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Randomized Controlled Trial

Success rate of surface-treated and non-treated orthodontic miniscrews as anchorage reinforcement in the lower arch for the Herbst appliance: A single-centre, randomised split-mouth clinical trial

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Summary

Background: Surface treatment of miniscrews was implemented to determine whether its application increased bone-to-surface contact and enhanced the interlock between the device and the surrounding bone.

Objectives: To compare the success rate of surface-treated and non-treated orthodontic miniscrews used as reinforcement of anchorage during treatment with the Herbst appliance.

Trial design: Split-mouth design with an allocation ratio of 1:1.

Methods: Eligibility criteria to enrol patients were skeletal and dental class II patients with a retrusive chin, use of the Herbst appliance to correct malocclusion, need for skeletal anchorage using a miniscrew both in the left and right side of the mouth, absence of systemic diseases, absence of using drugs that alter bone metabolism, and good oral hygiene. Patients received self-drilling miniscrews without surface treatment and with surface treatment. Both types presented a 1.4 or 1.2 mm diameter. Miniscrews were inserted between the first molar and second premolars or between the two premolars. The force applied to the screws was an elastic chain from the head of the miniscrews to a direct button applied on the canines. The success rate of each type of miniscrew was considered the primary outcome, and the association of success with demographical, clinical, and geometrical characteristics was investigated. Differences were tested by the generalised linear mixed effects model for the split-mouth design. Differences with a *P*-value < 0.05 were selected as significant.

Randomisation: A randomisation list was created for the mouth side assignment.

Blinding: The study was single blinded with regard to the statistical analysis.

Results: Thirty-nine miniscrews of the non-treated type and 39 miniscrews of the surface-treated type were inserted in 39 patients (23 female and 16 male, mean age: 15.55 ± 7.91) recruited between March 2018 and December 2020 with a split-mouth study design. The mean therapy duration was 9.3 months (SD = 1.31). No differences in failure rate were observed between miniscrew types. No serious harm was observed.

Conclusions: The success rate of surface-treated and non-treated miniscrews showed no significant differences.

Registration: This trial was not registered.

Introduction

Orthodontic miniscrews are now widely accepted and used as intraoral anchorage devices to define the biomechanics of orthodontic tooth movement (1-3), and a number of clinical studies and reviews have investigated their stability as anchor units and reported a failure rate ranging from 9.2% to 39% (4-6). Actually, failure rates may depend on insertion sites, e.g., midpalatal, paramedian, and parapalatal insertion sites would have different failure rates (9.2%, 9.7%, and 16.4%, respectively), while the failure rates for the maxillary buccal sites would be between 9.2% and 16.4%, and the failure rates for the mandibular buccal insertion sites would range between 9.9% and 13.5% (6). The study of Haddad and Saadeh reported a failure rate of 10% for the maxilla and 19.6% for the mandible (7). Moreover, the insertion site would not be the only clinical condition involved in determining the success rate: even age, sex, mandibular plane angle, tissue mobility (firm or movable tissue), inflammation, and distance to the root, both of which are characteristics of the device, such as type, length, and diameter, would play a role (8-11). Surface treatment is another miniscrew characteristic that was studied for its ability to increase bone-to-surface contact and enhance the interlock between the device and the surrounding bone (12-16). An *in vitro* and *in vivo* analysis of surface properties revealed that the removal torque of acid-etched miniscrews was higher than the removal torque of machined miniscrews, and histomorphometric results showed a significantly higher percentage of bone–implant contact for surface-treated devices (17).

However, the clinical implications of these *in vitro* evaluations are controversial, and clinical testing under standardised forces and biomechanics could be helpful to better understand whether surface treatment improves stability.

Recently, different studies have been published to prove how reinforcement of the anchorage using fixed functional appliances could lead to an increase in skeletal effects, reducing the dental compensation of overjet correction. The results from these reports indicate a mitigation or complete elimination of traditional side effects of functional therapy, such as lower incisor proclination (18–24). Then it appears that miniscrews facilitate the correction of class II malocclusions in patients requiring mandibular advancement with minimal dentoalveolar compensations. However, the achievement of these goals depends on the capability of miniscrews to serve as anchorage units for an adequate amount of time and only a few studies have reported the success rate of miniscrews used for anchorage during Herbst treatment. In a study of Manni *et al.*, 56 patients were allocated to either a test (combination of Herbst appliance and miniscrews) or control (traditional Herbst) group. The miniscrews were applied in mandibular bone at the level of marginal or attached gingiva or mucogingival junction, between the lower first molar and second premolar and no miniscrews were lost, or replaced, or became mobile during the treatment (25). In a study of Luzi *et al.*, five cases were treated with a modified mini-implant supported Herbst with anchorage either between the roots of the first and second premolars bilaterally, or between the roots of the second premolars and first molars bilaterally, and two miniscrews in two different patients lost stability during the treatment (26). The available data are not very different when we consider the Forsus Fatigue Resistance Device (FRD): 15 patients received such a treatment using miniscrew anchorage between the mandibular canine and first premolar roots and there was no looseness or mobility in the miniscrews according to Eissa (22), whereas mobility of miniscrews during FRD application with anchorage between the mandibular canine and first premolar root was determined bilaterally in two adolescent patients over 16 treated subjects in another study (23).

The objective of this randomised study is thus to evaluate the difference in success rate of surface-treated and non-treated orthodontic miniscrews used as reinforcement of the anchorage during treatment with the Herbst appliance.

Materials and methods

Trial design and any changes after trial commencement

This split-mouth single-blinded study was conducted on patients treated by the same operator for orthodontic purposes in a private practice between March 2018 and December 2020.

Participants, eligibility criteria, and setting

The eligibility criteria to be enrolled in the study were skeletal and dental class II patients with a retrusive chin, use of the Herbst appliance to correct malocclusion, need for skeletal anchorage using miniscrews both in the left and right side of the mouth, absence of systemic diseases, absence of using drugs that alter bone metabolism, and good oral hygiene. All miniscrews were placed by the same author (AM), while all data collected in this study were analysed at the University of Genova. The clinical study was approved by the University of Genova ethical committee with approval number 2136, and all patients signed an informed consent form (and their parents in the case of minors).

Interventions

Interventions consisted of therapy with a fixed functional appliance (MTH Herbst), during which two miniscrews were used to fulfil the objectives of the treatment.

The Herbst appliance (MTH Herbst, American Orthodontics, Sheboygan, WI, USA) keeps the mandible in a protracted position 24 h a day with a bilateral telescope mechanism consisting of a tube, a plunger, 2 pivots, and 2 locking screws. The amount of mandibular advancement is determined by the length of the tube. The Herbst appliance was activated initially with a mandibular advancement of 4–6 mm, and then the mandible was advanced in gradual increments (2 mm/2 months) until canine class I was achieved. All patients underwent palatal expansion with a rapid palatal expander before Herbst insertion.

Two kinds of miniscrews were randomly placed on the left and right sides of patients: machined surfaces and acid-etched surfaces (Osstem Implant, Busan, Korea. Acid etching was carried out by the manufacturer). Two different geometries were used: one with a diameter of 1.2 mm and a length of 8 mm and another with a diameter of 1.4 mm and a length of 8 mm; every patient received only miniscrews with the same geometry.

Temporary anchorage devices were placed in the lower arch only to act as reinforced anchorage during Herbst therapy (Figure 1). Insertion sites were between the first molar and second premolars or between the two premolars, depending on the available interradicular space. Ideal miniscrew insertion site: on the mucogingival line, or in the attached gingiva. The inclination of the miniscrew was either perpendicular or tilted 45° with respect to the alveolar bone, depending on clinical and anatomical conditions, such as the quantity of available bone and the need to have the head of the miniscrew placed as coronally as possible for a better anchorage. Pre- and postinsertion radiographs of the interradicular implant sites were taken to check the distance of the screws with neighbouring roots.

All screws were manually inserted without predrilling. The force applied to the screws was an elastic chain (Memory Chain; American Orthodontics, Sheboygan, WI, USA) from the head of the miniscrews to a direct button applied on the canines as a control for anterior tooth flaring. The elastic chains were immediately applied and changed at every appointment (every 4 weeks), and the applied force was 150 g. The selected insertion site (between the first molar and second premolars or between the two premolars) did not influence the setted amount of force. All patients were compliant with the scheduled appointments and were followed until the end of treatment. Success of the screw was defined as the screw that successfully remained until the end of orthodontic treatment with the Herbst appliance. The end of the Herbst treatment was decided upon achieving a canine class I. Miniscrews were left after Herbst removal for any additional purpose, but their success was assessed on their staying during the Herbst therapy only. The stability was assessed checking for mobility. No screw detected with mobility was left in place. Pre- and posttreatment records were collected: lateral rx and dental casts. Photograph. Intraoral RX pre- and post-miniscrew placement.

The allocation of patients to the two types of miniscrews with a split-mouth design was determined by a computer-generated randomisation list using Rv3.0.1 software (25).

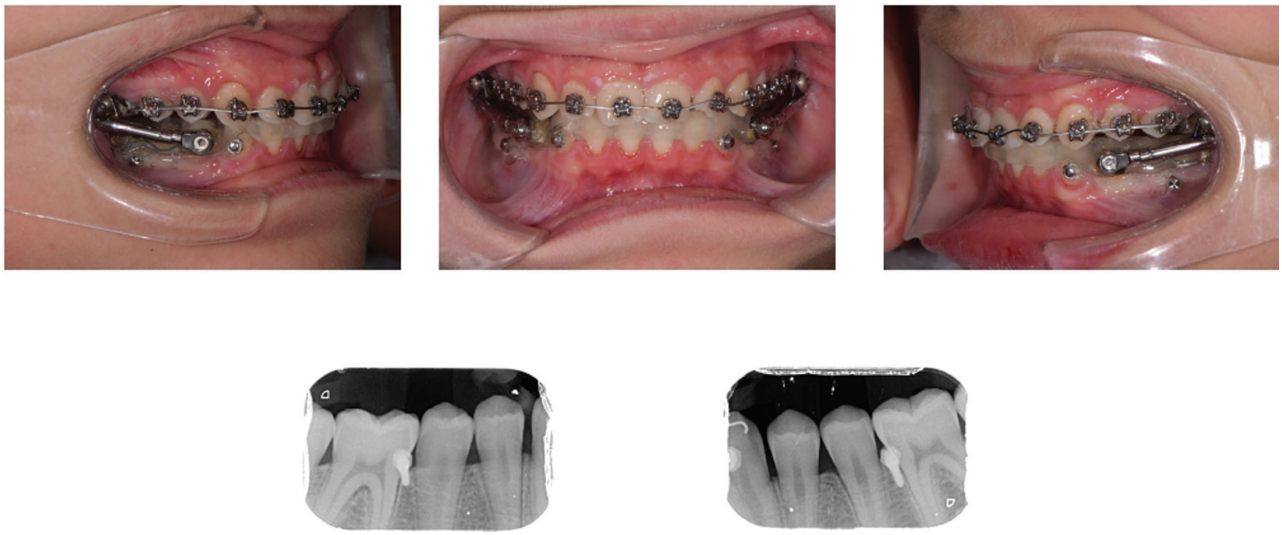

Figure 1. Intraoral photographs of the Herbst appliance with miniscrews in the lower arch used as reinforcement of the anchorage and control radiographs taken after miniscrew insertion. The force applied to the screws is an elastic chain from the head of the miniscrews to a direct button applied on the canines.

Outcomes (primary and secondary) and any changes after trial commencement

The primary outcome was the evaluation of miniscrew success rate differences between machined versus acid-etched miniscrews; the secondary outcome was the evaluation of location and diameter influence on stability.

Sample size

The study of Haddad and Saadeh (7) reported a failure rate of 10% for the maxilla and 19.6% for the mandible, then a 80% success could be expected when miniscrews are inserted for anchorge in the lower arch. The sample size was calculated on the basis of an 80% success rate of machined miniscrews and an expected 95% success rate of acid-etched miniscrews, since the latter are generally reported to have a higher success rate and it seemed interesting to size the study for a clinically significant (15%) difference between types. Then there were 84 patients (168 miniscrews by a split-mouth design) with a significance level (alpha) of 0.05 using a one-sided paired proportions McNemar's Z test.

Interim analyses and stopping guidelines

Data were analysed near to the completion of the first half of the recruitment to understand if the observed difference in success rates could possibly meet expectations. Recruitment stopped because it was already statistically evident that the hypothetical difference of 15% could not be reached.

Randomisation

A block randomisation sequence was generated with dedicated software (25), with the allocations concealed in sequentially numbered, opaque, sealed envelopes.

Blinding

Data were recorded and blinded to the statistician: blinding was obtained by eliminating every reference to patient group assignment from the elaboration file.

Statistical analysis

Data were analysed by a statistician. Continuous variables are given as the means with standard deviations (SD) and range, whereas categorical variables are given as the number and/or percentage of subjects. The frequency distribution of the observed groups among sex, diameter, miniscrew location, and clinical success was calculated.

The failure rate differences among the sex of patients, age, diameter of miniscrews, miniscrew location (5–6 or 4–5), and miniscrew type (machined or acid-etched) were tested by the generalised linear mixed effects model for the split-mouth design.

The likelihood ratio (LR) test was used as a test of statistical significance, and in each generalised linear mixed model, the sampling units were considered to be random factors. Differences with a P-value < 0.05 were selected as significant.

Data were acquired and analysed in the R v3.4.4 software environment (27).

Results

Participant flow

Thirty-nine miniscrews of the machined type and 39 miniscrews of the acid-etched type were inserted in 39 patients (23 females and 16 males, mean age: 15.55 ± 7.91) with a split-mouth study design (Figure 2). The mean therapy duration was 9.3 months (SD = 1.31). All randomised patients were analysed, and no dropout occurred. Recruitment started in March 2018, and the observation period ended in December 2020.

Numbers analysed for each outcome, estimation, precision, and subgroup analyses

Failure rates due to miniscrew loss were 25.6% for the machined type and 28.2% for the acid-etched type. The total failure rate was 26.9%. The failed screws mean survival was 52 days (SD = 58). No failures due to the Herbst appliance breakage were observed. Table 1 describes the demographic, geometrical, and clinical characteristics of the miniscrew observation groups.

No differences in failure rate were observed between miniscrew types, sexes, diameters, and location. The failure rate did not result in a significant difference according to age (Table 2).

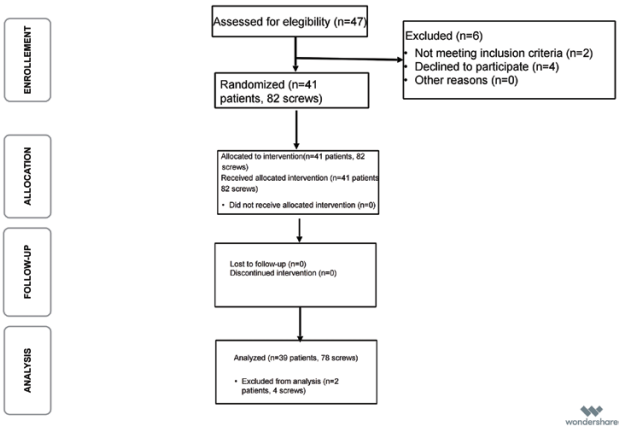

Figure 2. Study flow-chart.

Table 1. Demographic, geometrical, and clinical characteristics of the miniscrews observation groups. *N*, number of observations; %, percentage over the total of each subgroup.

	Machined miniscrews, *N* (%)	Acid-etched miniscrews, *N* (%)	Observed total, *N* (%)
Sex of the patient			
Female	23 (50.0)	23 (50.0)	46 (59.0)
Male	16 (50.0)	16 (50.0)	32 (41.0)
Age			
9 to ≤11	10 (25.6)	10 (25.6)	20 (25.6)
>11 to ≤13	14 (35.9)	14 (35.9)	28 (35.9)
>13 to ≤16	7 (17.9)	7 (17.9)	14 (17.9)
>16	8 (20.6)	8 (20.6)	16 (20.6)
Diameter			
1.4 mm	33 (84.6)	33 (84.6)	66 (84.6)
1.2 mm	6 (15.4)	6 (15.4)	12 (15.4)
Miniscrew location			
5–6	33 (84.6)	33 (84.6)	66 (84.6)
4–5	6 (15.4)	6 (15.4)	12 (15.4)
Miniscrew success			
Good	29 (74.4)	28 (71.8)	57 (73.1)
Failure	10 (25.6)	11 (28.2)	21 (26.9)

Harms

No serious harm was observed, but some peri-miniscrew inflammation was treated with clorexidina gel or spray twice a day (Corsodyl, GlaxoSmithKline, Brentford, UK).

Discussion

Limitations of the study and generalisability

The sample size of the present study was designed to assess a difference of 15% between the success rates of the two types of miniscrews in a split-mouth design; however, recruitment stopped after half of the patients had received their screws, and they were observed for a period of 6 months because it was already clear that the hypothetical difference of 15% could not be reached. In fact, no differences were observed in the success rates up to that moment, which could mean only one of the following: (1) there was no difference; (2) the difference was so small that it would have required a huge sample to see it.

Recent literature shows that root proximity is a major risk factor for the failure of miniscrews. Even though intraoral RX pre- and post-miniscrew placement were taken into account to visually assess root proximity, the present study did not take into account a numerical measure of this factor.

This trial was not randomised for miniscrew locations.

Table 2. Failure rate differences for every clinical or geometrical characteristic: Odds Ratio: the odds ratio related to the named variable (1 is the reference). Lower CI, 95% lower confidence interval; Upper CI, 95% upper confidence interval; LR adjusted *P*-value, likelihood ratio *P*-value adjusted by using Bonferroni method.

	Odds ratio	Lower CI	Upper CI	*P*-value
Sex of the patient				
Female	1	—	—	0.2379
Male	0.05	0.001	2.29	
Age				
9 to ≤11	1	—	—	0.7156
>11 to ≤13	1.74	0.056	54.5	
>13 to ≤16	0.89	0.014	55.3	
>16	28.00	0.375	2100.0	
Diameter				
1.4 mm	1	—	—	0.917
1.2 mm	0.741	0.002	207	
Miniscrew location				
5–6	1	—	—	0.5213
4–5	6.52	0.010	4190	
Type				
Machined	1	—	—	0.6147
Acid-etched	0.6	0.080	4.51	

Main findings and interpretation

The present study found no difference in failure rates between miniscrew types. In particular, the failure rates were 25.6% for the machined type and 28.2% for the acid-etched type. This result is unexpected with respect to the *in vitro* and *in vivo* evaluations of Yadav *et al.* (17) and reminds us that clinical experience may lead to a different conclusion mediated by the mechanisms of bone relaxation and cellular turnover. Bone relaxation takes part in the early bone response (approximately up to 11 days) and is due to bone viscoelastic properties.

Until new mineral content is organised, the bone contacting the screw undergoes loosening, which causes a decrease in primary stability in the early weeks (28,29).

The lack of a difference between types appears to be in contrast with the percentages reported by Park *et al.* as well: in a split-mouth design, they describe success rates of 85.7% and 91.8%, respectively, in a sample of 40 patients, even though this difference did not result in significance. It could be observed that a difference of almost 6% in the success (or failure) rate would have required a sample that should have been even larger than the one required for a difference of 15% to be detected, and for this reason, the difference was not significant. However, Park *et al.* noticed this difference between two

surface treatments. Moreover, the overall failure rate for acid-etched and machined surface miniscrews was 11.2% (13), and this value is considerably lower than that found in the present study (26.9%). This may depend on the fact that Park and colleagues considered a variety of insertion sites in both jaws, and they included patients with different sagittal and vertical patterns and different biomechanics, whereas in the present study, all patients received the same treatment.

On the other hand, a recent split-mouth study on 31 patients stated that the survival rate was 90.3% and 83.9% for the sandblasted and acid-etched versus the control group and that the difference was not significant (miniscrews were needed for en masse retraction of the upper six anterior teeth) (30).

Further studies randomising the location are required to understand the association between the success of the screw and the interradicular space chosen to anchor the fixed functional appliance in the lower arch. However, only one miniscrew of 12 implanted between 4 and 5 failed, revealing a higher success rate (91.7%) in this location, and this observation appears in accordance with a previous result of the literature that anterior localisation of the screw is more favourable to success (31). In the same retrospective study, the authors argued that the success rates were significantly higher for miniscrews in the maxilla (86.9%) than in the mandible (76.1%), and this difference could be due to the more frequent screw application in the anterior portion of the arches, the greater amount of keratinised tissue, the less demanding surgical procedure, and the greater vascularisation of the upper jaw (29).

Conclusions

The success rate of surface-treated and non-treated orthodontic miniscrews used as reinforcement of the anchorage during the treatment with the Herbst appliance did not differ in a statistically significant way.

Supplementary material

Supplementary data are available at *European Journal of Orthodontics* online.

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Author contribution

AM: Conceptualisation, methodology, investigation. SD: Formal analysis, data curation, writing-original draft preparation. MM: Supervision, project administration, writing-reviewing and editing.

Conflicts of interest

None to declare.

Data availability

The data underlying this article are available in the article and in online Supplementary Material.

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