

# Comparative assessment of relapse and failure between CAD/CAM stainless steel and standard stainless steel fixed retainers in orthodontic retention patients: *A randomized controlled trial*

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## ABSTRACT

**Objectives:** To compare relapse and failure rates of computer-aided design/computer-aided manufacturing (CAD/CAM) and standard fixed retainers.

**Materials and Methods:** This single-center, single-blinded, prospective randomized clinical trial included 46 patients who completed active orthodontic treatment and complied with retention visits. The patients were randomly assigned to three groups: CAD/CAM group with multistranded stainless steel wires (CAD/CAM,  $n = 16$ ), Lab group with the same multistranded wires (lab,  $n = 16$ ), and control group with stainless steel Ortho-FlexTech wires (traditional,  $n = 14$ ). Intraoral scans were obtained at placement of fixed retainers (T1), 3-month visit (T2), and 6-month visit (T3) and measured for intercanine width and Little's Irregularity Index. Failures were recorded.

**Results:** The CAD/CAM group experienced less intercanine width decrease than the traditional group at 3 months (mean difference,  $0.83 \pm 0.16$  mm; 95% confidence interval [CI], 0.44–1.22;  $P < .001$ ) and 6 months (mean difference,  $1.23 \pm 0.40$  mm; 95% CI, 0.19–2.27;  $P < .05$ ). The CAD/CAM group experienced less increase in Little's Irregularity Index compared with the lab group within 3 months (mean difference,  $0.81 \pm 0.27$  mm; 95% CI, 0.12–1.49;  $P < .05$ ). Failures from greatest to least were experienced by the lab group (43.8%), the CAD/CAM group (25%), and the traditional group (14.3%).

**Conclusions:** Within 6 months of bonding fixed retainers, CAD/CAM fixed retainers showed less relapse than lab-based and traditional chairside retainers and less failures than lab-based retainers. (*Angle Orthod.* 0000;00:000–000.)

**KEY WORDS:** CAD/CAM; Fixed retainers; Digital orthodontics

## INTRODUCTION

Retention or maintenance of tooth positions in function and esthetics after orthodontic treatment has

been a challenging subject for orthodontists. Methods of retention have been variable, and there are advantages and disadvantages to every approach. Removable retainers in the form of acrylic-wire Hawley appliances and thermoforming clear retainers were commonly used, but the greatest drawback was patient compliance. Hence, since its first documented use in the 1970s, fixed retainers have gained substantial popularity, with reported increased use in recent years.<sup>1,2</sup>

Despite its effectiveness in maintaining alignment, fixed retention has been a subject of controversy. Foremost, bonding sites for fixed retainers have been shown to be areas at greater risk of plaque accumulation, potentially leading to increased dental morbidity.<sup>3,4</sup> However, recent systematic reviews found otherwise: there was no difference in caries, gingival

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disease, and periodontal disease indicators between patients with and without fixed retainers; poor oral hygiene was cited as a greater risk than fixed retainers.<sup>3,4</sup> Another point of controversy was the failure rate of fixed retainers. Failure of fixed retainers can be due to separation, breakage of the retainer, and unwanted tooth movement; of these, separation was the most common.<sup>5</sup> Studies varied on the definition of failure, finding rates ranging from 3% to 71%.<sup>3-6</sup> Since their inception, fixed retainers have undergone variations, including wire composition, thickness, and bondable mesh pads, all of which have empirical advantages and disadvantages.<sup>1</sup> Recent studies have also investigated different curing methods, bonding techniques, and adhesive materials and their effect on failure, with variable outcomes.<sup>7-10</sup> However, the problem of failure remains. Lastly, fixed retainers were found to be insufficient in preventing relapse by themselves due to the short span for which they were commonly used.<sup>3-6</sup> Clinicians are generally in agreement that removable retainers should ideally be used even when fixed retainers are used. Evidence speaks to the importance of determining appropriate indications for the use of fixed retainers, followed by precise application when they are used to improve the success of fixed retainers.

In recent years, computer-aided design and computer-aided manufacturing (CAD/CAM) systems have been developed to assist in clinical orthodontics. While they have been widely used for active treatment, their use in fixed retention has been a more recent development with limited evidence. A case report<sup>11</sup> was published, followed by in vitro and in vivo observations demonstrating the safety of CAD/CAM-based fixed retainers and their potential to be more effective in minimizing plaque accumulation and preventing relapse.<sup>12,13</sup> Recent clinical trials demonstrated significant marginal improvement in periodontal indexes, but no substantial changes in preventing relapse and lowering failure rates compared with controls.<sup>13,14</sup> These studies were limited by their comparison of carved nickel-titanium wires to other types of wires for fixed retention. Additionally, the researchers did not account for the fact that these customized fixed retainers have to be requested from a third party, leading to additional costs and delays in delivery.

The primary aim of this study was to investigate, over a 6-month period, if novel CAD/CAM-based stainless steel fixed bonded retainers (CAD/CAM) resulted in less relapse than lab-based fixed retainers (lab) using the same type of wire as the CAD/CAM system or traditional chairside fixed retainers (traditional) using stainless steel Ortho-FlexTech wire. Relapse was measured as a change in intercanine

width (ICW) and Little's Irregularity Index (LII).<sup>15</sup> A secondary aim was to observe whether CAD/CAM fixed retainers resulted in less failure than the other retainers.

## MATERIALS AND METHODS

### Trial Design

This was a single-center, prospective, three-arm parallel randomized controlled trial with simple randomized allocation to the three study groups. No changes were made to the protocol after the trial commenced. The study was done in accordance with the tenets of the Declaration of Helsinki, and the protocol was approved by the Institutional Review Board of Saint Louis University School of Medicine (protocol No. 30648).

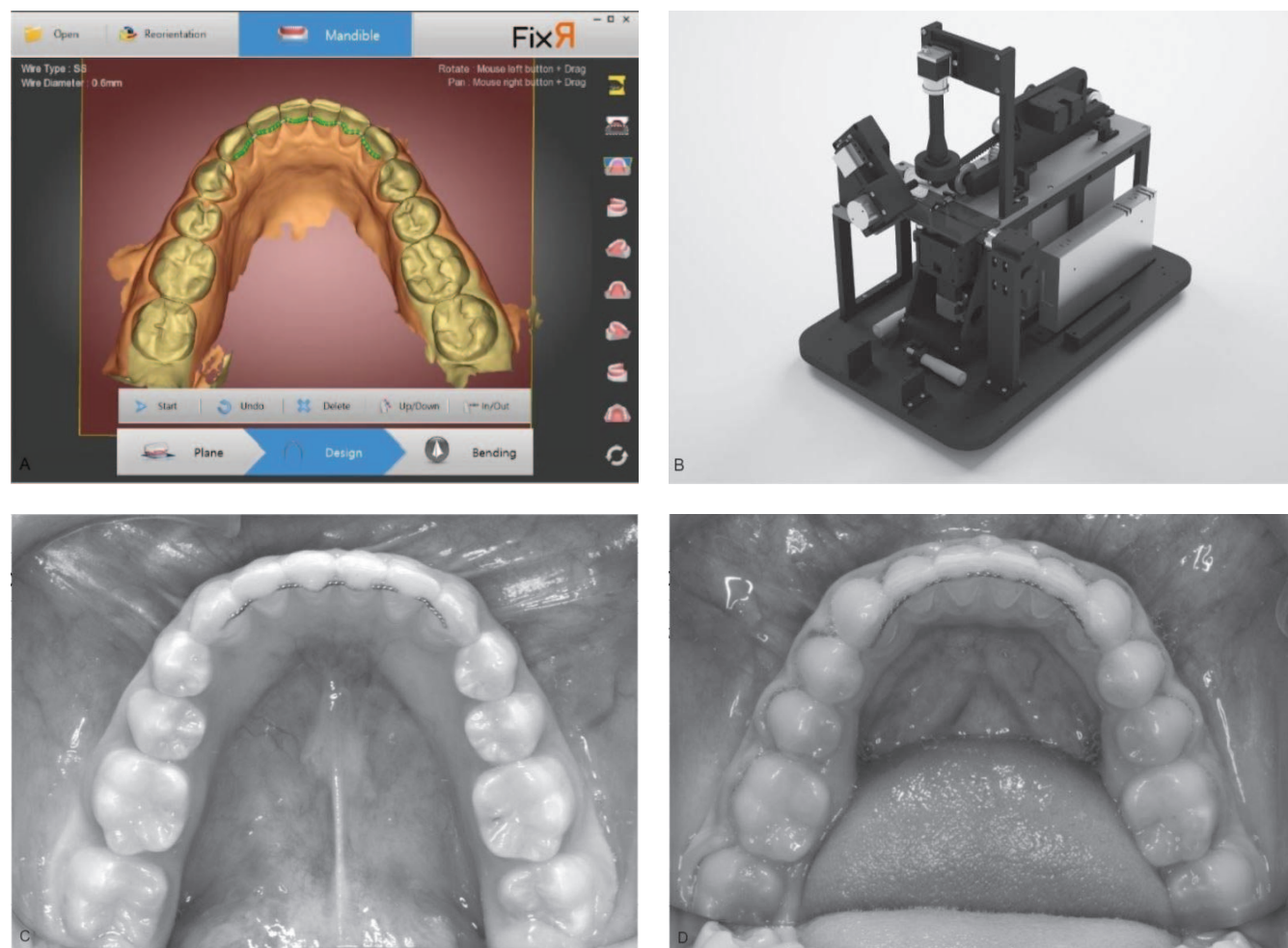
### Participants, Setting, and Eligibility Criteria

The study was carried out at the orthodontic clinic of Saint Louis University, Saint Louis, Missouri, from September 2019 to November 2020. Patients were recruited at the appointment before debonding orthodontic appliances. Inclusion criteria were (1) completion of comprehensive orthodontic treatment; (2) Class I molar and canine relationship based on Andrew's criteria for finishing,<sup>16</sup> and (3) need for a fixed retainer on the mandibular anterior teeth assessed before debonding. Patients were excluded based on refusal to participate in the study and conditions contraindicating fixed retainers, including poor oral hygiene and pathology.

### Intervention

The main intervention for this study was custom-bent fixed retainer wire from a novel in-office CAD/CAM system with FixR software (Figure 1A) and the Bender1 machine (Figure 1B) (YOAT Corporation, Lynwood, Wash) compared with controls. Multistranded stainless steel Dentaflex wires (Dentaurum GmbH & Co., Ispringen, Germany) were used (Figure 1C). The control groups were lab-based (lab) and traditional chairside (traditional) bonded retainers. The lab group used the same type of wire as the CAD/CAM group, but it was manually bent by a single experienced lab technician. The traditional group had stainless steel Ortho-FlexTech wires bonded (Reliance, Itasca, Ill) (Figure 1D).

On the day of active appliance removal, the fixed retainer wire was bonded on the lingual surfaces of the patient's mandibular anterior teeth in the following sequence: prophylaxis, application of 35% phosphoric acid etchant gel and Assure Plus bonding agent per the manufacturer's recommendations (Reliance),



**Figure 1.** Study group fixed retainer types: (A) FixR CAD software by YOAT Corporation. (B) Bender1 wire-bending robot. (C) DentaFlex-type fixed retainer for CAD/CAM and lab group; (D) Ortho-FlexTech fixed retainer for the traditional group.

placement of fixed retainer wire secured with floss, application of FlowTain low-viscosity flowable light cure resin (Reliance), curing with ELIPAR LED type curing light (3M, Saint Paul, Minn), and removal of excess cement.

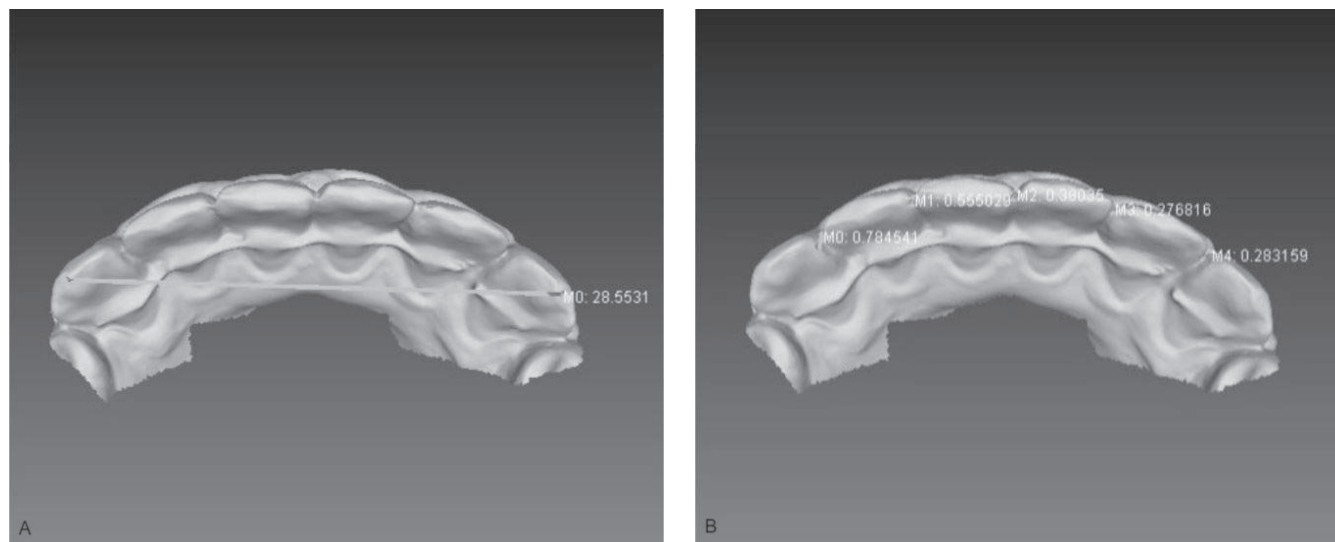
Information on patients' ages at the end of orthodontic treatment, gender, treatment duration, and pre-treatment Angle classification<sup>17</sup> was obtained. Preorthodontic treatment (T0) digital models scanned with an extraoral scanner from physical casts and stored on Orthoinsight software (Motion View Corporation, Chattanooga, Tenn) were measured for tooth size/arch length discrepancy.<sup>18</sup> Preorthodontic treatment and debond (T0 and T1) lateral cephalograms were traced and measured by a single calibrated examiner for lower incisor to mandibular plane angle (IMPA) using Dolphin software (Dolphin Imaging & Management Solutions & Patterson Technology, Lake Oswego, Oregon).<sup>19</sup> Intraoral digital impressions were obtained at debond (T1), 3-months (T2) and 6-months (T3) post-

treatment using calibrated TRIOS scanners (3Shape A/S, Copenhagen, Denmark). The primary measurements of the study, ICW (Figure 2A) and LII (Figure 2B), were made using the Meshlab open source software using the 3-dimensional (3D) ruler measurement tool. Secondly, failure of retainers was recorded at each visit. Complete or partial detachment were considered failures. If a patient were to lose the retainer wire, the patient was still scanned, but excluded from any further analysis.

### Sample-Size Calculation

A priori sample size was calculated using G\*Power (version 3.1.9.3; Franz Faul, Universitat Kiel, Kiel, Germany) software based on a previous retrospective study assessing relapse.<sup>20</sup> With an effect size of 0.5, the ideal sample size was determined to be 14 per group to obtain 80% power at alpha level of 0.05. Greater than standard attrition was expected as no incentives were given to the participants.





**Figure 2.** Meshlab software measuring tool: (A) ICW width measurement (m0:28.5531 mm). (B) LII measurement (m0: 0.784541 mm, m1: 0.555029 mm, m2: 0.38035 mm, m3: 0.276816 mm, m4: 0.283159 mm).

### Randomization

Participants were assigned to groups using a simple random pattern determined by a statistician not participating in the present study using online randomization software (randomization.com). To secure allocation concealment, the sequence generator was contacted by phone for group assignment after determining patient eligibility for enrollment.

### Blinding

The patients were blinded regarding their assignment to study groups. The principal investigator and the clinicians bonding the fixed retainers could not be blinded regarding the assignment of patients to groups in the clinical setting. Upon data analysis, patients' records were encrypted to minimize observer and measurement bias.

### Statistical Analysis

SPSS software (version 26.0; IBM Corporation, Armonk, NY) was used for statistical analysis. Chi-square test of independence was used to compare the study groups on baseline variables. A Shapiro-Wilk test was used to test for normality of the parametric variables. Analysis of variance (ANOVA) was used to compare the study groups with respect to confounding variables (age, treatment duration, crowding, T1-T0 IMPA, T1-T0 treatment ICW, and T1 LII). ANOVA was used to compare the study groups on the primary outcomes of interest (ICW and LII). Bonferroni post hoc analysis was used subsequent to a significant ANOVA. Failures of fixed retainers were noted and analyzed

with intention-to-treat. *P* values less than .05 were deemed significant.

### Error of the Method

Ten patients were randomly selected after 2 weeks from the initial date of measurement and remeasured for all parametric variables by the same operator.

### RESULTS

Of the 81 patients recruited, 6 were excluded due to lack of eligibility or refusal. Thus, 75 patients were randomized and allocated to the three study groups. Forty-six patients presented for follow-up visits at 3 months and 24 patients at 6 months (Figure 3). Analysis was carried out for patients who presented for the 3-month visits (*n* = 46).

Baseline characteristics of the compliant patients exhibited no significant differences based on sex, age, and molar classification (*P* > .05) (Table 1). Other confounding variables did not exhibit significant differences (*P* > .05) (Table 2). Two patients underwent extraction of two premolars in the mandibular arch in active orthodontic treatment, one each in the CAD/CAM and lab groups. All participants were treated with the edgewise appliance.

Comparison among the study groups was done for primary outcome variables (Table 3). ANOVA of T2-T1 ICW showed statistically significant (*P* < .001) differences among the groups. Post hoc analysis found less ICW change in the CAD/CAM group compared with the traditional group (mean difference,  $0.83 \pm 0.16$  mm; 95% confidence interval [CI], 0.44–1.22; *P* < .001) and less change in ICW in the lab group compared with the

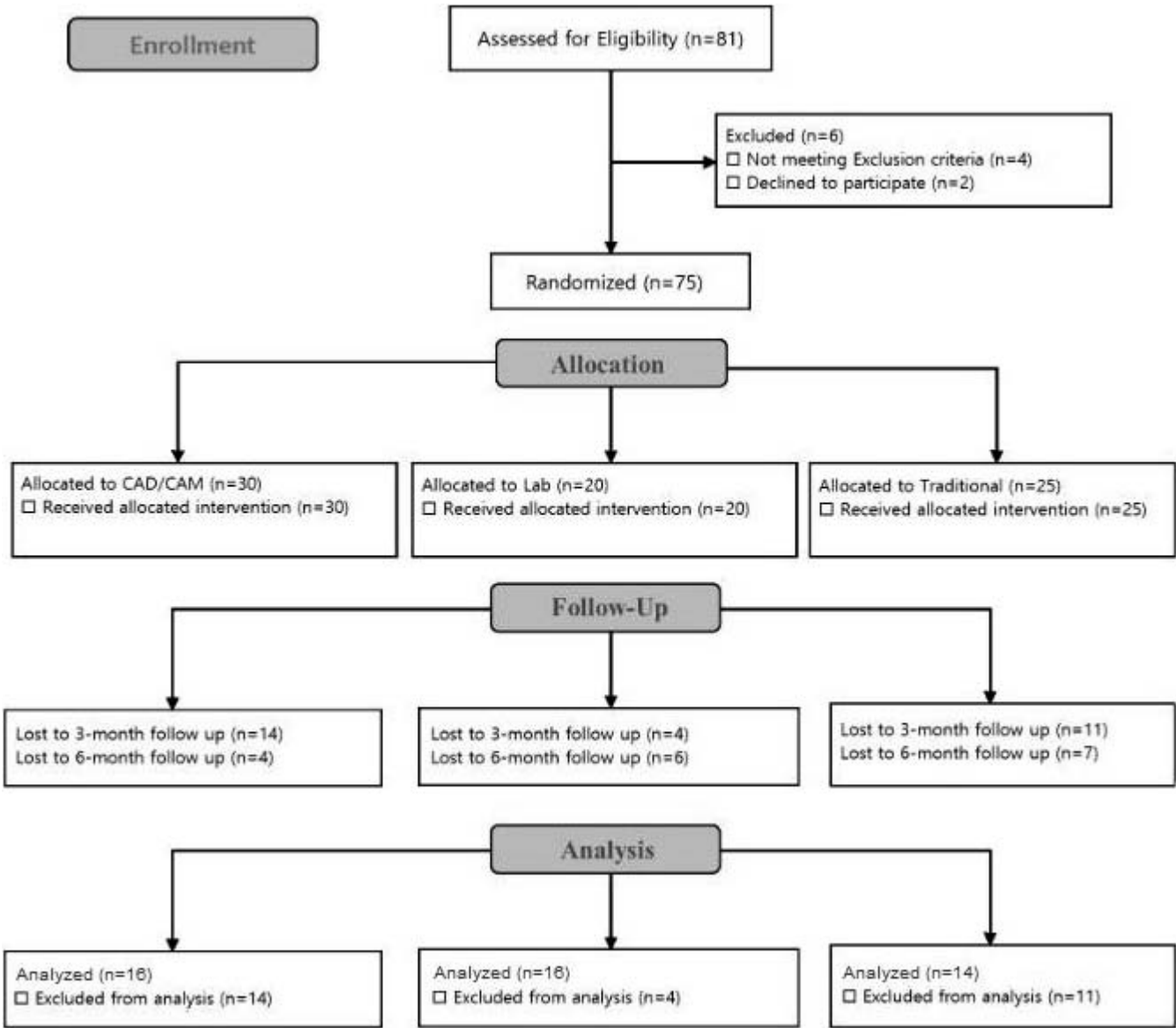


Figure 3. CONSORT diagram of patient flow during the trial.

Table 1. Baseline Characteristics of the Groups for Categorical Variables<sup>a</sup>

| Variable                 | CAD/CAM (n = 16),<br>Median (%/IQR) | Lab (n = 16),<br>Median (%/IQR) | Traditional (n = 14),<br>Median (%/IQR) | P Value <sup>b</sup> |
|--------------------------|-------------------------------------|---------------------------------|-----------------------------------------|----------------------|
| Gender, No. (%)          |                                     |                                 |                                         | .185                 |
| Male                     | 9 (19.6%)                           | 4 (8.7%)                        | 5 (10.9%)                               |                      |
| Female                   | 7 (15.2%)                           | 12 (26.1%)                      | 9 (19.6%)                               |                      |
| Age, y, median (IQR)     | 16.5 (15.3)                         | 15.8 (13.6)                     | 15.2 (13.6)                             | .707                 |
| Molar classification (%) |                                     |                                 |                                         | .750                 |
| I                        | 7 (15.2%)                           | 6 (13%)                         | 7 (15.2%)                               |                      |
| II                       | 8 (17.4%)                           | 10 (21.7%)                      | 6 (13%)                                 |                      |
| III                      | 1 (2.2%)                            | 0 (0%)                          | 1 (2.2%)                                |                      |

<sup>a</sup> CAD/CAM indicates computer-aided design/computer-aided manufacturing; IQR, interquartile range.

<sup>b</sup> Chi-square test (sex and molar classification) and Kruskal-Wallis test (age). Significance set at  $P < .05$ .

**Table 2.** Baseline Characteristics of the Groups for Continuous Variables<sup>a</sup>

| Variable               | CAD/CAM, Mean $\pm$ SD [95% CI] | Lab, Mean $\pm$ SD [95% CI]     | Traditional, Mean $\pm$ SD [95% CI] | P Value <sup>b</sup> |
|------------------------|---------------------------------|---------------------------------|-------------------------------------|----------------------|
| Treatment duration (d) | 625.4 $\pm$ 153.3 [543.7–707.1] | 721.8 $\pm$ 251.8 [580.0–863.5] | 738.2 $\pm$ 319.1 [554.0–922.4]     | .413                 |
| T0 IMPA                | 93.5 $\pm$ 10.0 [88.2–98.9]     | 97.8 $\pm$ 7.4 [93.8–101.7]     | 94.3 $\pm$ 8.6 [89.4–99.3]          | .354                 |
| T1 IMPA                | 98.7 $\pm$ 8.1 [91.1–101.0]     | 96.0 $\pm$ 9.3 [94.4–103.0]     | 96.3 $\pm$ 10.5 [90.2–102.3]        | .670                 |
| T1-T0 IMPA             | 2.5 $\pm$ 9.9 [–2.8–7.8]        | 0.9 $\pm$ 7.0 [–2.8–4.7]        | 1.9 $\pm$ 10.6 [–4.2–8.1]           | .890                 |
| T0 ICW (mm)            | 27.9 $\pm$ 3.4 [25.8–29.9]      | 26.7 $\pm$ 2.2 [25.4–28.0]      | 26.4 $\pm$ 3.1 [24.5–28.3]          | .412                 |
| T1 ICW (mm)            | 28.0 $\pm$ 2.2 [26.8–29.2]      | 27.4 $\pm$ 1.7 [26.6–28.3]      | 28.1 $\pm$ 2.0 [26.9–29.2]          | .626                 |
| T1-T0 ICW (mm)         | 0.3 $\pm$ 3.9 [–2.0–2.7]        | 0.8 $\pm$ 1.5 [–0.1–1.6]        | 1.7 $\pm$ 2.5 [0.2–3.2]             | .454                 |
| T0 crowding (mm)       | 3.0 $\pm$ 2.4 [0.5–3.3]         | 1.9 $\pm$ 2.4 [1.5–4.4]         | 2.2 $\pm$ 1.8 [1.2–3.4]             | .458                 |

<sup>a</sup> CAD/CAM indicates computer-aided design/computer-aided manufacturing; CI, confidence interval; ICW, intercanine width; SD, standard deviation.

<sup>b</sup> Significance set at  $P < .05$ .

traditional group (mean difference,  $0.62 \pm 0.16$  mm; 95% CI, 0.23–1.02;  $P = .001$ ). The T3-T1 ICW change was lower in the CAD/CAM group compared with the traditional group (mean difference,  $1.23 \pm 0.40$  mm; 95% CI, 0.19–2.27;  $P = .02$ ). For LII, the CAD/CAM group exhibited less change T2-T1 than the lab group (mean difference,  $0.81 \pm 0.27$  mm; 95% CI, 0.12–1.49;  $P = .02$ ).

Among compliant patients, the failure rate was 28.3%, with the lab group exhibiting the highest rate of failure (43.8%) and the traditional group exhibiting the lowest (14.3%), but with no significant difference between them ( $P = .19$ ) (Table 4). Three failures happened in time for the 6-month visit (T3) and were evenly distributed among the study groups. When all patients were included, the rates of failures were significantly different among the study groups ( $P < .05$ ). Failures were all in the form of complete or partial separation at the wire-tooth interface with varying locations and extent. All patients with failures had the same retainer wires reattached, so they were not excluded from the study.

Intraclass coefficient values were above 0.95 for all parametric variables measured by the examiner. No serious harms were noted among the patients during the trial.

## DISCUSSION

CAD/CAM-based fixed retainers have been an increasing area of interest in recent years. Although several studies have investigated CAD/CAM fixed retainers in vitro and in clinical trials, no study controlled for the wire material and used CAD/CAM-based stainless steel wires. Studies have investigated CAD/CAM nickel-titanium wires in comparison to standard wires with different wire properties.<sup>12–14</sup> This trial compared relapse and failure of CAD/CAM-based fixed retainers with standard controls, one group using same wires manually bent by a lab technician and another using flexible wires directly bonded at chair-side.

After controlling for baseline variables, both the CAD/CAM fixed retainer group and the lab group exhibited less reduction in ICW than the traditional fixed retainer group during the first three months of retention. However, over the entire 6-month duration (T3-T1), there was less ICW reduction in the CAD/CAM group than the traditional group, but no difference between the lab and traditional groups, which could have been confounded by higher levels of failures in the lab group. Greater increase in incisor irregularity was noted in the lab group compared with the CAD/CAM group, which could also be explained by increased failures in the lab group. The findings

**Table 3.** Differences Among the Study Groups at Various Time Intervals<sup>a</sup>

| Measurements (mm) | CAD/CAM, Mean $\pm$ SD [95% CI]               | Lab, Mean $\pm$ SD [95% CI]                   | Traditional, Mean $\pm$ SD [95% CI]             | P Value |
|-------------------|-----------------------------------------------|-----------------------------------------------|-------------------------------------------------|---------|
| T2-T1 ICW         | –0.13 $\pm$ 0.23 [–0.25–(–0.01)] <sup>y</sup> | –0.34 $\pm$ 0.53 [–0.62–(–0.06)] <sup>z</sup> | –0.96 $\pm$ 0.51 [–1.26–(–0.67)] <sup>y,z</sup> | <.001*  |
| T2-T1 LII         | 0.20 $\pm$ 0.21 [0.09–0.31] <sup>y</sup>      | 1.01 $\pm$ 1.18 [0.38–1.64] <sup>y</sup>      | 0.61 $\pm$ 0.59 [0.27–0.95]                     | .02*    |
| T3-T2 ICW         | –0.29 $\pm$ 0.53 [–0.66–0.09]                 | –0.22 $\pm$ 0.19 [–0.36–(–0.08)]              | –0.38 $\pm$ 0.09 [–0.52–(–0.23)]                | .76     |
| T3-T1 ICW         | –0.39 $\pm$ 0.68 [–0.88–0.09] <sup>y</sup>    | –0.70 $\pm$ 0.74 [–1.23–(–0.18)]              | –1.62 $\pm$ 0.45 [–2.34–(–0.91)] <sup>y</sup>   | .02*    |
| T3-T2 LII         | 0.55 $\pm$ 0.75 [0.01–1.09]                   | 0.18 $\pm$ 0.51 [–0.19–0.54]                  | 0.053 $\pm$ 0.16 [–0.20–0.31]                   | .27     |
| T3-T1 LII         | 0.79 $\pm$ 0.79 [0.23–1.35]                   | 1.37 $\pm$ 1.47 [0.32–2.41]                   | 0.76 $\pm$ 0.20 [0.43–1.08]                     | .45     |

<sup>a</sup> CAD/CAM indicates computer-aided design/computer-aided manufacturing; negative mean values indicate a decrease from earlier time point to later time point.

<sup>y,z</sup> Indicates significant differences between groups based on post hoc analysis.

\*  $P < .05$ .

**Table 4.** Fixed Retainer Failures Among Study Groups for Compliant Patients and Overall With Intention-to-Treat Analysis<sup>a</sup>

|                     | Failure Rate Within Compliant, n (%) | P Value | Failure Overall, n (%) | P Value |
|---------------------|--------------------------------------|---------|------------------------|---------|
| Traditional Control | 2/14 (14.3%)                         | .19     | 2/25 (8%)              | .045*   |
| Lab-based Control   | 7/16 (43.8%)                         |         | 7/30 (23.3%)           |         |
| CAD/CAM             | 4/16 (25%)                           |         | 4/20 (20%)             |         |
| Total               | 13/46 (28.3%)                        |         | 13/75 (17.3%)          |         |

<sup>1a</sup> CAD/CAM indicates computer-aided design/computer-aided manufacturing;

\*  $P < .05$ .

regarding ICW were consistent with previous findings based on wire properties. DentaFlex wires used in the CAD/CAM and lab groups were empirically more rigid and subject to permanent deformation compared with Ortho-FlexTech wires that were flexible, conforming to the surfaces on which they were placed. Butler and Dowling<sup>21</sup> reported that thicker and rigid wires were able to maintain intercanine width better than flexible ones. To the contrary, Alrawas et al.,<sup>14</sup> found no significant difference in intercanine width changes between two different fixed retainer wires. A possible explanation could have been comparable rigidity of the different wires observed. Another explanation could have been variability in orthodontic treatment, such as treatment duration and extent of changes in intercanine width.<sup>22</sup>

The failures observed were all in the form of separation, and the rate in this study was consistent with previous studies with rates ranging from 12% to 50%.<sup>4,5</sup> According to the intention-to-treat analysis, the failure rates were significantly different among the study groups. However, the shortcoming of the analysis was the assumption that the noncompliant patients did not experience failures; there could potentially have been unnoticed failures, especially if the terminal points of the retainer wires remained bonded. Conversely, the failure rates among the compliant patients could have been inflated, assuming the same rate of failure among the noncompliant patients. Comparatively, CAD/CAM retainers resulted in less failures than the lab retainers but did not result in more favorable failure rates compared with traditional stainless steel Ortho-FlexTech wire, contrary to expectations. A possible reason could have been that greater flexibility of Ortho-FlexTech wires compared with DentaFlex wires may have been easier for the clinician to apply and adapt to the tooth surfaces.<sup>8</sup> Other possibilities could include variable competence in isolation and bonding techniques and patient compliance with being cautious during masticatory function<sup>6</sup>.

This study did provide a substantial level of evidence by virtue of its study design. Randomization minimized selection bias. The prospective nature of the study and blinding of patients on their assignments negated patient-related biases and established a temporal

relationship between the intervention and the outcomes. Intrarater reliability analysis demonstrated precision for all parametric measurements. The study was controlled for the materials and method used for bonding the fixed retainers, except for the difference in wire material for the traditional control group.

### Limitations

Blinding of the principal investigator was not possible and may have caused observer bias. However, the data were encrypted prior to measurement to minimize this bias. Substantial loss to follow-up predisposed this study to attrition bias. LII was inherently limited as it only accounted for relapse of the incisal edges of individual teeth relative to adjacent teeth from the occlusal view. LII did not account for relapse of buccolingual angulation and vertical dimension<sup>15</sup>. Lastly, the shorter term of the present study limits clinical applicability, as retention is a long-term subject.

The present trial was not registered. The protocol was not published before trial commencement. No funding or conflict of interest was declared.

### CONCLUSIONS

- Within 6 months of retention, patients with CAD/CAM multistranded stainless steel fixed retainers experienced less relapse in intercanine width compared with patients with traditional flexible multistranded stainless steel fixed retainers.
- Patients with CAD/CAM fixed retainers demonstrated less increase in incisor irregularity and failure than patients with fixed retainers manually bent by a lab technician.

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