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Assessment of Resorbable and Non-resorbable Fixation Systems in Sagittal Split Ramus Osteotomy: An In vitro Study

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Abstract

Objective The internal fixation has been purpose of study for many years, but there is still no consensus on the best method of fixation in relation to resistance for bilateral sagittal split ramus osteotomy (BSSO) using plates. Therefore, the aim of this study was to assess five different methods of osteosynthesis using resorbable and non-

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resorbable plates and screws in simulated sagittal split osteotomy (SSO) of the mandibular ramus.

Materials and Methods SSO was performed in 25 polyurethane synthetic mandibular replicas. The distal segments were moved forward 5 mm, and the specimens were grouped according to the fixation method: Inion resorbable plate, KLS resorbable plate, standard four-hole titanium miniplate (Medartis), two standard four-hole titanium miniplates (Medartis) and an adjustable titanium miniplate (Slider/Medartis). Mechanical evaluation was performed by applying compression loads to first molar using an Instron universal testing machine up to a 5 mm displacement of the segments. Resistance forces were obtained in Newtons (N), and statistical analysis was performed using the software R v. 3.5 with significance level of 0.05. Linear mixed models were used to compare the force required to move each type of plate.

Results The results showed that the resistance of SSO was better accomplished using two titanium miniplates and KLS resorbable plate showed the least resistance. However, both titanium and resorbable plates behaved similarly in small displacements, which are most commonly observed in BSSO postoperative time.

Conclusion It can be concluded that both resorbable and non-resorbable systems might offer suitable mechanical resistance in the procedures where there are no mechanical postoperative complications.

Keywords Fixation · Bone plates · Titanium · Resorbable · Sagittal split ramus osteotomy · Mandibular advancement

Bilateral sagittal split osteotomy (BSSO) gained popularity among surgeons through the description of the sagittal division of the vertical ramus by Trauner and Obwegeser in 1955. The major changes of this technique, still in use today, were suggested by Dal Pont in 1961. It became the predominantly used osteotomy for correction of dentofacial deformities of the mandible [1].

Bone stabilization has progressed from osteosynthesis with steel wire and maxillomandibular fixation (MMF) to the use of titanium miniplates and screws and biodegradable materials [2]. In the 1980s, rigid internal fixation was used more often to stabilize the BSSO segments, with a MMF period of 2 to 6 weeks. Since then, many studies have been published on the stability of BSSO fixed rigidly with bicortical screws and with no postoperative MMF. It is now believed that MMF is not only unnecessary when combined with rigid fixation of sagittal osteotomies, but may also lead to adverse effects on the temporomandibular joint (TMJ) [3].

Titanium is considered the 'gold standard' material of fixation systems in maxillofacial surgery. Different fixation methods were then developed to allow mobilization and early function after the use of BSSO [2]. Among the stable internal fixation methods, we have bicortical screws, miniplates with monocortical screws and hybrid techniques. However, studies have reported that titanium systems present some disadvantages, such as the need for a second intervention to remove the devices in case it is indicated [4–6]; interference with imaging or radiotherapeutic techniques [6, 7]; growth disturbance or mutagenic effects [6, 8] and thermal sensitivity [6, 9].

2Thus, some limitations of titanium plates and screws used for the fixation of bones have led to the development of plates manufactured from bioresorbable materials. Using bioresorbable plates for the fixation of facial bones seems to cut the need for a further operation for the removal of metal plates. However, while resorbable plates seem to offer certain advantages over metal plates, concerns remain about how stable the fixation is, the time required for their resorption, the possibility of foreign body reactions, and the technical difficulties experienced with resorbable plates [10].

Current trends in fixation systems have attempted to decrease plate size and profile while maintaining tensile and compression forces. Still, in vitro mechanical tests of the various fixation systems have proven to be a useful tool in minimizing problems and establishing the ideal system. Therefore, the aim of this study was to assess the mechanical resistance of five different methods of osteosynthesis using resorbable and non-resorbable plates and screws in simulated sagittal split osteotomy (SSO) of the mandibular ramus.

Materials and Methods

This experimental in vitro study used 25 polyurethane replicates of human hemimandibles (Nacional, Jaú, São Paulo, Brazil). The material selection was based on innumerous studies which use synthetic mandibles [11, 13, 15–17, 21]. To standardize the study, the hemimandibles are from the same manufacturing. The osteotomy was performed by the manufacturer according to the technique of SSO. The advancement of the distal segments was 5 mm, and the specimens were divided into 5 groups with 5 hemimandibles each. The fixation material used was titanium (Medartis, Basel/Switzerland) or lactic and glycolic acid (Inion-Osteomed/USA/KLS System-Germany). All plates were installed following a previously made acrylic model.

In Inion group, we used fixation with a 2.0 mm Inion resorbable plate of 4 holes, 1.5 mm thickness, with 4 screws perpendicular to the hole of the plate (Fig. 1a). In KLS group, we fixed the osteotomy with a 2.0 mm KLS resorbable plate of 12 holes, 1 mm thickness, with 8 screws using the same orientation as group 1 (Fig. 1b). One titanium miniplate group was composed by hemimandibles fixed with one straight titanium miniplate of 4 holes, 2.0 mm system, 1 mm thickness, using 4 screws (Fig. 1c). In two titanium miniplates group, the mandibles were fixed with 2 straight titanium miniplates of 4 holes each, 2.0 mm system, 1 mm thickness, with 8 screws perpendicular to the holes of the plates (Fig. 1d). Finally, in the Slider group, we used a Slider titanium plate $(47 \times 12 \text{ mm})$ with 8 holes, 2.0 mm system, 0.8 mm thickness, with 8 screws perpendicular to the holes of the plate (Fig. 1e). All the screws used had the same dimensions, which were 2.0×5.0 mm.

For the template of the BSSO technique, with a 5 mm advancement of the hemimandibles segments, we used the method proposed by Asprino et al. (2006) [11]. They suggested using a guide made of acrylic resin for the displacement and attachment of miniplates and screws, where we established the proximal and distal segments allowing the free movement of the segments while we applied the loads.

Loading Test

All the samples were subjected to linear loading from top to the bottom in the first molar area in an Instron universal testing machine (EMIC DL-2000, São José dos Pinhais— Brazil) using a methodology similar to that designed by Armstrong et al. [12], which simulates the forces applied by the masticatory muscles. The material test unit produced linear displacement at a rate of 1 mm/min, and we recorded

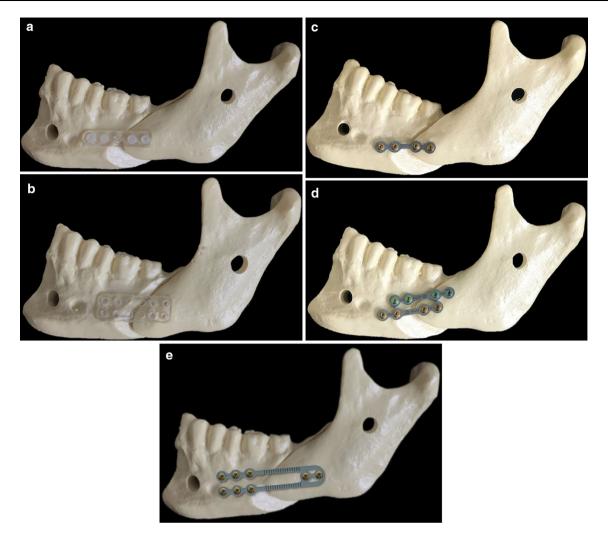


Fig. 1 Hemimandible fixed with \mathbf{a} one Inion resorbable miniplate, \mathbf{b} one KLS resorbable plate, \mathbf{c} one standard titanium miniplate, \mathbf{d} two standard titanium miniplate, \mathbf{e} one Slider titanium miniplate

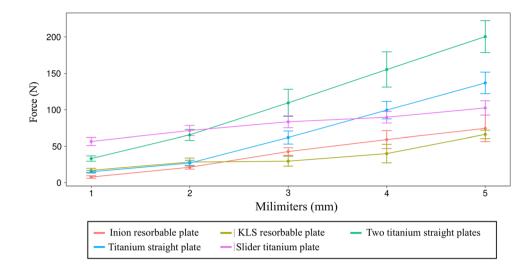
the force required to displace the distal segment of 1 mm, 2 mm, 3 mm, 4 mm and 5 mm. We obtained the data of movement (in millimeters) and force (in Newtons) in all groups. The results were submitted to statistical analysis, which was performed using the software R v. 3.5 with a significance level of 0.05. We presented the data by mean, standard deviation, minimum, median and maximum. To understand the behavior of the plates, we had to adjust a linear mixed model (repeated measures model) to analyze the results and statistically understand the force required to move each type of plate a certain amount of millimeters.

Results

Figure 2 shows the force required to move each sample 1, 2, 3, 4 and 5 mm. We used linear mixed models to compare the force required to move each type of plate. Table 1 presents the T-test results for this model and shows which

plates need a greater force to be moved some millimeters. With a significance level of 0.05, there were statistically significant differences between the average force required to move different plates in different moments.

Analyzing Table 1, we can highlight that the mean force required to move the plate depends on how far it was moved and which type of plate was used. The force required to move the Slider titanium plate is higher than others at the first two millimeters of displacement. The Slider titanium plate was more resistant in the beginning of the test. At 3 mm of displacement, the Slider titanium plate behaved better than the single titanium plate but worse than the two titanium plates. However, at the last displacement, the Slider plate had the worst force behavior among the titanium plates and the two straight titanium plates had the best performance among all 5 types tested. So, the force to move two standard titanium miniplates was higher than the one to move the other plates and the results showed that it was statistically significant (p < 0.001). Fig. 2 Graph of the mean force needed to move each plate. Vertical bars represent the standard error of the means. (Orange Line—Inion resorbable plate, Yellow Line—KLS resorbable plate, Green Line— Two straight titanium miniplates, Blue Line—One titanium miniplate and Pink line—Slider titanium plate)



The resorbable plates presented the worst results at the last displacement. At 1 and 2 mm displacement tests, the KLS resorbable plate behaved similarly to one straight titanium plate and better than the Inion resorbable plate. When tested at over 3 mm of displacement, Inion plate behaved better than KLS plate, but both resorbable plates presented worse results than the titanium miniplates.

Discussion

In recent years, there has been great interest in which type of fixation provides greater stability and generates less morbidity or complications [13]. In the literature, it is already a consensus that the resistance is invariably lower for miniplate fixation systems than bicortical screws. This is because of the ability of the screws to stabilize the threedimensional osteotomized segments by inserting fixation points, simultaneously acting on both segments, and so limiting the bending action and torsional forces [14]. Different fixation methods after sagittal split osteotomy, using three-dimensional finite elements, were analyzed and confirmed that the use of 2.0 mm screws placed in a triangular configuration had a greater mechanical resistance when compared to the linear configuration of the screws, two parallel miniplates and a single miniplate. However, the design of the plate influences the mechanical results obtained and the choice of the plate is very important in the fixation of the BSSO [2].

The use of miniplates with monocortical screws is based on the connection being installed to one point of the "bridge" miniplate between the segments. It provides greater freedom of twisting movement and less resistance to fixation. Moreover, this fixation has the advantages of inducing lower condylar torque and lower compression between the segments, which could cause injury to the inferior alveolar nerve [17]. Photoelastic tests proved that by using miniplates all stress is concentrated around the fixation system (plates and screws), which also explains the lower mechanical resistance of this technique compared to the positional screws [17]. In addition, in some situations,

Parameter	Value	Standard error	gl	t	p value
Intercepto (β)	- 10.360	11.112	93	- 0.932	0.354
KLS group (β2)	12.776	15.801	20	0.809	0.428
Two titanium miniplates group (β3)	- 4.060	15.715	20	- 0.258	0.799
One titanium miniplate group (β4)	- 16.500	15.715	20	- 1.050	0.306
Slider group (β5)	58.140	15.715	20	3.700	0.001*
Millimeters (a)	17.160	2.190	93	7.836	< 0.001*
KLS group: millimeters (α2)	- 5.550	3.232	93	- 1.717	0.089
Two titanium miniplates group: millimeters (\alpha3)	25.260	3.097	93	8.156	< 0.001*
One miniplate group: millimeters (a4)	14.500	3.097	93	4.682	< 0.001*
Slider group: millimeters (α5)	- 6.140	3.097	93	- 1.983	0.050*

the miniplates are the best choice, as in cases of great movements and asymmetries.

AL-MORAISSI et al. (2016), in their systematic review and meta-analysis, found that there is no significant difference in skeletal stability between bicortical screw fixation and monocortical plate fixation of the BSSO following mandibular advancement surgery [18]. Other study presented the biomechanical resistance of six commonly used fixation techniques and concluded that, for mandibular advancements, the resistance forces measured at displacements of 1, 3 and 5 mm were much higher using a 2.0 mm plate with an extra bicortical screw [17]. Some studies show that the use of bicortical screws associated with miniplates presents better biomechanical properties [15, 16]. Although a large part of the in vitro biomechanical studies has described the advantages of the hybrid technique [15–17], there are some disadvantages, such as condylar twist, risk of alveolar nerve compression, difficulty to remove bicortical screws in case of infection and other complications which need fixation removal [19]. Therefore, the choice of fixation type is usually based on the preference and personal experience of each surgeon [17]

Although bicortical screws present the best results in terms of resistance to masticatory forces compared to miniplates, clinical data showed no tendency to abandon the use of miniplates. That's because, clinically, this technique has very good results. Although it has a lower stiffness, several studies have shown that during the first postoperative weeks, when there was a significant reduction of masticatory forces, the miniplates were capable to provide enough resistance [19-21]. Thus, in clinical conditions in which there is great bone contact and favorable movement, with consequent lower influence on muscles and related joints, any of the fixation techniques described can be used, including resorbable plates [22–24]. However, in cases which immediate mandibular function is more critical, such as a patient with greater masticatory strength, the use of more rigid fixation techniques may be advisable (linear screws at a 90° angle or an inverted L arrangement) [3]. The use of miniplates represents a better clinical option in cases which large movement is necessary, with segments that have thin bone structures, and cases of bad split [3, 21].

Our results show that fixation with a Slider titanium miniplate was superior to the other four methods up to 2 mm displacement, where it gradually lost its resistance and finished as the least resistant among the titanium ones. In addition, KLS resorbable miniplate presented the worst results in relation to resistance in 3, 4 and 5 mm displacement. Considering this experiment, the performed fixation of mandibular SSO after 5 mm advancement with

two standard titanium miniplates was the most resistant of all methods tested and statistical difference was observed.

Also, mechanical tests showed that for the first 2 mm of displacement, the resorbable plates presented a mechanical behavior similar to the straight plate. Postoperative dislocations in orthognathic surgery which exceed 3 mm are considered postoperative complications with aesthetic and occlusal repercussion, with the need of a new procedure. Thus, it can be stated that the resorbable plates might offer suitable mechanical resistance in the procedures where there are no mechanical postoperative complications.

Moreover, our study has some limitations. Experimental models cannot fully reproduce how complex mandibular function and anatomical structures of cortical bone are, and it is not known if the healing process is affected by these differences. However, we believe that our study provided some information to influence the choice of fixation system to produce the most possible postoperative stability. Also, although the plates presented slight difference in thickness and, consequently, different penetration depth of the active part of the screws, we believe that this fact has not directly influenced the outcomes. Our proposal was to test distinct fixation systems, with different mechanical behaviors, subjected to the same loads. However, more studies are needed to clarify if there is a mechanical repercussion related to this limitation.

The results of the present study related to titanium plates are similar to the outcomes founded by Filho et al. [13]. They tested, in their in vitro study, the resistance of the sagittal osteotomy fixation using a specifically designed adjustable plate (Slider) and compared it with two fixation methods commonly used. They showed better results using conventional miniplates than the adjustable plate (Slider), which provided unstable fixation, maintaining just 60% of the load values reported for bicortical screws. The use of such plate could even indicate the need for a period of rigid intermaxillary fixation postoperatively [13]. Our results also agree with the one performed by Buijs et al. [6], who concluded that the titanium osteofixation systems were much stronger and stiffer than the biodegradable systems.

However, three reviews have been published comparing resorbable and titanium plates, and all of them concluded that resorbable plates are as stable as metal plates [22–24]. The results of Al-Moraissi and Ellis [22] also show that titanium fixation produced fewer broken screws during surgery compared with biodegradable screws. Agnihotry et al. [10], in their systematic review, state that they could not find enough evidence to decide whether titanium plates or resorbable plates are superior for fixation of bones after orthognathic surgery.

Therefore, it can be concluded that, although the resistance of BSSO was better accomplish using two titanium miniplates and KLS resorbable plate showed the worst resistance, both resorbable and non-resorbable systems might offer suitable mechanical resistance in the procedures where there are no mechanical postoperative complications. So, in usual clinical conditions, resorbable systems could be encouraged. However, for patients who present important oral parafunction or in extensive or unstable surgical movements, we suggest that the mandibular fixation should be performed with two titanium straight miniplates.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Not required.

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