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TITLE PAGE

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Comparative in vitro mechanical evaluation of techniques using a 2.0 mm locking fixation system for simulated fractures of the mandibular body

Purpose: To perform a comparative evaluation of the mechanical resistance of simulated fractures of the mandibular body which were repaired using different fixation techniques with two different brands of 2.0 mm locking fixation systems.

Materials and methods: Four aluminum hemimandibles with linear sectioning simulating a mandibular body fracture were used as the substrates and were fixed using the two techniques and two different brands of fixation plate. These were divided into four groups: groups I and II were fixed with one four-hole plate, with four 6 mm screws in the tension zone and one four-hole plate, with four 10 mm screws in the compression zone; and groups III and IV were fixed with one four-hole plate with four 6 mm screws in the neutral zone. Fixation plates manufactured by Tóride were used for groups I and III, and by Traumec for groups II and IV. The hemimandibles were submitted to vertical, linear load testing in an Instron 4411 servohydraulic mechanical testing unit, and the load/displacement (3mm, 5mm and 7mm) and the peak loads were measured. Means and standard deviations were evaluated applying variance analysis with a significance level of 5%.

Results: The only significant difference between the brands was seen at displacements of 7 mm. Comparing the techniques, groups I and II showed higher mechanical strength than groups III and IV, as expected.

Conclusion: For the treatment of mandibular linear body fracture, two locking plates, one in the tension zone and another in the compression zone, have a greater mechanical strength than a single locking plate in the neutral zone.

Keywords: Bone plate, Mandibular fracture, Rigid internal fixation

INTRODUCTION

The necessity for improvements in the internal fixation systems used to treat mandibular fractures led the Association for Osteosynthesis/Association for the Study of Internal Fixation (AO/ASIF) to introduce fixation plates with a screw locking system during the 1990s.

As opposed to conventional plates, these plates utilize screw locking, both on the underlying mandibular bone and on the plates, which already have threads on the internal surface of the holes that, associated with the threads on the screw heads, allow plate–screw engagement and, consequently, its locking, working as internal fixators. It is considered a more stable system, with fewer changes in fracture/osteotomy reduction and no necessity for perfect adaptation to the bone, reducing the interference in the blood supply due to the non-compression. Thus, it also reduces the number of complications and secondary interventions to remove the material due to the loosening of screws and consequential loss of the system (Alpert et al., 2003; Ellis and Graham, 2002; Gutwald et al., 2003; Singh et al., 2010).

The disadvantages of the locking system are the higher cost when compared with conventional systems and the need for additional instruments, such as a drill guide, that enables the perforation to be made perpendicular to the plate; otherwise, the screw head and the plate will not engage (Singh et al., 2011; Agarwal et al., 2011).

In order to analyze the superiority of the 2.0 mm locking system in relation to conventional systems, several studies have been made. The first study that described this comparison was by Gutwald (1999). Sixteen mandibles from human corpses with simulated angle fractures were used; after applying axial and vertical forces, a greater mechanical resistance was observed when using a system with locking plates.

Other studies, such as those by Gutwald et al. (2003 and 2011) presented the same result, unlike the studies by Ribeiro-Junior et al. (2010) and Chiodo et al. (2006) in which no statistical difference was observed in biomechanical tests performed between both systems. The latter authors also suggest that the failures are related to bone quality and, partially, to the surgical technique, instead of the fixation system.

Few studies in the literature have compared the mechanical resistance of different techniques using a locking system. Therefore, the purpose of this paper was to comparatively evaluate the in vitro resistance of two fixation techniques using 2.0 mm locking plates on aluminum hemimandibles with simulated fractures of the mandibular body.

MATERIALS AND METHODS

HEMIMANDIBLES

The methodology of this study was described by de Medeiros et al. (2014). The hemimandibles were manufactured in 5052-F aluminum (ASTM B-209-M-AA) by Tóride (São Paulo, Brazil).

They were submitted to sectioning, simulating a mandibular body fracture on the lower premolar and first molar region. They were also perforated according to each group and to the external diameter and the thread pitch of the screws from each brand. For groups I and II, the hemimandibles had four perforations in the tension zone, with two holes on each side of the fracture, according to the design of the plate, and four perforations in the compression zone similarly to the tension zone. For groups III and IV, four perforations were made in the neutral zone also similarly to the specifications for the tension zone in group I. All perforations were complete and went right through the body of the substrate.

In the present study, an aluminum hemimandible was chosen because of the need to evaluate the resistance of the plate and screw system with no interference from the substrate. A pilot study was conducted earlier, using polyurethane synthetic hemimandible; a substrate–plate–screw system failure was observed early in the linear loading phase, before 5 mm of displacement, because the screws worked loose from the substrate.

Thus, it was necessary to manufacture a hemimandible from a material that would not allow the system to fail due to the loosening of the screws in the screw–substrate interface during linear loading, allowing for plate fracture and subsequent analysis. Aluminum also has a low cost and is easily available, factors that influenced our choice of aluminum for the hemimandibles.

SAMPLES

The plates and screws used in this study were manufactured by Tóride (São Paulo, Brazil) and Traumec (São Paulo, Brazil). According to the specifications from the manufacturers, the plates were made from grade II commercially pure titanium, and the screws from titanium–aluminum–vanadium alloy (Ti-6Al-4V).

The samples were divided into the following groups:

- **Group I:** each aluminum hemimandible was fixed with a four-hole straight plate with a screw locking system and no intermediate space, in the tension zone, and with four 2.0 × 6 mm titanium screws, and another plate in the compression zone with four 2.0 × 10 mm titanium screws (Fig. 1A). Five samples using the Tóride system were used.
- **Group II:** each aluminum hemimandible was fixed with a four-hole straight plate with a screw locking system, no intermediate space, in the tension zone, and with four 2.0 × 6 mm titanium screws, and another plate in the compression zone with four 2.0 × 10 mm titanium screws. Five samples from Traumec were used.
- **Group III**: each aluminum hemimandible was fixed in the neutral zone with a four-hole straight locking plate, with no intermediate space, with four 2.0 × 6 mm titanium locking screws (Fig.1B). Five samples from Tóride were used.
- **Group IV**: each aluminum hemimandible was fixed in the neutral zone with a four-hole straight locking plate, with no intermediate space, with four 2.0 × 6 mm titanium locking screws. Five samples from Traumec were used.

MECHANICAL TESTS

A support device for the hemimandibles was manufactured that allowed the samples to be correctly positioned to perform the mechanical test, so that the load application device was perpendicular to the occlusal plane (Fig. 2).

The mechanical test was performed in the universal mechanical testing machine Instron, model 4411 (Instron Corp, Norwood, MA). The non-cyclical linear load was applied to a fixed point in the distal segment, in a region that is similar to the canine, at a speed of 1 mm/min, by a 5000 N load cell. The test was performed registering the load value for displacements of 3mm, 5mm and 7 mm and the peak load using the computer program Bluehill Materials Testing 2 (Instron, Norwood, MA, USA).

The values were analyzed by the statistical analysis program SAS (SAS Institute Inc., Cary, NC, USA). The comparative analysis was based on the applied variance analysis (2-way ANOVA) with a 5% significance level.

RESULTS

The loads, in Newtons, which gave rise to displacements of 3 mm, 5 mm and 7 mm, and the peak loads for the four groups tested are shown in Table 1.

The results showed a statistically significant difference between groups I and II, and between groups III and IV for displacements of 7 mm, but not for displacements of 3mm or 5mm or at peak loads (Table 2). Group I showed the highest mechanical resistance, and group IV had the lowest mechanical resistance of all the groups.

DISCUSSION

Studies on the mechanical analysis of internal fixation techniques are described in the literature and their intention is to understand both the behavior and the material. For this reason, they are increasingly important, since they have helped to qualify, develop and determine the potential of fixation materials for clinical use (Erkmen et al., 2005).

Comparing the two techniques studied, the hemimandibles of groups I and II were fixed with the most widely used technique for fixation of linear fractures of the mandibular body, based on the principles of internal fixation of the craniomaxillofacial skeleton of AO Foundation (Assael & Ueeck, 2012), however, using two locking plates. In groups III and IV, the hemimandibles were fixed with a single plate in the neutral zone; although less commonly used, this is based on Champy's ideal lines of osteosynthesis.

As expected, groups I and III presented greater resistance than groups II and IV and present a more consistent behavior. This could be explained by the greater torsion that occurred in some samples during the experiments using the Traumec brand. Although it was made of the same titanium alloy, variations in microstructure of the plates could change their mechanical resistance, suggesting that metallography studies are required for confirmation.

There are no studies in the literature comparing different fixation techniques for mandibular body fractures using different products for the locking system. In general, studies in the literature compared different techniques of fixation in fractures of the mandibular body using only conventional systems or comparing conventional systems to locking systems of the same thickness.

Choi et al. (2005) compared 13 groups with different fixation techniques with conventional systems (one plate in the tension zone or one plate in the tension zone and one plate in the compression zone, with four- or six-hole plates) in bovine ribs of different heights (20 mm, 15 mm, and 10 mm), simulating atrophic mandibles. The authors observed that the groups that had two plates were more stable than the groups that were fixed with only one plate in the tension zone at the different heights, with the load ranging from 443 N to 556 N for the groups with two plates, and from 188 N to 254 N for the groups with only one plate. There was no statistically significant difference when four-hole or six-hole plates were used. In comparison to this study, the loads supported by the locking system were larger both for group I and for group II, which suggests greater stability in relation to the conventional system. The group III behaved in similar way to the group that used only one plate in the tension zone, but the peak loads supported by group IV were half those of group III. However, in combination with the advantages presented by the locking system, the fixing of a mandibular body fracture with only one locking plate in the neutral zone could be indicated in a suitable fracture with little displacement, in a patient who is expected to be very cooperative in relation to diet in the postoperative period. This would reduce the cost of treatment and permit the same result, bone healing.

Studies by Gutwald (1999) and Haug (2002) state the superiority of the locking plates over the conventional ones, contrary to the findings of Chiodo et al.

(2006). Although the difference between both groups is not statistically significant in this latter study, a higher mean is observed in relation to the forces supported by the locking plates, which varied from 356 N to 1129 N, mean 637.8 N (SD 276.3), against the conventional plates, which varied from 333 N to 972 N, mean 559.9 N (SD 247.9). The peak loads supported by group I and II of this study were similar to loads supported by the conventional system and the locking system of the studies cited above. For this reason, one may consider it unnecessary to use two locking plates for the treatment of fractures of the mandibular body; this would increase treatment costs without increasing stability. Since this paper presents a different methodology, comparisons with other studies can be performed but consideration needs to be given to the specific methods used.

Clinical trials either found no statistical difference between the two techniques, during the bone healing or related to the incidence of complications. However, advantages are mentioned of the locking system: 1) major fixation stability offered by a better transmission of load forces through the screws, since they are locked in the plate; 2) lower interference in the blood supply, since the plate is not compressed on the bone surface; 3) greater rigidity; 4) less torsion; 5) lower loss of screws and, consequentially, lower infection and reduction in the number of new interventions (Alpert et al., 2003; Ellis and Graham, 2002; Gutwald et al., 2003; Singh et al., 2010).

As with any other in vitro study, the benefits and limitations of the research must be evaluated, observing which data may be transferred for clinical application (Haug, 1994; Asprino, 2006). Since it is impossible to quantify the maximum load that can be supported in vivo during the bone consolidation period without compromising healing, the association of in vitro studies with the clinical research is important in evaluating the fixation systems and assessing which features offer greater stability. Chiodo et al. (2006) also state that, associated with the results of biomechanical tests, the success or failure is related to other clinical variables, such as adaptation of the plate, bone quality and quantity, surgical technique, characteristics of the patient and the post-operative period, and not only to the thickness and type of fixation employed. The association of these factors will lead to a better understanding as to the behavior of the material.

CONCLUSIONS

For the treatment of a mandibular linear body fracture, two locking plates, one in the tension zone and another in the compression zone, have a greater mechanical strength than a single locking plate in the neutral zone.

REFERENCES

Agarwal M, Mohammad S, Singh RK, Singh V: Prospective Randomized Clinical Trial Comparing Bite Force in 2-mm Locking Plates Versus 2-mm Standard Plates in Treatment of Mandibular Fractures. J Oral Maxillofac Surg 69(7): 1995 2000, 2011.

Alpert B, Gutwald R, Schmelzeisen R: New innovations in craniomaxillo facial fixation: the 2,0 lock system. Keio J Med 52: 120 127, 2003.

Assael L, Ueeck B: Body and angle fractures of the mandible. In: Ehrenfeld M, Manson PN, Prein J. Principles of Internal Fixation of the Craniomaxillofacial Skeleton Trauma and Orthognathic Surgery. Davos Platz: AO Foundation147-58. 2012.

Asprino L, Consani S, de Moraes M: A comparative biomechanical evaluation of mandibular condyle fracture plating techniques. J OralMaxillofac Surg 64(3): 452 456, 2006.

Choi BH, Huh JY, Suh CH, Kim KN: An in vitro evaluation of miniplate fixation techniques for fractures of the atrophic edentulous mandible. Int J Oral Maxillofac Surg 34: 174 177, 2005.

Chiodo TA, Ziccardi VB, Janal M, Sabitini C: Failure strength of 2,0 locking versus 2,0 conventional Synthes mandibular plates: A laboratory model. J Oral Maxillofac Surg 64(10): 1475 1479, 2006.

Ellis III, Graham J: Use of a 2,0-mm locking plate/screw system for mandibular fracture surgery. J Oral Maxillofac Surg 60: 642 645, 2002.

Erkmen E, Simsek B, Yucel, E, Kunt A: Comparison of different methods following sagittal split ramus osteotomies using three dimensional finite elements analysis. Part I – Advancement Surgery – posterior loading. Int J Oral Maxillofac Surg 34: 551 558, 2005.

Gutwald R: Biomechanical stability of an internal mini-fixation system in maxillofacial osteosynthesis. J Med Biol Eng Comp v. 37, 1999.

Gutwald R, Alpert B, Schmelzeisen R: Principle and stability of locking plates. Keio J Med 52: 21 24, 2003.

Gutwald R, Scho¨n R, Metzger M, Kreutzer K, Rahn B, Schmelzeisen R, et al.: Miniplate osteosynthesis with four different systems in sheep. Int J Oral Maxillofac Surg 40: 94–102, 2011.

Haug RH, Hevtvedt AK, Michaels GC, Beals DW: Comparison of the resistance of miniplates and microplates to various in vitro forces [Discussion]. J Oral Maxillofac Surg 52(3): 257-258, 1994.

Haug RH, Street CC, Goltz M: Does plate adaptation affect stability? A biomechanical comparison of locking and nonlocking plates. J Oral Maxillofac Surg 60(11): 1319 1326, 2002.

Medeiros RC, Lauria de Moura A, Rodrigues DC, Mendes MBM, Sawazaki R, Moreira RWF: Fractographic analysis of 2.0-mm plates with a screw locking system in simulated fractures of the mandibular body. J Oral Maxillofac Surg 72(6):1130 1137, 2014.

Ribeiro-Junior PD, Magro-Filho O, Shastri KA, Papageorge MB: In vitro evaluation of conventional and locking miniplate/screw systems for the treatment of mandibular angle fractures. Int J Oral Maxillofac Surg 39: 1109 1114, 2010.

Singh V, Kumar I, Bhagol A: Comparative evaluation of 2.0-mm locking plate system vs 2.0-mm nonlocking plate system for mandibular fracture: a prospective randomized study. Int J Oral Maxillofac Surg 40(4):372 377, 2011.

The Figure Legend:

Fig. 1 A) Hemimandible from group I; B) hemimandible from group III.

Fig. 2 Hemimandible made from aluminum with two larger holes in the posterior region in order to adapt to the support device and linear osteotomy simulating a body fracture.

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"COMPARATIVE MECHANICAL EVALUATION *in vitro* OF TECHNIQUES OF A 2.0 mm LOCKING FIXATION SYSTEM IN SIMULATED FRACTURES OF A MANDIBULAR BODY "

List of Tables

Table 1: Average loads (N) which gave rise to displacements of 3 mm, 5 mm and 7 mm and the peak loads for the four groups tested

Group	Vertical loading value (N)			Peak load (N)
	3 mm	5 mm	7 mm	
I	197.2±61.2	425.5±97	615.7±79.8	657.6±74.4
II	295.1±78.4	383.1±64.2	485.2±64.8	592.7±123.5
III	133.7±62.7	77.9±11.8	38.2±11.6	296.8±39.3
IV	70±4.3	88.2±26.8	92±35.4	167.9±31.8

Mean±SD.

Table 2: Level of statistical significance between groups

Group	*p*			
	3 mm	5 mm	7 mm	Peak load
I *vs.* II	0.059	0.437	**0.021**	0.343
III *vs.* IV	0.053	0.451	**0.01**	0.06

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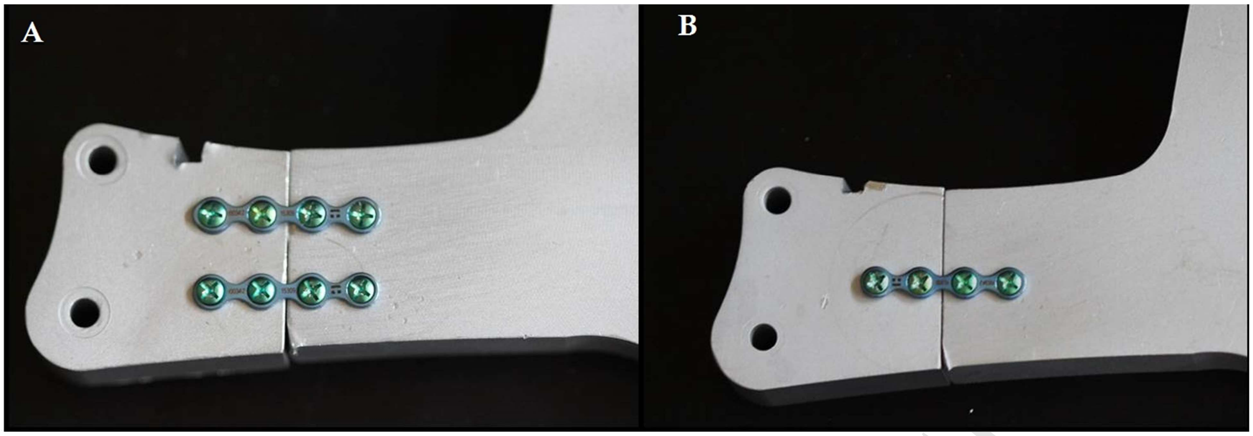
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