Cost-effectiveness and patient satisfaction: Hawley and vacuum-formed retainers

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SUMMARY In the United Kingdom (UK) over the last 10 years, there has been a significant increase in the use of vacuum-formed retainers (VFRs) rather than conventional Hawley retainers. There are currently no data to compare the cost-effectiveness of this change in practice. The two aims of this study were to compare (1) the cost-effectiveness of VFRs and Hawley retainers over 6 months, from the perspective of the National Health Service, orthodontic practice, and the patient and (2) patient satisfaction in the two retainer groups. A randomized controlled trial (RCT) was carried out in a specialist orthodontic practice. Three hundred and ninety-seven eligible patients were randomized to one of two retainer groups, and followed up for 6 months. All subjects were invited to complete patient satisfaction questionnaires. Additional data were collected for the cost analysis from the patient records and national databases. Descriptive and bivariate analyses were used to compare patient satisfaction between retainer groups.

In all, 196 subjects were randomized to the Hawley group (mean age 14 years 8 months, 63 per cent female, 37 per cent male) and 201 to the VFR group (mean age 15 years, 59 per cent female, 41 per cent male). VFRs were more cost-effective than Hawley retainers from all perspectives. The majority of subjects showed a preference for VFRs compared with Hawley retainers. There were also fewer breakages than in the Hawley group.

Introduction

Vacuum-formed retainers (VFRs) were introduced into the National Health Service (NHS) fee structure in 1996 and, since then, the rate of increase in their use has been approximately nine times greater than for Hawley retainers. In the financial year 2004–2005, 119,784 VFRs and 157,329 Hawley-type retainers were fitted in the general dental services in the United Kingdom (UK), at a cost of £7.25 and £11.75 million, respectively (Dental Practice Board, 2005). This change in prescribing pattern may, in part, have been driven by anecdotal evidence based on a ‘cost-comparison’ type of analysis. This has the limitation of not accounting for clinical effectiveness. There is, however, little clinical evidence to support the use of VFRs over Hawley retainers.

Randomized controlled trials (RCTs) are the gold standard for comparing the efficacy of one treatment over another (Damberg et al., 2003). Carrying out an economic evaluation alongside a clinical trial enables more meaningful data to be collected by valuing resource use relevant at the time of clinical evaluation. Cost-effectiveness analysis is traditionally a type of economic evaluation, which compares the costs and outcomes of two or more alternative procedures, when outcomes are measured in the same non-monetary natural units (Drummond and Jefferson, 1996), for example, reduction in Peer Assessment Rating score or change in Littles' Irregularity Index (LII). This type of analysis, however, is considered by some to be limited by its one-dimensional outcome measure (Robinson, 1993). This may not be a valid representation of the intervention. For example, the patients’ subjective experiences are often not taken into account.

Despite this, cost-effectiveness studies have been widely used in other fields of dentistry (Birch, 1990; Crowley et al., 1996; Edwards et al., 1999) and are becoming more popular in orthodontics (Konst et al., 2004; Richmond et al, 2004). There has been a growing emphasis on the importance of using qualitative research methods to gather data of patients’ views. As a result, the assessment of patient satisfaction, in the form of questionnaires, is increasingly being used in research and audit (Williams, 2003). There are few studies which have explored patient satisfaction with orthodontic treatment but the few that exist have highlighted a nearly universal dislike of orthodontic retainers. Some subjects find them to be more inconvenient than their fixed appliance (Bennett and Tulloch, 1999; Vig et al., 1999; Travess et al., 2004) and even headgear (Vig et al., 1999). The reasons given for patients’ intolerance of retainer wear include difficulty in speaking, eating (Bennett and Tulloch, 1999; Travess et al., 2004), extra salivation, smell, embarrassment, and ease with which they could be lost (Bennett and Tulloch, 1999). Unfortunately, none of these studies gave details as to the types of retainers the patients were wearing.
The primary aim of this study was to undertake a RCT in a specialist practice to compare the cost-effectiveness of Hawley retainers and VFRs over a 6-month period, from the perspectives of the NHS, orthodontic practice, and the patient. A secondary aim of the study was to compare levels of patient satisfaction of subjects fitted with Hawley retainers and those fitted with VFRs, during the first 6 months of the retention period. Since the majority of orthodontic treatment in the UK is carried out in specialist practice, a RCT undertaken in this setting is likely to provide relevant and meaningful data for the future provision of care.

Material and methods

Details of the participants, randomization, and study design have been described elsewhere (Rowland et al., 2007). The study was approved by the Local Research and Ethics Committee at the United Bristol Healthcare Trust (ethical approval number E5421). All subjects were reviewed by a member of the research team at 3 and 6 months into retention. Each subject was invited to complete a patient satisfaction questionnaire while waiting to be seen by the researcher for review of their retainers. These questionnaires had been previously piloted on a separate sample of patients on two occasions, 1 week apart, and were found to have good readability and reproducibility.

The researcher asked each subject whether they had attended extra appointments since the retainers were fitted. The information was confirmed from the practice computer database. If the subjects had attended an extra appointment, they were interviewed by the researcher using a structured interview schedule, to determine what costs the patient and their carer incurred in attending these extra appointments.

Assessment of patient satisfaction

The patient satisfaction questionnaires were coded by the research team and all responses were entered into a database in the Statistical Package for Social Sciences (SPSS Inc., Chicago, Illinois, USA) version 12.0. Descriptive and bivariate analyses were used to compare levels of satisfaction between the Hawley and VFR groups. Chi-squared tests for trend, or Fisher’s exact tests were used as appropriate.

Clinical outcome

The total change in LII, between debond and 6 months into retention, was used as the outcome measure to compare the clinical effectiveness in both arches. This was chosen because it was considered by the research team to be the most noticeable clinical feature to the patients and the clinicians. Earlier findings by Berg (1979) based on orthodontists’ and lay persons’ opinion on the success of post-treatment cases support this view. Details of measuring LII are reported elsewhere (Rowland et al., 2007). Mann–Whitney tests were used to compare the two study groups.

Cost analysis

The economic evaluation was conducted from the perspectives of the NHS, orthodontic practice, and the patient. Since the clinical trial commenced in March 2003, unit costs in euros (€) were used at 2003 prices to value the resources included in the analysis (Table 1). No adjustment or discount of the costs was carried out, as only the effects over 6 months were considered. All direct costs were included. The type of costs included in the analysis depended on the perspective. The cost of orthodontic retainers at the time of the study in the general dental services, in the UK, was based on a fee per item system. Therefore, the total costs to the NHS over 6 months included the fees for original repairs and replacement retainers. The costs to the orthodontic practice, however, also included the clinical time cost, the laboratory fees, and any fees paid by patients, if their retainers were replaced.

The total clinical time cost was calculated by multiplying the gross clinical time cost per minute by the total clinical time spent on retainer appointments, over the 6-month period, for each retainer group. The gross clinical time cost per minute was based on the typical gross income of a full-time orthodontist working in a specialist practice. The average fee for a dentist in England completing more than 200 appliance cases a year in 2003 was €400 489.78 (www.dpb.nhs.uk/dentaldata). This fee is the gross income of the specialist prior to paying for the overheads of the practice and income tax. The gross rate for a typical orthodontist working 35 hours a week, 46 weeks of the year, was calculated as €248.75 per hour, or €4.15 per minute.

The total clinical time for retainer appointments was based on data derived from a time and motion study which was carried out over a 1-month period. During this time, a member of the research team timed the period the patient was in the dental chair during appointments for the fitting of retainers, retainer adjustments, extra impressions, and retainer reviews, using a stop watch. The time taken to turnaround the surgery was not included because there were multiple dental chairs in the surgery. The mean clinical time taken for each procedure was then calculated. This was then multiplied by the number of visits attended by each subject over the 6-month follow-up, in order to determine the total clinical time cost per retainer group.

The costs to the patient were based on those incurred by the patient and their carer for attending unscheduled appointments during the 6-month study period. Costs incurred for attending scheduled appointments were not included because the number of scheduled appointments was the same for both groups. It was therefore assumed that there would not be a significant difference in these costs between the groups. The costs used in the analysis included travel costs, childcare costs, patient fees, and lost income. This information was retrieved from the structured interview schedule. The cost of fuel was calculated at €0.58 per mile, based on the Inland Revenue Tax Relief for
expenses of employment year ending 5 April 2003. The lost income was based on the mean gross hourly rate, in the UK, for the reported occupation of the carer, taken from http://www.statistics.gov.uk/downloads/theme_labour/ASHE_2003_inc/tab14.5a.

The cost analysis was performed according to the intention to treat principle. All cost data of patients lost to follow-up were included in the analysis. As resource use data are highly skewed, bootstrapping (1000 replications) was used to estimate confidence intervals (CIs) around the cost per patient and draw inferences about differences between the two groups (Thompson and Barber, 2000). This non-parametric technique, which involves resampling with replacement from the original dataset to produce a simulated distribution of mean cost, is commonly used in the analysis of resource use data. It enables the issue of uncertainty to be explored without having to make assumptions about the underlying distribution.

**Results**

**Participants and follow-up**

The different stages of the trial and the number of subjects who participated are shown in Figure 1. Of the 397 participants, 196 subjects were randomly allocated to the Hawley group and 201 subjects to the VFR group. A total of 367 subjects (Hawley 179, VFR 188) attended the 3-month review appointment, and a total of 355 subjects (Hawley 172, VFR 183) the 6-month review appointment.

**Patient satisfaction**

A total of 352 questionnaires (Hawley 171, VFR 181) were completed at 3 months, and 350 questionnaires (Hawley 168, VFR 182) at 6 months. Where subjects failed to attend the review appointment on two occasions, a patient satisfaction questionnaire was posted to the subject. A total of 330 questionnaires (Hawley 160, VFR 170) were completed at 3 and 6 months.

The frequency of responses to the most relevant questions in the patient satisfaction questionnaires is shown in Table 2. There was no change in the significance levels for the responses to the questions between 3 and 6 months. For this reason, only the responses at 6 months are reported.

It was clear that more subjects in the VFR group than the Hawley group wore their retainers as instructed during the 6 months ($P = 0.002$). Although retainers caused more embarrassment in the Hawley than the VFR group ($P = 0.005$), particularly in terms of speech and aesthetics, there was no statistically significant difference in the amount of retainer wear away from home. More subjects reported that...
they had broken their retainers in the Hawley group ($P < 0.001$). There was, however, no difference in the number of subjects who had lost their retainers between the different groups. There was also no difference in the amount of discomfort reported between subjects in either retainer group. Subjects in the VFR group gave a better overall rating for their retainers compared with fixed appliances ($P < 0.001$).

**Clinical outcome**

The change in mandibular and maxillary incisor irregularity, as measured by LII, was statistically significantly greater in the Hawley group compared with the VFR group, over 6 months. The results have been reported elsewhere (Rowland et al., 2007).

**Retainer outcomes**

A total of 60 subjects attended extra appointments because they encountered various problems with their retainers. A Mann–Whitney test showed that a statistically significantly greater number of subjects returned from the Hawley group ($n = 41$) than the VFR group ($n = 21$) for extra appointments ($P = 0.001$). Table 3 shows the reasons why subjects attended these appointments and the outcome of these appointments. Some subjects attended multiple extra appointments during the 6 months. A total of 26 Hawley retainers broke, of which six were upper retainers and 20 lower retainers. Most of the breakages occurred in the acrylic region of the lower retainers.
Cost analysis

Cost to the NHS. The mean cost to the NHS per subject was €152.42 for the Hawley group and €121.08 for the VFR group. The bootstrapped results give a mean (95 per cent CI) cost per patient of €152 (€150.86–€153.15) for the Hawley group and €122.02 (€120.84–€123.21) per patient for the VFR group. The difference in bootstrapped mean cost to the NHS per subject between retainer groups was €31.35 with a 95 per cent CI of €28.06–€34.68.

Cost to the orthodontic practice. The mean cost to the orthodontic practice per subject was −€1.22 for the Hawley group and −€33.83 for the VFR group. The negative sign denotes profit. The bootstrapped results give a mean (95 per cent CI) cost per patient of −€1.00 (−€1.78, −€0.22) and −€34.00 (−€34.57 to −€33.34), respectively. The difference in bootstrapped mean cost to the practice per subject between retainer groups was €32.60 with a 95 per cent CI of €30.58–€34.67.

Sensitivity analysis

Sensitivity analysis was carried out to determine whether the difference in clinical time between retainer groups, measured during the time and motion study, had a significant effect on the cost of Hawley retainers and VFRs to the orthodontic practice. The total cost to the orthodontic practice was recalculated for each retainer group, this time excluding the total clinical time cost for VFRs and Hawley retainers. The sensitivity analysis showed that despite removing this variable, there was still a cost difference between retainer groups, where VFRs were less costly than Hawley retainers (P < 0.001).

Cost to the patient

Sixty-two subjects attended extra appointments: 41 from the Hawley group and 21 from the VFR group. They were all interviewed by the researcher to ascertain travel costs, childcare costs, patient fees, and lost income. The mean cost per subject was €9.15 for the Hawley group and €6.93 for the VFR group. The bootstrapped results give a mean (95 per cent CI) cost per patient of €11.63 (€9.67–€13.59) and €6.92 (€5.29–€8.53), respectively. The difference in bootstrapped mean cost to the patients per subject between retainer groups was €2.15 with a 95 per cent CI of €2.90–€7.57.

*Fisher’s exact test.
†Linear-by-linear association.

Table 2 Responses to the most relevant questions in the patient satisfaction questionnaires following 6 months of retention.

<table>
<thead>
<tr>
<th>Question</th>
<th>Hawley (n = 49)</th>
<th>Vacuum-formed retainer (VFR) (n = 21)</th>
<th>Hawley versus (VFR) P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear retainer as instructed?</td>
<td>Yes 141 (84.9%)</td>
<td>172 (95.0%)</td>
<td>0.002*</td>
</tr>
<tr>
<td>Wear retainers away from home?</td>
<td>No 25 (15.1%)</td>
<td>9 (5.0%)</td>
<td>0.103†</td>
</tr>
<tr>
<td>Broken retainer?</td>
<td>Yes 32 (19.4%)</td>
<td>12 (6.6%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Lost retainer?</td>
<td>No 133 (80.6%)</td>
<td>170 (93.4%)</td>
<td>0.681*</td>
</tr>
<tr>
<td>Embarrassed to wear retainer?</td>
<td>Yes 29 (17.4%)</td>
<td>13 (7.2%)</td>
<td>0.005*</td>
</tr>
<tr>
<td>Amount of discomfort</td>
<td>Never 58 (34.7%)</td>
<td>70 (38.5%)</td>
<td>0.271†</td>
</tr>
<tr>
<td>Overall rate compared with fixed appliances</td>
<td>Much better 15 (9.0%)</td>
<td>60 (33.0%)</td>
<td>&lt;0.001†</td>
</tr>
<tr>
<td></td>
<td>Better 57 (34.1%)</td>
<td>88 (48.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Same 52 (31.1%)</td>
<td>29 (15.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Worse 32 (19.2%)</td>
<td>4 (2.2%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Much worse 11 (6.6%)</td>
<td>1 (0.5%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3 Reasons for subjects attending extra appointments and outcome of appointments, over 6 months.

<table>
<thead>
<tr>
<th>Reason</th>
<th>Total number of subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hawley, n = 49</td>
</tr>
<tr>
<td>Lost retainer (replaced)</td>
<td>12</td>
</tr>
<tr>
<td>Broken retainer (repaired, replaced, or left)</td>
<td>26</td>
</tr>
<tr>
<td>Not worn retainer and no longer fits (replaced)</td>
<td>2</td>
</tr>
<tr>
<td>Loose retainer (adjusted)</td>
<td>7</td>
</tr>
<tr>
<td>Uncomfortable (reassured)</td>
<td>2</td>
</tr>
</tbody>
</table>
Cost-effectiveness analysis

VFRs were clinically more effective than the Hawley retainers over 6 months, and were less costly from all three perspectives. Thus, in terms of cost-effectiveness, VFRs were ‘dominant’ over Hawley retainers. There was strong evidence of a difference in cost from the perspective of the NHS and the orthodontic practice, but only weak evidence from the perspective of the patient.

Discussion

The most important finding from this study was that VFRs were more cost-effective than Hawley retainers over 6 months of retention, from the perspectives of the NHS, the practices, and the patients. The strength of evidence for dominance was greatest in the case of the orthodontic practice.

It was necessary for the research team to estimate certain costs for the study, for example clinical time costs and lost income. These data were considered to be sensitive and were difficult to obtain directly from the orthodontic practice and the patient. It is recognized among cost analysts that a problem with economic evaluations is the difficulty of obtaining true values for all the key aspects of an intervention. Hence, in situations where values need to be estimated, there will be some uncertainty about the true cost-effectiveness between the interventions (Gold et al., 1996).

In this study, estimates were based on figures from national databases to provide best estimates of the costs involved.

There may be a number of reasons to explain the difference in the costs to the NHS found in this study. First, the initial NHS cost for original retainers was more for the Hawley group. Second, more of these retainers were broken than VFRs over 6 months. The NHS fee for fitting a VFR is approximately 20 per cent less than for fitting a Hawley retainer, whereas the NHS fee for replacing either retainer is the same. This may suggest that the current NHS fee schedule for replacing VFRs compared with Hawley retainers is unrealistic.

These findings indicate that although the total NHS fee received by orthodontists was approximately 20 per cent more for Hawley retainers than for VFRs, the cost to the orthodontic practice was significantly more for Hawley retainers compared with VFRs, over 6 months. This difference in cost may be explained by the following reasons: the total laboratory fee, charged to the orthodontic practice, for Hawley retainers was approximately twice the total laboratory fee for VFRs; the total clinical time cost was approximately 30 per cent more for Hawley retainers than VFRs. It is recognized that in orthodontics, the main determinant of the cost of treatment is chairside time (Kelly and Springate, 1996) and obtaining an exact value for such a variable is difficult. In this study, a time and motion analysis was carried out within the specialist practice to calculate typical clinical times for various types of retainer appointments. It was found that the mean clinical time was approximately 1 minute more for appointments involving Hawley retainers compared with VFRs. The accuracy with which these times were recorded could be a source of bias towards VFRs. A sensitivity analysis was therefore carried out to overcome some of the uncertainty related to this variable (Kobelt, 1996), and this showed that VFRs were still less costly than Hawley retainers, despite removing the variable of clinical time cost.

Economic evaluations within the NHS have tended to concentrate on health service costs rather than the costs to patients and carers. Significantly, Richmond et al. (2002) found that the costs to patients for attending unscheduled appointments were considerable. In this study, it was found that the total cost to all patients and carers in both retainer groups for attending extra appointments, over the 6 months, was approximately £3190. Although more than twice as many subjects returned for extra appointments from the Hawley group than the VFR group, there was no significant difference in cost between retainer groups. This may be explained by the relatively higher number of subjects in the VFR group who had to pay for replacement retainers when they broke or were lost, compared with the Hawley group. Although, approximately three times as many Hawley retainers were broken compared with VFRs, so long as the retainer was repairable, the orthodontic practice claimed from the NHS rather than charging the patient. This suggests that subjects in the Hawley group who broke their retainer did not sustain the same charges as subjects in the VFR group.

The second most important finding was that the majority of subjects showed a preference for VFRs compared with Hawley retainers. Wearing VFRs caused less embarrassment to subjects, especially in terms of speech and appearance, than Hawley retainers. Despite this, individuals from both groups were as likely to wear them away from home. Both types of retainers were as easily lost. Hawley retainers broke more often than VFRs. Lower Hawley retainers tended to fracture in the acrylic region. Interestingly, although more subjects in the VFR group wore their retainers as instructed compared with the Hawley group, there was no difference in complaints of discomfort between subjects in either group.

It has been recognized in the literature that removable retainers can initially affect the articulation of speech, although Haydar et al. (1996) found this to be a temporary problem with Hawley retainers. After 7 days, tongue adaptation occurs and these distortions decrease to an insignificant level. There are no published studies to date which have investigated the effect of Hawley retainers compared with VFRs with regard to speech. There is, however, some evidence to support the suggestion that the greater the amount of palatal coverage of removable retainers the greater the effect on speech (Stratton and Burkland, 1993). This may explain why more subjects in the Hawley group complained of speech problems compared with the subjects in the VFR group.
Following the completion of this study, the Department of Health introduced a new contract into the general dental services, where the cost of orthodontic retainers is no longer based on a fee per item system. These changes are likely to have significant implications on the results of this study for various reasons.

Within the new system, there is no difference in cost to the NHS for fitting either retainer, and no fee can be claimed by the orthodontist for breakages. Based on the findings from this study, the cost to the orthodontic practice was significantly more for Hawley retainers compared with VFRs. This would therefore imply that under the new contract, VFRs are likely to be more cost-effective than Hawley retainers from the perspective of the NHS and the orthodontic practice.

Conclusions
The results from this research support the hypothesis that VFRs are more cost-effective than Hawley retainers, from each investigated perspective, over the first 6 months of retention. The majority of subjects appear to prefer VFRs over Hawley retainers. Wearing VFRs causes less embarrassment and they are less likely to be broken, although both types of retainers are as likely to be lost and cause discomfort. This study has also demonstrated that it is feasible to conduct an economic evaluation within a RCT in specialist practice. The principles of this economic evaluation can be applied to other investigations, in order to compare the cost-effectiveness between two or more treatments, in specialist practice.

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