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Maximum insertion torque loss after miniscrew placement in orthodontic patients: A randomized controlled trial

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Abstract

Objectives: To compare torque recordings of immediately loaded orthodontic miniscrews between insertion time and different post-placement timepoints (2 weeks, 4 weeks and removal time, respectively).

Setting and sample population: Parallel trial with an allocation ratio of 1:1. Eligibility criteria were needs of fixed orthodontic treatment, no systemic disease and absence of using drugs altering bone metabolism.

Material and methods: Patients received miniscrews, 2.0 mm diameter and 10 mm length. All miniscrews underwent inter-radicular placement, and they were placed in the maxilla or in the mandible, palatally or buccally. No pre-drilling was performed. Miniscrews were loaded immediately after the insertion and were used for distalization, intrusion, extrusion, mesialization or indirect anchorage. Patients were randomly divided into three groups. For each patient, Maximum Insertion Torque (MIT) was evaluated at baseline. MIT was measured again after 2 weeks and after 4 weeks by tightening the screw a quarter of turn in Groups 1 and 2, respectively. At the end of the treatment, maximal removal torque was evaluated in Group 3. Torque variation with respect to insertion time was considered as the primary outcome. Baseline and longitudinal differences were tested using the linear mixed-effects (LME) model.

Results: Forty seven patients and 74 miniscrews were followed up. An association existed between maximum insertion torque and the observation time. A torque decrease of 26.9% and 30% after 2 weeks was observed for mandibular and maxillary miniscrews, respectively. After 1 month, torque values were similar to the baseline records. The overall success rate was 79.7%. No serious harm was observed.

Conclusions: Maximum insertion torque undergoes a loss during the first 2 weeks, and its values may depend on the insertion site and the anchorage purpose. Removal torque value is almost the same as the initial torque after 1 month.

KEYWORDS
anchorage, bone biology, clinical trials, orthodontics

1 | INTRODUCTION

Orthodontic miniscrews have been increasingly used in orthodontic treatments in order to overcome the problems of loss of anchorage and low compliance in wearing extra-oral appliances, and they provide a key contribution in increasing overall treatment efficacy and efficiency.[1-3] A number of clinical studies and reviews have investigated the stability of orthodontic miniscrews for acting as stable anchor units, and their validity is recognized and accepted.[4,5]

Nevertheless, compared with endosseous implants, they have a higher failure rate, ranging from 16.4% to 39%[6,7]; according to a systematic review and meta-analysis, the average failure rate is actually believed to be less than 20%.[8] According to another recent study, the overall failure rate for acid-etched and machined surface miniscrews would be 11.2%.[9] Moreover, 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%.[10] In the study of Haddad and Saadeh, failure rates were 10% for the maxilla and 19.6% for the mandible.[11]

Many factors have been proposed to be associated with the success rate of miniscrews; among these are age, gender, mandibular plane angle, jaw (maxilla or mandible), anatomical characteristics of the insertion site, tissue mobility (firm or movable tissue), inflammation, distance to the root, type, length and diameter of the miniscrew.[4,5,12-14] Technique-related factors play a role as well: among them we include the method of placement, maximum insertion torque (MIT) and loading.[15,16] A maximal insertion torque of 10 to 15 Ncm was deemed optimal for miniscrews success, with greater amounts reportedly causing stress, necrosis and local ischaemia,[15,17] even though insertion torque values did not result in predictions for long-term stability.[18] However, an experimental study found that bone properties are more important than the screw geometry in establishing primary mechanical retention,[19] and insertion torque values still provide an indirect clinical measurement of bone characteristics.[16,19-22]

Recently, a randomized clinical trial was focused on insertion and removal torque of immediately loaded and delayed miniscrews in order to understand how bone adapts to immediate force applied to orthodontic miniscrews in a short period. The study found no association between MIT and the loading time (immediate or 1-week delayed), but there were statistically significant effects of the miniscrew location (maxilla or mandible) and the measurement times on the MIT.[23] MIT variation across time can be interpreted under the consideration that once the miniscrew is inserted into the bone, a so-called relaxation phenomenon occurs.[24] This relaxation takes part in the early bone response (approximately up to 11 days) and is due to bone viscoelastic properties.[25] Its effects interact with those of the bone remodelling cycle in determining bone mechanical properties and until new mineral content is organized, the result is a loosening of the bone contacting the screw with a consequent decrease of primary stability in the early weeks.

To the best of our knowledge, there are no human studies on torque values that consider different post-placement times, sites and miniscrew purposes. The aim of the present randomized controlled trial is to compare torque recordings of immediately loaded orthodontic miniscrews between insertion time and three different post-placement timepoints (2 weeks, 4 weeks and removal time, respectively) and, secondarily, to describe any possible association of sex, age and placement sites with torque values. The null hypothesis is that all timepoints show similar torque recordings.

2 | MATERIALS AND METHODS

2.1 | Trial design and any changes after trial commencement

This clinical trial was designed as parallel with an allocation ratio of 1:1.

2.2 | Participants, eligibility criteria and settings

Eligibility criteria to enrol patients were as follows: need of fixed orthodontic treatment to both arches, need of skeletal anchorage using miniscrew, absence of systemic diseases and absence of using drugs altering bone metabolism. All patients were consecutively treated in a private practice and the miniscrews were placed by the same author (LA), while all data collected in this study were analysed at the University of Genova (Genova, Italy). All procedures were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

2.3 | Interventions

All patients received as intervention an orthodontic multibracket treatment, and miniscrews were planned for each patient to improve biomechanics efficiency and effectiveness.

The devices used in this trial were the STORM (LANCER orthodontics), 2.0 mm diameter and 10 mm length. All miniscrews underwent inter-radicular placement and they were placed in the maxilla or in the mandible, palatally or buccally. The inclination was approximately normal to the bone surface; the screws were inserted in the attached gingiva and at least 5 mm away from the interdental apical bone level. Intraoral radiographs were used for all the screws and for palatal insertion, we also used a CBCT.

No pre-drilling of the insertion site was performed and MIT was measured in Ncm at insertion time in all patients by a torque wrench (narrow right angle square driver tip, BIOMET 3i, Spain). Considering that MIT values can be observed in the early phase as well as at the end of insertion, MIT was not considered to be the final torque value, but rather the maximum value observed during placement. An alternative to evaluate the anchorage device's stability can be represented by the mean of resonance frequency analysis (RFA) with a dedicated instrument. As previously reported, no correlation has been found between MIT and RFA values, thus, to evaluate implants or miniscrews stability both can be effective. In this research, the use of MIT was preferred considering the possibility of obtaining information also during insertion of the devices into the bone.[26]

Miniscrews were loaded immediately after the insertion and were used for distalization, intrusion, extrusion and mesialization. In about half the cases, miniscrews were used for indirect anchorage; no auxiliary arms were applied on miniscrews (Table 2). Patients enrolled in the study were randomly assigned to one of three groups. The screw torque was measured again after 2 weeks and after 4 weeks in Groups 1 and 2, respectively. At the end of the treatment, maximal removal torque was evaluated in Group 3. In the first and second groups, MIT was measured again by tightening the screw a quarter of a turn 2 weeks and 4 weeks after insertion, respectively, while in the third group torque was measured as removal torque after a minimum period of 180 days. In a previous study, a quarter of turn was performed 1 week post-placement and no adverse effect on the stability was reported.[23]

Allocation of patients to the three groups was determined by a computer-generated randomization list using Rv3.0.1 software.[27] The applied biomechanics were for different purposes. The clinician who placed the miniscrews was the same who measured and registered data (LA). Miniscrews that lost primary stability and had to be removed were defined as failures.

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

Torque variation in the first 4 weeks was considered the primary outcome. We considered as a secondary outcome: (a) the association among the insertion site (mandibular or maxillary, vestibular or palatal) and the MIT values and (b) the assessment of adverse effects of these interventions.

2.5 | Sample size calculation, power of the study

Eleven patients achieved 85% power to detect a miniscrew maximum insertion torque (MIT) mean of paired differences of 6.84, with an estimated standard deviation of differences of 5.14 and with a significance level (alpha) of .05 using a paired t test.

The sample size calculation was performed on the basis of results from a previous study.[23]

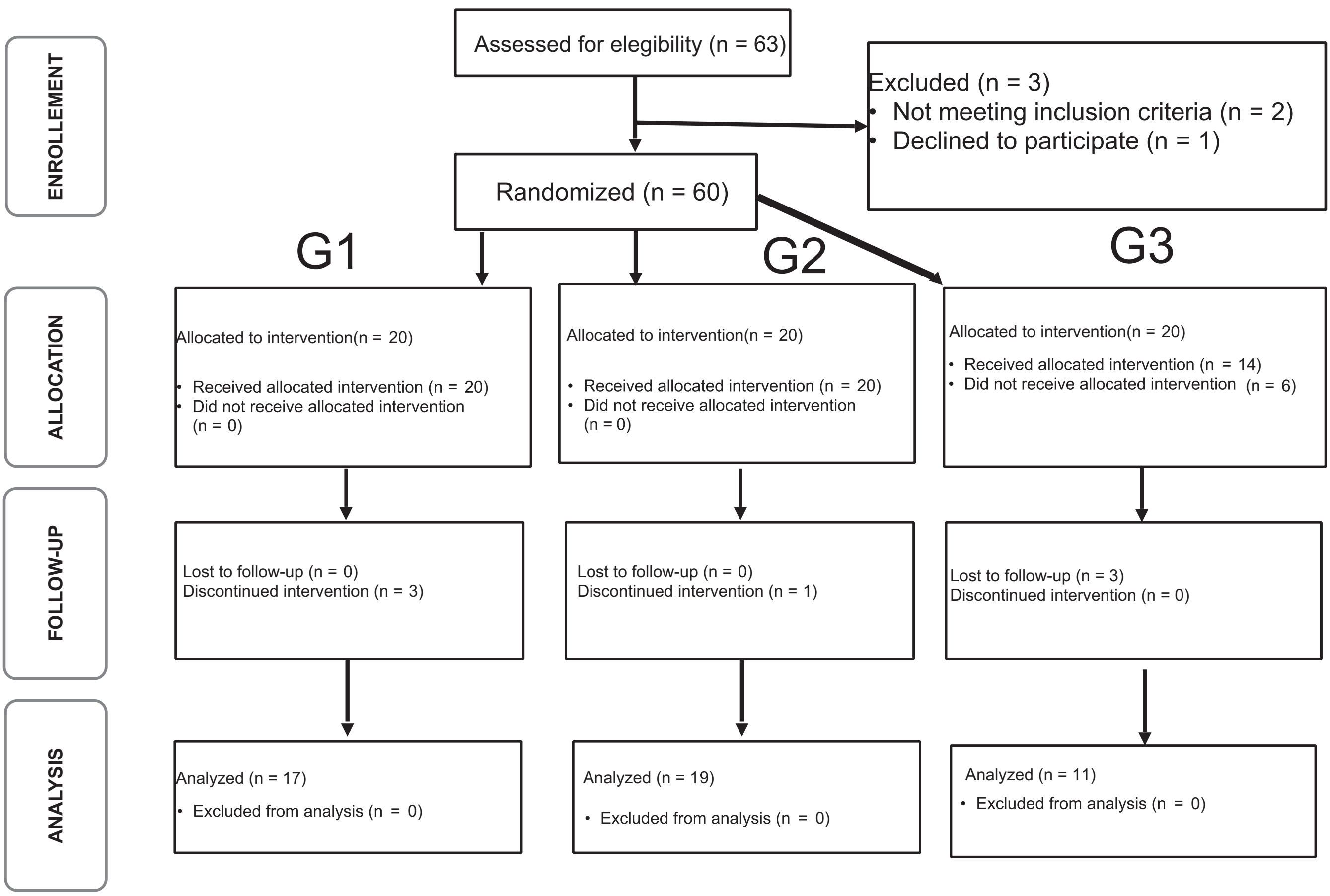

FIGURE 1 Study flow chart

2.6 | Interim analyses and stopping guidelines

Not applicable.

2.7 | Randomization

Patients were enrolled in three groups using a computer-generated randomization list with an allocation ratio of 1:1 and by a block size of 3. The randomization list was obtained by the R v3.0.1 software environment.[27]

2.8 | Blinding

Data were recorded and blinded for the statistician: blinding was obtained by eliminating from the elaboration file every reference to the received intervention.

2.9 | Statistical analysis

Continuous variables are given as means—standard deviations (SD) and range—whereas categorical variables are given as the number and/or percentage of subjects. Age was categorized using quartiles of the age distribution of our study population (9 to ≤ 11, >11 to ≤ 16, >16 to ≤ 33, >33 to 57). The MIT baseline differences among age, gender, purpose of miniscrews, miniscrew location (maxilla or mandible) and miniscrew position (lingual or buccal) were tested by the linear mixed-effects (LME) model.

In order to investigate the associations of the miniscrew MIT with observation times, age, gender, purpose of miniscrews and miniscrew position (lingual or buccal), the LME model was separately performed in each arch (maxilla and mandible). The analysis of the MIT Relative Differences (RD) was performed to test whether the RD means in groups were different comparing baseline vs the measurement time of each group.

TABLE 1 Demographic and clinical MIT values at the baseline

	N	Mean ± SD (Nmm)	Beta	Lower CI	Upper CI	LR-adjusted *P* value
Age (years)						
9 to ≤ 11	24	25.92 ± 8.41	0	—	—	.0018
>11 to ≤ 16	16	30.53 ± 7.18	4.87	−1.57	11.30	
>16 to ≤ 33	17	30.94 ± 9.21	5.10	−1.03	11.22	
>33	17	29.88 ± 8.59	4.25	−2.26	10.76	
Gender						
Female	39	30.74 ± 9.42	0	—	—	.0246
Male	35	27.03 ± 6.93	−2.93	−7.57	1.70	
Location						
Mandible	18	35.83 ± 10.52	0	—	—	<.0001
Maxilla	56	26.79 ± 6.41	−10.69	−14.40	−6.99	
Position						
Lingual	38	27.37 ± 8.12	0	—	—	.0232
Buccal	36	30.69 ± 8.64	2.96	−0.98	6.91	
Purpose						
Distalization	4	25.75 ± 0.96	0	—	—	<.0001
Distalization and intrusion	4	28.50 ± 3.11	3.98	−8.46	16.42	
Intrusion	14	33.21 ± 10.36	9.41	0.39	18.43	
Indirect anchorage	38	26.79 ± 7.69	2.36	−5.73	10.46	
Extrusion	4	30.50 ± 6.14	5.50	−5.87	16.87	
Mesialization	10	32.30 ± 10.20	7.59	−2.18	17.36	
Group						
Group 1	27	28.81 ± 9.95	0	—	—	.5838
Group 2	30	27.77 ± 8.19	−0.15	−5.48	5.19	
Group 3	17	31.41 ± 6.08	2.82	−3.39	9.03	

Abbreviations: Beta, regression coefficient of the linear mixed-effects models; Lower CI, 95% lower confidence interval; LR-adjusted *P* value, likelihood ratio *P* value adjusted by using Bonferroni method; Mean ± SD, mean and standard deviation; N, number of observations; Upper CI, 95% upper confidence interval.

Baseline torque values were categorized using quartiles of the baseline torque distribution (13 to ≤ 24,>24 to ≤ 27, >27 to ≤ 34, >34 Ncm). The frequency distribution of the observed success (defined as the capability of serving as an anchorage unit for a minimum period of 180 days) among the gender of the patients, age, miniscrew location (maxilla or mandible), miniscrew position (palatal/lingual or vestibular), baseline torque values, purpose and groups were calculated and evaluated by the Fisher's exact test; the failure rate differences among clinical (placement site, baseline torque values) or demographic (sex, age) characteristics and groups were tested by the generalized linear mixed-effects model.

The likelihood ratio (LR) test was used as a test of statistical significance, and in each LME model, the sampling units were considered to be random factors. Differences with a *P* value <.01 were selected as significant. Data were acquired and analysed in the R v3.4.4 software environment.[27]

3 | RESULTS

3.1 | Participants flow

In this trial, 60 patients were randomly assigned to the interventions. The final sample that received the intended treatment and analysis included 47 patients and 74 miniscrews (Figure 1). The mean miniscrew duration was 282 days, and the minimum was 185 days. The miniscrews used for analysis were 28 for group 1, 29 for group 2 and 17 for group 3. The recruitment started in January 2016 and the observation period ended in June 2019.

3.2 | Baseline data

The baseline MIT distribution in the levels of the age, gender, location, position and purpose of miniscrews with a summary of the used tests are reported in Table 1. The mean MIT at T0 was 28.99 Ncm (SD = 8.49). Regarding miniscrew location, the MIT mean values at T0 were 26.79 Ncm (SD = 6.41) and 35.83 Ncm (SD = 10.52) for the maxillary and mandibular arch, respectively. Group 1 showed a MIT mean of 28.81 Ncm (SD = 9.95) while a mean of 27.77 Ncm (SD = 8.19) was observed in group 2 and a mean of 31.41 Ncm (SD = 6.08) was observed in group 3 (Table 1).

No significant MIT baseline differences among gender, position and groups were detected (Table 1, LR-adjusted *P* values: .0246, .0232 and .5838). Comparing the MIT baseline mean in the mandibular arch with that in the baseline maxillary arch, a 10.69 Ncm significant difference was observed (Table 1, LR-adjusted *P* value <.001).

Demographic and clinical characteristics of the treatment groups at baseline are reported in Table 2.

The torque value distribution according to age categories is reported in Figure 2A.

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

The MIT mean in group 1, group 2 and group 3 was 19.58 Ncm (SD = 4.05), 25.75 Ncm (SD = 9.16) and 25.54 Ncm (SD = 16.11), respectively, in the maxilla; 25.00 Ncm (SD = 9.35), 25.20 Ncm (SD = 8.41) and 29.50 (SD = 21.24) in the mandible (Figure 2B,C). The LME model performed separately for each location (Table 3 and 4) demonstrated that an association existed between MIT and the observation time (LR-adjusted *P* value <.0001); in particular, comparing MIT to the baseline, about a − 5.04 Ncm significant RD (95% CI: −8.74; −1.33) was observed in group 1 in the upper arch and about a −12.70 Ncm RD was observed in group 1 in the lower arch.

Moreover, there were statistically significant effects of the miniscrew purpose on the MIT in the maxilla (LR-adjusted *P* values: <.0001), and there were statistically significant effects of the miniscrew purpose and position in the mandible (LR-adjusted *P* values: <.0001 and = .0088, respectively). In both arches, there were statistically significant effects of the age of the patient on the MIT (LR-adjusted *P* values: <.0001 and = .0007). With regard to

TABLE 2 Demographic and clinical characteristics of groups

	Groups			
	Group 1	Group 2	Group 3	Observed total
Age (years)				
9 to ≤ 11	7	15	2	24
>11 to ≤ 16	5	7	4	16
>16 to ≤ 33	9	4	4	17
>33	7	3	7	17
Gender				
Female	19	11	9	39
Male	9	18	8	35
Purpose				
Distalization	2	1	1	4
Distalization and intrusion	3	0	1	4
Intrusion	7	3	4	14
Indirect anchorage	14	21	3	38
Extrusion	1	1	2	4
Mesialization	1	3	6	10
Miniscrew location				
Maxilla	19	24	13	56
Mandible	9	5	4	18
Miniscrew position				
Palatal/Lingual	11	21	6	38
Buccal	17	8	11	36

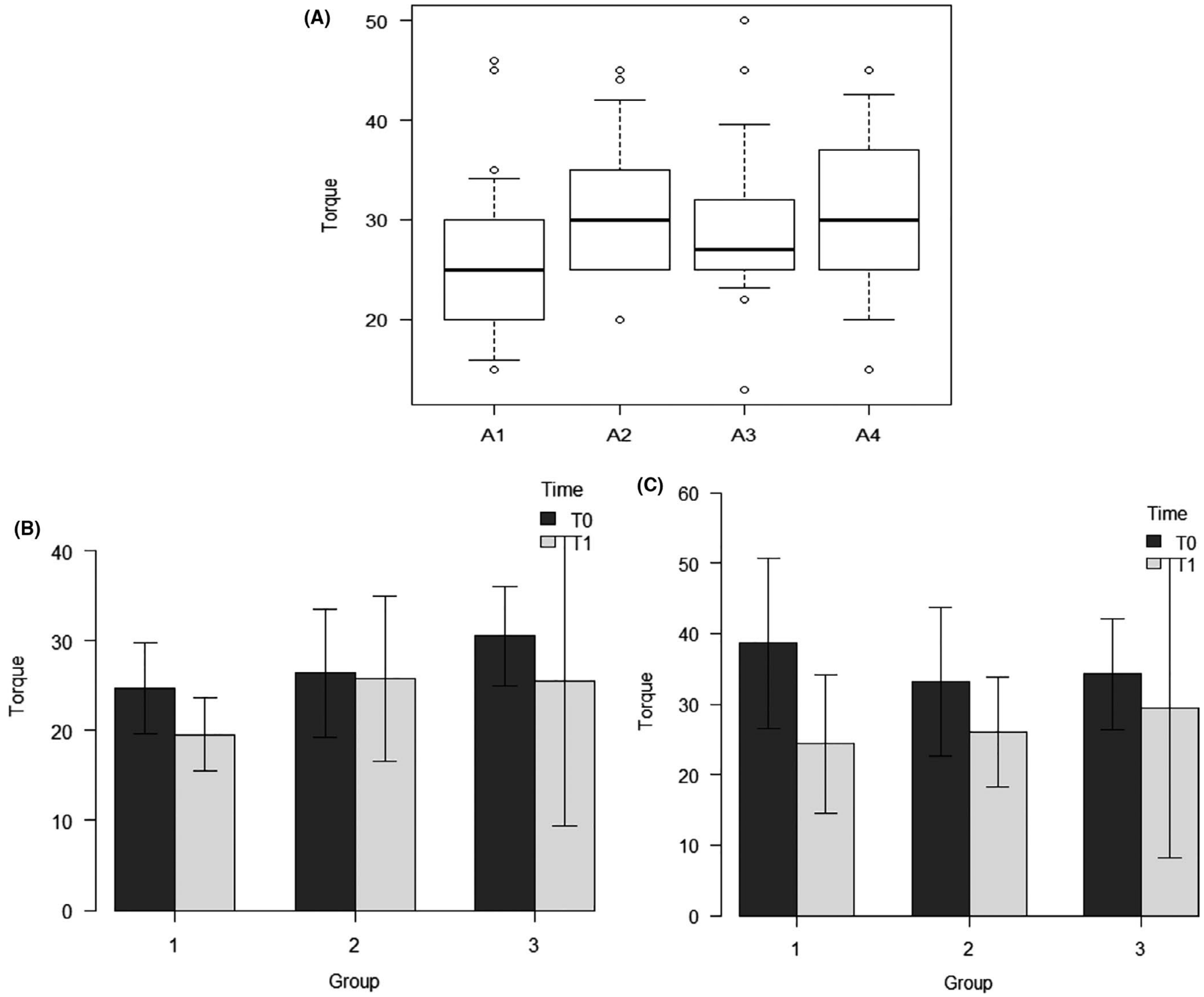

FIGURE 2 (A) Torque value distribution (Ncm) at baseline according to Age categories. A1: 9 to ≤ 11 y, A2: >11 to ≤ 16 y, A3: >16 to ≤ 33 y; A4: >33 y. (B) Torque value distribution (Ncm, mean and SD) in the different groups in the maxilla. (C) Torque value distribution (Ncm, mean and SD) in the different groups in the mandible. T0: baseline; T1: measurement time

the miniscrew position, a −3.34 Ncm decrease (95% CI: −9.10; 2.42) was observed in the maxilla comparing the MIT mean in the buccal position with that in the palatal position (Table 3), but a 5.49 Ncm increase was observed in the mandible comparing the MIT mean in the buccal position with that in the lingual position (Table 4).

The overall success rate was 79.7%. In particular, 81.5% was observed for group 1 while a success rate of 73.3% was estimated for group 2 and 88.2% for group 3. No statistically significant difference was found (*P* value = .456, data not shown) among groups.

There were no frequency distribution differences of the observed success among the gender of the patients, age, miniscrew location (maxilla or mandible), miniscrew position (palatal/lingual or vestibular), baseline torque values and groups.

3.4 | Harms

No serious harm was observed, but 10 miniscrews showed peri-inflammation, for which therapy was the application of chlorhexidine gel or spray twice a day (Corsodyl, GlaxoSmithKline, Brentford, UK).

4 | DISCUSSION

4.1 | Limitations and generalizability

This study was performed on a variety of insertion sites and biomechanical purposes, with different types of orthodontic loads, such as direct and indirect anchorage, which may have different effects on the torque values. No quantitative data on bone

TABLE 3 Descriptive statistics and output of linear mixed-effects model in the upper arch

	N	Mean ± SD (Nmm)	Beta	Lower CI	Upper CI	LR-adjusted	Post hoc analysis: Contrast	Post hoc analysis: *P* value
Group								
Baseline	56	26.79 ± 6.41	0	—	—	<.0001	Group 1 vs Baseline	<.0001
Group 1	19	19.58 ± 4.05	−5.04	−8.74	−1.33		Group 2 vs Baseline	.5625
Group 2	24	25.75 ± 9.16	−1.25	−4.59	2.10		Group 3 vs Baseline	.6518
Group 3	13	25.54 ± 16.11	−4.02	−8.43	0.38			
Age (years)								
9 to ≤ 11	46	24.35 ± 7.25	0	—	—	.0007		
>11 to ≤ 16	22	27.00 ± 9.21	5.44	−2.32	13.22			
>16 to ≤ 33	26	25.23 ± 7.22	0.58	−8.71	9.88			
>33	18	25.11 ± 12.82	−5.06	−15.49	5.38			
Gender								
Female	50	23.98 ± 7.61	0	—	—	.0414		
Male	62	26.18 ± 9.39	1.63	−4.18	7.43			
Position								
Lingual	70	25.23 ± 8.45	0	—	—	.023		
Buccal	42	25.14 ± 9.14	−3.34	−9.10	2.42			
Purpose								
Distalization	6	22.00 ± 4.29	0	—	—	<.0001		
Distalization and intrusion	8	23.62 ± 7.91	3.74	−12.10	19.58			
Intrusion	18	24.67 ± 11.73	−0.60	−11.53	10.33			
Indirect anchorage	64	24.83 ± 7.61	−3.95	−15.81	7.90			
Extrusion	4	31.00 ± 14.76	1.67	−10.94	14.28			
Mesialization	12	28.67 ± 8.57	5.85	−4.17	7.43			

Note: All *P* values were adjusted by using Bonferroni method.

Abbreviations: Beta, regression coefficient of the linear mixed-effects models; Contrast, contrast taken into account; Lower CI, 95% lower confidence interval; LR-adjusted *P* value, likelihood ratio *P* value; Mean ± SD, mean and standard deviation; N, number of observations; *P* value; *t* test *P* value; Upper CI, 95% upper confidence interval.

quality or root proximity to miniscrew were available (no CBCT on patients).

The present study considered only maximum insertion torque. The measuring of torque in a continuous mode during the entire insertion path, a measure that allows for an understanding of when MIT is encountered and which can only be obtained with digital torque recorders, was not included in the present study. Furthermore, the measuring of torque in group 3 (unscrewing) is a different procedure from that of groups 1 and 2.

The study was focused on 2 mm diameter miniscrews; comparison with other TADs with smaller diameter can be considered even though the diameter is known to be a fundamental parameter for primary stability; nevertheless, even if the absolute torque values can be different from other screw diameters, the percentage of torque variation (primary stability) can be evaluated similarly.

4.2 | Main findings and interpretation

The present study showed that there is a torque loss of 26.9% with regard to the baseline in the upper arch and of 30.0% in the lower arch in the first 2 weeks. If we put this information together with the results of a previous study,[23] we see that the highest torque loss occurs in the first week and that the trend is inverted before completion of the second week. Thus, the lowest bone-to-screw contact is not found during the second week; this interpretation is consistent with what we know from the literature on bone viscoelastic properties, which is that a relaxation phenomenon occurs every time the bone remains in a deformed position, such as after miniscrew insertion. Over time, the initial tensile state is reduced, very quickly at the beginning (10^4 seconds), and very slowly in the subsequent period, taking times of the order of 10^6 seconds

TABLE 4 Descriptive statistics and output of linear mixed-effects model in the lower arch

	N	Mean ± SD (Nmm)	Beta	LR-adjusted *P* value	Post hoc analysis Contrast	*P* value
Group						
Baseline	18	35.83 ± 10.52	0	<.0001	Group 1 vs Baseline	.0150
Group 1	9	25.00 ± 9.35	−12.70		Group 2 vs Baseline	.0508
Group 2	5	25.20 ± 8.41	−9.19		Group 3 vs Baseline	.3786
Group 3	4	29.50 ± 21.24	−5.47			
Age (years)						
9 to ≤ 11	6	40.00 ± 10.22	21.09	<.0001[a]		
>11 to ≤ 16	6	32.33 ± 12.75	13.03			
>16 to ≤ 33	8	28.12 ± 14.27	3.37			
>33	16	28.44 ± 10.68	6.13			
Gender						
Female	28	31.86 ± 12.97	0	.0107		
Male	8	27.75 ± 8.40	2.64			
Position						
Lingual	6	33.17 ± 12.91	0	.0088		
Buccal	30	30.50 ± 12.14	5.49			
Purpose						
Distalization	2	15.00 ± 16.97	0	<.0001		
Intrusion	10	33.20 ± 14.34	22.31			
Indirect anchorage	12	28.92 ± 10.18	14.53			
Extrusion	4	30.50 ± 3.32	16.66			
Mesialization	8	35.38 ± 12.30	11.12			

Note: All *P* values were adjusted by using Bonferroni method.

Abbreviations: Beta, regression coefficient of the linear mixed-effects models; Contrast, contrast taken into account; LR-adjusted *P* value, likelihood ratio *P* value; Mean ± SD, mean and standard deviation; N, number of observations; *P* value; *t* test *P* value.

[a]Due to convergence problems, the likelihood ratio-adjusted *P* value for age was calculated with only patients considered to be random factor.

to complete.[25] Then, relaxation completion (11.6 days) is roughly comparable with the remodelling cycle in bone, and the study of the two overlapping effects is very difficult. Maybe for this reason, a comprehensive analysis of the mechanical behaviour of miniscrew implants and the viscoelastic response of the surrounding osseous structures for different directions of force application has been carried out mainly with in vitro studies and finite element analysis.[28] In conclusion, we may retain that torque values of orthodontic miniscrews decrease during the first 2 weeks and regain similar initial torque values after 4 weeks.

Removal torque values after 180 days (Group 3) resulted almost the same as the initial torque and it would probably have shown a similar value after 4 weeks only. This interpretation is in contrast with that of Sharifi et al, in fact their study on removal torque in the first 6 weeks showed a reduced value,[29] a finding that is in accordance with previous literature.[30,31] A different analysis could be performed considering the surface type of minsicrews. In fact, according to a recent animal study on the removal torque values at 1, 2, 4, and 8 weeks after placement of 1.6 mm diameter miniscrews, the removal torque of machined miniscrews was significantly decreased at 4 weeks compared with the previous measurements, while in the etched group, it was significantly increased at 4 weeks. Meanwhile, for blasts treated with calcium phosphate, except for the lower 1/3 of the cutting edge, the removal torque began to significantly increase at 2 weeks, and this trend persisted to 8 weeks.[32]

Another finding of the present study is an estimation of the average baseline insertion torque for miniscrews that could serve as a reference in the upper and lower arch. Torque insertion values depend on geometrical characteristics, such as the diameter and the shank shape (tapered or not), but the present values can be taken into account for a 2.0 mm diameter tapered miniscrew. It is known that insertion torque values do not result in predictions for long-term stability,[17] and the present study found no association between baseline torque values and success. However, reference values may help to assess as a diagnostic test for root contact (a previously published study showed that miniscrews with root contact have different insertion torque values compared with those without)[33] and have less adverse effects than radiographic images.[34]

Associations of clinical and demographic characteristics with success were investigated as well. Significantly higher success rates were reported in the literature for miniscrews inserted in the maxilla, for patients ≥20 years of age and for long miniscrews (≥8 mm) and miniscrews with a large diameter (>1.4 mm). Increasing age was positively related to success and the found OR in the maxilla was comprised of the values previously reported by prospective and retrospective studies,[35] but their association with success was not significant. This could be due to the fact that the present study was not sized to detect differences in success rate, in fact assessing differences in a percentage outcome would require a much larger sample.

5 | CONCLUSION

The present clinical study focused on the primary stability observation of directly inserted miniscrews in both arches. The trend of the stability curve can be comprehensively described in the first month, with a tendency of torque values to decrease from the insertion time until the second week and to regain a similar insertion torque value after 4 weeks.

In particular:

1. 2 weeks after TADs insertion, torque values decreased 26.9% and 30.0% for maxillary and mandibular insertion sites, respectively.
2. 1 month after TADs insertion, torque showed similar values to baseline measurements.
3. Maximum removal torque showed values close to baseline data while the miniscrews' overall success rate was 79.7%.

CONFLICT OF INTEREST

The authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS

Conceptualization: Marco Migliorati. Formal Analysis: Sara Drago. Investigation: Leonardo Amorfini. Methodology: Marco Migliorati, Leonardo Amorfini. Supervision: Armando Silvestrini-Biavati. Writing—original draft: Marco Migliorati and Sara Drago. Writing—review and editing: Riccardo Nucera and Armando Silvestrini-Biavati.

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