One-year prosthetic outcomes with implant overdentures: a randomized clinical trial
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Two methods for retaining implant overdentures (IODs) were considered. Retention was with either two individual ball attachments (2.5-mm ball abutment with titanium alloy cap; Nobel Biocare Canada) or a bar-clip mechanism (round gold bar system; Nobel Biocare).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised individuals recruited by advertising around the greater Vancouver area. Patients had to be endentulous with at least 1 year's experience in wearing conventional complete dentures, and be medically and psychologically suited for implant surgery in the opinion of the study surgeon. They also had to be able to complete the study forms and communicate verbally in English, and be available for the duration of the study. Patients were excluded if they had insufficient bone height for at least an 8.5-mm mandibular implant, or a history of head and neck radiation, or systemic or neurologic diseases. Those with prior oral implant treatment, or a need for additional preprosthetic surgery (as determined by the study surgeon), were also excluded.

Setting
The setting was secondary care. The economic study was carried out at the department of Oral Health Sciences, University of British Columbia, Vancouver, Canada.

Dates to which data relate
The dates to which the effectiveness, resource use and price data related were not specified.

Source of effectiveness data
The effectiveness evidence was derived from a single study. Further details of the parent clinical study are available elsewhere (Walton J N 2003, see "Other Publications of Related Interest" below for bibliographic details). Details of the patient satisfaction data can be obtained from McEntee et al 2005 (see "Other Publications of Related Interest" below for bibliographic details.)

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used for the effectiveness study.
Study sample
No power calculations to determine the sample size were reported. The study sample consisted of 67 patients (of the initial 100 initially enrolled) who had had their IOD for a minimum of 1 year prior to the analysis.

Study design
This was a randomised trial. The patients were stratified according to gender and the amount of mandibular residual ridge resorption. Blocks of patients within each stratum were then randomised according to whether their mandibular IODs would be retained by a ball-attachment mechanism or by bar and clips, with or without a framework (randomisation formed two attachment groups, each containing two sub-groups). Surgeons placing the implants were blinded to the planned prosthodontic treatment, but blinding was not possible for either the patients or the prosthodontist. The duration of follow-up was 2 years. Three of the 67 patients were lost to follow-up (1 died, 1 delayed treatment because of financial problems, and 1 was lost to follow-up after implant placement surgery).

Analysis of effectiveness
Only treatment completers were included in this study. The primary health outcome was the score on a visual analogue scale used to measure patient satisfaction with their dentures in each of eight categories. The categories were pain, comfort, appearance, function, stability, speech, cleaning difficulty, and overall satisfaction. Other outcomes assessed were fabrication time, number of appointments and chair time. The treatment groups were compared in terms of baseline variables (i.e. gender, ridge resorption, and age) and demographic variables (e.g. socio-economic data) and, generally, no significant differences were found. The exception was patients receiving a bar-clip attachment mechanism reported better overall health, (p=0.008), at baseline than those who received a ball-attachment denture.

Effectiveness results
There were no statistically significant differences in patient satisfaction between the two techniques (Mann-Whitney-Wilcoxon 2-sample rank tests). Fabrication time, number of appointments and chair time were similar between the two denture designs. Ball-adjustment dentures required approximately 8 times longer for repairs than bar-clip prostheses.

Clinical conclusions
The study showed that there were no significant differences in overall patient satisfaction with the treatments provided.

Measure of benefits used in the economic analysis
The authors did not develop a summary measure of benefit for use in the economic analysis. In effect, a cost-consequences analysis was carried out.

Direct costs
The cost/quantity boundary adopted for the costing was not clear from the report of the study. Only the median cost of repair for ball-attachment and bar-clip IODs were included. The quantities and the costs were not reported separately. Discounting was not relevant because of the short follow-up period. No price year was reported.

Statistical analysis of costs
The costs were treated stochastically. A Mann-Whitney-Wilcoxon test was performed to analyse cost-differences between the two technologies.

Indirect Costs
No indirect costs were included.
Currency
Canadian dollars (Can$).

Sensitivity analysis
No areas of uncertainty were identified or investigated.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The median costs of repair were Can$168 for ball-attachment IODs and Can$88 for bar-clip IODs. The difference was not statistically significant.

Synthesis of costs and benefits
The costs and benefits were not combined because of the cost-consequences approach taken.

Authors' conclusions
Given the equivalent levels of patient satisfaction with either method of retention, and a much higher repair rate for the ball attachment, it is suggested that a bar-clip design be used rather than the particular ball attachment utilised in this study.

CRD COMMENTARY - Selection of comparators
The comparator was explicitly reported. The study compared the use of a bar with two clips and a bar with two ball attachments for denture retention. Both alternatives represent standard practice in Vancouver. You should determine if these technologies are relevant for your own setting.

Validity of estimate of measure of effectiveness
The study was a randomised trial and, as such, should be associated with high validity. The patients were stratified and randomly allocated to the treatment options to adjust for potential confounding factors. It was unclear, however, whether the sample size was large enough to obtain robust results (these details are available in Walton J M 2003). The authors used a visual analogue scale to measure patient satisfaction, although they did not report any values. It is therefore unclear whether the effectiveness analysis was handled credibly (further details of the parent study are available in MacEntee et al 2005).

Validity of estimate of measure of benefit
Since a cost consequences approach was adopted, the comments in the 'Validity of estimate of measure of effectiveness' field (above) apply.

Validity of estimate of costs
The perspective adopted for the costing was unclear, thus it was difficult to assess whether all the relevant cost items were included in the cost analysis. The authors limited their analysis to repair costs. The resource quantities were not reported separately, and no price year was reported. This limits the transferability of the results to other settings.

Other issues
The results of this study favoured the use of the bar-clip IOD, but, because of the scope of the costing and the lack of
sample size calculations, the conclusions should be treated with some caution. Also, as there was no summary measure of benefits, it is difficult to make comparisons with other studies and technologies necessary to help decision-makers in the allocation of resources.

**Implications of the study**
The study suggested that, given equivalent levels of patient satisfaction with either method of retention, and a much higher repair rate for the ball attachment, a bar-clip design should be used.

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**Bibliographic details**

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**Other publications of related interest**


**Indexing Status**
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