Assessment of the rate of premolar extraction space closure in the maxillary arch with the AcceleDent Aura appliance vs no appliance in adolescents: A single-blind randomized clinical trial

Peter Miles,[a] Elizabeth Fisher,[b] and Nikolaos Pandis[c]
Greensburg, Pa; Caloundra, and Brisbane, Queensland, Australia; Bern, Switzerland, and Corfu, Greece

Introduction: The purpose of this 2-arm parallel trial was to assess the effect of the AcceleDent Aura appliance (OrthoAccel Technologies, Houston, Tex) on the rate of maxillary premolar extraction space closure in adolescent patients. **Methods:** Forty Class II adolescents treated with full fixed appliances and maxillary premolar extractions participated in this randomized clinical trial. They were recruited in a private practice and treated by 1 clinician. Randomization was accomplished in blocks of 10 patients assigned to either a no-appliance group or the AcceleDent Aura appliance group with the allocations concealed in opaque, sealed envelopes. Both the operator and the outcome assessor were blinded; however, it was not feasible to blind the patients. Models were taken of the maxillary arch at the start of space closure and just before complete space closure. The space was measured parallel to the occlusal plane from the cusp tips of the teeth mesial and distal to the extraction spaces. **Results:** There was no clinically (0.05 mm per month; 95% confidence interval [CI], –0.24, 0.34) or statistically significant difference in the rate of space closure ($P = 0.74$). In both the univariable and multivariable analyses, the mean rate of tooth movement was slower by 0.13 mm per month (95% CI, –.26, .005) on the left side compared with the right side, but this was not statistically significant ($P = 0.06$). **Conclusions:** The AcceleDent Aura appliance had no effect on the rate of maxillary premolar extraction space closure. Only a few participants were considered to be good compliers with the appliance. However, the rate of space closure in the good compliers was similar to the overall group and did not appear to influence the result. **Registration:** This trial was not registered. **Protocol:** The protocol was not published before trial commencement. (Am J Orthod Dentofacial Orthop 2018;153:8-14)

As professionals, orthodontists aim to deliver a quality outcome for their patients; as business people, we would like to deliver that in an expeditious and cost-efficient manner. Not surprisingly, there is a demand by the public for shorter treatment times, with parents wanting treatment completed in 12 to 18 months, although adolescent patients would like it completed in 6 months or less.[1] Traditionally, orthodontic treatment involved 2 or more years in fixed appliances[2]; more recently, it has been reported to have shortened to less than 2 years.[3] This is longer than many patients would prefer, so to cater to this demand there are several appliances and techniques, both surgical and nonsurgical, currently claiming to accelerate tooth movement and thereby shorten orthodontic treatment. Unfortunately, the paucity of clinical research evaluating their efficacy is of low quality.[4,5]

It is known that treatment involving extractions in general results in longer treatment times.[6,7] If it were possible to accelerate the rate of extraction space closure, this would obviously be a desirable outcome,

[a]Center for Orthodontics, Seton Hill University, Greensburg, Pa; private practice, Caloundra, Queensland, Australia.
[b]Private practice, Brisbane, Queensland, Australia.
[c]Department of Orthodontics and Dentofacial Orthopedics, School of Dental Medicine/Medical Faculty, University of Bern, Bern, Switzerland; private practice, Corfu, Greece.
All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and none were reported.
Address correspondence to: Peter Miles, 10 Mayes Ave., Caloundra QLD 4551, Australia; e-mail, pmiles@newwaveorthodontics.com.au.
Submitted, June 2017; revised and accepted, August 2017.
0889-5406/$36.00

http://dx.doi.org/10.1016/j.ajodo.2017.08.007

especially if it could be accomplished in a noninvasive manner. Microvibration has been reported in a retrospective, unblinded study to result in a 30% increase in the rates of leveling and alignment with the AcceleDent appliance (30 Hz, 0.2 N or about 20 g).[8] However, authors of 2 prospective randomized clinical trials using the AcceleDent appliance during initial alignment with fixed appliances found no differences in the time for leveling or alignment.[9,10] Authors of a clinical trial supported by a research grant from OrthoAccel Technologies (Bellaire, Tex) when evaluating the AcceleDent appliance during maxillary canine retraction reported an accelerated rate of canine retraction in the appliance group.[11] However, there are potential concerns with the methodology used in that study because the rate of movement was measured directly in the mouth and from a miniscrew/temporary anchorage device, which is a potentially unstable landmark, and also diagonally and therefore not a true indicator of space closure. See Supplemental Materials for a short video presentation about this study.

Specific objectives or hypotheses

The primary purpose of this study was to assess any possible effect of the AcceleDent Aura appliance (OrthoAccel Technologies, Houston, Tex) when closing maxillary premolar extraction spaces in the treatment of adolescent patients. The null hypothesis is that the AcceleDent Aura appliance does not increase the rate of maxillary premolar extraction space closure.

MATERIAL AND METHODS

Trial design and any changes after trial commencement

This was the second part of an ongoing single-center, randomized clinical trial with a 1:1 allocation.[10] No changes occurred during the trial.

Participants, eligibility criteria, and settings

Ethical approval was obtained from the Dental Sciences Research Ethics Committee (project number 1315) of the University of Queensland in Brisbane, Australia, and written informed consent was obtained from all patients and parents. A special research grant was obtained from the Australian Society of Orthodontists Foundation for Research and Education to purchase the AcceleDent Aura appliances. Details of the experimental design, study groups, and treatment methods were published in the earlier article.[10] Adolescent patients up to the age of 16 years who were planned to have maxillary first or second premolars extracted and no mandibular extractions for the treatment of a Class II malocclusion were eligible for inclusion.

Sample size calculation

As previously described, a power analysis based on the arch perimeter data from an unpublished study from the University of Texas Health Science Center at San Antonio (means, 1.32 mm per week [SD, 1] vs 2.71 mm per week [SD, 1.42]) indicated that a sample size of 17 subjects per group (n = 34) would be required to have 90% power at $P = 0.05$.[10] It was therefore decided to enroll 20 participants per group (n = 40). A separate power analysis based on the same study and using the data for space closure in adolescents (0.25 mm per week [SD, 0.08]) and aimed at saving a clinically meaningful 2 months of treatment time when closing a 6-mm extraction space indicated that a sample size of only 7 participants per group would be required.

Randomization (random number generation, allocation concealment, implementation)

Randomization was performed with permuted blocks of 10 randomly generated numbers using the random generation function in Excel (Microsoft, Redmond, Wash) that were sealed in opaque envelopes and shuffled by a staff member. Clinical assistants opened the envelopes for group assignments after the brackets were bonded during routine instructions in a closed consultation room to ensure that the operator was blinded.

Blinding

The patients were aware of their treatment group, whereas both the operator (P.M.) and the model assessor (E.F.) were blinded to the treatment groups and the model time points.

Interventions

Each eligible patient was randomly assigned to either a group using the AcceleDent Aura appliance for 20 minutes per day or a group receiving no appliance. All patients were indirectly bonded with conventional 0.018-in slot, MBT prescription brackets (Victory Series; 3M Unitek, Monrovia, Calif) on all mandibular teeth and the maxillary premolars and molars, whereas the maxillary incisors and canines were bonded with MBT equivalent prescription self-ligating In-Ovation C ceramic brackets (GAC International, Bohemia, NY). The maxillary first or second premolars were extracted after the brackets were placed but before placement of the second 0.016 × 0.022-in M5 Heaters thermal nickel-titanium wire (G&H Wire, Franklin, Ind). Approximately 10 weeks later, a 0.016 × 0.022-in stainless steel wire with soldered posts (G&H Wire) was placed and allowed to align for 5 weeks, and an elastomeric chain was placed to consolidate the anterior 6 or 8 teeth depending

on which premolar was extracted. At the next visit, photos and alginate impressions of the maxillary arch were taken for the baseline data. In subjects having extractions of first premolars, the second premolar was tied with a stainless steel ligature that was left in place until the extraction space was closed. A 9-mm nickel-titanium medium Sentalloy coil spring (GAC International) was placed across the extraction sites from the bracket hook on the first molar, and the spring was activated between 6 and 9 mm and then ligated with a stainless steel ligature to the archwire hook mesial to the canine as per a previous study to deliver approximately 150 g, confirmed with a Dontrix gauge (E.T.M. Corporation, Monrovia, CA).[12] Based on how much space remained to be closed, patients were recalled at 5- to 8-week intervals to reactivate the coil spring. New alginate impressions were taken when the spaces on 1 side or both sides of the arch were almost but not fully closed; this was considered the end-point for this study.

Outcomes and any changes after trial commencement

The primary outcome of the study was the rate of space closure. The models were measured parallel to the occlusal plane from the cusp tips of the teeth mesial and distal to the extraction spaces. The rate of space closure was calculated by deducting the final measurement from the initial distance and dividing by the time interval. This yielded a rate of space closure for each side in millimeters per month. As in part 1 of this trial, patients assigned to the appliance group were asked to bring their AcceleDent Aura appliance for the staff to download the data from the appliance that recorded their daily usage during the period of space closure. Patients who used the appliance 75% of the time or more were considered to be good compliers.

Interim analyses and stopping guidelines

Not applicable.

Statistical analysis

Descriptive statistics on demographic and clinical parameters were calculated. To account for the correlated nature of the data during the simultaneous analyses of the right and left extraction space closure rates, univariable and multivariable random effects linear regression analyses were implemented. For all analyses, the dependent variable was the rate of tooth movement in millimeters. In the univariable model, the effect on the rate of tooth movement was assessed individually for each of the following predictors: age at treatment start, sex, extraction pattern, side (left or right), and elastic wear pattern. In the multivariable analyses, the same dependent variable (rate of space closure) was regressed on the same predictors individually after adjusting only for treatment group (AcceleDent or control). Ten randomly selected baseline models of participants were measured again after a 2-week interval. The intraclass correlation coefficients were 0.999 for the left side and 0.998 for the right at the first measurement, and 0.991 and 0.997, respectively, at the second measurement, indicating excellent measurement agreement. All analyses were conducted using statistical software (version 14.2; StataCorp, College Station, Tex).

Table I. Baseline demographics

	AcceleDent n = 20 mean (SD) or %†	*Control n = 20 mean (SD) or %*†	*Total n = 40 mean (SD) or %**
Demographic characteristics			
Age (y)	12.66 (1.19)	13.03 (1.48)	12.84 (1.34)
Sex			
Female	14 (53.8%)	12 (46.2%)	26 (65.0%)
Male	6 (42.9%)	8 (57.1%)	14 (35.0%)
Clinical characteristics			
Extraction pattern			
4	12 (54.5%)	10 (45.5%)	22 (70.0%)
5	8 (44.4%)	10 (55.6%)	18 (30.0%)
Elastic use*			
1	2 (50.0%)	2 (50.0%)	4 (10.0%)
2	12 (46.2%)	14 (53.8%)	26 (65.0%)
3	6 (60.0%)	4 (40.0%)	10 (25.0%)

*Column totals; †Row totals.

Table II. Rate of tooth movement per maxillary side (millimeters per month)

	AcceleDent	*Control*	*Total*
Right side			
n	20	20	40
Mean (SD)	1.41 (0.50)	1.30 (0.61)	1.35 (0.55)
Range	0.69-2.23	0.58-2.57	0.58-2.57
Left side			
n	20	20	40
Mean (SD)	1.25 (0.51)	1.25 (0.46)	1.22 (0.48)
Range	0.42-2.04	0.30-1.88	0.30-2.04

RESULTS

Participant flow

All 40 patients completed this part of the study and were recruited between May 2014 and June 2015. The first sets of impressions for assessing space closure were taken in October 2014 and the final set in July 2016.

Baseline data

Information regarding age, sex, extraction pattern, and elastic use are reported in Table I.

Table III. Estimates, 95% confidence intervals, and *P* values for the rate of tooth movement (millimetres per month) from univariable and multivariable random effects linear regression

	Univariable analysis		*Multivariable analysis**	
Predictor	*β coefficient (95% CI)*	P *value*	*β coefficient (95% CI)*	P *value*
Group				
Control	Reference			
AcceleDent	0.05 (−0.24, 0.34)	0.74		
Group				
Control			Reference	
AcceleDent			0.02 (−0.26, 0.30)	0.89
Age (per year)	−0.08 (−0.19, 0.03)	0.14	−0.08 (−0.19, 0.03)	0.15
Group				
Control			Reference	
AcceleDent			0.04 (−0.25, 0.33)	0.78
Sex				
Female	Reference		Reference	
Male	−0.08 (−0.38, 0.22)	0.62	−0.07 (−0.37, 0.23)	0.64
Group				
Control			Reference	
AcceleDent			0.05 (−0.23, 0.33)	0.73
Extraction				
First premolar	Reference		Reference	
Second premolar	0.16 (−0.13, 0.44)	0.28	0.16 (−0.13, 0.44)	0.28
Group				
Control			Reference	
AcceleDent			0.05 (−0.24, 0.34)	0.74
Side				
Right	Reference		Reference	
Left	−0.13 (−0.26, 0.005)	0.06	−0.13 (−0.26, 0.005)	0.06
Group				
Control			Reference	
AcceleDent			0.03 (−0.26, 0.32)	0.85
Elastics				
1	Reference		Reference	
2	−0.29 (−0.77, 0.19)	0.23	−0.29 (−0.77, 0.19)	0.24
3	−0.18 (−0.71, 0.34)	0.50	−0.19 (−0.72, 0.34)	0.49

*Multivariable analysis adjusted only for treatment group (AcceleDent or control).

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

No impressions were missed for any time point, and all AcceleDent Aura appliances were returned to record compliance data, so no data were missing. Table I shows the similarity in the distributions across treatment groups of the demographic and clinical patient characteristics. Table II displays the mean rates of tooth movement, standard deviations, and ranges for the right and left sides. Table III summarizes the results from the regression analyses. In the univariable analysis, we can see that the use of AcceleDent had no effect on the rate of tooth movement. There was a difference of 0.05 mm (95% CI, −0.24, 0.34) in the rate of tooth movement in favor of AcceleDent; however, this finding was not statistically ($P = 0.74$) or clinically significant. In the multivariable analyses, the effect of treatment after adjusting individually for the other predictors did not alter the results. In both univariable and multivariable analyses, the mean rate of tooth movement was slower by 0.13 mm per month (95% CI, −.26, .005; $P = 0.06$) on the left side compared with the right side.

Compliance was found to drop off markedly during the period of the trial so that only 7 participants (35%) met the criterion of being considered as good compliers by using it 75% of the time or more (Table IV). The mean rates of movement in the good compliers were 1.45 mm per month on the right side of the AcceleDent group and 1.23 mm per month on the left side; these were similar to the total group, and the rate of movement had a similar distribution regardless of the level of compliance (Fig). Although the power analysis showed that only 7 participants were required, considering the low numbers, a separate statistical analysis was not considered appropriate.

Table IV. Compliance with the AcceleDent appliance and rates of space closure on both sides

Compliance (%)	*Left (mm/mo)*	*Right (mm/mo)*
96.8	1.5	1.8
88.3	1.1	2.2
86.5	1.9	1.7
80.2	1.0	0.8
79	1.3	1.5
76.5	0.7	1.0
75	1.4	1.2
71.3	1.5	2.0
69.9	1.2	1.3
56.7	1.4	1.8
53.8	0.5	0.7
49.8	0.6	0.8
40.9	1.9	1.8
27.7	0.6	0.7
23.9	0.4	1.4
23.4	1.9	2.1
9.1	2.0	1.8
7.8	0.9	0.9
0	1.2	1.0
0	1.3	1.8

Harms

No negative outcomes were reported by any participant during the trial.

DISCUSSION

Main findings in the context of the existing evidence, interpretation

It is easy to become excited by the possibility of new appliances and techniques in our desire to deliver more efficient and effective orthodontic treatment for our patients. In the wider medical literature, there is evidence of optimism bias when newly introduced treatments are falsely believed to be superior to the older treatments.[13] Some jump in with fervor and may be considered the pioneers and become key opinion leaders for the manufacturing company, whereas others are more cautious and wait for feedback and evidence. However, as with many new techniques and appliances, those associated with the company usually have the first access to using the appliance clinically and therefore are likely to produce the first publications, but this also leads to a greater potential for bias. The results they produce need to be examined carefully as to the quality of the study design and this potential for bias; otherwise, the results could be misleading. The problem with studies of low quality and a high risk of bias is that our degree of certainty in believing their findings is low. Patients should be informed of this so that they can make a fully informed decision about trying a new technique or device. Otherwise, the practitioner potentially creates a liability for a breach of contract.[14]

In the first part of this prospective randomized clinical trial, the amount of alignment during the first 10 weeks of treatment was examined, and no difference was found.[10] This agreed with a previous prospective randomized controlled trial of the AcceleDent evaluating the mandibular arch's initial and final amounts of alignment in extraction patients.[9] However, the authors of this study only examined the initial stage of treatment, and the argument could be made that the effect of vibration takes time to become apparent and is cumulative so that it may not be clearly evident until a longer interval is examined. We examined a longer interval when any effect should have been more evident. However, our study also suffered from a drop in compliance. As a real-world study, it is not unusual for compliance to fade over time, and the numbers of good compliers were not sufficient to examine in a meaningful manner. It therefore must be examined as a whole, and the findings were that in the overall pool of AcceleDent users, there was no difference in the rates of extraction space closure.

When we examined the combined rates of space closure (left side, 1.22 mm/mo; right side, 1.35 mm/mo), they were commensurate with previous studies or slightly faster. A study examining the use of nickel-titanium coil springs in the 0.022-in appliance (activated no more than 9 mm) demonstrated space closure of 0.81 mm per month.[15] Like this study, the authors concluded that intermaxillary elastics were not a factor in the rate of space closure. Another study also in the 0.022-in appliance and using 9-mm nickel-titanium springs achieved 0.26 mm per week (about 1.1 mm/mo). When examining en-masse space closure in the 0.018-in appliance using nickel-titanium springs, a rate of 1.2 mm per month was shown; this is similar to our study in methodology and rate.[12] Interestingly, when compared with a study reporting accelerated canine retraction over 28 days with microosteoperforations, the accelerated rate of retraction reported at the incisal tip was about 1.3 mm per month; this is also like our study.[16] The trial evaluating canine retraction using the AcceleDent appliance reported a significant 48.1% increased rate of canine retraction.[11] This accelerated rate was 1.16 mm per month compared with the control at 0.79 mm per month. Again, the reported accelerated rate of movement was similar to this trial in both the appliance and control groups. It would therefore seem that, at least in the 0.018-in appliance, these rates of movement are achievable with the conventional methodology applied in this trial without the use of additional devices or surgical intervention. This would ideally be the subject of additional prospective randomized trials in the 0.022-in appliance to

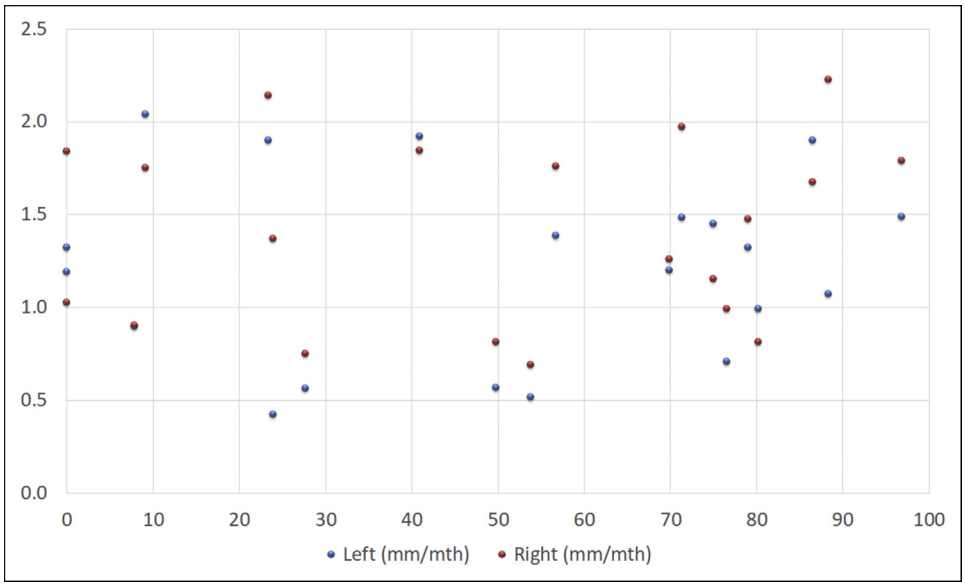

Fig. Plot of movement in mm/month on the left and right sides against the percentage compliance with the AcceleDent appliance.

support this finding. The results of this trial highlight the issue of potential research waste as discussed by Seehra et al.[17] They examined the findings of trials published between 2012 and 2016 that investigated marketed products after their introduction. They found that 44% of those trials did not support the effectiveness claims of the industry. This should encourage the orthodontic industry to seek independent clinical research earlier in the research and development process.[18]

Limitations

The initial sample was 20 participants per group with the power analysis for space closure indicating that only 7 participants were required per group for this portion of the study. Although there were 7 participants who were considered good compliers, considering the small number, this was thought to be unsuitable for a meaningful analysis. Although potentially confounding variables were present, including differing maxillary premolar extraction patterns and elastic use, the analysis showed that these did not interact in a meaningful manner.

Generalizability

Because there is a lack of long-term data on compliance with the AcceleDent appliance, a comparison cannot be made with other studies. Participants were not blinded to the appliance group but the clinician (P.M.) and the assessor (E.F.) were, and our results would be expected to reflect real-world use of the appliance. It would therefore be expected to have generalizability to other adolescent participants with fixed appliances for a Class II malocclusion involving 2 maxillary premolar extractions.

CONCLUSIONS

1. The AcceleDent Aura appliance had no effect on the rate of extraction space closure in the maxillary arch.
2. Although only a few participants were considered good compliers with the appliance, the rate of space closure was similar to the overall group and did not appear to have any influence.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ajodo.2017.08.007.

REFERENCES

1. Uribe F, Padala S, Allareddy V, Nanda R. Patients', parents', and orthodontists' perceptions of the need for and costs of additional procedures to reduce treatment time. Am J Orthod Dentofacial Orthop 2014;145(Suppl):S65-73.
2. Fink DF, Smith RJ. The duration of orthodontic treatment. Am J Orthod Dentofacial Orthop 1992;102:45-51.
3. Tsichlaki A, Chin SY, Pandis N, Fleming PS. How long does treatment with fixed orthodontic appliances last? A systematic review. Am J Orthod Dentofacial Orthop 2016;149:308-18.
4. El-Angbawi A, McIntyre GT, Fleming PS, Bearn DR. Non-surgical adjunctive interventions for accelerating tooth movement in patients undergoing fixed orthodontic treatment. Cochrane Database Syst Rev 2015;(11):CD010887.

5. Fleming PS, Fedorowicz Z, Johal A, El-Angbawi A, Pandis N. Surgical adjunctive procedures for accelerating orthodontic treatment. Cochrane Database Syst Rev 2015;(6):CD010572.
6. Salzmann JA. Handicapping malocclusion assessment to establish treatment priority. Am J Orthod 1967;54:749-65.
7. O'Brien KD, Robbins R, Vig KW, Vig PS, Shnorhokian H, Weyant R. The effectiveness of Class II, division 1 treatment. Am J Orthod Dentofacial Orthop 1995;107:329-34.
8. Bowman SJ. The effect of vibration on the rate of leveling and alignment. J Clin Orthod 2014;48:678-88.
9. Woodhouse NR, DiBiase AT, Johnson N, Slipper C, Grant J, Alsaleh M, et al. Supplemental vibrational force during orthodontic alignment: a randomized trial. J Dent Res 2015;94:682-9.
10. Miles P, Fisher E. Assessment of the changes in arch perimeter and irregularity in the mandibular arch during initial alignment with the AcceleDent Aura appliance vs no appliance in adolescents: a single-blind randomized clinical trial. Am J Orthod Dentofacial Orthop 2016;150:928-36.
11. Pavlin D, Anthony R, Raj V, Gakunga PT. Cyclic loading (vibration) accelerates tooth movement in orthodontic patients: a double-blind, randomized controlled trial. Semin Orthod 2015; 21:187-94.
12. Miles PG. Self-ligating vs conventional twin brackets during en-masse space closure with sliding mechanics. Am J Orthod Dentofacial Orthop 2007;132:223-5.
13. Chalmers I, Matthews R. What are the implications of optimism bias in clinical research? Lancet 2006;367:449-50.
14. Jerrold L. Accelerated orthodontics or accelerated liability? Am J Orthod Dentofacial Orthop 2014;145(Suppl):S148-51.
15. Dixon V, Read MJ, O'Brien KD, Worthington HV, Mandall NA. A randomized clinical trial to compare three methods of orthodontic space closure. J Orthod 2002;29:31-6.
16. Alikhani M, Raptis M, Zoldan B, Sangsuwon C, Lee YB, Alyami B, et al. Effect of micro-osteoperforations on the rate of tooth movement. Am J Orthod Dentofacial Orthop 2013;144:639-48.
17. Seehra J, Pandis N, Fleming PS. Clinical evaluation of marketed orthodontic products: are researchers behind the times? A meta-epidemiological study. Prog Orthod 2017;18:14-9.
18. Powell W, Owen-Smith J. Universities as creators and retailers of intellectual property: life-sciences research and commercial development. In: Weisbrod BA, editor. To profit or not to profit: the commercial transformation of the nonprofit sector. Cambridge, United Kingdom: Cambridge University Press; 1998. p. 169-94.