Journal of the World Federation of Orthodontists 8 (2019) 95–99

Contents lists available at ScienceDirect

Journal of the World Federation of Orthodontists

journal homepage: www.jwfo.org

Featured Original Research

Patient perceptions and oral impacts following labial and lingual biocreative therapy: A randomized clinical trial

Mais Medhat Sadek [a,*], Noha Ezzat Sabet [b], Islam Tarek Hassan [c]

[a] Lecturer, Department of Orthodontics, Faculty of Dentistry, Ain Shams University, Cairo, Egypt
[b] Professor and Vice Dean of Postgraduate Affairs and Research, Faculty of Dentistry, Ain Shams University, Cairo, Egypt
[c] Professor and Head of Orthodontic Department, Faculty of Dentistry, Ain Shams University, Cairo, Egypt

ARTICLE INFO

Article history:
Received 11 March 2019
Received in revised form
11 May 2019
Accepted 14 May 2019
Available online 19 June 2019

Keywords:
Oral impacts
Treatment satisfaction
Biocreative therapy
Lingual
Anterior retraction

ABSTRACT

Purpose: The aim of this study was to compare patient satisfaction and oral impacts experienced by patients treated with labial or lingual biocreative therapy.
Material and methods: Twenty-eight patients (17–25 years) were randomly divided into two groups: group 1, labial biocreative therapy type II, and group 2, lingual biocreative therapy. At the end of the retraction phase, patients were asked to complete a questionnaire to assess oral impacts caused by the appliance and patient satisfaction from treatment. Frequency and percent values were calculated for every question for both groups. Independent-sample *t*-test was conducted to assess differences between the two groups. Fischer exact test was used to compare the answers of the two groups with each question separately.
Results: Difficulty in chewing, pain, and discomfort caused by the appliance were the most commonly reported adverse effects of the appliance used by patients in both groups. Statistically highly significant differences were found between the two groups regarding appliance esthetics and social disability scale, whereas no significant differences were found for the other domains.
Conclusions: Oral impacts are commonly experienced during both labial and lingual biocreative therapies. No statistically significant differences were found between the two groups regarding functional limitation, physical pain, and adverse effects on quality of life. Patients treated with labial biocreative therapy were more annoyed by the appearance of the appliance and were more likely to be embarrassed compared with those treated by the lingual biocreative technique. Both groups had similar levels of treatment satisfaction.

1. Introduction

The impact of orthodontic treatment on oral health–related quality of life (OHRQoL) as well as patient satisfaction from treatment has drawn increased attention from clinicians and researchers. The concept of OHRQoL has been defined as "a standard of health of oral and related tissues which enables an individual to eat, speak, and socialize without active disease, discomfort, or embarrassment" [1]. Successful orthodontic treatment results in improvement in facial and smile esthetics, which subsequently enhances psychosocial well-being. This directly contributes to quality of life [2].

Adult orthodontics is an increasing part of the orthodontic practice; however, adult patients are often annoyed by the appearance of labial brackets and tend to delay or avoid starting orthodontic treatment. Lingual orthodontics is a viable option for these patients as being "invisible orthodontic treatment." However, special consideration should be given to discomfort caused by conventional lingual orthodontic appliances. It has been reported that lingual appliances do have an effect on speech, most distortions in speech being evident immediately after placement and then diminishing with time [3]. Miyawaki et al. [4] found that 57% to 76% of patients treated with bonded lingual orthodontic appliances complained of tongue soreness, difficulty in chewing fibrous food, difficulty in pronouncing the 's' and 't' sounds, and difficulty in tooth brushing after the bonding of lingual appliances; the levels were significantly higher than those undergoing edgewise labial treatment.

Funding: The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.
Competing interest: Authors have completed and submitted the ICMJE Form for Disclosure of potential conflicts of interest. None declared.
Provenance and peer review: Not commissioned; Externally peer reviewed.
* Corresponding author. Department of Orthodontics, Faculty of Dentistry, Ain Shams University, African Union Organization Street, Cairo 11566, Egypt.
E-mail address: maismedhat@asfd.asu.edu.eg (M.M. Sadek).

2212-4438/$ – see front matter © 2019 World Federation of Orthodontists.
https://doi.org/10.1016/j.ejwf.2019.05.001

Recently, a systematic review assessed the prevalence of adverse effects associated with lingual and buccal fixed orthodontic techniques [5]. Meta-analysis showed a statistically greater risk of pain of the tongue, cheeks, and lips, as well as for the variables of speech difficulties and oral hygiene, with lingual orthodontics. However, no statistical difference was found with respect to eating difficulties and caries. This systematic review suggests that patients wearing lingual appliances have more pain, speech difficulties, and problems in maintaining adequate oral hygiene, although no differences for eating and caries risk were identified.

The "biocreative therapy" technique was introduced by Chung et al. [6,7]. In this technique, brackets are bonded only on the six anterior teeth, and temporary anchorage devices are used as the only source of anchorage. To provide bodily tooth movement during retraction, anterior torque moment is generated on the anterior teeth using gable bends in labial biocreative therapy type I [6], and an overlay intrusion arch in type II [7]. On the other hand, lingual biocreative therapy was introduced [8] to overcome many of the disadvantages of conventional lingual orthodontics, such as excessive chair time, patient discomfort, and expensive laboratory procedures. Lingual biocreative therapy comprises a bonded lingual retractor and a palatal plate for en masse anterior retraction. A soldered hook on the lingual retractor carries the point of application of the retraction force close to the center of resistance of the anterior segment to provide torque control during retraction. Biocreative therapy thus can offer significant advantages, including controlled tooth movement, no need for complex appliances, and skeletal anchorage with minimal reliance on patient compliance.

Several case reports were published showing successful anterior retraction using labial [6,7,9] and lingual biocreative therapy [8,10]; however, only a few studies analyzed the results of anterior retraction using these techniques. Kim et al. [11,12] conducted two retrospective studies; one to evaluate labial biocreative therapy in 2009 [11] and the other to evaluate lingual biocreative therapy in 2011 [12]. It was found that significant anterior retraction was achieved with maximum anchorage using temporary anchorage devices as the only source of anchorage.

Several measures have been applied to assess the influence of orthodontic treatment on quality of life, and patient satisfaction from treatment, none being the gold standard. All measures assess key oral impacts: oral discomfort, oral self-care, mastication, speech disturbances, and social activities. Up to the time of this writing, no study evaluated the impact of anterior retraction using the biocreative technique on the OHRQoL. In this study we aimed to compare the patient satisfaction and oral impacts experienced by patients treated with labial or lingual biocreative therapy.

2. Material and methods

This study was a two-arm randomized clinical trial, with 1:1 allocation ratio. The trial was registered at ClinicalTrials.gov with an identifier number of NCT03239275. The protocol of this study was approved by the ethical committee of the Faculty of Dentistry, Ain Shams University. Before treatment, all participants signed a detailed written consent. Participants for this study were subjects with full permanent dentition (excluding third molars), and whose treatment plan included extraction of the upper first premolars and retraction of the maxillary anterior teeth with maximum anchorage. Subjects were excluded if they had any systemic diseases (examples include bleeding disorders, bisphosphonate therapy, chemotherapy, and radiotherapy), craniofacial anomaly, or obvious periodontal disease and signs of bone loss.

Twenty-eight patients (age range 17–25 years) were enrolled in the trial. The baseline demographic characteristics are presented in Table 1. Patients were selected from subjects who visited the outpatient clinic, Faculty of Dentistry, Ain Shams University, for fixed orthodontic treatment and fulfilled the inclusion criteria. Patients were randomly assigned using a computer-generated random list to either group A or B. The patients were randomly allocated into the two groups using sequentially numbered, opaque, sealed envelopes. Group A (14 patients, 20.5 ± 2.1 years) was treated with labial biocreative therapy type II. Group B (14 patients, 21.1 ± 2.5 years) were treated with lingual biocreative therapy technique.

2.1. Intervention and questionnaire design

En masse retraction of the upper six anterior teeth was performed in both groups according to the technique described by Chung et al. [7,8]. In group A (labial biocreative therapy), preadjusted straight wire brackets 0.018 × 0.025 in slot were bonded to the upper six anterior teeth. Leveling and alignment were then carried out until 0.017 × 0.025-inch stainless steel wire was reached. The upper first premolars were then extracted, and en masse anterior retraction was done. Closed nickle-titanium (NiTi) coil springs (G4 NiTi closed coil springs; G&H Wire Company, Franklin, IN, USA) were used to provide consistent force of 200 g applied between 10-mm-length hooks crimped to the archwire distal to the lateral incisors and the mini-implants (1.6-mm diameter and 8-mm length) placed buccally, in the mucogingival junction between the maxillary second premolar and first molar. An overlay reverse curve 0.016 × 0.022-inch NiTi wire was inserted posteriorly into the hole of the mini-implant and ligated anteriorly (one-point contact) onto the wire at the midline between the two central incisors (Fig. 1A–C).

In group B (lingual biocreative therapy), the lingual retractor with 10-mm retraction hooks was fabricated from a chrome cobalt alloy and was bonded to the lingual surface of the six anterior teeth. A cross-type miniplate (C palatal plate; GebrÜder Martin GmbH, Tuttlingen, Germany) was fixed mid-palatally and NiTi closing coil springs were used to apply retraction force of 200 g per side (Fig. 1D). In both groups, Patient follow-up was carried out every 6 weeks. Retraction was stopped when a class I canine relationship was achieved, and adequate incisor relationship was obtained.

The main outcome of the study was to assess oral impacts during the retraction phase, as well as patient satisfaction from treatment. This was done by asking patients to complete a questionnaire designed for this study at the end of the retraction phase (Supplementary Table 1). The questions assessed how frequently patients had experienced functional limitation (questions 1, 2, and 3), physical pain (questions 4, 5, and 6), adverse effects on quality of life (question 7), annoyance from appliance appearance (question 8), social disability (questions 9 and 10), and patient satisfaction from treatment (questions 11 to 14), giving a total of 14 questions. Each question was scored on a 5-point Likert scale where 4 indicates very much; 3, to a great extent; 2, somewhat; 1, to a slight extent; and 0, never. The questionnaire score was calculated as the sum of all question values. Treatment satisfaction is a positive

Table 1
Baseline data for both treatment groups

Baseline characteristics	Labial group, n = 14		Lingual group, n = 14	
	Mean	SD	Mean	SD
Age, y	20.5	2.1	21.1	2.5
Overjet, mm	7.2	1.1	7.5	0.8
Overbite, mm	5.9	0.9	5.6	1.2
Upper central incisor inclination to palatal plane, degrees	116.7	1.5	117.1	1.8

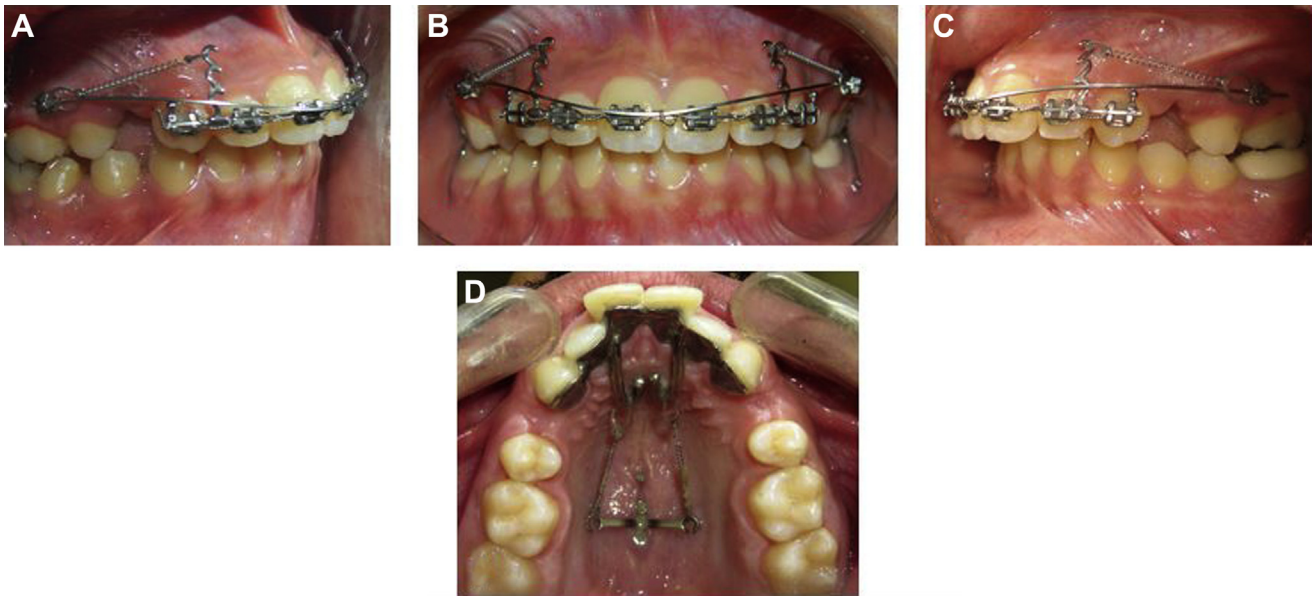

Fig. 1. (A–C) Labial biocreative therapy type II; (D) lingual biocreative therapy.

domain, whereas the other domains are negative domains. Total score ranged from 0 to 56, with higher scores indicating fewer oral impacts and more satisfaction from treatment.

2.2. Evaluation of the questionnaire: validity and reliability

Before conducting the study, content validity was established by asking a panel of experts to review the questionnaire items and come to some level of agreement as to which items should be included in the final questionnaire. Scale Content Validity Index (S-CVI) was used to assess validity. A value of S-CVI of 0.94 was obtained, which suggested good validity of the questionnaire.

Test-retest reliability of the questionnaire was evaluated through administering the questionnaire to the same individuals under the same conditions after some period of time. Test-retest reliability is estimated using Kendall's tau and Spearman's rho. Correlation coefficient values obtained ranged between 0.743 and 0.978, which can be considered good.

2.3. Statistics

Statistical analysis was performed with SPSS for Windows (version 17.0; SPSS Inc., Chicago, IL, USA). Score for the questionnaire was calculated by summing the item response codes. Frequency and percentage values were calculated for every question for both groups. Independent-sample *t*-test was conducted to assess differences between the two groups. Fischer exact test was then used to compare the answers of the two groups to each question separately.

3. Results

Twenty-eight patients (age range 17–25 years) were enrolled in the trial. Four patients were lost to follow-up. The details are given in the CONSORT flow diagram (Fig. 2). The mean retraction duration for the labial group was 12.3 ± 2.72 months and 11.93 ± 3.17 months in the lingual group.

Participants' responses to the questionnaire are shown in Supplementary Tables 2–5 (Supplemental Data). Difficulty in chewing, pain during the treatment, and discomfort caused by the appliance were the most commonly reported adverse effects of the appliance used by patients in both groups (Supplementary Tables 2 and 3). However, independent-sample *t*-test showed no statistically significant differences between the two groups for these domains (Table 2). On the other hand, patients reported no adverse effects on speech, oral hygiene measures, and quality of life in both groups (Supplementary Tables 2 and 4). Similarly, no statistically significant differences were found between the two groups for these domains (Table 2).

Statistically highly significant differences were found between the two groups regarding annoyance from appliance appearance and social disability scale (Table 2). The labial group had significantly lower mean values (1.5 ± 1.43 for the labial group, 3.9 ± 0.32 for the lingual group). Similar results were found when the Fisher exact test was used, with statistically significant differences found between the two groups for questions 8 and 9 (Table 3).

Regarding the treatment satisfaction domain (questions 11 to 14), patients in both groups were highly satisfied with treatment results (Supplementary Table 5) and would recommend it to others, with no statistically significant differences found between the two groups (Table 2).

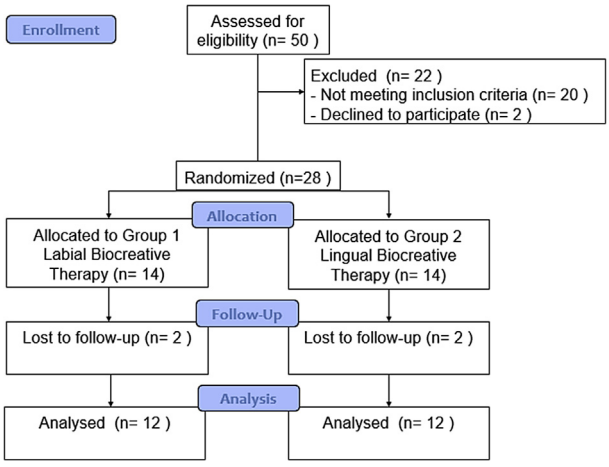

Fig. 2. CONSORT 2010 flow diagram.

Table 2
Comparison of questionnaire scores between the two groups

	Group	Mean	Standard deviation	*P*
Functional limitation scale	Lingual	3.00	0.57	0.26
	Labial	3.27	0.44	
Physical pain scale	Lingual	2.57	0.89	0.54
	Labial	2.77	0.47	
Quality of life scale	Lingual	3.60	0.52	0.66
	Labial	3.70	0.48	
Appliance esthetics scale	Lingual	3.90	0.32	<0.001[a]
	Labial	1.50	1.43	
Social disability scale	Lingual	3.85	0.34	<0.001[a]
	Labial	2.95	0.55	
Treatment satisfaction scale	Lingual	2.80	0.71	0.12
	Labial	3.25	0.49	
Total scale	Lingual	3.08	0.39	0.72
	Labial	3.01	0.41	

Descriptive statistics and results of independent-sample *t* test for comparison between the two groups.
[a] Significant at $P \leq 0.05$.

Table 3
Fisher exact test for comparison between the two groups

	Group	No	Yes	Fisher exact test *P* value
1	Lingual	7 (58.3)	5 (41.7)	1.000
	Labial	8 (66.7)	4 (33.3)	
2	Lingual	11 (91.7)	1 (8.3)	Equal values
	Labial	11 (91.7)	1 (8.3)	
3	Lingual	9 (75)	3 (25)	0.590
	Labial	11 (91.7)	1 (8.3)	
4	Lingual	6 (50)	6 (50)	Equal values
	Labial	6 (50)	6 (50)	
5	Lingual	7 (58.3)	5 (41.7)	0.414
	Labial	4 (33.3)	8 (66.7)	
6	Lingual	6 (50)	6 (50)	0.400
	Labial	9 (75)	3 (25)	
7	Lingual	12 (100)	0 (0)	Equal values
	Labial	12 (100)	0 (0)	
8	Lingual	12 (100)	0 (0)	<0.001[a]
	Labial	3 (25)	9 (75)	
9	Lingual	12 (100)	0 (0)	0.037[a]
	Labial	7 (58.3)	5 (41.7)	
10	Lingual	12 (100)	0 (0)	0.478
	Labial	10 (83.3)	2 (16.7)	
11	Lingual	1 (8.3)	11 (91.7)	1.000
	Labial	0 (0)	12 (100)	
12	Lingual	1 (8.3)	11 (91.7)	1.000
	Labial	0 (0)	12 (100)	
13	Lingual	1 (8.3)	11 (91.7)	1.000
	Labial	0 (0)	12 (100)	
14	Lingual	1 (8.3)	11 (91.7)	1.000
	Labial	0 (0)	12 (100)	

Values expressed as n (%).
[a] Significant at $P \leq 0.05$.

4. Discussion

As the importance of patient-centered outcome measure is increasing, the inclusion of quality-of-life measurements in clinical studies has been recommended by the World Health Organization [13]. The patient's overall OHRQoL must be well considered when evaluating different treatment procedures, and our focus should be directed to the patient as a whole, rather than merely focusing on the oral cavity.

Chung et al. [6–10] reported several advantages of the biocreative therapy technique. It can be used to provide patients with esthetic treatment, excellent anchorage control offered by skeletal anchorage, rapid and controlled retraction, simplified orthodontic biomechanics, and avoiding unnecessary use of complex orthodontic devices. Posterior teeth are not disturbed by friction in the appliance. However, no studies assessed the oral discomfort caused by either the labial or lingual biocreative therapy and its effect on the OHRQoL.

In this study, we aimed to compare patient satisfaction and oral impacts experienced by patients treated with labial or lingual biocreative therapy. A questionnaire was designed to assess oral impacts during the retraction phase. Four other questions assessed patient's satisfaction from treatment.

As expected, statistically highly significant differences were found between the two groups regarding appliance esthetics and social disability scales. The labial group had significantly lower mean values. This means that patients treated by the lingual biocreative therapy group were much more pleased by the invisibility of the appliance and were less likely to be embarrassed. This is important regarding the increased demand for esthetic treatment; a trend that will doubtless continue. However, despite the obvious advantage of the invisibility of conventional lingual orthodontics, it was previously blamed to cause more oral discomfort, difficulty in chewing, speech problems, and difficulty in practicing oral hygiene measures as compared with labial appliances [4]. This can have a negative impact on the OHRQoL and can negatively affect a patient's satisfaction from treatment.

Regarding the oral impacts caused by the biocreative therapy technique, difficulty in chewing, pain during the treatment, and discomfort caused by the appliance were the most common adverse effects reported by patients in both groups. However, patients reported no adverse effects on speech, oral hygiene measures, and quality of life in both groups.

Wu et al. [14] found that a similar level of overall pain experienced during treatment was reported by patients treated with labial or lingual appliances. Patients treated with lingual appliances reported higher ratings of tongue pain, whereas those treated with labial appliances reported higher ratings of lip and cheek pain. This is similar to the finding of our study in which no statistically significant differences were found regarding physical pain scale between the two groups.

It was reported that oral impacts were commonly experienced during both labial and customized lingual fixed orthodontic therapies [15]; however, it was found that patients treated with customized lingual appliances reported more oral discomfort, swallowing difficulty, dietary changes, and speech disturbances, than did those in the labial group. Similarly, Miyawaki et al. [4] reported that 57% to 76% of patients complained of tongue soreness, difficulty in pronouncing the 's' and 't' sounds, difficulty in chewing fibrous food, and difficulty in tooth brushing after the bonding of lingual appliances; the levels were significantly higher than those undergoing edgewise labial treatment. In our study, no statistically significant differences were found between the two groups regarding functional limitation and adverse effects on quality of life.

It, thus, can be assumed that lingual biocreative therapy can pose few problems related to speech and oral hygiene. This can be related to the fact that using a flat lingual retractor bonded to the lingual surface of the anterior teeth, with no brackets, wires, or ligature ties, can cause less discomfort to patients and have fewer speech and hygiene problems. Further study can be undertaken to compare the oral impacts caused by conventional lingual appliances and lingual biocreative therapy technique.

Equally important is the finding that patients in both groups were highly satisfied with treatment and said they would recommend it to others. No significant differences were found between the two groups.

These findings may have implications in informing patients' treatment decision-making processes regarding labial and lingual appliances and in the management of discomfort associated with different treatment modalities.

5. Conclusions

- Both groups had difficulty in chewing, pain, and discomfort caused by the appliance.
- Functional limitation and physical pain were not significantly different between the two groups.
- Patients treated with labial biocreative therapy were more annoyed by the appearance of the appliance and were more likely to be embarrassed compared with those treated by the lingual biocreative technique.
- Both groups had similar levels of treatment satisfaction and would recommend it to others.

Supplemental materials

Supplemental material accompanying this article can be found in the online version as a hyperlink at https://doi.org/10.1016/j.ejwf.2019.05.001 or, if a hard copy of article, at http://ees.elsevier.com/jwfo/ (select volume, issue, and article).

References

[1] Department of Health. An Oral Health Strategy for England. London: HMSO; 1994. http://www.dh.gov.uk. [Accessed 10 January 2013].
[2] Oliveira PG, Rodrigues TR, Freitas JC. Assessment of motivation, expectations and satisfaction of adult patients submitted to orthodontic treatment. Dental Press J Orthod 2013;18:81–7.
[3] Mariotti J, Subtelny D, Baker R, Mariotti M. The speech effect of the lingual appliance [MS thesis]. Rochester, NY: Eastman Dental Center; 1983.
[4] Miyawaki S, Yasuhara M, Koh Y. Discomfort caused by bonded lingual orthodontic appliances in adult patients as examined by retrospective questionnaire. Am J Orthod Dentofacial Orthop 1999;115:83–8.
[5] Ata-Ali F, Ata-Ali J, Ferrer-Molina M, Cobo T, De Carlos F, Cobo J. Systematic review: Adverse effects of lingual and buccal orthodontics techniques: a systematic review and meta-analysis. Am J Orthod Dentofacial Orthop 2016;149:820–9.
[6] Chung KR, Kim SH, Kook YA, Sohn JH. Anterior torque control using partial-osseointegrated mini-implants: biocreative therapy type I technique. World J Orthod 2008;9:95–104.
[7] Chung KR, Kim SH, Kook YA, Choo HR. Anterior torque control using partial osseointegration based mini-implants: biocreative therapy type II technique. World J Orthod 2008;9:105–13.
[8] Chung KR, Kook YA, Kim SH, Mo SS, Jung JA. Class II malocclusion treated by combining a lingual retractor and a palatal plate. Am J Orthod Dentofacial Orthop 2008;133:112–23.
[9] Chung KR, Cho JH, Kim SH, Kook YA, Cozzani M. Unusual extraction treatment in Class II Division 1 using c-orthodontic mini-implants. Angle Orthod 2007;77:155–66.
[10] Chung KR, Jeong DM, Park HJ, Kim SH, Nelson G. Severe bidentoalveolar protrusion treated with lingual biocreative therapy using palatal miniplate. Korean J Orthod 2010;40:276–87.
[11] Kim SH, Hwang YS, Ferreira A, Chung KR. Analysis of temporary skeletal anchorage devices used for en-masse retraction: a preliminary study. Am J Orthod Dentofacial Orthop 2009;136:268–76.
[12] Kim JS, Kim SH, Kook YA, Chung KR, Nelson G. Analysis of lingual en masse retraction combining a C-lingual retractor and a palatal plate. Angle Orthod 2011;81:662–9.
[13] Petersen PE. The World Oral Health Report 2003: continuous improvement of oral health in the 21st century—the approach of the WHO Global Oral Health Programme. Community Dent Oral Epidemiol 2003;11(Suppl 1):3–23.
[14] Wu AK, McGrath C, Wong RW, Wiechmann D, Rabie AB. A comparison of pain experienced by patients treated with labial and lingual orthodontic appliances. Eur J Orthod 2010;32:403–7.
[15] Papageorgiou SN, Gölz L, Jäger A, Eliades T, Bourauel C. Lingual vs. labial fixed orthodontic appliances: systematic review and meta-analysis of treatment effects. Eur J Oral Sci 2016;124:105–18.