A 12 month clinical study of bond failures of recycled versus new stainless steel orthodontic brackets

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SUMMARY The purpose of this prospective longitudinal randomized study was to compare the clinical performance of recycled brackets with that of new stainless steel brackets (Orthos). Twenty patients treated with fixed appliances were included in the investigation. Using a 'split-mouth' design, the dentition of each patient was divided into four quadrants. In 11 randomly selected patients, the maxillary left and mandibular right quadrants were bonded with recycled brackets, and the remaining quadrants with new stainless steel brackets. In the other nine patients the quadrants were inverted. Three hundred and ten stainless steel brackets were examined: 156 were recycled and the remaining 154 were new. All the brackets were bonded with a self-cured resin-modified glass ionomer (GC Fuji Ortho). The number, cause, and date of bracket failures were recorded over 12 months. Statistical analysis was performed by means of a paired t-test, Kaplan–Meier survival estimates, and the log-rank test.

No statistically significant differences were found between: (a) the total bond failure rate of recycled and new stainless steel brackets; (b) the upper and lower arches; (c) the anterior and posterior segments. These findings demonstrate that recycling metallic orthodontic brackets can be of benefit to the profession, both economically and ecologically, as long as the orthodontist is aware of the various aspects of the recycling methods, and that patients are informed about the type of bracket that will be used for their treatment.

Introduction

Orthodontists are commonly faced with the decision of what to do with debonded or inaccurately positioned brackets that require re-positioning during treatment (Wright and Powers, 1985; Regan *et al.*, 1993). One solution is to recycle the brackets (Basudan and Al-Emran, 2001). The aim of any bracket recycling system is to remove the adhesive from the bracket base completely without causing structural damage, in order to eliminate all impurities related to orthodontic treatment, so that the bracket can be rebonded to enamel producing a new adhesive bond of adequate strength (Postlethwaite, 1992).

While there are several commercial recycling methods available, these are impractical to perform at the chairside. As a result, several in-office bracket reconditioning methods have been introduced (Papadopoulos *et al.*, 2000; Basudan and Al-Emran, 2001). The two main commercial processes for recycling orthodontic brackets use a thermal or chemical method to remove the adhesive. The first method, relying on heat application, is the recycling process used by the Esmadent Company (Highland Park, Illinois, USA). With this system, the brackets are heated to 454°C for 45 minutes. Following this the hot brackets are immersed in a cold cement

solvent and ultrasonically cleaned for 10–15 minutes. The brackets are then washed, dried, and electropolished for 30–45 seconds and placed in sodium bicarbonate solution to neutralize the electrolyte, followed by hot water rinsing. Fifty micrometres of metal are removed by this method. Esmadent also sells a recycling machine (Big Jane) to enable orthodontists to recycle their own brackets (Postlethwaite, 1992). McClea and Wallbridge (1986) reported that reconditioning using the Esmadent Big Jane was as effective as commercial recycling.

In contrast, the second method used by the Orthocycle Company (Hollywood, Florida, USA) employs chemical solvents. A solvent stripping process together with high-frequency vibration is carried out at temperatures below 100°C to remove the composite. This is followed by heating to 250°C for sterilization and a very short electropolishing stage (45 seconds). The company states that 5–10 µm of metal are removed (Postlethwaite, 1992).

The effects of recycling depend on the type of reconditioning process used, the type of steel from which the bracket is constructed, whether the bracket is milled or cast, and whether the bracket has a mesh pad or a non-mesh undercut integral pad (Postlethwaite, 1992). Many *in vitro* studies evaluating the effect of recycling on bracket bond strength have shown that

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reconditioning produces a reduction in bond strength which is statistically significant compared with new brackets, both for stainless steel (Mascia and Chen, 1982; Wright and Powers, 1985; Buchwald, 1989; Regan et al., 1990) and ceramic (Lew et al., 1991; Martina et al., 1997; Chung et al., 2002) brackets. The recycling process may also produce a minimal alteration in bracket slot tolerance (Buchman, 1980; Buchwald, 1989; Martina et al., 1997; Papadopoulos et al., 2000), physical distortion of the bracket (Buchman, 1980), and a reduced resistance to corrosion (Buchman, 1980; Maijer and Smith, 1986; Postlethwaite, 1992).

The reduced cost of using recycled brackets represents a significant financial advantage when bonding orthodontic brackets. To date, however, the clinical bonding performance of reconditioned brackets has not been investigated. Studies conducted under ideal laboratory conditions do not describe how materials might perform intraorally. Clinically, intraoral contamination, moisture, temperature, masticatory forces, trauma, and orthodontic mechanics can influence bond strength. Therefore, a prospective longitudinal in vivo clinical study is needed to determine whether recycled brackets can provide a clinically acceptable bond strength compared with new brackets. Thus, the purpose of the present study was to compare the clinical performance of recycled with new brackets (Orthos, SDS/Ormco, Glendora, California, USA) using a self-cured resin-modified glass ionomer cement as the bonding agent (GC Fuji Ortho, GC Europe, Leuven, Belgium). The null hypothesis of the study was that there is no significant difference in bond failure rate between new and recycled brackets.

Materials and methods

Sample

Twenty consecutive patients (13 females and seven males, mean age 18.2 ± 3.5 years), with a range of malocclusions, attending the Department of Orthodontics, University of Aarhus, Denmark, participated in this study. They were eligible for inclusion if the following criteria were satisfied: (a) required single or two-arch fixed appliance therapy; (b) were free of caries, fillings or hypoplasia; (c) were free of occlusal interferences in order to eliminate the influence of trauma; (d) consented to be in the trial. Gender, age or race differences were ignored. Ethical approval was obtained from the local research committee. Written patient and parental informed consent were also obtained.

Using a 'split-mouth' design, the dentition of each patient was divided into four quadrants. In 11 randomly selected patients (group A), the maxillary left and mandibular right quadrants were bonded with recycled brackets and the remaining quadrants with new brackets. In the other nine patients (group B) the quadrants were

inverted. The sides were allocated using random number tables. Three hundred and ten stainless steel brackets (Orthos) were studied: 156 were recycled and the remaining 154 were new stainless steel brackets.

The split-mouth design was randomly alternated from patient to patient in order to eliminate any bias that may have been introduced from the clinician being right handed.

Recycling method

The brackets were reconditioned using the recycling process of the Alpident Company (Villar Perosa, Torino, Italy). This method involves washing the brackets in a non-acid solution, followed by drying and heating to 350°C for 24 hours. The brackets were then washed twice in a non-acid solution, dried, and electropolished for 20 seconds, and finally sterilized at 250°C.

Method

All teeth were isolated with cheek retractors and cleaned with a mixture of water and fluoride-free pumice using a rubber polishing cup in a low speed handpiece. The teeth were rinsed with water, and dried with an oil-free air syringe. No conditioner was applied to the enamel surface.

Stainless steel brackets with an 0.022 inch slot (Orthos) were bonded to the incisors, canines, and premolars with a self-cured resin-modified glass ionomer cement (GC Fuji Ortho). The adhesive was placed on to the mesh pad of the bracket, and then positioned on the labial surface of the teeth with sufficient pressure to squeeze the excess adhesive. This was then removed from the margins of the bracket base with an explorer before polymerization. All brackets were bonded by the same operator (VC).

Although the patient was not aware of the type of bracket used, it was not possible to blind the operator.

At least 15 minutes was allowed from the time of bonding of the last bracket to placement of the initial 0.014 inch Ni-Ti aligning wires. Both groups of patients were monitored for a period of 12 months. If a bond failed the following was recorded: (a) the tooth where the failure occurred and the cause; (b) the type of bracket used and (c) the time elapsed since bonding. The duration of treatment for each failure was calculated as the difference between the date the breakage was noted and the date the initial bonding was carried out. Verbal and written instructions regarding appliance care were issued to each patient, along with a specific request to return if a bracket became loose or if any problem arose with the appliance. Teeth that were rebonded after failure were not included in the success analysis, as the act of replacing a bracket could affect bond strength (Trimpeneers and Dermaut, 1996; Lindauer et al., 1997). Appliances were adjusted at intervals of 4 weeks.

The statistical analysis was performed using the Statistica 99 program (StatSoft Inc., Tulsa, Oklahoma, USA) by means of a paired t-test. In addition to the simple event of failure, the time to bond failure was also considered. Kaplan–Meier estimates of survival curves were constructed and compared using the log-rank test. The level of significance was set at P = 0.05. After failure, the bracket bases and enamel surfaces were clinically examined and the site of bond failure was recorded.

Results

Over the 12 months of active orthodontic treatment there were 20 failures (6.4 per cent), of which nine (5.8 per cent) occurred with the new, and 11 (7.1 per cent) with the recycled brackets. The overall failure rate recorded with reconditioned brackets was not significantly different (P = 0.65) from that of new brackets. The distribution of the bracket failures is presented in Table 1.

Within each bracket type, no statistically significant differences were found (P > 0.33) between the upper and lower arches. Within each arch, no statistically significant differences were found between the two bracket types in both upper and lower arches (P > 0.08). Table 1 illustrates the distribution of bond failures in the upper and lower arches.

When the bonding performance of the six anterior teeth was compared with that of the first and second premolars, no statistically significant differences were found with either bracket type in either arch (P > 0.08). Table 2 shows the distribution of failures of anterior versus posterior segments.

No statistically significant differences were found (P > 0.33) between the bracket types in the anterior and posterior segments (Table 3).

Kaplan–Meier survival plots for the two bracket types are shown in Figure 1. There was no significant difference in terms of bracket failure risk over the subsequent 12 months between new and recycled brackets (hazard ratio = 0.77, 95 per cent confidence interval 0.31–1.93, log-rank test P = 0.58).

The analysis of failure sites revealed that in the two groups of patients both bracket types failed at the enamel–adhesive interface, with most of the adhesive attached to the bracket base. No enamel damage was clinically detected.

Discussion

The null hypothesis of the study was accepted. In fact, the present investigation demonstrated that, when using Orthos brackets, the clinical bond failure rate of

Table 1 Number and percentage of failed brackets in the upper and lower arches.

Brackets	Upper arch			Lower arch			Paired <i>t</i> -test
	No. bonded	No. failed	Percentage	No. bonded	No. failed	Percentage	
New brackets	77	3	3.9	77	6	7.8	ns
Recycled brackets	78	6	7.7	78	5	6.4	ns
Total	155	9	5.8	155	11	7.1	ns
Paired t-test	ns			ns			

ns, not significant.

Table 2 Number and percentage of failed brackets in anterior versus posterior segments.

Brackets	Upper arch anterior			Upper arch posterior			Paired t-test
	No. bonded	No. failed	Percentage	No. bonded	No. failed	Percentage	
New brackets	46	0	0	31	3	9.7	ns
Recycled brackets	47	3	6.4	31	3	9.7	ns
Paired t-test	ns			ns			
	Lower arch anterior			Lower arch posterior			
New brackets	46	3	6.4	31	3	9.7	ns
Recycled brackets	47	3	6.5	31	2	6.4	ns
Paired t-test	ns			ns			

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Table 3	Combined upper and lower nu	imbers and percentages	s of failed brackets in anterior	versus posterior segments.

Brackets	Anterior			Posterior			Paired t-test
	No. bonded	No. failed	Percentage	No. bonded	No. failed	Percentage	
New brackets	92	3	3.3	62	6	9.7	ns
Recycled brackets	94	6	6.4	62	5	8.1	ns
Total	186	9	4.8	124	11	8.9	ns
Paired t-test	ns			ns			

ns, not significant.

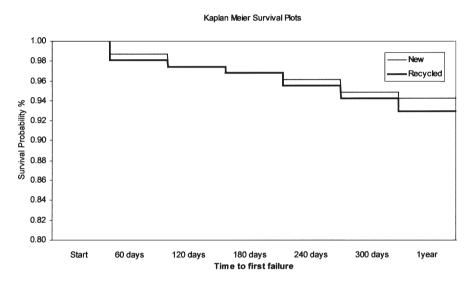


Figure 1 Survival plots for new and recycled brackets.

recycled brackets was not significantly different from that of new ones. No statistically significant differences were noted between the percentage of failures of the two different bracket types when comparing the clinical performance of the upper and lower arches as well as of the anterior and posterior segments.

There are very few clinical investigations that have evaluated the failure rate of recycled brackets bonded with a resin-modified glass ionomer. Previous *in vitro* studies that have evaluated the effect of recycling on metallic bracket bond strength showed that reconditioning produces a reduction in bond strength which is statistically significant when compared with new brackets (Mascia and Chen, 1982; Wright and Powers, 1985; Buchwald, 1989; Regan *et al.*, 1990). However, according to the present findings, the bond strength of recycled metallic brackets should be able to withstand masticatory and orthodontic forces.

The analysis of failure sites revealed that both bracket types failed at the enamel–adhesive interface, with most of the adhesive attached to the bracket base. This is in agreement with the findings of previous *in vitro* (Jobalia *et al.*, 1997; Millett *et al.*, 1999; Bishara *et al.*, 1999;

Sfondrini *et al.*, 2001) and *in vivo* (Cacciafesta *et al.*, 1998, 1999) studies which have evaluated resin-modified glass ionomer cements as bonding agents.

Reconditioning systems cause other effects. These can be classified into those that are produced by the debonding procedure (slot closing, base shape alteration, tie wing gap narrowing, and power arm distortion), those that are caused by the heat cycle (steel corrosion, structural metal weakening, and blocking of self-ligating systems), and those resulting from electropolishing (slot enlargement, base flattening, and power arm thinning) (Matasa, 1989). Therefore, debonding procedures, heat, and electropolishing are the key factors for bracket reconditioning methods (Hixson *et al.*, 1982).

Heat is used for primer removal and sterilization (Buchman, 1980). It is only between 420 and 500°C that composites are transformed into white powder and can be easily eliminated by ultrasonic cleaning. Maintaining steel at a temperature higher than 450°C causes the precipitation of carbides and a chromium impoverishment, leading to localized corrosion (Buchman, 1980).

Another key factor is electropolishing, which is used to remove staining and the oxide layer during the process of primer removal from the bracket base. Therefore, during this stage, both oxides and metal components are removed, and consequently corrosion is reduced, but a decrease in base roughness and mechanical retention may occur. Material loss mainly involves the areas of the wings, hooks, and power arms or edges of the brackets leading to thinning, whereas bracket slots are the least affected areas (Matasa, 1989).

Previous studies which evaluated base slot width, slot depth, torque, inter-wing gap, and total bracket base area found no significant differences between new and reconditioned brackets; although clinical use of an appliance can lead to some minor deformation, the debonding step is responsible for most bracket distortion and damage (Buchman, 1980; Oliver and Pal, 1989; Matasa, 1989; Basudan and Al-Emran, 2001). There is greater variability in archwire/slot fit produced by the variation in the thickness of rectangular wires than that caused by the increased tolerance of the slot produced by recycling (Hixson *et al.*, 1982).

Studies which considered the effect of cumulative recycling reported conflicting results. Some authors found no statistically significant reduction in bond strength when brackets were recycled up to five times (Martina *et al.*, 1997; Regan *et al.*, 1990), whereas Buchwald (1989) showed that the percentage of the appliance that could be reused diminished with each recycling process.

The patient's sex, age, and malocclusion type were not evaluated in the present investigation. Previous studies which considered these variables reported conflicting results: some authors found significant differences in bracket failures in patients with different malocclusion types (Millett *et al.*, 2000), of different ages (Millett and Gordon, 1994), and between males and females (Shammaa *et al.*, 1999). However, several reports found no significant differences in bracket failure rate between males and females (Marcusson *et al.*, 1997; Millett *et al.*, 1998, 2000), among patients of different ages (Marcusson *et al.*, 1997; Millett *et al.*, 1998) or among patients with different malocclusion types (Millett *et al.*, 1998; Shammaa *et al.*, 1999); thus, these variables were not considered in the present investigation.

Different from the reuse of most medical devices, orthodontic brackets are exempt from both pre-market notification requirement and Food and Drug Administration (FDA) clearance, as long as good manufacturing practices are followed (Matasa, 2000). The FDA found recycled brackets to be equivalent to the legally marketed predicated devices, permitting these to proceed to the market. According to Matasa (2000), Ortho-Cycle is soon to have the ISO 2002 certification, while being in the process of obtaining the afferent CE mark.

Most companies place the indication 'to be used once' on the brackets they manufacture. Thus, from the legal point of view, they are not responsible in case

the orthodontist to whom the liability is finally passed reuses these brackets (Papadopoulos *et al.*, 2000).

Another aspect of the use of recycled products is that it may produce an increase in the risk of cross-infection. However, any contamination due to the previous use of a recycled appliance is not possible, as the reconditioning treatments to which they are subjected will effectively clean and decontaminate the appliances (Buchman, 1980; Matasa, 1989). Furthermore, most recycling companies now sterilize brackets after inspection and remarking, prior to packaging (Martina *et al.*, 1997).

Conclusions

The present clinical study demonstrated that there are no statistically significant differences between the total bond failure rate of new and recycled brackets. No statistically significant differences were found between the percentage failures of the two different bracket types, when comparing the clinical performance of the upper and lower arches, as well as of the anterior and posterior segments.

Therefore, reconditioned brackets can be of benefit to the profession, both economically and ecologically, as long as the orthodontist is aware of the various aspects of the recycling methods, and that patients are informed about the type of bracket that will be used for their treatment.

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