IRIS AperTO

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Università degli Studi di Torino - Via Verdi, 8 - 10124 Torino
Centralino +39 011 6706111

Title

PERIODONTAL HEALTH DURING CLEAR ALIGNERS TREATMENT: A SYSTEMATIC REVIEW.

Summary

BACKGROUND: Clear aligner treatment (CAT) has been cited as a safe and comfortable orthodontic procedure for adult patients. However the available evidence is scarce.

OBJECTIVE: To perform a systematic review of the existing literature in order to assess periodontal health during CAT.

SEARCH METHODS AND SELECTION CRITERIA: Pubmed, Pubmed Central, National Library of Medicine's Medline, Embase, Cochrane Central Register of Controlled Clinical trials, Web of Knowledge, Scopus, Google Scholar and LILACs. were searched from January 1945 to September 2014 to identify all peer-reviewed papers potentially relevant to the review.

DATA COLLECTION AND ANALYSIS: After duplicate selection and extraction procedures, the risk of bias was assessed according to the Centre for Reviews and Dissemination criteria, and a 3-point grading system, as described by the Swedish Council on Technology Assessment in Health Care (SBU) was used to rate the methodological quality of the selected papers. A PICOS table was used for data extraction.

RESULTS: 5 relevant articles were selected from the 1247 identified articles. The level of evidence was moderate for all the studies. A significant improvement of the periodontal health indexes was revealed, in particular when CAT was compared to fixed appliances. No periodontal CAT adverse effects were observed in the selected studies.

CONCLUSIONS: Periodontal health indexes were significantly improved during CAT. The results of this review should be interpreted with some caution because of the number, quality, and heterogeneity of the included studies.

INTRODUCTION

Direct or indirect effects of orthodontic treatments on periodontal status and oral health are well known and quite extensively described in the existing literature (1). The periodontal reaction to an orthodontic appliance depends on several factors, such as host resistance, the presence of systemic conditions, and the amount and composition of dental plaque. Lifestyle factors, including smoking, can also compromise periodontal support. Oral hygiene procedures have a great impact on the periodontal health during orthodontic treatment (2). The existing literature supports the link between the increase of plaque indexes and the decrease in overall oral health conditions in orthodontic patients, especially when treated with fixed appliances (3-6). The use of removable appliances can minimize the orthodontics related negative effects on periodontal health allowing patients easier oral hygiene procedures.

In recent years, increasing numbers of adult patients have sought orthodontic treatment and expressed a desire for aesthetic and comfortable alternatives to conventional fixed appliances (7, 8).

Clear aligners orthodontic treatment (CAT) was introduced to answer this requests. Although CAT has been cited as a safe, aesthetic and comfortable orthodontic procedure for adult patients, only few trials were focused on its side effects (9,10). Considering that teeth and keratinized gingiva are covered almost all day long by aligners, it is important from a clinical perspective to have a sound

judgment regarding the periodontal effects of CAT. Two systematic reviews were conducted about CAT and were mainly focused on its potentials (11,12). None of them reported information about the periodontal effects of this kind of orthodontic treatment.

The present systematic review was undertaken to answer the following clinical research question in permanent dentition subjects:

- Does CAT produce detrimental effects on periodontal structures?

MATERIALS AND METHODS

The protocol for this systematic review (CRD42014009982) was registered in the International Prospective Register of Systematic Review (http://www.crd.york.ac.uk/PROSPERO/).

On September, 25 2014 a systematic search in the medical literature produced between January 1945 and September 2014 was performed to identify all peer-reviewed papers reporting possible periodontal effects of CAT. In order to retrieve lists of potential papers to be included in the review, the search strategy illustrated in Table 1 was used in the following databases:

- Pubmed
- Pubmed Central
- National Library of Medicine's Medline
- Embase
- Cochrane Central Register of Controlled Clinical trials
- Web of Knowledge
- Scopus
- Google Scholar
- LILACS

Title and abstract (TIAB) screening was performed to select articles for full text retrieval.

The inclusion and exclusion criteria for admittance in the systematic review were based on the type of study, were dependent on the clinical research questions and are reported in Table 2. The reference lists of these articles were perused, and references related to the articles were followed up.

Duplicate papers were removed and the studies were selected for inclusion independently by two of the authors (GR, SP). Disagreements were solved by discussion between all the authors.

The 'PICO' approach was used to extract data from the selected papers independently and in duplicate by two review authors (SP, GR). The acronym PICO stands for Population (Participants), Intervention (or Exposure for observational studies), Comparator and Outcomes. For the purposes of this systematic review the PICO format was modified in the PICOS one, where "S" stands for study design (Table 3) (13). The authors of the selected papers were contacted in case of missing information about sample selection and characteristics of their studies.

The primary outcome included the periodontal effects of CAT evaluated on the basis of periodontal indexes variations detected during CAT. The secondary outcome included the eventual CAT orthodontic movements with detrimental effects on dental and periodontal structures.

According to the CRD (Centre for Reviews and Dissemination, University of York) and to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statements, evaluation of methodological quality gives an indication of the strength of evidence provided by the study because flaws in the design or in the conduction of a study can result in biases (14, 15). However, no single approach for assessing methodological soundness is appropriate to all systematic reviews (15). A 3-point grading system, described by the Swedish Council on Technology Assessment in Health Care (SBU) and the CRD, was used to rate the methodological

quality of the selected papers (Table 3) (14,16). Articles were graded according to the SBU criteria as follow:

- Grade A (High level of evidence): RCTs or prospective study with a well defined control group; presence of defined diagnosis and endpoints; well described diagnostic reliability tests and reproducibility tests; blinding outcome assessment.
- Grade B (Moderate level of evidence): Same criteria as grade A except for the blinding outcome assessment.
- Grade C (Low level of evidence): Articles that do not meet the criteria of grade A and B.

SBU tool permitted to assess the level of the available evidence of the systematic review accordingly to the following classification:

- Strong: at least two studies of level "A"
- Moderate: One study of level ''A'' and at least two studies of level ''B''
- Limited: At least two studies of level ''B''
- Scarce: Fewer than two studies of level "B"

RESULTS

The search strategy yielded 5 relevant publications. 4 studies were prospective non-randomized and 1 study was prospective randomized (17-21). The article selection process is illustrated in the PRISMA Flow Diagram (Fig. 1).

Sample size in individual studies ranged from 30 to 60 subjects with a total of 218 subjects. Mean age at the start of CAT in the evaluated samples ranged from 16 to 75 years.

From a methodological point of view the selected papers used different procedures to detect treatment effects: four studies observed periodontal indexes variations while one study collected biofilm samples from aligners surfaces in order to analyze its ultrastructure and morphology.

Four studies performed a comparison between groups while one study used the analyzed cases as own control group (17-21).

QUALITY ANALYSIS

According to the SBU tool the quality of the collected evidences was moderate (grade B) in all the five studies (17-21). Thus, conclusions with a limited level of evidence could be drawn from the review process. The most important sources of bias were the absence of clues about randomization procedures and the lack of adequate blinding procedures. The quality grading of the selected papers is shown in PICOS Table (Table 3).

EFFECTS OF INTERVENTIONS

Five studies (1 RCT , 4 prospective CCTs) analyzed the CAT effects on periodontal health (17-21). All the selected studies analyzed Invisalign (Align Technology, San Jose, CA, USA) treatments.

Levrini et al. in their RCT recorded periodontal indexes from 3 groups of patients (10 treated with CAT, 10 treated with fixed buccal appliances and 10 not-treated subjects) and evaluated the total biofilm mass and the bacterial population in the collected plaque samples (21). Significantly better values of Plaque Index (PI) (OR: 0.09/95% CI: 0.05-0.15, $p < 0.001$), Bleeding on Probing (BOP) (OR: 0.20/95% CI: 0.11-0,36, $p < 0.001$), Probing Pocket Depth (PPD) ($p = 0.002$) and amount of biofilm mass ($p = 0.003$) were found in the CAT sample. Miethke et al in their 2005 and 2007 studies

compared periodontal indexes from patients treated with clear aligners or fixed buccal or fixed lingual appliances (30 patients for each group) (17, 18). Significant differences were found for PI (difference: 0.2) between CAT and fixed buccal appliance group ($p < 0.05$) and for PI (difference: 0.5) between CAT and lingual appliance group, Gingival Index (GI) (difference: 0.4), Papillary Bleeding Index (PBI) (difference: 0.2) and Sulcus Probing Depth (SPD) (T3 difference: 0.2) between CAT and fixed lingual appliance group ($p < 0.05$). Karkhanechi et al. evaluated periodontal indexes variations between patients treated with fixed appliances (22 patients) and patients treated with clear aligners (20 patients) after 6 weeks, 6 months, and 12 months from therapy beginning (20). Significant differences between CAT and fixed appliances for PI after 6 months ($p < 0.001$) and 12 months ($p < 0.001$), BOP after 12 months ($p < 0.05$), GI after 6 months ($p < 0.01$) and 12 months ($p < 0.01$), and PPD after 6 weeks ($p = 0.012$), 6 months ($p < 0.021$) and 12 months ($p < 0.003$) were revealed. Low et al. collecting and analyzing biofilm samples from clear aligners surfaces of 56 volunteers, didn't find any significant variation of the plaque percentage index during treatment (19).

DISCUSSION

The present review evaluated the existing literature related to the periodontal effects of CAT.

Both retrospective and prospective studies, of which only 1 was randomized, were included in the review process. Despite the widespread use of CAT there is still a lack of strong evidence about the type and entity of periodontal effects. Accordingly to the SBU tool the evidence emerging from the selected papers is of moderate level. The analysis of possible sources of bias revealed the lack of some methodological features: a very strong limitation of all studies was the absence of proper blinding procedures, as well as the lack of information about sample selection, while in one study a proper control group was not available (19). Therefore, the results should be interpreted with

caution. Incomplete reporting of outcomes was investigated according to the Cochrane Collaboration guidelines (14). Results showed complete and reliable data reports among the sample. A meta-analysis of the results of the studies was planned. However, due to the high heterogeneity ($I^2 > 75\%$), meta-analysis was omitted as suggested by the Cochrane Collaboration (14).

A systematic review by Bollen et al. stated the absence of reliable evidence about the effects of orthodontic treatment on periodontal health (22). Furthermore, other systematic reviews by Van Gastel et al. and Talic NF focused on plaque retention as the main risk factor for periodontal diseases after orthodontic treatment, confirmed that orthodontic treatment itself does not increase the incidence of periodontal pathologies (2, 23). However oral hygiene procedures have a great impact on the periodontal status of orthodontic patients (2). In this systematic review the five selected studies (1 RCT, 4 prospective CCTs) analyzed the influence of CAT on periodontal health (17-21). Four studies assessed a statistically significant reduction ($p<0.05$) of plaque index (PI) in CAT patients with respect to fixed (lingual and/or buccal) appliances patients (17,18,20,21). Other periodontal indexes, as gingival index (GI), papillary bleeding index (PBI), bleeding on probing (BOP) and pocket probing depth (PPD), were analyzed in these studies (18, 20, 21). In each study and for each parameter a significant improvement during CAT was obtained with respect to fixed appliance treatment.

As widely stated in the scientific literature, the most important periodontal disease risk factors orthodontics related are the increase of plaque retention and the worsening of plaque quality (3-6, 24).

Between 3-12 weeks after the beginning of supragingival plaque formation, a distinctive subgingival microflora predominantly made up of gram-negative, anaerobic bacteria and including some motile species, becomes established. In order to establish in a periodontal site, a species

must be able to attach to one of several surfaces including the tooth (or retentive surfaces attached to the tooth), the sulcular or pocket epithelium, or other bacterial species that are attached to these surfaces (24).

The studies by Low et al. and Levrini et al. regarding the quality and morphology of the oral biofilm of patients treated with CAT or fixed appliances, stated respectively that biofilm starts forming on the raised edges or textural surfaces of the aligners and that the types of bacteria included in the biofilm were associated to a low risk of periodontal diseases (19, 21).

From a clinical point of view, CAT seems to be a safe procedure for periodontal tissues with respect to fixed appliance treatment techniques, with particular reference to the amount of possible plaque retention. This seems to be due to the removable nature of CAT, facilitating oral hygiene procedures, and to the reduced amount of plaque retentive surfaces. Considering all these observations CAT could be indicated in the orthodontic treatment of patients with compromised periodontal health. However there is still a lack of strong evidence to support this hypothesis. Future RCTs on this topic should be encouraged.

Considering all the results of this systematic review strong limitations come from the heterogeneity and the low number of the selected studies, as well as multiple sources of bias that decreased the overall quality of evidence. It is recommended that future researches in this field should include randomized controlled design with rigorous methodology and proper sample size, in order to increase the power of the studies for estimating the periodontal effects.

CONCLUSIONS

- Most of the studies presented with methodological problems: bias and confounding variables, lack of adequate blinding procedures and absence of proper randomization methods. Thus conclusions with a moderate level of evidence could be drawn from the

review process.

- Periodontal health, as well as quantity and quality of plaque, were better during CAT than during fixed appliance treatments
- A significant decrease of periodontal indices (GI, PBI, BoP, PPD) during CAT was observed in the analyzed sample of patients.

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FIGURE LEGENDS

- Fig. 1 – Flow chart according to the PRISMA Statement