

Research program

Vacuum-formed retainer versus bonded cuspid-to-cuspid retainer to prevent relapse after orthodontic treatment– A randomized controlled trial about stability and patients' perceptions

NCT03070444

PhD student Anke Krämer, Senior consultant, Department of orthodontics, Gävle

Supervisor: Mats Hallman, Associate professor, PhD, Department of oral and maxillofacial surgery, Umeå University

Assistant supervisor: Ingallill Feldmann, PhD, Senior consultant, Department of orthodontics, Gävle

Assistant supervisor: Mats Sjöström, PhD, Associate professor, Department of oral and maxillofacial surgery, Umeå University

Aim

The overall objective of this randomized trial is to evaluate and compare stability after orthodontic treatment with an Essix retainer and a bonded cuspid-to-cuspid retainer (CTC) respectively in the mandibular arch and longitudinally follow these patients over time up to 5 years. The patients' perceptions of the two methods are also evaluated with questionnaires during the follow-up period.

A further aim of this study is to analyze the relationship between diagnosis, treatment outcome, treatment time, age at start of treatment and stability with an Essix-retainer in the maxilla.

Introduction

For successful orthodontic treatment the teeth need to be maintained in their corrected position after removal of orthodontic appliances. According to Proffit (2012) orthodontic treatment results are potentially unstable and therefore retention is necessary for three major reasons: the gingival and periodontal tissues require time for reorganization, growth changes can cause relapse and pressure from soft tissues i.e tongue, lips and cheeks can cause the teeth to move or rotate in an unwanted direction.

To prevent relapse patients are provided with fixed or removable retainers. The advantage of fixed retainers is that they are bonded to the palatal or lingual surfaces and do not depend on the patient's compliance. On the other hand these retainers demand good oral hygiene procedures to avoid plaque and calculus accumulation and the bonding procedure is time consuming and technique sensitive (Dahl and Zachrisson, 1991).

Hawley retainers are the most commonly used removable appliance since it was introduced in 1919, almost a century ago (Atack et al, 2007). However, patients have difficulties with speech, are embarrassed over the esthetics and cooperate less the first six months in retention (the critical phase) with the Hawley retainer (Hichens et al, 2007) (Bennett and Tulloch, 1999).

In the early 1990s thermoplastic vacuum-formed retainers were introduced and became very popular (Sheridan et al, 1993). Essix retainers are aesthetically well accepted, comfortable and less expensive than bonded retainers or Hawley retainers. Lindauer and Shoff (1998) and Rowland et al (2007) showed that vacuum-formed retainers are more effective than Hawley devices to maintain teeth in their new position after 6 months of retention.

In the literature the wear regimen of Essix retainers is not standardized. Lindauer and Shoff recommended 3 months full time wear and thereafter at night while Rowland et al recommended only one week full time wear. Jäderberg et al (2012), however, found no significant difference between full time wear for 3 months and 1 week, respectively, followed by night time. Their conclusions agree with the finding of Thickett and Power (2010) that there is no difference in the full time vs. part time wear regimen.

Transection of fibrous tissue (supra-alveolar fibers) to prevent relapse has been described already in the 1960s. Reitan (1967) observed that orthodontically derotated teeth are more

unstable and due to supra-alveolar tissue contraction rotational relapse may occur even after a retention period of more than 230 days. A long-term prospective study by Edwards (1988) showed that circumferential supracrestal fiberotomy (CSF) could alleviate dental relapse, especially of rotated teeth. Side effects such as clinically significant increase of periodontal sulcus depth or decrease in the labially attached gingiva were not observed.

There are several studies published investigating the effectiveness of bonded retainers and removable appliances to maintain tooth position after orthodontic treatment. Nevertheless, a systematic review by Littlewood et al (2006) stated that there is no evidence concerning the most appropriate retention strategy. They concluded that further research with well-designed randomized controlled trials to compare the effectiveness of different retention appliances is needed.

Only a few studies have analyzed patients' perception of orthodontic treatment (Bennett et al 1999, Hichens 2007, Feldmann et al 2012). Very few studies have analyzed patients' perception of retention appliances. Kumar and Bansal (2011) compared in a prospective study the effectiveness and acceptability of Essix and Begg retainers. They found that both appliances allowed some relapse but the differences were small and not clinically significant. The patients liked the comfort and appearance of the Essix retainer and preferred the Begg retainer for chewing and biting.

Although retention is a decisive factor for successful orthodontic treatment there are no evidence-based recommendations in the literature for retention appliances considering diagnoses before treatment such as vertical and skeletal deviations, the type of orthodontic movement (e.g. expansion or extraction cases) or for patients treated with fixed appliances and orthognathic surgery. Especially for patients with orthognathic surgery the choice of retention method and prevention of relapse are crucial since both skeletal and dental changes occur during treatment.

Materials and methods

The study is conducted at the Orthodontic Clinic, Gävle, Sweden and consists of 104 patients. All patients are treated with fixed appliances in the upper and lower jaw (standard .022 straight wire), both with and without extractions.

Patients treated with Rapid Maxillary Expansion (RME), orthognathic surgery, segmented appliance and patients with syndromes or agenesis of a mandibular incisor were excluded from the trial.

All patients who meet the inclusion criteria are invited to enter the trial. One experienced orthodontist (AK) provides the patients and parents with both oral and written information about the study protocol. After written consent is obtained from both the patient and parent the patients are randomized in blocks and stratified by gender into two groups. The allocation sequence is computer generated by a statistician at Gävleborg Count Hospital and concealed in opaque envelopes until randomization.

The patients are randomized into two groups with 52 patients in each group. All patients have Essix retainers in the maxilla covering all erupted teeth. The extension of the Essix retainers in the mandible covers only the dentition from first premolar to first premolar. The CTC-retainer is bonded to lingual surfaces of the mandibular canines.

Patients with rotated lower incisors (more than 30 degree) are treated with circumferential supracrestal fiberotomy 2 weeks prior to retention.

Group A: Retention with a CTC in the mandible and Essix retainer in the maxilla.

Two weeks before debonding an impression of the mandibular jaw is taken in order to manufacture the CTC retainer. The CTC-retainer is bonded to the canines directly after debonding. The Essix retainer is manufactured on dental casts after debonding and handed out to the patients the same day. The patients are instructed to wear the Essix retainer full-time the first week and thereafter night only.

Group B: Retention with Essix retainers in the maxilla and mandible.

The Essix retainers are manufactured on dental casts after debonding and handed out to the patients the same day. The patients are instructed to wear the Essix retainers full-time the first week and thereafter night only.

Dental cast are obtained at the debond appointment (T1) and at the follow-up controls after six months (T2), 18 months (T3) and 5 years (T4) for both groups. All measurements on casts are made with an electronic digital calliper to the nearest 0.25 mm. Comparisons within and between groups are performed.

Stability after retention is also analyzed depending on diagnoses before treatment and treatment outcome.

Outcome measures on the dental casts are as follow:

- Little's irregularity index
- Intercanine width
- Intermolar width
- Arch length
- Overjet
- Overbite

To assess measurement precision and reliability, 30 randomly selected dental casts are measured by the same examiner at a five weeks interval.

At the visit two weeks in retention and at the follow-up visits after 6, 18 and 60 months the patients assessed questionnaires in order to evaluate their experience of retention with an Essix retainer and a CTC respectively. The questionnaires include self-report questions from a previous study where reliability and face validity were found to be acceptable (Feldmann et al 2007). In addition, a few questions modified for this study are included. The fit of the retainers and the CTC are checked at each visit. All questionnaires are evaluated and compared between the two groups

Statistical analysis

Descriptive statistics are calculated for both groups (median, interquartile ranges, and test for normal distribution). The post-treatment changes are described by comparing measurements at debond (T1), after 6 months (T2), after 18 months (T3), and after 5 years (T4). Generalized estimating equations (GEE) are used to estimate the effect of the two treatment groups over time for the outcome variables. In the GEE analysis, all digital measurements, extraction therapy, sex, retention group, and time and the interaction of time with retention group are tested as explanatory variables (predictors). The GEE correlation structure is set to autoregressive, a convenient option for models with time-dependent observations.

Mann-Whitney U tests are used to analyse and compare the answers on questionnaires for the VFR/VFR and VFR/CTC group. Spearman's correlation coefficient is calculated to determine the relationship between patients' perceptions, self-reported VFR compliance, and LII. Demographic data are analysed with cross tabulations. P-values less than 0.05 are considered statistically significant.

Ethical considerations

All patients and parents are given oral and written information and sign a written consent before being included in the trial. The participation is voluntary and patients can leave the trial at any time without giving reasons.

Both of the tested retention-appliances are common and used frequently in orthodontic practices. The impressions at the follow-up visits are additional for this study.

The Ethics Committee of Uppsala (Regionala etikprövningsnämnden) approved the study protocol (diarienummer: 2009/177).

Research projects:

1. Effectiveness of Essix retainer versus bonded CTC in the mandibular arch after 6 and 18 months.

Aim: The aim of this project is to evaluate and compare stability in the mandibular arch 6 and 18 months after retention with an Essix retainer compared to retention with a bonded cuspid-to-cuspid retainer (CTC).

Material and methods: 104 patient are randomized into 2 groups; CTC (group A) and Essix retainer (group B). Little's Irregularity Index, intercanine width, intermolar width, arch length, overjet and overbite are measured on dental casts and analysed at the debond appointment, after 6 months and after 18 months.

The null hypothesis is that there is no difference in retention capacity between Essix retainer and cuspid-to-cuspid retainer.

The results from this study will be presented at the Swedish Dental Congress in 2018.

2. Evaluation of patients' perception of the retention appliances by questionnaires after 6 months and 18 months.

Aim: The aim of this project is to evaluate and compare patients' perception of their retention with an Essix retainer compared to retention with a bonded cuspid-to-cuspid retainer (CTC) 6 and 18 months after debonding.

Material and methods: 104 patients assessed a questionnaire after debonding and at the follow-up visit after six and 18 months to evaluate their experience of retention with an Essix retainer and a CTC respectively.

The null hypothesis is that there is no difference in patients' perception between Essix retainer and cuspid-to-cuspid retainer.

The results from this study will be presented at the Swedish Dental Congress in 2019.

3. Long-term stability in the mandibular arch after 5 years of retention.

Aim: The aim of this project is to evaluate and compare stability in the mandibular arch 5 years after retention with an Essix retainer compared to retention with a bonded cuspid-to-cuspid retainer (CTC).

Material and methods: 104 patients are randomized into 2 groups; CTC (group A) and Essix retainer (group B). Little's Irregularity Index, intercanine width, intermolar width, arch length, overjet and overbite are measured on dental casts and analysed after 5 years of retention.

The null hypothesis is that there is no difference in retention capacity between Essix retainer and cuspid-to-cuspid retainer.

The results from this study will be presented at the Swedish Dental Congress and the European Orthodontic Society Congress in 2021.

4. Retention stability in the maxilla depending on the diagnoses before treatment and on the treatment outcome after fixed orthodontic appliances.

Aim: The aim of this project is to evaluate and compare stability in the maxilla 6 months, 18 months and 5 years after retention with an Essix retainer.

Material and methods: Dental casts of 104 patients are measured and analyzed concerning overbite, overjet, intercanine width, intermolar width and arch length after 6 months, 18 months and 5 years of retention.

The null hypothesis is that there is no difference in retention capacity for Essix retainer in the maxilla concerning diagnosis before treatment, treatment outcomes, treatment time and age at start of treatment.

Relevance

CTC and Essix retainer are frequently used after orthodontic treatment. Since this is a randomized trial with a large sample size we hope to contribute to increase the knowledge and

also to clarify if diagnoses before treatment and/or treatment outcome, treatment time and age are factors that must be considered when retention is planned.

Furthermore, there is very little knowledge about patient's perception of different retention strategies which of course is an important factor to consider.

References

Atack N, Harradine N, Sandy JR, Ireland AJ.

Which way forward? Fixed or removable lower retainers.

Angle Orthodontist. 2007;77:954-9 PMID: 18004927

Bennett ME, Tulloch JF.

Understanding orthodontic treatment satisfaction from the patients' perspective: a qualitative approach.

Clinical Orthodontics and Research. 1999;2:53-61 PMID: 10534980

Bland JM, Altman DG

Statistical methods for assessing agreement between two methods of clinical measurement.

International Journal of Nursing Studies. 2010; 47: 931-6

Dahl EH, Zachrisson BU.

Long-term experience with direct-bonded lingual retainers.

Journal of Clinical Orthodontics. 1991;25:619-30 PMID:1814943

Edwards JG.

A long-term prospective evaluation of the circumferential supracrestal fiberotomy in alleviating orthodontic relapse.

American Journal of Orthodontics and Dentofacial Orthopedics. 1988;93:380-7. PMID: 3163217.

Feldmann I, List T, John MT, Bondemark L.

Reliability of a questionnaire assessing experiences of adolescents in orthodontic treatment.

Angle Orthodontist. 2007;77:311-7. PMID: 17319767

Feldmann I, List T, Bondemark L.

Orthodontic anchoring techniques and its influence on pain, discomfort, and jaw function--a randomized controlled trial.

European Journal of Orthodontics. 2012;34:102-8 PMID:21300723

Hichens L, Rowland H, Williams A, Hollinghurst S, Ewings P, Clark S, Ireland A, Sandy J
Cost-effectiveness and patient satisfaction: Hawley and vacuum-formed retainers.
European Journal of Orthodontics. 2007;29:372-8 PMID:17702797

Jäderberg S, Feldmann I, Engström C.
Removable thermoplastic appliances as orthodontic retainers--a prospective study of different wear regimens.
European Journal of Orthodontics. 2012 ;34:475-9 PMID:21508267

Lindauer SJ, Shoff RC
Comparison of Essix and Hawley retainers
Journal of Clinical Orthodontics. 1998;32:95-7. PMID: 9709631

Little RM
The irregularity index: a quantitative score of mandibular anterior alignment
American Journal of Orthodontics. 1975; 68: 554-63 PMID:1059332

Littlewood SJ, Millett DT, Doubleday B, Bearn DR, Worthington HV.
Orthodontic retention: a systematic review
J Orthod. 2006;33:205-12 PMID:16926314

Kumar AG, Bansal A
Effectiveness and acceptability of Essix and Begg retainers: a prospective study
Australian Orthodontic Journal. 2011;27:52-6. PMID:21696115

Proffit WR, Fields HW Jr, Sarver DM
Retention. In: Contemporary orthodontics.5th ed. Mosby Elsevier, 2012

Reitan K
Clinical and histologic observations on tooth movement during and after orthodontic treatment.
American Journal of Orthodontics. 1967;53:721-45 PMID: 5233926

Renkema AM, Al-Assad S, Bronkhorst E, Weindel S, Katsaros C, Lisson JA.
Effectiveness of lingual retainers bonded to the canines in preventing mandibular incisor relapse.
American Journal of Orthodontics and Dentofacial Orthopedics. 2008; 134: 179e1-8
PMID:18675196

Rowland H, Hichens L, Williams A, Hills D, Killingback N, Ewings P, Clark S, Ireland AJ, Sandy JR.

The effectiveness of Hawley and vacuum-formed retainers: a single-center randomized controlled trial.

American Journal of Orthodontics and Dentofacial Orthopedics. 2007;132:730-7
PMID:18068589

Sheridan JJ, LeDoux W, McMinn R.

Essix retainers: fabrication and supervision for permanent retention.

Journal of Clinical Orthodontics. 1993;27:37-45 PMID:8478438

Thickett E, Power S

A randomized clinical trial of thermoplastic retainer wear.

European Journal of Orthodontics. 2010; 32: 1-5 PMID:19828592

Yu Y, Sun J, Lai W, Wu T, Koshy S, Shi Z

Interventions for managing relapse of the lower front teeth after orthodontic treatment.

Cochrane Database Syst Rev. 2013 Sep 6;9: CD008734. PMID:24014170