo-hydraulic testing unit for a biodegradable fixation system in a rabbit model

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O. Atali, A. Varol, S. Basa, C. Ergun, S. Hartomacıoğlu: Comparison and validation of finite element analysis with a servo-hydraulic testing unit for a biodegradable fixation system in a rabbit model. Int. J. Oral Maxillofac. Surg. 2014; 43: 32–39.

Abstract. The aim of this study was the biomechanical validation of three-dimensional finite element analysis (FEA) with a servo-hydraulic testing unit (STU) for a resorbable fixation system (RFS) in a rabbit model. Bilateral mandibular vertical body osteotomies (BMVBO) were performed in 15 female New Zealand rabbits. The animals were divided into three groups. The STU and FEA tests were done immediately after surgery in group 1 (1 day), at the first postoperative month in group 2, and at the third postoperative month in group 3. Both stress tests were carried out by applying vertical forces at the lower incisal edge, loading from 0 N force and increasing this until breakage occurred at the bone. The maximum forces that the hemimandibles could stand and the amount of deformation were recorded and analysed with the FEA and STU tests. We found the STU and FEA test results to be similar and that they could be used interchangeably for groups 1 and 3. However, the FEA results differed most from the real STU values in group 2 because of callus formation that had not ossified at the osteotomy line.

Key words: biodegradable implant; biomechanics; finite element analysis; mandible; osteotomy.

Accepted for publication 17 June 2013
Available online 15 July 2013

There are several studies describing the use of osteosynthesis systems for the treatment of jaw fractures and during facial osteotomies.[1–3] Nowadays, the tendency towards the usage of resorbable osteosynthesis systems is gradually increasing.[4,5] Various engineering techniques, such as tension and photoelastic measurement studies, as well as analytical and finite element-based approaches,[6–8] have been used for biomechanical studies of the mandible.[9] A test model fixated at two points may be used for this purpose.[10]

Servo-hydraulic tests (STU) have been used to mimic strain gauges at the bone surface of autopsy mandibles and to register the direction and magnitude of the principal strains under loading.[11] In these studies, certain necessary assumptions have been made for the points of application and the magnitudes and directions of the forces acting on the jaw. In addition, these analyses have been limited to static situations, and information is obtained

0901-5027/01032 + 08 $36.00/0

only on the strains in the superficial bone layer of the jaw.

Another approach is to use mathematical models for the mandible. Models in which the mandible has been treated as a straight or curved beam can provide an insight into the biomechanics of the mandible.[12] This can be achieved by use of finite element analysis (FEA), in which the mandible is subdivided into a large number of small elements of finite dimensions.[12] FEA is an analytical tool that allows virtual modelling of complex problems,[13] estimation of regional stresses,[14] and determination of structural stresses in a highly reliable way and enables computers to solve problems.[13] It is an important tool to investigate the pattern of tensile forces in complex biological structures.[15] The range and distribution of stress and strain along a mandible can be determined for a given set of muscle, bite, and joint forces with a three-dimensional (3D) FEA model. This enables the analysis of the effect on stress and strain patterns, such as changes in loading, mandibular geometry, bone distribution, tooth loss, orthodontic forces, and implants.

Validation is the process of ensuring that a computational model accurately represents the physics of the real-world system.[16] While some consider validation of natural systems to be impossible,[17] the engineering viewpoint suggests the 'truth' about the system is a statistically meaningful prediction that can be made for a specific set of boundary conditions.[18] This does not suggest that *in vitro* experimental validation (in a controlled laboratory environment) represents the *in vivo* case (within the living system) since the boundary conditions are likely impossible to mimic. It means that if a simplified model cannot predict the outcome of a basic experiment, it is probably not suited to simulate a more complex system.[16]

The aim of this study was to perform a biomechanical validation of 3D FEA with STU for a resorbable fixation system (RFS) in bilateral mandibular vertical body osteotomies (BMVBO) in a rabbit model.

Materials and methods

The study protocol was reviewed and approved by the institutional animal care and use committee and was carried out in accordance with the Declaration of Helsinki on medical protocol and ethics.

Fifteen healthy female adult New Zealand rabbits, ranging in age from 6 to 8 months and weighing from 3 to 3.5 kg, were used as subjects. The animals were divided into three experimental groups, each including five animals (groups 1, 2, and 3). A total of 30 hemimandibles of 15 rabbits were used. The biomechanical analyses of rabbit hemimandibles were performed immediately after the operations in group 1, at the first postoperative month in group 2, and at the third postoperative month in group 3.

The resorbable fixation system (RFS) and surgery

The RFS system consisted of 2.0-mm profile four-hole straight miniplates and 7-mm long screws from Inion (Inion CPS Biodegradable Fixation System; Inion Oy, Tampere, Finland). The resorbable plate was made of amorphous poly-L-lactide (PLLA), poly-D,L-lactide (PDLLA), and trimethylene carbonate (TMC) copolymers.

The most appropriate area to apply the RFS was determined to be between the mental foramen and masseter muscle attachment at the posterior mandible. The animals were sedated with 35 mg/kg ketamine HCl (Ketalar; Parke–Davis, Detroit, MI, USA) intramuscular (i.m.) and 10 mg/kg xylazine (Rompun; Bayer, Germany). Ketamine HCl 17.5 mg/kg and xylazine 5 mg/kg were administered i.m. as maintenance dose. Four percent of articaine HCl with 1/100,000 epinephrine HCl (Ultracaine D-S Forte, Hoechst) was used as local anaesthesia.[19]

The operation areas were disinfected with 1% povidone–iodine (Batticon, ADEKA, Turkey). After administration of the local anaesthetic, a 2-cm long submandibular incision and blunt dissection were performed to skeletonize the mandibular bodies. The osteotomies of all the hemimandibles were performed between the first premolar teeth and 1 mm distal to the mental nerve. One four-hole straight miniplate and four screws were placed in a perpendicular fashion.

The osteotomies were performed using oscillating sagittal saws (NSK, Japan) (Fig. 1). After completion of the cuts, the biodegradable miniplate/screws were placed by drilling and tapping procedures. The plates were biomechanically stable *in situ* in all of the models. Once fixations had been completed bilaterally, the wounds were rinsed with sterile saline and incisions were closed with 4/0 polyglactin 910 sutures (Vicryl, Ethicon, Johnson & Johnson, USA).

Postoperative care

All animals were fed with their normal diets beginning from the second postoperative day and kept in separate cages under the inspection of a vet. Penicillin G procaine 40,000 IU/kg (Pencain-K 800,000 IU, i.m.; Eczacıbaşı İlaç, Turkey) and ketoprofen 2 mg/kg (Profenid 100 mg, IM, Eczacıbaşı İlaç, Turkey) were given once daily for 5 days. None of the rabbits experienced weight loss during the study.

After healing, group 2 were sacrificed at the first postoperative month and group 3 at the third postoperative month. Group 1 were sacrificed immediately after the operations. Animals were sacrificed using an anaesthetic overdose of 20 mg/kg xylazine (Rompun). Following this, the heads were removed and the mandibles extracted with care and prepared for STU analysis. The models were kept moist at 15 °C during the tests (Fig. 2).

All models were examined in the STU and by FEA for: (1) the maximum force (N) that the hemimandibles could resist before fracture formation (force at which elastic deformation occurs; MF), and (2) the amount of displacement (ΔH; mm) from the initiation of the test until its completion (maximum displacement; MD).

Biomechanical tests

The soft tissues of all models were stripped off and mandibles were sectioned from the anterior midline. Due to difficulty in placing the models into the STU, a special stainless steel device was manufactured. The ramus portions of all models were kept inside this device and fixated with acrylic resin polymer to imitate the masseter muscle attachment. Two cylindrical 17-mm diameter holes were created to adapt the models to the STU easily.

The models were fixed at the condyle, which was the first point of fixation; the second point of fixation was applied bilaterally at the rami instead of in the incisor region. A Shimadzu Autograph (AG-IS MS, 50 kN; Shimadzu Corp., Kyoto, Japan) continuous force device was used as the STU tester.[15,20] Forces were applied parallel to the osteotomy line and fixation system by applying vertical lower incisal continuous forces after stabilization of the posterior segment to the two-point STU (Fig. 3).

The data obtained from the STU were transferred to a PC, and load–displacement values were recorded using Trapezium 2 software (Shimadzu Corp.,