A cost-minimization analysis of an RCT of three retention methods

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SUMMARY
BACKGROUND: There are few cost evaluation studies of orthodontic retention treatment. The aim of this study was to compare the costs in a randomized controlled trial of three retention methods during 2 years of retention treatment.

MATERIALS/METHODS: To determine which alternative has the lower cost, a cost-minimization analysis (CMA) was undertaken, based on that the outcome of the treatment alternatives was equivalent. The study comprised 75 patients in 3 groups consisting of 25 each. The first group had a vacuum-formed retainer (VFR) in the maxilla and a cuspid retainer in the mandible (group V-CTC), the second group had a VFR in the maxilla combined with stripping of the incisors and cuspids in the mandible (group V-S), and the third group had a prefabricated positioner (group P). Direct cost (premises, staff salaries, material and laboratory costs) and indirect costs (loss of time at school) were calculated. Societal costs were defined as the sum of direct and indirect costs.

RESULTS: The societal costs/patient for scheduled appointments for 2 years of retention treatment in group V-CTC were €497, group V-S €451 and group P €420. Societal costs for unscheduled appointments in group V-CTC were €807, and in group V-S €303. In group P, there were no unscheduled appointments.

CONCLUSIONS/IMPLICATIONS: After 2 years of retention in compliant patients, the cuspid retainer was the least cost-effective retention appliance. The CMA showed that for a clinically similar result, there were differences in societal costs, but treatment decisions should always be performed on an individual basis.

Introduction

A significant amount of research in orthodontics has focused on the effectiveness of various orthodontic treatments in terms of treatment results and stability. This is true for removable and fixed appliance treatments as well as retention treatments (Littlewood et al., 2006). However, the method of choice for orthodontic treatment should be dependent not only on clinical skills but also on an economic evaluation.

For many years, there has been an increasing emphasis on economic evaluation of health care interventions (Elixhauser et al., 1993). Economic evaluations are expected to assume importance in the delivery of publically funded orthodontic services. During the last 20 years, the interest for analysing the costs in the field of orthodontic treatment has increased. Many studies have been published describing and comparing treatment costs following various orthodontic diagnosis and treatment circumstances (Panula et al., 2002; Richmond et al., 2005; Deans et al., 2009). In the future, when allocating resources, health service planners will require evidence not only of the clinical effectiveness of treatment but also of the data disclosing ‘value for money’ (Buck, 2000).

Economic evaluation is defined as ‘the comparative analysis of alternative courses of action in terms of their costs and consequences’ (Drummond et al., 2005). Depending on the way in which the consequences are analysed, four types of evaluations can be used to gather evidence and compare the expected costs and consequences of different procedures. A cost-effectiveness analysis (CEA) is characterized by analysis of both costs and outcomes, where the outcomes of alternative methods might differ in magnitude. In a ‘cost-minimization analysis’ (CMA), which is a form of CEA, the outcomes of the treatment alternatives are identical (e.g. three retention methods will retain the treatment result irrespective of which treatment is applied) and the aim is to identify which alternative has the lowest cost. A ‘cost-utility analysis’ is concerned with the quality of the health outcome following treatment and is used for example in health-related quality of life studies. In a cost-benefit analysis, the consequences are expressed in monetary units. This is used to evaluate distribution of resources to diverse areas of health care (Drummond et al., 2005).

Hichens et al. (2007) presented one of the very few studies analysing the costs of orthodontic retention treatment. In a randomized controlled trial (RCT), it was shown that a vacuum-formed retainer (VFR) was the most cost-effective appliance compared to a Hawley retainer after 6 months of retention treatment.
Systematic reviews of relevant literature have highlighted the need for studies of cost-effectiveness in orthodontics (The Swedish Council on Technology Assessment in Health Care, 2005). Such studies are of course dependent on the quality of the underlying clinical evidence and should therefore be based on the outcome of RCT studies. Edman Tyndelius et al. (2010, 2013) showed in two RCT studies that three retention methods were equally efficient in retaining orthodontic treatment results after 1 and 2 years. Since Edman Tyndelius et al. used a RCT methodology when analysing the three retention methods, the study was appropriate for a CMA. Petren et al. (2011) performed a CMA on early correction of posterior crossbite, and in this study, a similar analysis was performed. Thus, the aim of this study was to evaluate and compare the costs for the three compared retention methods. It was hypothesized that the three retention methods will be equally cost-effective.

Materials and methods

Subjects

The ethics committee of Lund University, Sweden, approved the protocol and the informed consent form (LU515-01). Eighty-two patients (51 girls and 31 boys) and their parents were given oral as well as written information and 75 patients (45 girls and 30 boys) signed the written consent before being included in the trial (Figure 1). The National Health Service (NHS) in Sweden offers free dental care including orthodontic treatment to patients with a certain degree of malocclusion up to the age of 20 years. This study was carried out on patients referred to an orthodontic clinic in the NHS, Ystad, Sweden. The NHS clinic was responsible for the orthodontic care of patients in the southeast County Council of Scania.

The same team, i.e. one experienced orthodontist and two experienced orthodontic auxiliaries, treated all patients. The patients taking part in this study underwent orthodontic treatment between 2001 and 2007 and the following inclusion criteria were to be met:

- no previous orthodontic treatment,
- permanent dentition,
- space deficiencies in both jaws,
- normal skeletal and dentoalveolar sagittal, vertical, and transverse relationships,
- class I molar relationship or 3 mm anterior or posterior deviation, and
- a treatment plan involving extraction of four premolars followed by fixed straight wire appliances (0.022 in., McLaughlin, Bennett, Trevisi) in both jaws.

The generation of randomisation sequence was performed in blocks of five to ensure that equal numbers of patients were allocated to each of the three retention groups. Fifteen paper sheets and five ballots of each retention method were placed in a basket. The patient then decided the retention treatment by picking a ballot from the basket and was included in one of the three groups consisting of 25 patients each (Figure 1).

Retention methods

The three retention methods of choice were as follows:

- A removable VFR covering the palate and the maxillary anterior teeth from cuspid-to-cuspid and a bonded cuspid-to-cuspid retainer (CTC) in the lower arch (group V-CTC, 25 patients; Figure 2a).
- An identical maxillary VFR as in group V-CTC was combined with stripping (S) of the lower anterior teeth and no lower retention device (group V-S, 25 patients; Figure 2b).
- A prefabricated positioner (P) covering all erupted teeth in the maxilla and the mandible (group P, 25 patients; Figure 2c).

The VFRs were made of 2 mm Biolon (Dreve Dentamid GmbH, Unna, Germany) in a Scheu Ministar press (Scheu-Dental GmbH, Iserlohn, Germany). The cuspid retainers consisted of 0.7 mm spring hard wire (Dentaurem non-inium, Dentaurem, Ispringen, Germany) bonded with Transbond LC (3M Unitek Orthodontic Products, Monrovia, California, USA) to the lower cuspids.

Mechanical stripping of the lower incisors and cuspids was performed either by hand with single-sided medium
and fine metal blades (TP Orthodontics, La Porte, Indiana, USA) or with Ortho-Strips for the EVA system (GAC International, Bohemia, New York, USA). The method of stripping was dependent on tooth form, non-triangular or triangular, respectively. It was either performed on the visit 5–6 weeks prior to debonding or at debonding. The aim of stripping was to obtain small but distinct enamel flattening of the contact surfaces. The reduction of any contact point between two teeth amounted approximately to the thickness of the coarse blade of either system, i.e. 0.22 mm for hand stripping or 0.34 mm for EVA stripping. At debonding, all spaces were closed and no additional stripping was performed.

The prefabricated positioner (Ortho-Tain Positioner; Ortho-Tain Inc., Toa Alta, Puerto Rico, USA) was a soft plastic device covering all erupted teeth.

All retention appliances were handed out within 1 hour after debonding. The patients in groups V-CTC and V-S were instructed to wear the VFR 22–24 hours per day for 2 days and nights and then during the night for 12 months. In group P, the positioner was to be worn for 30 minutes during daytime and during sleep for 12 months. During the daytime wear, patients were instructed to actively chew into their positioners. The second year of retention patients used their retainers every other night and visited the clinic twice for control of cooperation and appliances.

Figure 2 Vacuum-formed retainer (VFR) in the maxilla and cuspid-to-cuspid retainer in the mandible (a), VFR in the maxilla and stripping of the mandibular incisors and cuspids (b), and positioner (c).
At the end of the second year, all retention appliances were removed.

**Costs**

‘Direct costs’ comprised material costs and treatment time costs. Material costs (i.e. impression material, orthodontic bonding material, laboratory material and fees, consumables, etc.) were compiled and calculated according to average commercial prices. Treatment time costs included the costs of premises, dental equipment, maintenance, and cleaning and were calculated according to average commercial prices in Sweden. Staff salaries, including payroll tax, were calculated for the dental auxiliaries (€93/hour) and the orthodontist (€230/hour). The treatment costs were calculated and estimated in Euros (€; Table 1). Treatment times in minutes for both scheduled and unscheduled appointments were estimated and not measured with a stopwatch for each patient on the assumption that the randomization process would make groups equal.

‘Indirect costs’ were defined as loss of time at school and in travelling to and fro the orthodontic clinic, i.e. for school children €12/hour (Table 1). As the majority of patients were adolescents and came to the clinic for their retention controls on their own, without parents, we did not include parental time. The clinic is situated close to the school and thus, the travelling time to the clinic was estimated to 15 minutes. All costs were based on 2013 prices and were expressed in Euros (€), SEK 100 = €11.63 on 25 April 2013 (www.xe.com).

‘Societal costs’ were defined as the sum of direct and indirect costs. The cost analysis was based on the intention-to-treat (ITT) principle, i.e. the analysis included all data on 75 patients.

**Table 1** Direct and indirect costs in Euros (€). CTC, cuspid-to-cuspid retainer.

<table>
<thead>
<tr>
<th>Direct costs</th>
<th>Indirect costs</th>
<th>Societal costs/patient in Euros (€) with estimated treatment times. VFR, vacuum-formed retainer; CTC, cuspid-to-cuspid retainer; S, stripping; P, prefabricated positioner.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Orthodontist (€/h)</strong></td>
<td><strong>Orthodontic auxiliaries (€/h)</strong></td>
<td><strong>Alginate/impression</strong></td>
</tr>
<tr>
<td>230</td>
<td>93</td>
<td>1</td>
</tr>
</tbody>
</table>

**Table 2** Societal costs/patient in Euros (€) with estimated treatment times. VFR, vacuum-formed retainer; CTC, cuspid-to-cuspid retainer; S, stripping; P, prefabricated positioner.
Cost-minimization analysis

A CMA was undertaken, since the consequences of the treatment alternatives were equal. Several calculations were made; with higher values (i.e. higher costs) indicating relatively less cost-minimization than lower values (i.e. lower costs).

\[\text{CMA} = \frac{\text{Societal costs}}{\text{Number of patients} (75)}\]

This calculation divides the societal costs by the total number of patients after 2 years of retention (Table 2). A second CMA was made on the group of patients with unscheduled appointments (Table 3).

Effects

The outcome to be assessed was to calculate and estimate the costs for 2 years of retention treatment, including both scheduled and unscheduled appointments. It was shown in two previous studies that the three retention methods had equal capacity in retaining the result of the orthodontic treatment in compliant patients (Edman Tynelius et al., 2010, 2013). During the 2 year retention treatment period, all patients were scheduled for five appointments. As the trial was randomized, broken appointments and cancellations could be expected to be equal in all three groups. All measurements were blinded and one orthodontist (GET) undertook all measurements.

Results

After 2 years of retention, all societal costs were estimated for 75 patients regardless if they attended the 2 year follow-up or not (Figure 1). One girl in group V-CTC failed to show up at the 2 year appointment, two boys in group V-S, and one boy in group P (Figure 1).

Societal costs for scheduled appointments

The societal costs/patient for 2 years of retention treatment in group V-CTC were €497, group V-S €451, and group P €420.

Table 3 Societal costs for scheduled and unscheduled appointments for the three retention groups of 25 patients: groups V-CTC, V-S, and P. CTC, cuspid-to-cuspid retainer; P, prefabricated positioner; S, stripping; VFR, vacuum-formed retainer.

<table>
<thead>
<tr>
<th>Costs for 25 patients, €</th>
<th>Direct</th>
<th>Indirect</th>
<th>Societal</th>
<th>Societal unscheduled costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group V-CTC</td>
<td>10 950</td>
<td>1475</td>
<td>12 425</td>
<td>807</td>
</tr>
<tr>
<td>Group V-S</td>
<td>9 875</td>
<td>1400</td>
<td>11 275</td>
<td>303</td>
</tr>
<tr>
<td>Group P</td>
<td>9 300</td>
<td>1200</td>
<td>10 500</td>
<td>0</td>
</tr>
</tbody>
</table>

Societal costs for unscheduled appointments

Societal costs for a bonded/rebonded CTC were €35, a new CTC €75, a new VFR €101, and a new positioner €67 (Table 4). Group V-CTC: Thirteen patients had their CTC bonded/rebonded, two patients had a new CTC, and two patients had a new VFR. The total cost for unscheduled appointments in this group was €807 or €63/patient.

Discussion

This study clearly shows that retention treatment with either VFR combined with stripping of the lower anterior teeth or prefabricated positioner are more cost-effective than retention treatment with VFR in the maxilla and CTC retainer in the lower arch. These results reject the null hypothesis that the three retention methods are equally cost-effective. Thus, the CTC retainer is the least cost-effective retention treatment in compliant patients after 2 years of retention.

There are few published studies of economic evaluations of orthodontic retention treatment after fixed appliance treatment.

An RCT study has several advantages as a basis for health economic evaluation. The random allocation of
subjects reduces bias and confounding variables by ensuring that both known and unknown determinants of outcome are evenly distributed among the subjects. The prospective design also ensures that the baseline characteristics, treatment progression, treatment time, number of appointments, and side effects can be strictly controlled and accurately observed. However, in studies of limited sample size, the clinician's skills or lack of experience might still be a confounding factor. In the two previous RCT studies analyzing the same group of patients after 1 (Edman Tynelius et al., 2010) and 2 years of retention (Edman Tynelius et al., 2013), power analysis was made to achieve the highest level of evidence. The same team, i.e., one experienced orthodontist and two experienced orthodontic auxiliaries, treated all patients.

This evaluation of treatment costs is based on the ITT approach, meaning that all cases, successful or not, are included in the analysis.

The results of this study verify the results of Hichens et al. (2007) concerning the VFRs. The VFRs were made in the clinic. Had we used the nearby technician, the cost would have been higher. Not only because of the technician’s fee but also because patients would have to come back the next day, i.e. both direct and indirect costs would have been higher.

Treatment time is estimated, but some patients are more time consuming than others. Then again, as this is an RCT study, these patients should be evenly distributed between the three groups. As treatment times are estimated and expected to be the same for each patient, there is no statistical material to process.

Why did we not have any unscheduled appointments with the positioner group? There are several plausible answers to that. It is a stronger appliance and does not easily break. Some patients perhaps did not like it and did not want a new one? However, in this study, no patient declared that they had lost it and that remains a fact.

The indirect costs were higher in the V-CTC and V-S groups than in the P group due to the fact that the P group spent less time in the clinic. Overall, indirect costs were fairly low as most of the patients were adolescents attending high school in the same small city where the orthodontic clinic was situated. Indirect costs will increase in larger cities with longer distances. The catchment area for the patients probably represents a good average for the Swedish socioeconomic status. There were no retreatments during the retention period.

The costs are dependent on local factors such as staff, technicians, urban versus rural areas etc and cannot be said to be applicable everywhere in the world. In Sweden, it is getting more and more common for orthodontic auxiliaries to do the technical work for retention appliances and this reduces laboratory costs.

The crucial questions in retention treatment planning are always for how long should the patients wear their retainers and who shall decide when to take it off? We decided to take off all retention appliances after 2 years of retention. At that time, the three retention methods were equally effective in retaining the treatment result and it was good timing to do a CMA. This is an ongoing project and in forthcoming studies we will look at the same group of patients in other aspects.

**Conclusions**

After 2 years of retention in compliant patients, the cuspid retainer was the least cost-effective retention appliance. The CMA showed that for a clinically similar result there were differences in societal costs, but treatment decisions should always be performed on an individual basis and not only from economical aspects.

**Funding**

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**References**


