European Journal of Orthodontics, 2023, **45**, 58–67
https://doi.org/10.1093/ejo/cjac042
Advance Access publication 14 August 2022
Randomized Controlled Trial (RCT)

Stability, survival, and patient satisfaction with CAD/CAM versus conventional multistranded fixed retainers in orthodontic patients: a 6-month follow-up of a two-centre randomized controlled clinical trial

Arwa Gera[1], Helen Pullisaar[2], Paolo M. Cattaneo[3,†], Shadi Gera[4,†], Vaska Vandevska-Radunovic[2] and Marie A. Cornelis[3,†]

[1]Section of Orthodontics, Department of Dentistry and Oral Health, Aarhus University, Aarhus, Denmark
[2]Department of Orthodontics, Institute of Clinical Dentistry, Faculty of Dentistry, University of Oslo, Norway
[3]Melbourne Dental School, Faculty of Medicine, Dentistry and Health Sciences, Melbourne, Australia
[4]Private Practice, Jerusalem, Israel
[†]Formerly, Section of Orthodontics, Department of Dentistry and Oral Health, Aarhus University, Aarhus, Denmark

Correspondence to: Marie A. Cornelis, Melbourne Dental School, Faculty of Medicine, Dentistry and Health Sciences, University of Melbourne,720 Swanston Street, Carlton 3053, Australia. E-mail: marie.cornelis@unimelb.edu.au

Summary

Objectives: The primary aim of this two-arm parallel two-centre randomized controlled trial was to compare computer-aided design and computer-aided manufacturing (CAD/CAM) versus conventional multistranded fixed retainers (FRs) in terms of stability over 6 months. Secondary outcomes were failure rates and patient satisfaction.

Methods: Patients were randomized to CAD/CAM or conventional FRs in both arches, in 1:1 ratio and blocks of four. Allocation concealment was secured by using sequentially numbered envelopes. Patients were blinded. Retainers were bonded at the end of orthodontic treatment (T0), and patients were recalled after 1 (T1), 3 (T3), and 6 (T6) months. First-time retainer failures were recorded and digital impressions were taken. Arch widths and lengths, as well as Little's Irregularity Index (LII), were measured. Additionally, patients answered satisfaction questionnaires. Linear mixed models were applied for measurements and patient satisfaction. Survival analyses were estimated with Kaplan-Meier curves, along with Cox-regression modelling.

Results: One hundred and eighty-one patients were randomized (98 in Centre 1, and 83 in Centre 2): Ninety in the CAD/CAM group and 91 in the conventional group. Three subjects dropped out at baseline, as they did not attend any of the follow-up appointments.168 patients attended the T6 visit. There were no significant differences in arch dimensions between T0 and T6, whilst the LII was different only in the CAD/CAM group (mean difference: 0.2 mm; 95% confidence interval: 0.1 to 0.4; $P < 0.001$). Within 6 months, 39 upper retainers (19 out of 88 CAD/CAM and 20 out of 90 conventional retainers) and 52 lower retainers failed (26 out of 88 CAD/CAM and 26 out of 90 conventional retainers), with no significant difference between the survival of both types of retainers (hazard ratios conventional to CAD/CAM: upper arch: 0.99 [P =0.99], lower arch: 0.93 [P = 0.80]). There were no significant changes in patient satisfaction between the groups. No harms were observed.

Conclusions: There were no clinically significant differences in LII, arch widths and lengths between CAD/CAM and conventional retainers after 6 months. There was no difference in failures and in patient satisfaction between both types of FRs.

Registration: ClinicalTrials.gov NCT04389879.

Introduction

Retention after orthodontic treatment is considered mandatory to maintain the stability of treatment outcome (1). Nevertheless, retention remains one of the most challenging areas in orthodontics. A Cochrane systematic review concluded in 2016 that there is insufficient evidence to favour one retention method over another in terms of post-treatment stability, harms, long-term implications, and patient satisfaction (2). However, more recently, in 2019, a Dutch team has developed a clinical practice guideline for retention (3).

Retention protocols are constantly refined to improve their effectiveness. Nevertheless, both fixed and removable retainers continue to be the trend (4). There is a marked geographical variation with the use of retention protocols. In the Netherlands, in 2009, fixed retainers (FRs) were reported to be the most common retainers (97%) and were used for both arches (5). Seventy percent of patients had canine-to-canine FRs in the lower arch, and 34% in the upper arch. In 2018, a Dutch study reported that the most used retention protocol in the upper arch was a combination of FR and removable retainer (54%) and mainly a FR in the lower arch (83%) (6). A similar trend was observed in Norway (7). By contrast, in Australia and New Zealand, mandibular fixed and maxillary vacuum-formed retainers (VFRs) are the most prevalent combination (8,9).

In the literature, a wide variety of FR protocols are used, which differ significantly in terms of wires/materials used, bonding technique and teeth involved (2). FRs have shown to be efficient, reliable, and to offer good short-term stability (10). However, besides the benefits, the use of these devices is associated with potential drawbacks and harms, such as failure associated with relapse and risk of undesirable adverse effects (11–14). Moreover, FRs can impair the patient's comfort and ability to maintain oral hygiene. Ideally, FRs should be flexible enough to allow some degree of physiologic movement of the retained teeth, hence, providing homeostasis to the periodontium as well as reducing tension within the composite bonding material (15). In addition, an ideal FR should not be susceptible to fracture and plaque retention.

To limit the negative aspects of conventional retainers, advances in material science and computer-aided design and computer-aided manufacturing (CAD/CAM) technology have made it possible to generate innovative custom-cut nitinol FRs (16,17). CAD/CAM FRs are considered a potential alternative to conventional multistranded (MS) FRs, and are claimed to deliver utmost accuracy, and to reduce chair-time and need for operator dexterity (18). Furthermore, they seem to offer high predictability when limited bonding surface is available, as well as in anatomically demanding regions (19). In addition, CAD/CAM FRs might provide a very accurate passive fitting to the lingual tooth surface, which is critical as wire tension produced during bonding procedure can result in undesirable adverse effects over the long term, such as unexpected post-treatment tooth movements; unrelated to the initial malocclusion, caused by residual stress between the bonding points (20–22). The clinical effectiveness of CAD/CAM FRs has not been tested extensively. Three recent prospective studies found no significant differences between CAD/CAM and MS FRs in terms of stability and failure rate (23–25). However, those studies are characterized by relatively small samples.

To our knowledge, this is the largest randomized controlled trial (RCT) assessing stability, failure rate and patient satisfaction of CAD/CAM retainers vs. conventional MS retainers in both arches, and is also one of the largest RCTs about FRs in general. The present report focuses on the preliminary results of this trial, that is, 6 months after retainer placement.

Objectives and hypotheses

The aims of the present RCT were to assess and compare the clinical effectiveness of CAD/CAM versus conventional MS FRs in terms of post-treatment stability (primary outcome), failure rate, and patient satisfaction (secondary outcomes) over a 6-month period. The null hypothesis was that CAD/CAM FRs present no significant differences when compared with MS FRs in terms of stability, failure rate, and patient satisfaction.

Material and methods

Trial design and any changes after trial commencement

This study is a two-centre, two-arm, parallel, RCT with a 1:1 allocation ratio. No changes occurred after trial commencement.

Participants, eligibility criteria, and settings

Patients treated at two postgraduate orthodontic clinics (Section of Orthodontics, Department of Dentistry and Oral Health, Aarhus University, Denmark and Department of Orthodontics, Institute of Clinical Dentistry, Faculty of Dentistry, University of Oslo, Norway) who were about to finish their orthodontic treatment, were invited to participate. Patient enrollment started on 15 January 2019 and finished on 15 June 2019 in Centre 1 (Aarhus University), and started on 15 May 2019 and finished on 7 October 2020 in Centre 2 (University of Oslo). The following inclusion criteria were applied:

1. Good general health
2. Age range 12–25 years old
3. Presence of all maxillary and mandibular anterior teeth with normal shape and size
4. Completion of treatment with full fixed appliance.

There was no restriction to presenting initial malocclusion. The following exclusion criteria were applied:

1. Patients with cleft lip and/or palate or any other craniofacial syndrome
2. Patients with compromised oral hygiene or periodontal disease
3. Patients who had orthognathic surgery
4. Lingual appliance treatments
5. Enamel hypoplasia, fluorosis, active caries, restorations, or fractures in the anterior teeth
6. Patients who had separate arch debondings with a difference of more than 2 months in-between jaws
7. Re-treatments
8. Patients who were assigned to another retention protocol due to their initial malocclusion.

Recruited patients (or a parent/guardian in case of a minor patient) received oral and written information about the study. Patients who agreed to participate were asked to sign an informed consent at their last appointment before debonding. This study was approved by the Health Research Ethics Committee—Central Jutland, Denmark (case number: 1-10-72-266-18), and by the Regional Committees for Medical and Health Research Ethics, Norway (case number: 2018-1655).

Interventions

FRs

Intraoral scan and laboratory procedure:

1. At the last appointment before debonding, subjects had supra-gingival debridement followed by an intraoral scan (Trios 3, 3Shape, Copenhagen, Denmark) of both arches with bite registration.
2. Intraoral scans for CAD/CAM FRs were sent to CA Digital lab via 3Shape Communicate® (Copenhagen, Denmark), while intraoral scans for conventional MS FRs were sent to the Departments' internal laboratories.
3. Laboratory work:

    a. CAD/CAM FRs: 0.014 X 0.014-inch rectangular Nitinol retainers (Memotain, CA Digital, Hilden, Germany) were digitally designed by a dental technician (CA Digital lab) using OnyxCeph 3D Pro Software (Image Instruments, Chemnitz, Germany). Afterwards, they were custom-cut from a nitinol sheet and electro-polished. A silicone transfer key was prepared (Figure 1a and b) to facilitate the positioning of the retainers (19).

b. Conventional MS FRs: 0.0215-inch six-stranded stainless steel ([SS] G&H, Franklin, Indiana, USA) retainers were prepared by the same dental technician at each centre. The wire was shaped to adapt passively to the lingual surfaces of upper and lower anterior teeth on the plaster model, without heat treatment. A silicone transfer key was prepared for each FR (Figure 1c and d).

Bonding procedures:

In each centre, one operator (SG and HP) bonded all FRs (T0). The operators:

1. Tried the retainers, cleaned the teeth and isolated.
2. Acid-etched the lingual surfaces of all anterior teeth with 37% phosphoric acid (30 s), rinsed (10 s) and dried.
3. Applied bonding (Transbond™ XT, 3M Unitek, Monrovia, California, USA). Inserted the lower FR with transfer key, applied a small amount of composite Tetric Flow (Ivoclar Vivadent, Switzerland) on tooth 43, followed by tooth 33. Removed the transfer key, and applied composite on the rest of the teeth from right to left side, and light cured each tooth for 10 s. Bonded the upper retainer following the same steps (retainer bonding started from tooth 12, then tooth 22 in case of a lateral incisor-to-lateral incisor retainer, or started from tooth 13, then tooth 23 in case of a canine-to-canine retainer).
4. Removed brackets and polished the teeth.
5. Informed the patient about hygiene instructions (oral and written).

An intraoral scan (Trios 3) and intraoral photographs were taken at the end of the bonding procedure (T0).

Patients received an upper removable retainer after debonding, to be worn at night-time.

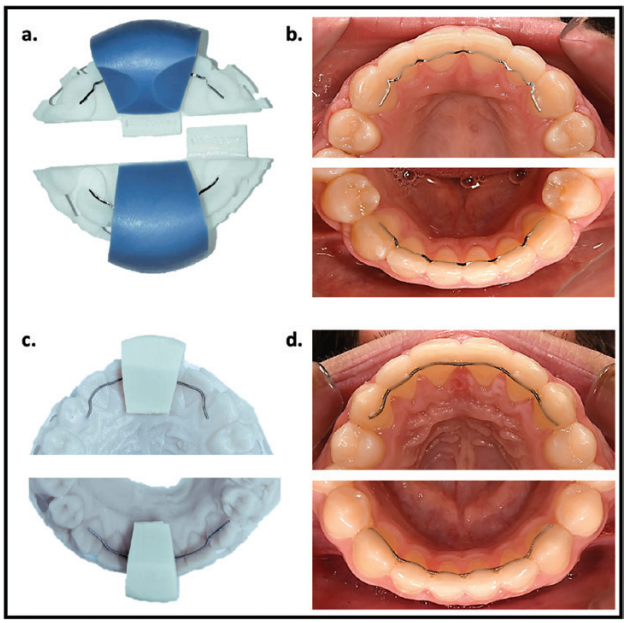

Figure 1. (a) 0.014 × 0.014-inch rectangular Nitinol CAD/CAM generated fixed retainers (Memotain), with silicone transfer key on printed models. (b) Upper and lower Memotain retainers bonded canine-to-canine. (c) 0.0215-inch conventional six-stranded stainless-steel retainers, with silicone transfer key on printed models. (d) Upper and lower six-stranded stainless-steel retainers bonded canine-to-canine.

Follow-up

Patients were recalled for follow-up appointments after 1 (T1), 3 (T3), and 6 (T6) months. At all visits, a clinical examination was performed. The pattern of retainer failure was recorded as follows: (1) debonding at enamel-composite interface: one or more bonding sites detached from the enamel surface but the retainer was still in situ; (2) debonding at wire-composite interface: one or more bonding sites detached from the wire surface but the retainer was still in situ; (3) wire fracture: the retainer fractured at one or more sites; (4) complete detachment from all teeth: all bonding sites of a retainer detached; and (5) removed by the clinician: the retainer was completely removed due to relapse or unexpected post-treatment changes. For each failure, the affected teeth were recorded. Participants were advised to contact the clinic as soon as possible if they encountered any problems or concerns.

In addition, at T1 and T6, the patients were asked to answer a 5-item visual analogue scale (VAS) regarding comfort/satisfaction with the FRs (Table 1).

At T6, an intraoral scan (Trios 3) and intraoral photographs were taken.

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

The primary outcome was the post-treatment stability. The secondary outcomes were retainer failures and patient satisfaction. No changes were made after trial commencement.

Post-treatment stability

As previously mentioned, intra-oral scans were taken at T0 and T6. The resulting digital models (both arches) were measured at T0 and T6. One operator in each centre (AG and HP) measured the Little's Irregularity Index (LII), and the upper and lower arch widths and lengths using the Ortho Analyzer software (3Shape) to a precision of 0.01 mm (Figure 2). The LII was also assessed before orthodontic treatment to determine baseline characteristics of the sample.

Failures

The survival time and pattern of FR failure were recorded separately for each arch over the follow-up period. The survival time was calculated from the day of bonding to the day of the first failure event (debonding/wire breakage/complete

Table 1. Visual analogue scale (VAS) for the evaluation of patient satisfaction.

Instructions to the patient: please tell us about your experience with **your fixed retainers** (that is the thin pieces of wires glued to the back of your front teeth). There are five questions relating to how comfortable you find your retainers and how they affect your daily life. The left side represents 0 = complete satisfaction/comfort and the right side represents 100 = complete discomfort/unsatisfaction.	
1	**How comfortable is it to wear** your fixed retainers compared to braces?
2	**How comfortable is it to clean** your teeth together with your fixed retainers?
3	**How comfortable is it to remove trapped food between** your teeth and your fixed retainers?
4	**How comfortable is it to talk?**
5	**How comfortable is it to eat?**

detachment/removal by clinician). Only the first failure event was considered for the survival analysis. The date of failure was reported as the day the patient became aware of the problem or alternatively the date the clinician noted the failure when a participant was unaware of the failure. If some patients did not attend the last appointment (T6) but still attended one of the retention visits (i.e. T1 and/or T3), the status (failure or no failure) observed at their last visit was taken into consideration for the survival analysis.

Patient satisfaction

Patient satisfaction was determined at T1 and T6 using the VAS described above. The questionnaires were sent by email to the patients who did not attend the visits.

Sample size calculation

The sample size calculation was determined based on the primary outcome (post-treatment stability). To demonstrate a difference of 1.5 mm in LII (26) between both groups, and assuming that the standard deviation (SD) of LII is 3 mm (27), the study needed 63 subjects per group, with a power of 80% and a significance level of 5%. To account for a potential dropout rate of 40% over the total planned follow-up period of the study, the sample size was increased to a total of 90 subjects per group.

Randomization

The patients were randomized in 1:1 ratio into blocks of four following an online computer-generated sequence (randomization.com), by one author in each centre (AG and HP), to either CAD/CAM FR or conventional MS FR. Randomization took place shortly before debonding. The same two authors enrolled participants. Allocation concealment was ensured by using sequentially numbered, opaque, sealed envelopes prepared in advance of the trial by a colleague not involved in the study. The same two authors assigned the participants to the interventions. Recruitment was terminated when the planned number of subjects was reached.

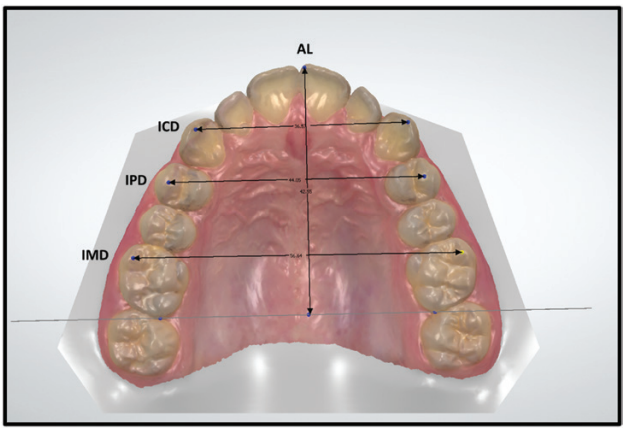

Figure 2. Arch width and length (mm). *ICD*, inter-canine distance; distance between the cusp tips of right and left permanent canines; *IPD*, inter-premolar distance; distance between the tip of the buccal cusp of the right and left first premolars; *IMD*, inter-molar distance; distance between the tip of the mesiobuccal cusp of the right and left first permanent molars; *AL*, arch length; the distance between the incisal edge of the most prominent central incisor to the frontal/coronal plane passing through the most posterior aspect of the first permanent molars. In case of abrasion of a cusp, the centre of the abrasion facet was used instead of the centre of the cusp.

Blinding

Patients were blinded but blinding of the operator was not possible due to the nature of the intervention. Blinding of the outcome assessor regarding stability (based on digital models) and failures (based on clinical assessment) was not possible due to the evident differences between the retainers, but blinding the assessor for patient satisfaction was ensured by removing patient identifying information from the completed forms.

Statistical analysis

Data collection and management were performed using REDCap (Research Electronic Data Capture) (Centre 1) and TSD (services for sensitive data) (Centre 2). All analyses were conducted using Stata Statistical Software (Release 16. College Station, StataCorp, Texas, USA). Descriptive statistics were performed. To assess the similarity of baseline characteristics, two-sample hypothesis tests were conducted to

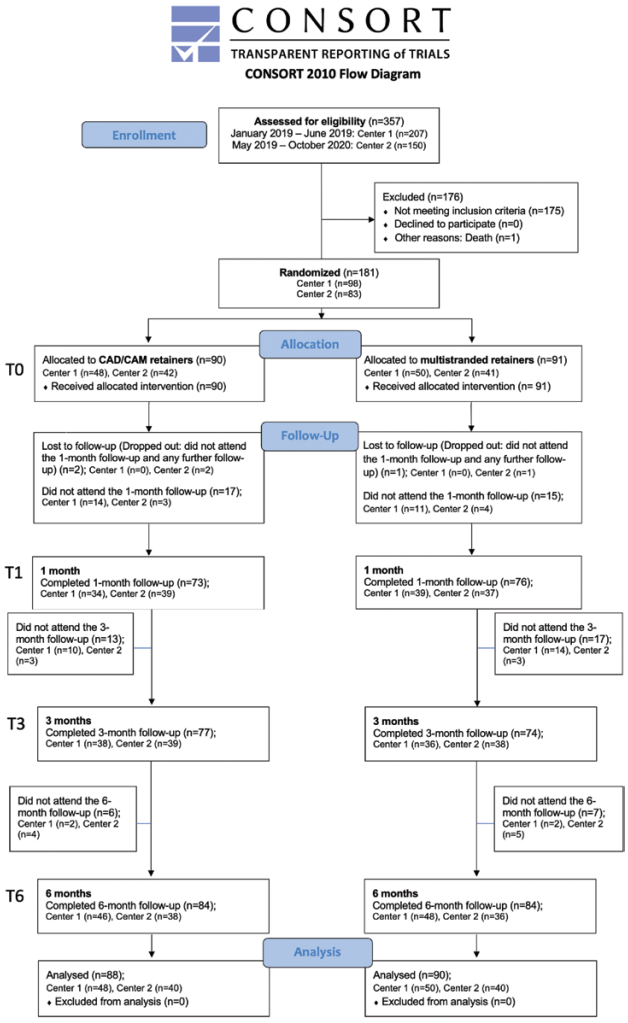

Figure 3. CONSORT diagram showing the flow of patients through the trial.

compare distribution of genders, extraction status, ages and pre-treatment LII between groups. For arch dimensions and LII, each individual measurement was modelled by a linear mixed model with an unstructured marginal covariance pattern to induce correlation between two repeated measures on the same subject (28). The survival analyses were conducted using the Kaplan-Meier curves separately for the upper and lower retainers, along with a Cox-regression modelling with Breslow method for ties to assess predictors for retainer survival. VAS results were adjusted for age, gender, randomization group, and time, in addition to modelling by a linear mixed regression model, but with two repeated measures on the same subject. All linear mixed models included a Kenward-Roger adjustment for the denominator degrees of freedom. For example, if five outcomes were being modelled, the individual significance level for each outcome was revised down to 1%.

Error of the method

To evaluate inter-examiner reliability, two operators (AG and HP) measured 60 randomly selected models. The intra-class correlation coefficients (ICC) were used to assess reliability. Twenty-six patients answered the same VAS again at a 1-week interval after T1. Test-retest reliability of the VAS results was assessed using ICC, computed by a linear mixed model for components of variance, also with a Kenward-Roger adjustment for denominator degrees of freedom.

Results

Participant flow

A total of 357 subjects were assessed for eligibility (207 in Centre 1, and 150 in Centre 2), as shown in the CONSORT flow diagram (Figure 3). One hundred and eighty-one patients were randomized (90 to the CAD/CAM group and 91 to the conventional group).

One hundred and sixty-eight patients attended the T6 appointment (84 patients in each group) and were considered for the 6-month evaluation (Figure 3). Patients who did not show up within 2 months from the planned T6 appointment were no longer considered for the 6-month evaluation.

Baseline data

The baseline characteristics of the patients in each group were similar in terms of gender, age, treatment modality (extraction, non-extraction) and LII (Table 2).

Main outcome: stability

The upper FRs were distributed as follows: 12–22 (n = 26; 14 in the CAD/CAM and 12 in the conventional group), 13–23 (n = 152; 74 in the CAD/CAM and 78 in the conventional group), others (12–23; n = 2; one in the CAD/CAM and one in the conventional group and 11–21; n = 1; in the CAD/CAM group). The lower FRs were distributed as follows: 43–33 (n = 180; 90 in the CAD/CAM and 90 in the conventional group), 44–34 (n = 1; in the conventional group). There was no evidence of a statistically significant difference in LII, upper and lower arch lengths and widths (inter-canine, inter-premolar, and inter-molar distances) between T0 and T6, except for the LII in the CAD/CAM group (mean difference: 0.2 mm; 95% confidence interval: 0.1 mm, 0.4 mm; $P < 0.001$). There were no differences between the groups at the different timepoints (Table 3).

Secondary outcome: failures

Within 6 months, in the upper arch, 19 out of 88 CAD/CAM retainers (22%) and 20 out of 90 conventional retainers (22%) failed (total upper failures: 39), whilst in the lower arch 26 out of 88 (30%) CAD/CAM retainers and 26 out of 90 (29%) conventional retainers failed (total lower failures: 52). There was no statistically significant difference in survival between the two groups. The hazard ratios are reported in Table 4. The Kaplan-Meier survival curves for both groups are presented in Figure 4. The distribution of the upper and lower first-time failure patterns in each group are illustrated in Table 5. Bond failure was the most common pattern of failure in both groups and both arches, in particular at the enamel-composite interface. The distribution of failures per tooth is shown in Figure 5. Lower central incisors (tooth 41) were the most prone to debondings. Out of the 13 patients who did not attend the 6-month visit, three did not attend any of the follow-up appointments, four had already encountered a failure event at an earlier retention follow-up (one CAD/CAM [in the lower jaw only] and three conventional [two in the upper jaw and one in both jaws]). The remaining

Table 2. Baseline characteristics (n = 181).

	CAD/CAM n = 90			Conventional n = 91			Total (%)	P (test of proportions/ unpaired sample t-test)
Gender	n =			n =				
Female	44			52			96 (53.0)	0.26
Male	46			39			85 (47.1)	
Treatment modality								
Extraction cases	12			16			28 (15.5)	0.43
Non-extraction cases	78			75			153 (84.5)	
	Mean	SD	Range	Mean	SD	Range		
Age at start of retention T0 (years)	16.0	2.6	12.1–25.8	16.4	3.0	12.1–25.8		0.28
LII[a] (pre-treatment)	5.3	2.9	0.6–13.7	6.1	2.8	1.2–15.1		0.08

[a]Pre-treatment models were lost for one patient in the CAD/CAM group (n = 89), and for two patients in the Conventional group (n = 89).

six patients (three CAD/CAM and three conventional) were event-free at their 3-month visit.

Secondary outcome: patient satisfaction

Hundred eighty-one patients completed the VAS at T1, and 105 at T6. Patient satisfaction improved significantly at T6 compared to T1 for all questions except question 2 ('How comfortable is it to clean your teeth together with your FRs?') (Figure 6). There was no statistically significant difference between the CAD/CAM and the conventional groups, except for question 2, favouring the CAD/CAM group.

Error of the method

Inter-examiner reliability results were excellent for the measurements of arch dimensions and LII (Supplementary Table 1). The ICC for the VAS was excellent (Supplementary Table 2).

Harms

No serious harm was observed.

Discussion

Post-treatment stability, survival, and patient satisfaction are parameters that a clinician must consider when choosing a retention protocol. To our knowledge, the present RCT is the largest one to compare stability, failure rate, and patient satisfaction of CAD/CAM versus conventional FRs in both upper and lower arches. There was no evidence of a statistically significant difference in arch dimensions, failure rate, and patient satisfaction between CAD/CAM and conventional FRs at 6-month post-treatment. Those findings seem to validate the use of CAD/CAM FRs since they perform equally well compared to conventional MS FRs, which used to be the gold standard (4).

As it is believed that the stability of the lower arch is limited and that this arch is the key to stability or relapse as the upper arch wraps around the lower and follows changes in the lower arch alignment (29), many studies investigate FRs in the lower arch only. Alrawas *et al*. performed an RCT that compared CAD/CAM FRs with conventional MS FRs in terms of stability, with a protocol that included the lower arch only (23). The sample size (n = 60) was smaller than in the present study (24).

It is known that FRs allow for good preservation of the intercanine distance in the short-term (30). The results of the present study are aligned with these findings. Furthermore, Forde et al. reported no difference in stability when comparing FRs with VFRs (31). Regarding CAD/CAM technology, Alrawas *et al*. found no statistical significance in terms of stability between 0.012 × 0.018-inch CAD/CAM FRs (Robofix, Istanbul, Turkey) and 0.017-inch MS conventional FRs, which is, once again, in agreement with the present findings (23). In the present study, a statistically significant difference in LII was observed between bonding and 6-month follow-up for the CAD/CAM retainers, however, this difference seems not to be clinically relevant (0.2 mm).

Unexpected post-treatment changes are defined as dental changes that occur in terms of torque and/or rotational movements not related to the initial malocclusion (32). Since MS wires are suspected to be responsible for those movements (33), one may hypothesize that a by definition fully passive CAD/

Table 3. Arch dimensions and LII: adjusted means, 95% confidence interval (CI), and *P* values.

			UIC	UIP	UIM	UAL	LIC	LIP	LIM	LAL	LII
CAD/CAM	T0	Mean	34.1	42.0	50.4	38.2	26.6	34.3	43.4	34.0	0.7
		CI	33.7 to 34.5	41.5 to 42.5	49.9 to 51.0	37.7 to 38.7	26.4 to 27.0	33.9 to 34.6	42.9 to 44.0	33.5 to 34.5	0.6 to 0.8
	T6	Mean	34.2	42.1	50.1	38.3	26.7	34.4	43.5	34.0	0.9
		CI	33.8 to 34.7	41.6 to 42.5	49.5 to 50.8	37.7 to 38.8	26.4 to 27.0	34.1 to 34.8	42.9 to 44.0	33.5 to 34.5	0.8 to 1.1
	T0 vs T6	P value	0.221	0.747	0.117	0.276	0.855	0.089	0.925	0.781	<0.001*
Conventional	T0	Mean	34.0	42.0	50.4	38.1	26.5	34.3	43.8	33.7	0.9
		CI	33.6 to 34.4	41.5 to 42.4	49.8 to 51.0	37.6 to 38.7	26.2 to 26.8	34.0 to 34.7	43.2 to 44.3	33.2 to 34.2	0.8 to 1.0
	T6	Mean	34.1	41.8	50.3	38.2	26.5	34.4	43.7	33.8	1.0
		CI	33.7 to 34.6	41.3 to 42.3	49.7 to 51.0	37.7 to 38.7	26.2 to 26.8	34.1 to 34.8	43.2 to 44.3	33.2 to 34.3	0.9 to 1.2
	T0 vs T6	*P* value	0.469	0.143	0.592	0.515	0.639	0.316	0.835	0.589	0.054
CAD/CAM vs Conventional	T0 (n = 180)[a]	*P* value	0.835	0.914	0.972	0.860	0.545	0.556	0.413	0.415	0.116
	T6 (n = 163)[b]	*P* value	0.708	0.463	0.723	0.815	0.412	0.664	0.435	0.505	0.387

UIC, upper inter-canine distance; *UIP*, upper inter-premolar distance; *UIM*, upper inter-molar distance; *UAL*, upper arch length; *LIC*, lower inter-canine distance; *LIP*, lower inter-premolar distance; *LIM*, lower inter-molar distance; *LAL*, lower arch length; *LII*, Little's Irregularity Index.
[a]one digital model was lost.
[b]four digital models were lost, 13 patients did not attend the T6 visit, and 1 patient had no models taken because of a re-treatment in the upper arch due to space opening after retainer failure.
*P < 0.001.

Table 4. Hazard ratios for types of retainers and for gender.

	Upper arch				Lower arch			
	Hazard ratio	*P*	95% confidence interval		Hazard ratio	*P*	95% confidence interval	
Conventional to CAD/CAM	0.99	0.99	0.52	1.90	0.93	0.80	0.53	1.63
Male to female	1.31	0.43	0.66	2.57	0.73	0.28	0.41	1.30

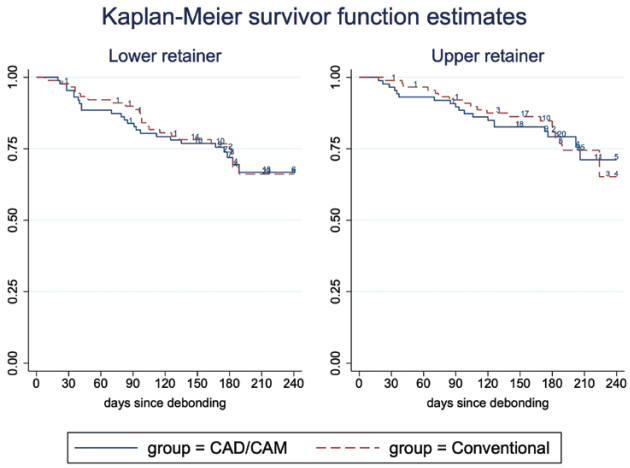

Figure 4. Kaplan-Meier survival curves for the upper and lower arches according to CAD/CAM and Conventional FRs. CAD/CAM, computer-aided design and computer-aided manufacturing; *FR*, fixed retainers.

Table 5. Distribution of upper and lower FR failure patterns in each group over the 6-month follow-up.

	Group		Total
	CAD/CAM	Conventional	
Upper arch			
Complete detachment from all teeth	1	2	3
Debonding at enamel-composite interface	8	6	14
Debonding at wire-composite interface	5	7	12
Retainer removed by clinician	0	1	1
Wire fracture	5	4	9
Total	**19**	**20**	**39**
Lower arch			
Complete detachment from all teeth	4	5	9
Debonding at enamel-composite interface	13	15	28
Debonding at wire-composite interface	6	6	12
Retainer removed by clinician	1	0	1
Wire fracture	2	0	2
Total	**26**	**26**	**52**

FR, fixed retainers.

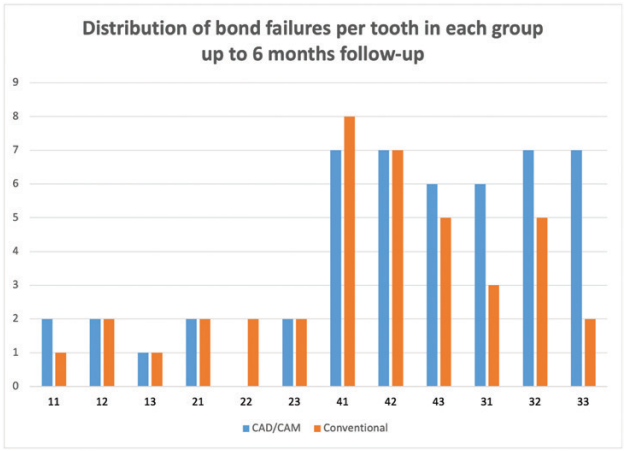

Figure 5. Distribution of bond failures per tooth in each group up to 6-month follow-up.

CAM FR could be less subject to such side effects. In the present sample, after 6 months follow-up, no unexpected post-treatment changes were observed, in none of the groups, which was expected as those kinds of changes generally occur later (33).

A large number of studies have investigated survival time of FRs, but mostly for the lower arch (34–36). In the present study, the failure rate in the upper arch was 22% for both types of FRs, whereas, in the lower arch, the failure rate was 30% for the CAD/CAM FRs and 29% for the conventional FRs. For the ten patients who did not attend the 6-month visit but still attended one of the retention visits (i.e. T1 and/or T3), the status (failure or no failure) observed at their last visit was taken into consideration. Another assumption considering all retainers of those patients as failures would still result in no difference between the two groups (23 out of 88 CAD/CAM retainers (26%) and 23 out of 90 conventional retainers (26%), 29 out of 88 (33%) CAD/CAM retainers and 31 out of 90 (34%) conventional retainers).

Failure of FRs is a common clinical complication. Bond failure in metal FRs is reported to be between 3.5% and 53% (37,38). The failure rate for canine-to-canine FRs (0.0215 inch) has been reported to be as high as 53% (37), which is higher than the failure rates observed in the present study. The present findings indicate that the failure rates were similar for CAD/CAM and conventional FRs. Likewise, Alrawas *et al.* reported no statistical significance in failure rate between CAD/CAM FRs and conventional MS FRs after 6 months (23). Another recent prospective study with 6 months follow-up concluded that lower FRs using Memotain (77% survival rate) and five-stranded wires (73% survival rate) were similar in terms of survival rates after 6 months follow-up (25).

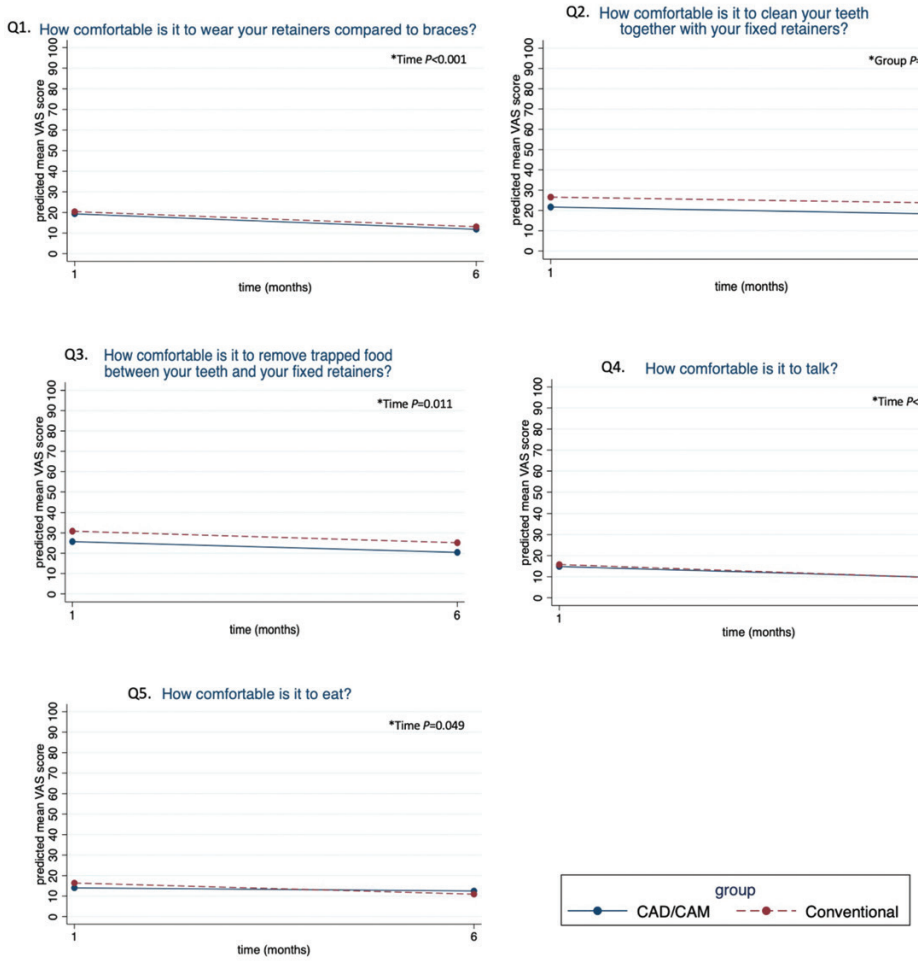

Figure 6. Patients' satisfaction visual analogue scale (VAS) changes over time.

The present study reported lower failure rates for upper FRs compared to lower FRs. By contrast, Forde *et al.* (31). reported much higher failures rates at 12 months follow up of upper versus lower MS FRs (64% and 50%, respectively).

FRs may fail at the wire-composite interface, at the composite-enamel interface or can be subject to stress fracture of the wire at the inter-proximal areas, which can result in tooth displacement (14,39). Bond failure, in particular at the enamel-composite interface, was the most common pattern of failure in both groups and in both arches in the present study. Gelin *et al.*, comparing CAD/CAM FRs to conventional FRs in a considerably smaller sample (62 subjects), reported no FR fractures, and observed a similar proportion of wire-composite and enamel-composite debondings with CAD/CAM FRs compared to conventional FRs (24). Two other studies comparing CAD/CAM FRs to conventional FRs did not report failure patterns (23,25). One recent RCT (40) assessed failure rate in the lower arch only and reported lower failure rates of MS FRs (31%) when compared with fibre reinforced composite retainers.

Some studies have reported the attitudes and preferences of orthodontists towards various retention protocols, but only few have explored patient satisfaction (12,41). Scribante *et al.* investigated patient satisfaction for FRs in the lower arch and found that in terms of aesthetics, polyethylene ribbon-reinforced resin FRs were favoured more than MS FRs (42). On the other hand, Forde *et al* reported that patients found VFRs easier to clean than FRs (31). In the present study, there was no statistically significant difference in patient satisfaction between CAD/CAM and conventional FRs, except for the question 'How comfortable is it to clean your teeth together with your FRs?', which showed an estimated difference of 5.2% in favour of CAD/CAM FRs. Gelin *et al.* found no difference in overall satisfaction and level of discomfort for the tongue with CAD/CAM versus conventional FRS, but did not investigate cleaning issues.

This paper covers preliminary results of an ongoing randomized controlled clinical trial. At the present stage, an intention-to-treat (ITT) analysis was not performed for the assessment of stability, as attrition was minimal (8.8%). An ITT analysis will be performed in the future reports of this RCT, if attrition becomes more severe.

Limitations

In the present study, the CAD/CAM Nitinol Memotain® 1.0 FRs were used. After the present study was initiated, an optimized version was introduced, Memotain® 2.0, which is 'serrated to overcome the sliding effect, designed to fit better at the interdental areas and is assumed to have minimum risk of fracture', according to the manufacturer. Thus, the present study could not assess if Memotain® 2.0 would offer better retention to the tooth surface, thus leading to lower failure rate, specifically at the enamel-composite interface, which

was the most common failure pattern in the present study, or if it would reduce composite wear.

Although new technology is appealing, present drawbacks of CAD/CAM retainers are cost, and dependency on an external laboratory for laser cutting technology, potentially generating long waiting times between ordering and receiving FRs, with potential risk of tooth movement.

This study was powered on a continuous outcome (LII), which usually requires a lower sample size than outcomes of binary nature such as rates. Hence, one should be aware that the secondary outcomes of binary nature, like satisfaction or failure rate, have a lower statistical power than that of the primary outcome.

Patients were given an upper removable retainer after debonding and were advised to use at night-time, as dual retention is a relatively standard procedure for the maxilla in Denmark and Norway. This could have influenced the upper arch stability; however, it is known that upper anterior alignment is similarly stable with FRs combined to removable retainers, compared to FRs only (43). Furthermore, it is not possible to know how consistently the patients were wearing their removable retainers.

Finally, as previously mentioned, this report describes the preliminary results of an ongoing study. The 6-month follow-up results reported here only represent short-term retention outcomes.

Generalizability

One experienced operator at each centre bonded all retainers, which is a strength of the present study. However, this might not reflect the variability of a larger group of clinicians.

Conclusion

- There was no evidence of a statistically significant difference in arch dimensions, failure rate, and patient satisfaction between CAD/CAM Nitinol and MS conventional FRs in the upper and lower arches over a duration of 6 months post-treatment. In the CAD/CAM group, the LII increased statistically, but not clinically significantly over the 6-month follow-up.
- Within 6 months, 22% upper CAD/CAM FRs and 22 % upper conventional FRs failed, as well as 30% lower CAD/CAM FRs and 29% lower conventional FRs.
- The most common failure pattern in both groups was debonding at enamel-composite interface.

Acknowledgements

The authors express their gratitude to Sandro Leidi for statistical assistance and Dirk Leonhardt for laboratory assistance.

Funding

This study was supported by Aarhus University Forskingsfond [AUFF 2432] and by a European Orthodontic Society Research Grant.

Conflicts of interest

No conflict of interest to be declared.

Data availability

Data available on request: The data underlying this article will be shared on reasonable request to the corresponding author.

Ethical approval

Health Research Ethics Committee—Central Jutland, Denmark (case number: 1-10-72-266-18) and Regional Committees for Medical and Health Research Ethics, Norway (case number: 2018-1655).

Supplementary material

Supplementary material is available at *European Journal of Orthodontics* online.

References

1. Papagiannis, A., Koletsi, D., Halazonetis, D.J. and Sifakakis, I. (2021) Relapse 1 week after bracket removal: a 3D superimpositional analysis. *European Journal of Orthodontics*, 43, 128–135.
2. Littlewood, S.J., Millett, D.T., Doubleday, B., Bearn, D.R. and Worthington, H.V. (2016) Retention procedures for stabilising tooth position after treatment with orthodontic braces. *Cochrane Database of Systematic Reviews*, 2016, CD002283.
3. Wouters, C., Lamberts, T.A., Kuijpers-Jagtman, A.M. and Renkema, A.M. (2019) Development of a clinical practice guideline for orthodontic retention. *Orthodontics & Craniofacial Research*, 22, 69–80.
4. Bearn, D.R. (1995) Bonded orthodontic retainers: a review. *American Journal of Orthodontics and Dentofacial Orthopedics*, 108, 207–213.
5. Renkema, A.M., Sips, E.T., Bronkhorst, E. and Kuijpers-Jagtman, A.M. (2009) A survey on orthodontic retention procedures in The Netherlands. *European Journal of Orthodontics*, 31, 432–437.
6. Padmos, J., Fudalej, P. and Renkema, A. (2018) Epidemiologic study of orthodontic retention procedures. *American Journal of Orthodontics and Dentofacial Orthopedics*, 153, 496–504.
7. Vandevska-Radunovic, V., Espeland, L. and Stenvik, A. (2013) Retention: type, duration and need for common guidelines. A survey of Norwegian orthodontists. *Orthodontics: The Art and Practice of Dentofacial Enhancement*, 14, e110–e117. doi:10.11607/ortho.964
8. Meade, M. J., Dreyer, C. W. (2019) A survey of retention and retainer practices of orthodontists in Australia. *Australian Orthodontic Journal*, 35, 174–183.
9. Padmos, J., Mei, L., Wouters, C. and Renkema, A.M. (2019) Orthodontic retention procedures in New Zealand: a survey to benefit clinical practice guideline development. *Journal of the World Federation of Orthodontists*, 8, 24–30.
10. Taner, T. and Aksu, M. (2012) A prospective clinical evaluation of mandibular lingual retainer survival. *European Journal of Orthodontics*, 34, 470–474. doi:10.1093/ejo/cjr038
11. Al-Moghrabi, D., Pandis, N. and Fleming, P.S. (2016) The effects of fixed and removable orthodontic retainers: a systematic review. *Progress in Orthodontics*, 17, 24.
12. Bondemark, L., Holm, A.K., Hansen, K., Axelsson, S., Mohlin, B., Brattstrom, V., Paulin, G. and Pietila, T. (2007) Long-term stability of orthodontic treatment and patient satisfaction. A systematic review. *Angle Orthodontist*, 77, 181–191.
13. Booth, F.A., Edelman, J.M. and Proffit, W.R. (2008) Twenty-year follow-up of patients with permanently bonded mandibular canine-to-canine retainers. *American Journal of Orthodontics and Dentofacial Orthopedics*, 133, 70–76.
14. Renkema, A.M., Renkema, A., Bronkhorst, E. and Katsaros, C. (2011) Long-term effectiveness of canine-to-canine bonded flexible

spiral wire lingual retainers. *American Journal of Orthodontics and Dentofacial Orthopedics*, 139, 614–621.
15. Cooke, M.E. and Sherriff, M. (2010) Debonding force and deformation of two multi-stranded lingual retainer wires bonded to incisor enamel: an in vitro study. *European Journal of Orthodontics*, 32, 741–746.
16. Kravitz, N.D., Grauer, D., Schumacher, P. and Jo, Y.-m (2017) Memotain: a CAD/CAM nickel-titanium lingual retainer. *American Journal of Orthodontics and Dentofacial Orthopedics*, 151, 812–815.
17. Shim, H., Foley, P., Bankhead, B. and Kim, K.B. (2022) Comparative assessment of relapse and failure between CAD/CAM stainless steel and standard stainless steel fixed retainers in orthodontic retention patients. *Angle Orthodontist*, 92, 87–94.
18. Jost-Brinkmann, P.G., Cacciafesta, V. and Miethke, R.R. (1996) Computer-aided fabrication of bonded lingual retainers. *Journal of Clinical Orthodontics*, 30, 559–563.
19. Wolf, M., Schumacher, P., Jäger, F., Wego, J., Fritz, U., Korbmacher-Steiner, H., Jäger, A. and Schauseil, M. (2015) Novel lingual retainer created using CAD/CAM technology: evaluation of its positioning accuracy. *Journal of Orofacial Orthopedics*, 76, 164–174.
20. Artun, J. and Zachrisson, B. (1982) Improving the handling properties of a composite resin for direct bonding. *American Journal of Orthodontics*, 81, 269–276.
21. Katsaros, C., Livas, C. and Renkema, A.-M. (2007) Unexpected complications of bonded mandibular lingual retainers. *American Journal of Orthodontics and Dentofacial Orthopedics*, 132, 838–841.
22. Livas, C. and Delli, K. (2013) Subjective and objective perception of orthodontic treatment need: a systematic review. *European Journal of Orthodontics*, 35, 347–353.
23. Alrawas, M.B., Kashoura, Y., Tosun, O. and Öz, U. (2021) Comparing the effects of CAD/CAM nickel-titanium lingual retainers on teeth stability and periodontal health with conventional fixed and removable retainers: a randomized clinical trial. *Orthodontics & Craniofacial Research*, 24, 241–250.
24. Gelin, E., Seidel, L., Bruwier, A., Albert, A. and Charavet, C. (2020) Innovative customized CAD/CAM nickel-titanium lingual retainer versus standard stainless-steel lingual retainer: a randomized controlled trial. *Korean Journal of Orthodontics*, 50, 373–382.
25. Kartal, Y., Kaya, B. and Polat-Özsoy, O. (2021) Comparative evaluation of periodontal effects and survival rates of Memotain and five-stranded bonded retainers: a prospective short-term study. *Journal of Orofacial Orthopedics*, 82, 32–41.
26. Little, R.M. (1975) The irregularity index: a quantitative score of mandibular anterior alignment. *American Journal of Orthodontics*, 68, 554–563.
27. Bjering, R., Sandvik, L., Midtbo, M. and Vandevska-Radunovic, V. (2017) Stability of anterior tooth alignment 10 years out of retention. *Journal of Orofacial Orthopedics*, 78, 275–283.
28. Lindsey, J. K. (1999) *Models for Repeated Measurements*. 2 edn. Oxford University Press, OUP Catalogue, Oxford, UK.
29. Shah, A.A. (2003) Postretention changes in mandibular crowding: a review of the literature. *American Journal of Orthodontics and Dentofacial Orthopedics*, 124, 298–308.
30. Egli, F., Bovali, E., Kiliaridis, S. and Cornelis, M.A. (2017) Indirect vs direct bonding of mandibular fixed retainers in orthodontic patients: comparison of retainer failures and posttreatment stability. A 2-year follow-up of a single-center randomized controlled trial. *American Journal of Orthodontics and Dentofacial Orthopedics*, 151, 15–27.
31. Forde, K., Storey, M., Littlewood, S.J., Scott, P., Luther, F. and Kang, J. (2017) Bonded versus vacuum-formed retainers: a randomized controlled trial. Part 1: stability, retainer survival, and patient satisfaction outcomes after 12 months. *European Journal of Orthodontics*, 40, 387–398.
32. Pazera, P., Fudalej, P. and Katsaros, C. (2012) Severe complication of a bonded mandibular lingual retainer. *American Journal of Orthodontics and Dentofacial Orthopedics*, 142, 406–409.
33. Shaughnessy, T.G., Proffit, W.R. and Samara, S.A. (2016) Inadvertent tooth movement with fixed lingual retainers. *American Journal of Orthodontics and Dentofacial Orthopedics*, 149, 277–286.
34. Artun, J., Spadafora, A.T. and Shapiro, P.A. (1997) A 3-year follow-up study of various types of orthodontic canine-to-canine retainers. *European Journal of Orthodontics*, 19, 501–509.
35. Bolla, E., Cozzani, M., Doldo, T. and Fontana, M. (2012) Failure evaluation after a 6-year retention period: a comparison between glass fiber-reinforced (GFR) and multistranded bonded retainers. *International Orthodontics*, 10, 16–28.
36. Bovali, E., Kiliaridis, S. and Cornelis, M.A. (2014) Indirect vs direct bonding of mandibular fixed retainers in orthodontic patients: a single-center randomized controlled trial comparing placement time and failure over a 6-month period. *American Journal of Orthodontics and Dentofacial Orthopedics*, 146, 701–708.
37. Stormann, I. and Ehmer, U. (2002) A prospective randomized study of different retainer types. *Journal of Orofacial Orthopedics*, 63, 42–50.
38. Zachrisson, B. U. (2007) Long-term experience with direct-bonded retainers: update and clinical advice. *Journal of clinical orthodontics: JCO*, 41, 728–737; quiz 749
39. Lumsden, K.W., Saidler, G. and McColl, J.H. (1999) Breakage incidence with direct-bonded lingual retainers. *British Journal of Orthodontics*, 26, 191–194.
40. Nagani, N.I., Ahmed, I., Tanveer, F., Khursheed, H.M. and Farooqui, W.A. (2020) Clinical comparison of bond failure rate between two types of mandibular canine-canine bonded orthodontic retainers- a randomized clinical trial. *BMC Oral Health*, 20, 180.
41. Wong, P. and Freer, T.J. (2005) Patients' attitudes towards compliance with retainer wear. *Australian Orthodontic Journal*, 21, 45–53.
42. Scribante, A., Sfondrini, M.F., Broggini, S., D'Allocco, M. and Gandini, P. (2011) Efficacy of ESTHETIC RETAINERS: clinical comparison between multistranded wires and direct-bond glass fiber-reinforced composite splints. *International Journal of Dentistry*, 2011, 548356.
43. Bjering, R., Birkeland, K. and Vandevska-Radunovic, V. (2015) Anterior tooth alignment: a comparison of orthodontic retention regimens 5 years posttreatment. *The Angle Orthodontist*, 85, 353–359.