Comparative assessment of the survival, stability and occlusal settling between two types of thermoplastic retainers: a prospective clinical trial

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Introduction: A controlled clinical trial was undertaken to compare the effectiveness of Vivera® and Duran® retainers with regard to the survival, stability and occlusal settling over the first 6 months of retention following the completion of clear aligner treatment.
Methods: Consenting participants who met the inclusion criteria were recruited from a single, metropolitan Melbourne orthodontic practice. The participants were divided according to their retainer type, Vivera® (n = 10) or Duran® (n = 14). Each retainer type was fabricated to a standardised design. Intra-oral scans were taken at the time of debond (T_0), at 3 months (T_2) and at 6 months (T_3). The participants wore their retainers full-time for the first 3 months and part-time for the remaining 3 months. The retainers were inspected at each review for damage that required replacement and failures were recorded in 'days from insert'. Patient reported failures were also recorded. Intra-oral scans were assessed for changes in incisor irregularity and the number of occlusal contacts and comparisons between the two retainer groups were investigated. The impact of full-time and part-time wear on occlusal settling was also assessed for each retainer type.
Results: Vivera® retainers showed a greater survival time in comparison to Duran® retainers, as no Vivera® failures were observed over the initial 6 months of retention. Both retainer groups showed similar results related to incisor stability and occlusal settling. Part-time wear resulted in increased posterior settling for both retainer types.
Conclusion: Vivera® retainers were as clinically effective as the Duran® retainer but exhibit a significantly higher survival rate. Part-time wear of full-coverage thermoplastic retainers appears to increase posterior settling.
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Introduction

Preventing relapse following orthodontic treatment remains an ongoing challenge for every practitioner. The inability to accurately predict which patients will be affected and, to what extent,[1] means that most patients will be prescribed retainers as a long-term preventive measure.[2]

Orthodontic retainers are available in a variety of forms, including fixed retainers, removable wire and acrylic appliances or thermoplastic retainers. Currently, there is no consensus regarding which retainer type and wear regime is best, and further research is indicated.[1]

A recent Australian survey found that thermoplastic retainers are the most-commonly prescribed removable retainer.[2] Studies undertaken elsewhere in the world have reported similar findings.[3–5] The increase in popularity of thermoplastic retainers is due to their superior aesthetics, improved patient comfort and reduced speech disturbance.[6–8] From the orthodontic

perspective, they are also cheaper and easier to fabricate.[9]

A key disadvantage of a thermoplastic retainer is its lower survival rate when compared with conventional wire and acrylic removable retainers, such as the Hawley appliance.[10–13] The reduced survival rate is due to poor wear resistance of the material, and also the changes that occur to its physical properties when placed in the oral environment.[14–19] It has been previously expressed that future developments in material quality may help improve the survival time of thermoplastic retainers.[9]

Historically, polypropylene and polyethylene co-polymers have been the two most frequently used materials to manufacture thermoplastic retainers.[20] Within the polyethylene co-polymers, the polyethylene terephthalate glycol co-polymer (PETG) is the most widely used. Independent studies have shown that PETG has better wear resistance[20,21] and dimensional stability[22] when compared with its polypropylene counterparts. However, a number of studies have reported that thermoplastic retainers made from PETG have a reduced survival time when compared with those of conventional wire and acrylic removable retainers.[10,11,13,23–25]

In 2007, Align Technology Inc (CA, USA) launched the Vivera® retainer. It is made from a polyurethane (PU) based material and, according to internal laboratory testing, it is marketed to be twice as durable and thirty percent stronger than other leading thermoplastic materials.[26] An independent laboratory study which compared a PU- with a PETG-based material, reported that the PU-based material exhibited greater hardness. Based on this finding, it was concluded that the PU-based material was likely to show greater wear resistance in the clinical setting than the PETG-based material.[27] However to date, no clinical trial has been conducted to provide verification.

Due to their occlusal coverage, thermoplastic retainers have the potential to interfere with occlusal settling, which is considered a favourable form of tooth movement following orthodontic treatment.[7,28] The development and use of a retainer material with greater wear resistance may mean vertical movement is impeded to an even greater extent, as the material possibly maintains its thickness and rigidity for a longer period of time.

The aim of the present study was to compare the survival time of two thermoplastic retainer materials, PU-based (Vivera®) and PETG-based (Duran®), during the initial 6 months of retention. A secondary outcome was to determine the effectiveness of each retainer to allow occlusal settling and maintain incisor alignment. The null hypothesis was that 'there would be no significant difference in the clinical efficacy of either retainer made of the different thermoplastic materials during the initial 6 months of retention'.

Methods

The present clinical trial was approved by the University of Melbourne Human Research Ethics Committee (ID: 1647697). It was undertaken in a single, private metropolitan orthodontic practice, which ensured that all participants received the same retention protocol. Participant recruitment commenced in February 2019 and ceased in September 2019. Patients nearing the end of their active clear aligner orthodontic treatment (Invisalign®, Align Technology Inc., CA, USA) were assessed by their treating orthodontist [clinical investigator S.L.] for inclusion in the prospective clinical trial according to the following inclusion criteria: (1) clear aligner treatment (CAT) completed in both maxillary and mandibular arches for a minimum 9 months, (2) non-extraction orthodontic treatment, (3) minimum age of 15 years and (4) prescribed removable retainers for both arches. Participants who received fixed retainers were excluded. Participants under the age of 15 years were excluded to manage and avoid their peak pubertal growth and the eruption of permanent teeth, especially second permanent molars, which may have been confounding factors related to stability and occlusal settling results.

A sample size calculation was undertaken based on the survival time in days between the two retainer types. It was assumed that a clinically meaningful difference in survival time would be thirty days with a standard deviation of twenty days, being two-thirds of the difference. With a significance level of 0.05 and 90% power, it was calculated that the minimum sample size would be 18 participants (nine in each group). The recruitment of participants in excess of this number was attempted to allow for possible drop-outs.

Participants who met the eligibility criteria were identified by the treating orthodontist at their appointment prior to debonding. The clinician outlined the study's

purpose to the participant, parent or legal guardian if the participant was under 18 years of age. Details of the study were explained using both verbal and written information. A written consent form was completed by participants prior to enrolment and debonding. There were no changes to the method following patient recruitment.

At the debond appointment (T_0), the clear aligner attachments were removed, an intraoral scan was acquired of the maxillary and mandibular dentitions and a bite registration taken in maximum intercuspation (iTero Element®, Align Technology Inc., CA, USA). The completed intraoral scan was sent to either Align Technology Inc., for fabrication of a Vivera® retainer, or to the practice's in-house laboratory with a standardised prescription for a Duran® retainer. As part of the orthodontic practice treatment planning process, the participant was given their preferred choice of retainer. The discussed and highlighted deciding factors included the difference in cost and that Vivera® came with three sets of retainers, which were manufactured by the same company that produced the clear aligners.

Once Align Technology Inc. received the intraoral scan for retainer fabrication, a 3D model was printed and used to produce the full-occlusal-coverage Vivera® retainer. The margins were scalloped and followed the gingival contour but no reason for this design was available. The exact fabrication procedure for Vivera® retainers is proprietary knowledge, including the initial thickness of the material blanks. It has been reported that the same highly automated system used to manufacture Align Technology's active aligners is also used to produce the Vivera® retainer.[29]

The Duran® retainers were fabricated by the orthodontic practice's in-house laboratory. An experienced technician manufactured each Duran® retainer in accordance with the manufacturer's instructions, which involved the use of a Biostar V® pressure forming machine (Sheu-Dental, Iserlohn, Germany). The blank material sheets were of 1 mm thickness. The buccal and lingual extensions were trimmed in a straight line covering the gingival margin of each tooth, following the standard thermoplastic retainer design.[30] The Duran® retainers covered all teeth in the maxillary and mandibular arches, as was the case for the Vivera® retainers.

All participants were scheduled to return fourteen days after their debond appointment for the insertion of their retainers' and were instructed to continue wearing their last aligner at night-time whilst waiting for their retainers to be delivered, which was the usual practice protocol. This period was standardised to fourteen days for both groups to allow for the fabrication and shipping of the Vivera® retainers and meant that any potential effect that the alteration in wear regime may have would be the same for each group.

At the retainer insertion appointment (T_1), all patients were given one maxillary and one mandibular retainer and instructed to wear the retainers full-time (20 + hours per day) for the first 3 months except when eating, drinking or cleaning of the teeth. The retainers were inserted and assessed by the orthodontist to ensure a retentive and firm fit across all teeth. Any manufacturing errors were recorded and replacement retainers were fabricated using the same protocol. Care and maintenance instructions, including the recommended use of Retainer Brite® (Dentsply Sirona, PA, USA), were standardised and provided to all participants. The next appointment was scheduled for 3 months from the day of initial retainer insertion. The participants were instructed to contact the practice immediately and return to the clinic earlier if they had any concerns or retainer breakages.

At the 3-month (T_2) and 6-month (T_3) review appointments, an intraoral scan was taken following the same protocol described for T_0. The maxillary and mandibular retainers were inspected for correct fit and for any damage that rendered the retainer a failure and required replacement. Following T_2, the patients were instructed to reduce wear to night-time only (6-10 hours per day) until T_3.

Failure was defined as any fracture of the retainer, which included cracks in the margins and/or perforation of the retainer material. Although cracks and perforations do not always render a retainer ineffective or requiring replacement, it was felt they were indicative of the material's durability and resistance to wear. Hence, for the present study, cracks and perforations were included in the definition of a failure.

If a patient presented for an unscheduled emergency prior to T_2 and T_3 appointments, the same survival evaluation was undertaken. These appointments were recorded and contributed to the survival analysis. The loss of a retainer would be recorded but not counted as a failure, as this was not deemed to be a failure of

the retainer material itself but rather, a general care issue associated with removable appliances. Patients who failed to attend T_2 and T_3 appointments were contacted and rescheduled. When rescheduling T_3 appointments, each patient was asked to check their retainers for any cracks or perforations. If these were present, the retainer was deemed a failure. If cracks or perforations were not present, the retainer survival was recorded in 'days from insert' to the date at which its continued survival was determined. T_3 stability and occlusal contact data were collected from the intra-oral scan once it was taken at their rescheduled appointment time.

The primary outcome was retainer survival over the initial 6 month period of retention. Survival time was defined as the number of days between initial retainer insertion and the date that a failure was determined to have occurred by the orthodontist. If a retainer did not fail, its survival time was recorded as the observational 6 months.

The secondary outcomes were stability and occlusal settling (Table I). Stability was determined using Little's Irregularity Index (LII), which has been widely used as an assessment tool[1,31] to measure the displacement of the five contact points between the anterior teeth. Both the maxillary and mandibular anterior teeth were assessed. Each participant's de-identified intraoral scans from pre-treatment, T_0, T_2 and T_3 were imported into MeshLab® software (version 2016.12, National Research Council, Rome, Italy[32]). The maxillary and mandibular arches were measured separately from the occlusal view (Fig. 1). The software linear measuring tool was selected and the sum of the anatomical contact point displacements of the six anterior teeth were tallied to produce the final value. Each linear measurement was

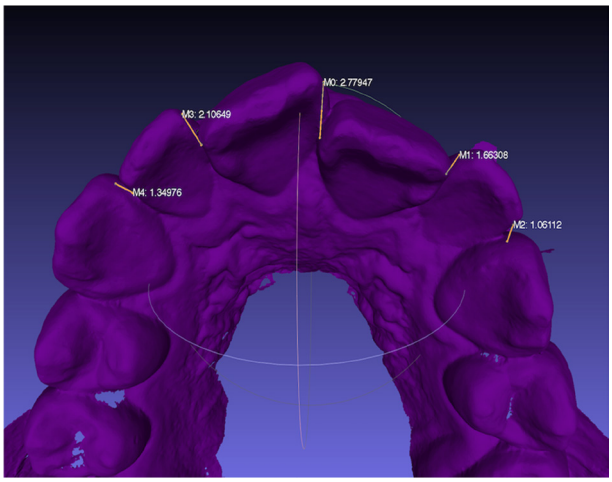

Figure 1. Demonstration of Little's Irregularity Index applied to the maxillary anterior teeth using MeshLab® software. The index is the sum of contact point displacements.

obtained level to the occlusal plane and was recorded and measured twice by one investigator (B.C) in a single session. The two linear measurements were averaged and calculated to one decimal point. Post-treatment stability data was collected for both T_2 and T_3 reviews by subtracting the previous intra-oral scan's LII value from the more recent LII value.

Occlusal settling was measured by manually counting the number of occlusal contacts present on the intraoral scan taken at each time point and comparing the score with the number counted on a previous scan. The de-identified T_0, T_2 and T_3 intraoral scans were imported into OrthoCad® software (version 5.6.0.222, Align Technology Inc., CA, USA) (Fig. 2). The mandibular arch was assessed from the occlusal view and the occlusalgram command was selected in the software at a sensitivity level of less than but not equal to 0.2 mm and the number of occlusal contact

Table I. The secondary outcomes (stability and occlusal settling) measurement methods are displayed.

	Unit	Description
Stability		
Little's Irregularity Index	mm	The sum of the five contact point displacements for the anterior teeth.
Occlusal settling		
Occlusal contacts	Number of contacts	The numerical value of contact points measured on the mandibular arch. Two sensitivity levels measured: 'Occlusal Contact' = < 0.2 mm 'Near Occlusal Contact' = 0.2 mm < *x* < 0.4 mm

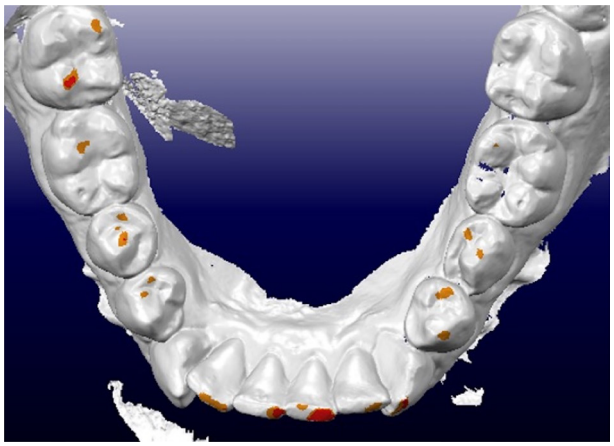

Figure 2. Demonstration of occlusal contacts using OrthoCAD® software. The coloured dots indicate occlusal contacts of less than 0.2 mm sensitivity.

points were then manually counted. The total count of the occlusal contact points across the mandibular arch formed the final determination. This method was repeated for occlusal contacts at a sensitivity level of 0.2 mm to less than but not equal to 0.4 mm and these measurements were recorded separately as 'near' occlusal contacts. No attempt was made to categorise the location of the occlusal contact points as either ideal or non-ideal. All measurements were recorded by the primary investigator (B.C). Changes in the number of occlusal contacts between time points was calculated by subtracting the number of the previous scan from the current scan, that is, T_2–T_0 and T_3–T_2.

Blinding of the clinical investigator to the retainer type was not possible, as that person was responsible for appliance ordering and manufacture. The data collector/outcome assessor (B.C) was blinded to the participant's retainer allocation when assessing and measuring the outcomes, which reduced the potential for reporting bias. An external statistician who was not blinded was allocated the role of analysing the data.

Statistical analysis

All analyses were conducted using the Statistical Package for the Social Sciences (version 26, IBM SPSS Inc., NY, USA) and R statistical software (Version 4.0.2, R Foundation for Statistical Computing, Vienna, Austria), with statistical significance set at 5% and bias-corrected. A survival analysis was carried out to compare the two retainer types. This included a comparison of the number of failures between the retainer groups and a calculated survival time in days. Kaplan-Meier plots were used to compare the breakage rates of Vivera® and Duran® retainers. Each retainer was considered an independent entity and replacement retainers were included in the analysis. A comparison of the retainer types was made by the use of a log-rank test of the available data collected for each participant over the initial 6 months of retention. As the Vivera® group did not experience any failures during the observation period, a non-parametric re-sampling bootstrap method was used to calculate the mean number of days to failure for the Duran® group. The bias corrected and accelerated method was used to calculate 95% confidence intervals based on 9,999 bootstrap replicates.

The stability data of LII approximated a normal distribution. Therefore, an independent t-test statistic, not assuming equal variance, was performed using the mean and standard deviations between the retainer groups. This compared the change in LII for each retainer group recorded between T_0 and T_2 and T_2 and T_3. A change of 1 mm was considered clinically significant, as reported in a previous study.[33]

The occlusal settling data did not approximate a normal distribution. Therefore, a comparison between retainer groups was conducted using the non-parametric Mann-Whitney test, which assessed any change in distribution between the two retainer groups. Separate analyses were completed for occlusal contacts and near occlusal contacts and also anterior and posterior locations. A change in the number of occlusal contacts based on full-time wear and night-time wear was also assessed for each retainer type. As this compared the 3 month and 6 month data within the same retainer group, a paired Wilcoxon Signed Rank test was applied.

Any participant who had missing data from a particular outcome measure was still included in other outcome measures, where other data for that participant was available.

Results

Twenty-four patients (median age 31 years, IQR 26–39) who met the inclusion criteria consented to participate in the study. Ten chose to receive Vivera® retainers (4 males, 6 females, median age 34 years, IQR 24–48) and fourteen selected the 'in-house' Duran® retainer (6 males, 8 females, median age 31 years, IQR 26–38). One Vivera®

participant was excluded from the study due to the presence of fixed retention at the time of the 3 month scan. This resulted in no data being obtained from this participant for study inclusion. The remaining 23 participants attended their 3 month recall appointment. However, due to operator error, two (1 Vivera®, 1 Duran®) 3 month intra-oral scans were irretrievable or not taken. At the 6 month recall, operator error resulted in seven participants' (2 Vivera®, 5 Duran®) intra-oral scans being irretrievable or not taken. One Vivera® participant also had a maxillary lateral incisor extracted just prior to their 6 month recall. This made the maxillary scan unusable for stability data and the overall scan unusable for occlusal settling data. The participant flow is visually summarised in Figure 3.

Baseline data were collected for all participants and there were similar median age and gender distributions between the groups (Table II). There was no statistically significant difference in the mean pre-treatment LII between the retainer groups in either the maxillary ($P = 0.24$) or mandibular ($P = 0.95$) arches.

Primary outcome: retainer survival

The mean follow-up period (T_1–T_3) of all participants was 216.8 days (SD = 47.9). The difference in the mean number of failures between the groups was statistically significant ($P = 0.007$). None of the Vivera® participants experienced an appliance failure. In comparison, 57% of Duran® participants (8 of 14) suffered at least one failed retainer over the

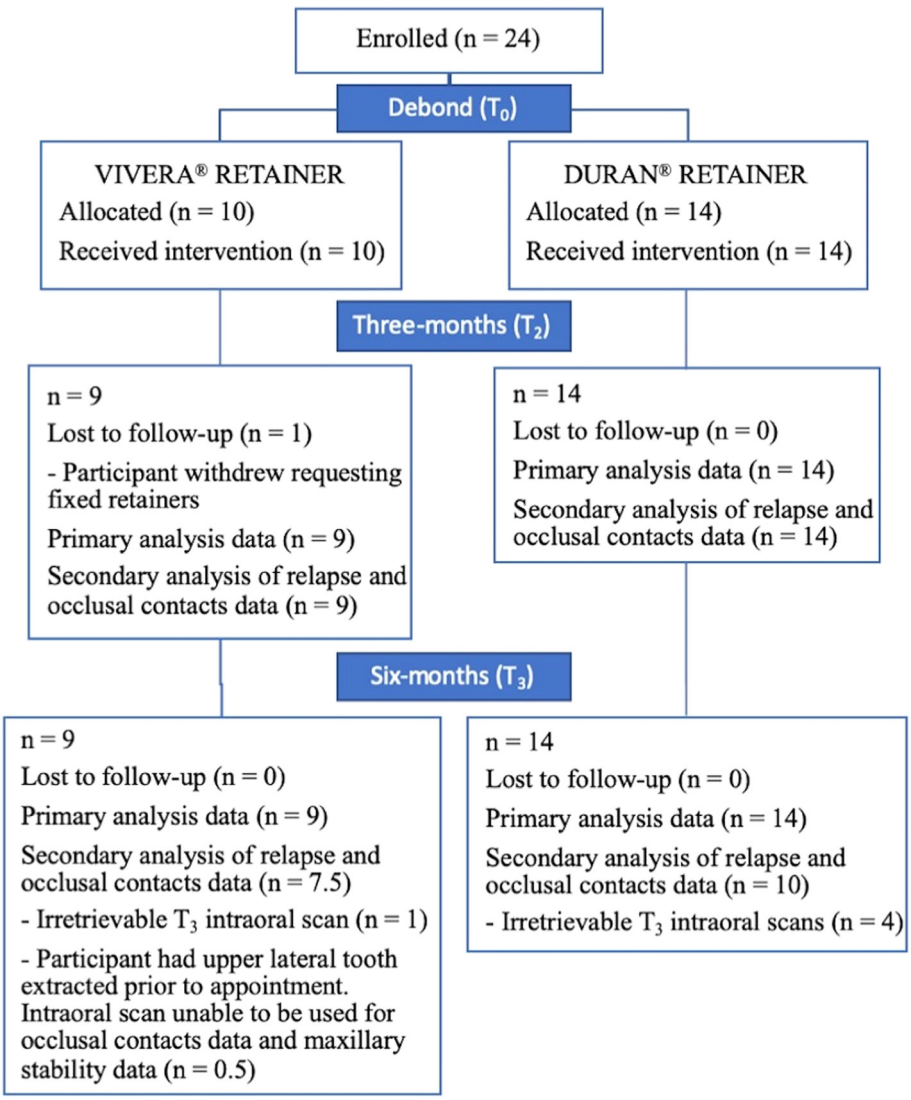

Figure 3. Flowchart of participants in the study.

Table II. Patient demographic information at the time of T_0 and pre-treatment clinical characteristics of subjects in Vivera® and Duran® retainer groups.

	Vivera® (*n* = 10)	Duran® (*n* = 14)
Gender		
Male	4 (40%)	6 (42.8%)
Female	6 (60%)	8 (57.1%)
Age (yr)		
Median (IQR)	34 (28-48)	31 (26-38)
Pre-treatment characteristics		
Skeletal classification		
Class I	5 (50%)	8 (57.1%)
Class II	4 (40%)	6 (42.8%)
Class III	1 (10%)	0
Dental classification		
Class I	7 (70%)	10 (71.4%)
Class II division 1	2 (20%)	1 (7.1%)
Class II division 2	1 (10%)	3 (21.4%)
Class III	0	0
Missing teeth (excluding third molars)		
None	9 (90%)	14 (100%)
Missing two premolars	1 (10%)	0
Missing four premolars	0	0

6-month observation period (Table III). Based on the initial Duran® retainers alone, the survival rate of the maxillary retainer was 71% and the mandibular retainer was 93%.

The eight Duran® failure patients experienced failure of the maxillary retainer. Only two of the patients exhibited mandibular retainer failure. Three participants experienced repeated issues with two episodes of maxillary retainer breakage. Of the eleven maxillary retainers deemed failures, one fractured in half, nine cracked at various locations along the material margin and one had both perforations and a cracked margin. The two mandibular retainer failures were due to unilateral cracks in the canine/premolar region. No participants misplaced their retainers during the 6 month period.

No failures were observed in the Vivera® retainer group over an absolute mean time of 220.4 days (SD = 52). The absolute observed mean survival time for the Duran® retainer group was 130.4 days (SD = 56.6). As the Vivera® retainer group did not experience any failures, a standard survival analysis could not be performed. Instead the non-parametric re-sampling bootstrap method was used to determine the mean number of days to failure for the Duran® retainer group. This estimated the mean days to failure for the Duran® retainers to be 388 (95% CI = 223–708). This survival analysis was calculated on a per-retainer basis, meaning that each retainer was considered an independent entity, and all fabricated retainers were counted, including the initial and any replacement retainers. A Kaplan–Meier plot comparing the proportion of broken retainers over time between the two retainer groups is included in Figure 4.

Secondary outcome: Stability

The LII measurements at T_0 and the change in LII at T_2 and T_3 were tabulated (Table IV). There was no statistically significant difference in the mean change of LII in the mandibular arch between the two groups at either T_2 ($P = 0.53$) or T_3 ($P = 0.39$). There was also no statistically significant difference in the mean change of LII in the maxillary arch between the two groups at either T_2 ($P = 0.41$) or T_3 ($P = 0.08$) (Figs. 5, 6).

Table III. Reason for retainer failure over 6 months, including initial and subsequent retainers inserted.

	Vivera® Retainer		Duran® Retainer	
Total number of subjects	9		14	
Total number of retainers	18		41	
	Maxillary	Mandibular	Maxillary	Mandibular
Reason				
Fractured/cracked	0	0	10	2
Perforated	0	0	1	0

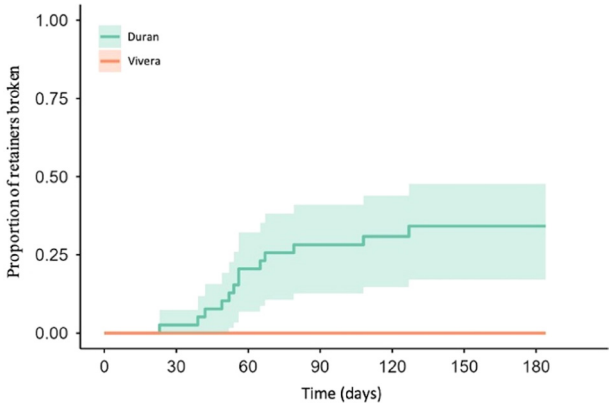

Figure 4. Kaplan-Meier plot comparing the proportion of retainers broken over time between the two retainer groups.

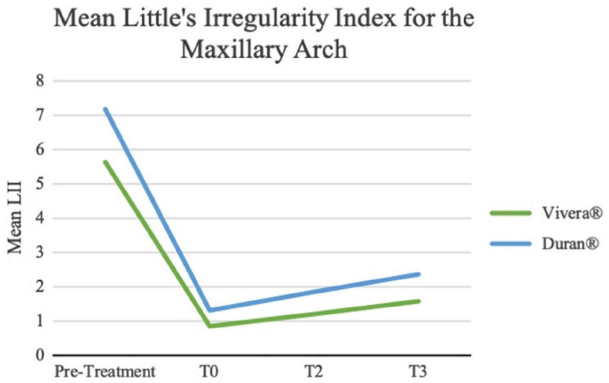

Figure 5. Mean Little's Irregularity Index (mm) for the maxillary arch at pre-treatment, T_0, T_2 and T_3 for the Vivera® and Duran® retainer groups.

Secondary outcome: Occlusal settling

The occlusal contacts measured at T_0 and the change in the number of occlusal contacts at T_2 and T_3 were tabulated (Table V). Occlusal contacts were separated into anterior and posterior. For the median change in the number of occlusal contacts, there was no statistically significant difference between retainer groups either anteriorly ($P = 0.65$) or posteriorly ($P = 0.8$) at T_2. At T_3, there was also no statistically significant difference in the median change in the number of occlusal contacts either anteriorly ($P = 0.3$) or posteriorly ($P = 0.54$) between the two groups.

For the median change in the number of near occlusal contacts, there was no statistically significant difference between the retainer groups either anteriorly ($P = 0.41$) or posteriorly ($P = 0.6$) at T_2. At T_3, there was also no statistically significant difference in the change in median number of near occlusal contacts either anteriorly ($P = 0.06$) or posteriorly ($P = 0.3$) between the two groups.

The median number of occlusal contacts was also compared between full-time (T_1–T_2) and night-time (T_2–T_3) wear for each retainer group (Tables VI and VII). The Vivera® group showed no statistically significant change in anterior occlusal contacts ($P = 0.057$) or near occlusal contacts (i = 0.21). However, the posterior contacts showed a statistically significant increase in the median number following the night-time wear regime. This was true for both occlusal contacts ($P = 0.02$) and near occlusal contacts ($P = 0.05$). The Duran® group showed no statistically significant change in anterior occlusal contacts ($P = 0.75$) or near occlusal contacts ($P = 0.46$). There was a statistically significant increase in the median number of posterior occlusal contacts following the night-time wear regime ($P = 0.03$). However, for the posterior near occlusal contacts, there was no

Table IV. Stability measurements of Little's Irregularity Index (mm). Data are presented in the form of mean, standard deviation and P-value due to normal distribution.

	Vivera®		Duran®			95% CI		
Little's Irregularity Index	Mean	SD	Mean	SD	*P*-value	Difference in Mean	Lower	Upper
Pre-treatment maxillary	5.62	2.77	7.55	2.83	0.16	1.93	-4.67	0.83
Pre-treatment mandibular	7.53	4.1	8.03	3.9	0.8	0.5	-4.48	3.48
3-month relapse (T_2–T_0) maxillary	0.35	0.5	0.51	0.39	0.47	0.16	-0.62	0.3
3-month relapse (T_2–T_0) mandibular	0.34	0.31	0.24	0.4	0.55	0.1	-0.24	0.44
6-month relapse (T_3–T_2) maxillary	0.13	0.08	0.33	0.32	0.14	0.2	-0.46	0.08
6-month relapse (T_3–T_2) mandibular	0.51	0.53	0.29	0.55	0.43	0.22	-0.38	0.83

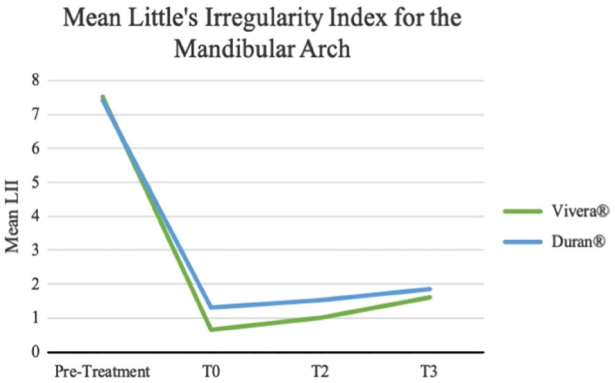

Figure 6. Mean Little's Irregularity Index (mm) for the mandibular arch at pre-treatment, T_0, T_2 and T_3 for the Vivera® and Duran® retainer groups.

statistically significant change in median number (P = 0.12) (Figs. 7, 8).

Discussion

This prospective clinical trial compared the survival of the PU-based Vivera® retainer with a PETG-based Duran® retainer over an initial 6 months of retention. Secondary measured outcomes were treatment stability and changes in occlusal contacts. The study was undertaken in a private, metropolitan orthodontic practice, which allowed for control and consistency of treatment, as well as the recruitment process and retainer manufacture. It also enabled an assessment of the efficacy of the retainers in a real-world clinical setting.

The present study found a statistically significant difference in the mean number of failures between the retainer groups. The Vivera® group did not experience any failures during the 6 month observation period, whereas 57% of Duran® participants experienced at least one retainer failure. The survival rate of the Duran® maxillary retainers was 71% and of the mandibular retainers was 93%. These results are consistent with those of Forde and colleagues who found a higher rate of retainer failure in the maxillary arch than in the mandibular arch.[12] No correlation between retainer failure and the patient's age or gender was found and no retainer manufacturing errors or loss, occurred.

The survival rate of thermoplastic retainers has been reported to be between 73% and 89%[11,12,23,24,34] based on studies conducted over 3[24], 6[34] and 12 month periods.[11,12] The 71% survival rate of the initial maxillary Duran® retainers in the present study is similar to the survival rate reported by Moslemzadeh and colleagues[24] who observed a 76.9% survival rate of the maxillary PETG thermoplastic retainer, made

Table V. Occlusal and near occlusal contact results analysed using non-parametric Mann–Whitney test and presented as median, IQR and *P*-value.

Sensitivity measurement	Location	Vivera® Median (IQR)	Duran® Median (IQR)	*P*-value
Number of occlusal contacts at T_0				
Occlusal contact	Anterior	1 (0-3)	1 (0-3)	0.46
	Posterior	7 (3–7)	7 (3–7)	0.01*
Near occlusal contact	Anterior	7 (2–7.25)	3 (1–6)	0.37
	Posterior	7.5 (6.75–8)	11 (7–15)	0.08
Change in number of occlusal contacts from T_0 to T_2				
Occlusal contact	Anterior	0.5 (-0.5 to 1.25)	1 (0–2)	0.65
	Posterior	0.5 (-1.25 to 1.25)	1 (-1 to 2)	0.81
Near occlusal contact	Anterior	0 (-1.25 to 0)	0 (-1 to 1)	0.41
	Posterior	0.5 (-3.25 to 1.25)	0 (-1 to 4)	0.6
Change in number of occlusal contacts from T_2 to T_3				
Occlusal contact	Anterior	2 (0.5–3)	0 (0–1)	0.3
	Posterior	7 (4–10)	5 (4–9)	0.54
Near occlusal contact	Anterior	1 (-0.5 to 4)	0 (0–3)	0.06
	Posterior	10 (3–11.5)	1 (0–6)	0.3

Note: *Indicates statistical significance $P < 0.05$.

Table VI. Occlusal and near occlusal contacts measured at T_0, T_2 and T_3 for each retainer type. Recorded as median and IQR due to data not being of normal distribution.

		T_0 Median (IQR)		T_2 Median (IQR)		T_3 Median (IQR)	
	Sensitivity measurement (mm)	Anterior	Posterior	Anterior	Posterior	Anterior	Posterior
Vivera®	< 0.2	1 (0–3)	7 (3–7)	2 (1–5)	1.5 (0.75–4.25)	6 (3.5–7)	8 (7–11)
	0.2 < *x* < 0.4	7 (2–7.25)	7.5 (6.75–8)	5 (1.75–7)	8 (4–8)	7 (4.5–9)	14 (11–5.5)
Duran®	< 0.2	1 (0–3)	7 (3–7)	2 (1–5)	7 (3–11)	4 (2–5)	12 (11–13)
	0.2 < *x* < 0.4	3 (1–6)	11 (7–15)	4 (2–6)	14 (12–17)	6 (2–6)	18 (15–22)

Table VII. Comparison of the number of occlusal and near occlusal contacts following full-time and night-time wear regimes for each retainer type. Assessed using non-parametric, paired Wilcoxon Signed Rank test. *P*-value recorded.

		T_0 vs T_2		T_2 vs T_3	
	Sensitivity Measurement (mm)	Anterior	Posterior	Anterior	Posterior
Vivera® (*P*-value)	< 0.2	0.92	0.86	0.06	0.02*
	0.2 < *x* < 0.4	0.11	0.73	0.21	0.05*
Duran® (*P*-value)	< 0.2	0.11	0.43	0.75	0.03*
	0.2 < *x* < 0.4	0.96	0.37	0.46	0.11

Note: *Indicates statistical significance $P < 0.05$.

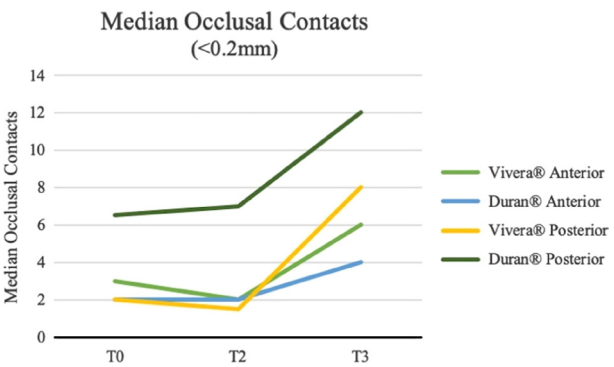

Figure 7. Median number of anterior and posterior occlusal contacts (<0.2 mm) at T_0, T_2 and T_3 for the Vivera® and Duran® retainer groups.

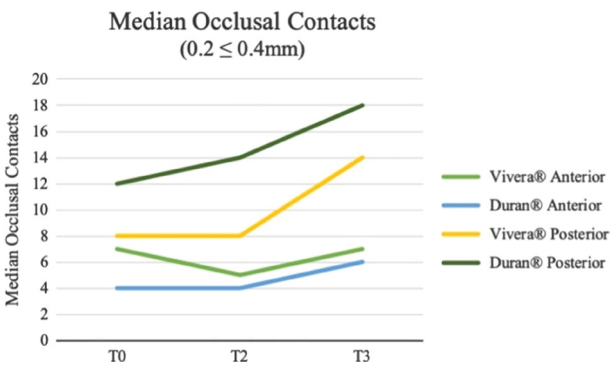

Figure 8. Median number of anterior and posterior near occlusal contacts (0.2 mm < *x* < 0.4 mm) at T_0, T_2 and T_3 for the Vivera® and Duran® retainer groups.

from 1 mm thick blanks, over the initial 3 months of retention. However, by the 6 month review, the survival rate for the maxillary retainer had reduced to 58.8%[24].

The failure of the Duran® retainer in the present study was mainly caused by cracks in the retainer material. Several previous studies have reported retainer breakage as the most common reason for failure.[13,23,35] Three Duran® participants experienced a second retainer failure, all of which were due to cracks in the material at the gingival margin. Two of the three participants were skeletally and dentally Class I, indicating that the final occlusal finish was unlikely to have contributed to the failures. No history of bruxism nor incorrect retainer care was recorded in the clinical notes. As a result, determining the exact reason why these patients experienced secondary failures was not possible. It may simply be due to individual patient factors and future studies with larger, randomised samples would help eliminate this as a confounding factor.

Previous survival studies have not included cracks[13,35] nor perforations[13] in their definition of a retainer failure. These definitions are acceptable, as cracks and perforations do not necessarily render a retainer ineffective and in need of immediate replacement. However, the research question for the present study was based around the claim by Align Technology Inc. that Vivera® retainers are more durable and wear resistant than retainers made from other thermoplastic retainer materials.[26] It was felt that the presence of cracks or perforations in the retainer was indicative of the material's resistance to wear and overall durability. As a result, the definition of a failure applied in the present study differed from those used previously but aimed to identify failures that were believed to reflect the material's long-term survivability.

There were no failures of the Vivera® retainers during the 6 month observation period of the present study; easily exceeding the reported survival rate of between 73% and 89% for thermoplastics retainers.[11,12,23,24] It is also longer than the 6 month survival rate of thermoplastic retainers made from 1.5 mm thick blanks (66.7%) and Hawley retainers (94.4%) reported by Moslemzadeh and colleagues.[24]

The increased survival rate of the Vivera® retainer, compared to the Duran® retainer in the present study is in part due to the difference in composition of the thermoplastic material. Duran® is a PETG material[36], whereas Vivera® is a PU-based material made from methylene diphenyl diisocyanate and 1, 6-hexanediol.[37] Prior to PU-based materials, studies have shown that PETG materials were more wear resistant than other available thermoplastic materials.[20,21] A recent laboratory study reported that the PU-based material had a higher hardness and elastic modulus than the PETG materials.[27] Based on the findings, it was expected that PU-based materials would demonstrate a greater wear resistance in the clinical setting.[27] That no Vivera® retainers failed in the present study appears to support the hypothesis.

Retainer survival is potentially impacted by material thickness, the manufacturing process, intraoral fluid exposure and associated temperature changes and intraoral function.[14–19] The Duran® retainers were made from 1 mm thick blanks. The thickness of Vivera® retainer blanks is proprietary knowledge and therefore unknown. The lack of specific details regarding the Vivera® manufacturing process unfortunately prevents a true comparison between the two retainer types and allows for the differences in fabrication process to have an unknown impact on the results of the present study. Future studies should aim to use a standardised retainer thickness, design and manufacturing process to eliminate the impact that these factors might have on the research outcomes.

Vivera®'s manufacturer, Align Technology Inc., has advised that their retainer should survive on average for 3 months with full-time wear or 9 months with part-time wear.[29] The results of the present study indicate that this time frame underestimates the true survival time of the Vivera® retainer but further research is required. Based on the the current findings, clinicians should feel confident that Vivera® retainers will have a longer lifespan when compared with PETG retainers made from 1 mm thick blanks. Even though the initial cost to the patient is higher, the reduced need for future appointments and costs associated with retainer replacement will likely outweigh the initial burden. Especially when the patient receives three sets of Vivera® retainers as part of the initial cost outlay.

There was no statistically significant difference in the stability of incisor alignment between the two retainer types in the amount of recorded change in LII between T_0 and T_2 and T_2 and T_3. This was the case for both the maxillary and mandibular arches. Previous studies have shown PETG retainer materials to be at least as effective as conventional wire and acrylic retainers.[38,39] The results of the present study therefore indicate that Vivera® is equally as effective at maintaining alignment as both PETG thermoplastic and wire and acrylic retainers.

In the present study, the change in the number of anterior and posterior occlusal and near occlusal contacts was compared between the two retainer groups. No statistically significant difference was noted at either T_2 or T_3 for both occlusal contacts (<0.2 mm) and near occlusal contacts (0.2 mm < x < 0.4 mm). The manufacturer of Vivera® advertises that the material is stronger and more wear resistant than other commonly-used thermoplastic materials.[26] Based on the present findings, the increased level of wear resistance did not appear to negatively impact occlusal settling over the initial 6 months of retention.

A comparison of the number of occlusal and near occlusal contacts recorded at T_0, after the initial 3 months of full-time wear (T_2) and the following

3 months of night-time wear (T_3) was also conducted for each retainer type. No statistically significant increase in the number of anterior occlusal or near occlusal contacts was found in either retainer group. However, there was a statistically significant increase in the number of posterior occlusal and near occlusal contacts in the Vivera® group following the 3 months of night-time wear. The Duran® group also showed a statistically significant increase in posterior occlusal contacts following night-time wear. These results indicate that night-time wear improves occlusal settling, at least posteriorly, which is considered a desirable tooth movement during retention.[7,28]

The impact of thermoplastic retainers on occlusal settling has been investigated previously.[6,7,28,40–44] However, inconsistency in study designs and retention protocols has resulted in conflicting outcomes. It has been proposed that the wear of maxillary and mandibular full-coverage thermoplastic appliances can result in premature posterior contacts and, if not properly equilibrated[45], full-time wear can result in a 'bite block' effect.[10,46,47] The 'bite block' effect may cause slight intrusion of the posterior teeth and therefore, potentially reduce the number of posterior occlusal contacts.[48] The results of the present study did not show a statistically significant reduction in posterior occlusal contacts following full-time wear but indicated that posterior occlusal settling improved with part-time wear, particularly for the Vivera® retainers. Previous studies have also concluded that part-time wear of removable retainers from the onset of retention would be sufficient to maintain incisor alignment.[49,50] Based on this recommendation and the results of the present study, clinicians could expect that, if patients wear thermoplastic retainers part-time from the outset of the retention phase, anterior tooth alignment will be maintained and posterior occlusal settling will likely occur. Part-time wear time may also, theoretically, increase the retainer's survival time by reducing the number of insertion/removals and associated material fatigue.

There are a number of limitations associated with the present study. The small sample size, when compared with other survival studies[13,35], inhibits the ability to generalise the study's results and increases the risk of individual patient influences, such as differing levels of retainer care or a bruxing habit. Patients were also not randomised and blinded to their retainer type, due to the selected convenience sample. This allows inclusion of inherent biases related to a participant's decision to choose one retainer type over another. There was also a large drop-out rate, with several participant's T_3 data not collected in full due to operator errors. This means that the outcomes reported at T_2 and T_3 were not an identical comparison and data loss may have impacted the outcomes. Inconsistencies regarding the retainer designs, thicknesses and manufacturing processes have also been highlighted. Future studies should incorporate a randomised controlled study design, a large sample size and standardised retainer design/manufacture in order to control for the variable factors and, by so doing, reduce their impact on the overall study results.

Conclusion

Vivera® retainers made from a PU-based material have a significantly higher survival rate than Duran® retainers made from PETG material over the first 6 months of retention. The Vivera® group experienced no failures. There was no statistically significant difference between the two groups when comparing their ability to maintain incisor alignment or allow for occlusal settling. However, changing from full-time to part-time wear showed a statistically significant increase in the number of posterior occlusal and near occlusal contacts for the Vivera® retainer and occlusal contacts for the Duran® retainer.

The overall results of the present study indicate that Vivera® retainers are as clinically effective as retainers made from PETG materials but exhibit a significantly higher survival rate. When using maxillary and mandibular thermoplastic retainers, part-time wear from the outset of retention may be beneficial to allow for greater posterior occlusal settling, regardless of the thermoplastic material used.

Conflict of Interest

The authors declare that there is no conflict of interest.

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