Impact of implant support for mandibular dentures on satisfaction, oral and general health-related quality of life: a meta-analysis of randomized-controlled trials

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Key words: implant overdenture, meta-analysis, oral and general health-related quality of life, patient satisfaction, randomized clinical trial, systematic review

Abstract
Objectives: The aim of this study was to examine systematically the data published on the efficacy of mandibular implant-retained overdentures from the patient’s perspective.

Material and methods: Medline, Embase, The Cochrane Central Register of Controlled Trials and The Cochrane Systematic Reviews Database were searched and complemented by hand searching. All randomized-controlled trials published in English or French up to April 2007 were included, in which conventional dentures and mandibular implant overdentures in adult edentulous individuals were compared. The outcomes of interest were patient satisfaction, oral and general health-related quality of life. Random effects models were used to pool the effect sizes (ES) of all included studies.

Results: Ten publications of seven randomized-controlled trials were identified and eight were included in the meta-analysis. When compared with mandibular conventional dentures, implant overdentures were rated to be more satisfactory at a clinically relevant level [pooled ES 0.80, z = 3.56, 95% confidence intervals (CI) 0.36–1.24, P = 0.0004], but a statistical heterogeneity was found (χ² = 31.63, df = 5, P < 0.0001, I² = 84%). The pooled ES for oral health quality of life was –0.41 (z = 1.31, 95% CI, –1.02 to 0.20; P = 0.19, χ² = 11.53, df = 2, P < 0.003, I² = 83%). There was a lack of evidence to show the impact of mandibular implant overdenture on perceived general health.

Conclusions: Our findings suggest that, although mandibular implant-retained overdentures may be more satisfying for edentulous patients than new conventional dentures, the magnitude of the effect is still uncertain. There is a need for additional evidence including cost-effectiveness analyses on the impact of mandibular implant overdentures and conventional dentures.

Dependence on removable dentures is still a reality of life for millions of people all around the world (Douglass et al. 2002, Petersen et al. 2003). Conventional complete denture wearers experience a number of problems on a daily basis, such as instability of their mandibular dentures, inability to comminute foods, decreased self-confidence, decreased quality of life and decreased social contact and satisfaction (Redford et al. 1996). One of the major goals in health promotion is to develop a new technology that addresses these daily problems. Although the positive impact of implant therapy on patient-based outcomes has been shown in recent years (Geertman et al. 1994; Allen & McMillan 2003; Awad et al. 2003b), there is a controversy regarding the best prosthetic treatment for edentulous patients [Burns 2000;
Feine et al. 2002; Fitzpatrick 2006; Strassburger et al. 2006).

Therefore, a systematic review might shed some light on this topic. This study aimed to assess the efficacy of mandibular implant-retained overdentures from the patient’s perspective through a systematic review and meta-analysis. It focused on the following question: do edentulous individuals who wear mandibular conventional dentures or implant-retained overdentures rate their general satisfaction, oral and general health quality of life differently? Our hypothesis was that there is no difference in general satisfaction, oral health quality of life and perceived general health between conventional denture wearers and those wearing mandibular implant-retained overdentures.

Material and methods

The structure of this report is based on guidelines proposed at the Quality of Reporting of Meta-Analyses conference [Moher et al. 1999a].

Search strategy and eligibility criteria

We conducted a systematic literature search until April 2007 of MEDLINE from 1966, EMBASE from 1980, The Cochrane Central Register of Controlled Trials and the Cochrane Systematic Reviews Database. We included all relevant randomized-controlled trials in which edentulous individuals aged 18 or older wearing maxillary conventional dentures and either mandibular implant-retained overdentures or conventional dentures rated general satisfaction and general and oral health-related quality of life with a follow-up period of at least 2 months. The exclusion criteria for this study were randomized-controlled trials without conventional denture wearers as a control group, insufficient data that could not be rectified by imputation or author contact or outcomes of no interest to this review. Quasi-randomized trials were not included. Study populations that appeared in more than one publication were included only once in meta-analysis, using the more informative publication regarding the outcome of interest.

We developed a detailed search strategy for Medline (PubMed), and then revised the other three databases for each. We created groupings of words which were internally combined with the Boolean term ‘OR’. The first group consisted of the terms: denture, complete denture, complete lower dental prosthesis, dental prosthesis, implant supported, implant overdenture, overdenture, dental implantation and dental implant. The second group consisted of the terms related to the outcomes of interest: health, general health, oral health, patient satisfaction, quality of life, outcome assessment, outcome and process assessment, treatment outcome, health status, health status indicators, public health, mental health, oral hygiene, SF-36, OHIP and physical activity scale. These two groups of terms were then combined using the Boolean term ‘AND’. The search was run with the Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision); PubMed format. Language was not restricted.


Two reviewers [E. E. and G. H.] independently screened the titles and abstracts of each citation and identified all citations for full review if there was any possibility that the study included the comparison of interest. Intra-examiner calibration at the beginning of the systematic review and duplicate examinations throughout study collection were carried out. Kappa values were 0.83 and 0.86, respectively, indicating a high and consistent agreement. Disagreement between reviewers was discussed and resolved by consensus. The full copy of all possibly or definitely relevant studies was retained for further assessment. The search procedure and reasons for exclusion of studies are shown in Fig. 1.

Assessment of methodological quality

This assessment used a domain-based evaluation, including reports of sample size estimation and parameters of quality: sequence generation, allocation concealment, completeness of follow-up and intention-to-treat (ITT) analysis.

The quality of included studies was assessed following the Cochrane Handbook for Systematic Reviews of Interventions [Higgins & Green 2008]. We graded each parameter of trial methodological quality as: ‘adequate’, ‘inadequate’ and ‘unclear or not reported’:

1. Sequence generation was evaluated as ‘adequate’, if it included any one of the following methods of randomization: computer generated or a table of random numbers, drawing of lots, coin-toss, shuffling cards or throw of a dice. It was judged as ‘inadequate’ for methods of randomization utilizing any of the following: case record number, date of birth or alternate numbers.
2. Concealment of allocation was graded ‘adequate’ if methods of allocation concealment included either central randomization or sequentially numbered sealed opaque envelopes. This criterion was considered ‘inadequate’ if there was an open allocation sequence and the participants and trialists could foresee the upcoming assignment.
3. The handling of withdrawals and losses was assessed according to whether there was a clear description given for withdrawals and dropouts in each treatment group.

Assessment of ITT analyses was based on two criteria:

1. That all participants were analyzed with the groups to which they were randomized, regardless of which treatment they actually received, and
2. That all participants were included, regardless of whether their outcomes were collected.

Masking outcome assessors, blinding of care providers or participants was not feasible in these trials and hence these aspects were not used as measures of study quality.

Data extraction and outcomes
From each study, we collected the following data: authors, country, years of study, study design, recruitment methods, population characteristics and sampling criteria, randomization method, number randomized, intervention characteristics, main outcomes (general satisfaction, oral and general health-related quality of life), type of measurement instrument, baseline and post-treatment scores, follow-up period and dropout percentage. Additional information was sought from authors when necessary.

Data were abstracted by one investigator using a data extraction form, and were then checked by the other investigator.

Statistical analysis
All analyses were performed using Review Manager Version 5.0 software [Cochrane Collaboration 2008]. Only studies of similar comparisons reporting the same outcomes were included in the meta-analysis. Studies included in this meta-analysis were also required to have a minimum follow-up time of 2 months.

Effect sizes (ES) were calculated to compare the results across studies. Effects were expressed as standard mean differences (SMD). SMD standardized the measurements on a uniform scale. The magnitude of an ES has been described by Cohen; 0.3 represents a small effect, 0.5 a medium effect and 1.0 a large effect (Cohen 1988). When medians were presented, the values were converted to means (SD). Differences in the direction of scales were adjusted by multiplying the mean values by \( -1 \). Data extracted from visual analogue scales (VAS) were transformed to Likert-type scales.

The analyses were carried out using a random effect model that accounts for inter-study variation and provides a more conservative estimate than a fixed model (Higgins & Green 2008). The Cochrane \( Q \) test and \( I^2 \) statistic were used to test heterogeneity between the trials. \( I^2 \) approximates the proportion of total variation in the ES that is due to heterogeneity, rather than sampling error. An \( \alpha \) error of \( P < 0.20 \) and \( I^2 \) of at least 50% were taken as indicators of heterogeneity of outcomes. To explore the sources of heterogeneity across the studies, we planned to conduct a priori subgroup analyses according to the recruitment method (general population recruited via advertisement, and participants with a poor oral condition and severe problem recruited via referral to specialist clinics). When comparisons were made between pooled standardized mean differences, statistical differences were assessed using a \( Z \)-test; \( P < 0.05 \) was considered significant. Funnel plots were used to assess potential retrieval bias (Petitti 2000).

Results
Characteristics of trials, patients and interventions
In total, 2262 non-duplicate articles were identified from database searches, of which 37 were eligible for full-text searching (Fig. 1). Any unpublished data were found by contacting the companies or investigators; all missing data were rectified through author contact. All the studies were published in English. Of these, 27 papers were excluded because: (1) they did not meet the

A total of 10 manuscripts on seven randomized-controlled trials were included in this review. Details of the characteristics of each trial are shown in Table 1. The earliest study was published in 1995 (Boerrigter et al. 1995a), and the last in 2006 (Allen et al. 2006). All included trials used a parallel design with two arms, except for one trial, with three arms (Bouma et al. 1997). One study was a multicenter, randomized clinical trial (Bouma et al. 1997; Meijer et al. 2003). Other publications stemming from this multi-center trial were excluded because of the same population.

The unit of allocation chosen was each individual in all the trials. The trials varied by recruitment methods, inclusion criteria, sample size, population characteristics, implant and retention systems and follow-up durations. Participants were recruited in three different ways: (1) patients with severely resorbed mandibles and severe problems with their dentures, referred by their general practitioners to university hospitals or prosthodontic departments (Boerrigter et al. 1995a; Bouma et al. 1997; Meijer et al. 2003; Allen et al. 2006); (2) controlled diabetic patients from medical centers with varying degrees of satisfaction with their existing conventional dentures (Kapur et al. 1999); and (3) general population recruited via newspaper advertisements (Awad et al. 2000a, 2003a, 2003b; Thomason et al. 2003; Heydecke et al. 2003).

Complete edentulousness in the maxilla and mandible for at least 1 year (Boerrigter et al. 1995a; Bouma et al. 1997; Meijer et al. 2003), 5 years (Awad et al. 2003b; Thomason et al. 2003; Allen et al. 2006), 10 years (Awad et al. 2000a, 2003a; Heydecke et al. 2005), adequate bone support and no medical contra-indications for dental implants or surgical procedures were common inclusion criteria in all trials. In some studies, a specified minimum mandibular bone height (variation between 8 and 25 mm) was one of the inclusion criteria (Boerrigter et al. 1995a; Bouma et al. 1997; Meijer et al. 2003).

The sample sizes in these trials varied from \( n = 60 \) to 157 participants. For all trials, the groups seemed comparable at baseline with respect to the primary outcomes. All trials were conducted at University dental clinics or hospitals, except one, in which the participants were treated at a Veterans Affairs Medical Center (Kapur et al. 1999). All dentures were made by prosthodontists or senior prosthodontic residents.

Participants assigned to the implant groups received various implant systems, including the Branemark System [Nobel Biocare, Nobelpharma, Göteborg, Sweden], the IMZ System [Friadent, Freidrichsfeld AG, Interpole International, Germany], the ITI system [Straumann, Basel, Switzerland] or the TMI system [Krijnen medical BV, Beesd, the Netherlands]. Two implants were placed in the interferominal region of the mandible in all trials, except in one trial, in which a group received transmandibular implants (Boerrigter et al. 1995a). Overdentures were retained by clip attachment to a bar or two ball attachments. In all trials, participants received conventional maxillary dentures.

The follow-up periods ranged from 2 months to 10 years. The dropout rate ranged from a minimum of 4% at 2 months to 10 years (Awad et al. 2000a, 2003a; Thomason et al. 2003). A large number of trials reported that analyses were carried out on an ‘intention-to-treat’ basis (Boerrigter et al. 1995a, Awad et al. 2000a, 2003a, 2003b; Thomason et al. 2003; Allen et al. 2006). However, many trials were reported to have included ITT analysis when they actually met only the first of the two criteria for a proper ITT analysis: all participants were analyzed with the groups to which they were randomized, but the dropouts after randomization were not included (Boerrigter et al. 1995a; Awad et al. 2003b; Allen et al. 2006). Statistical analyses were adequate in all of the studies.

### Effect of type of mandibular prosthesis on patient satisfaction

A summary of the retrieved literature on the effect of mandibular prostheses on patient satisfaction is presented in Table 1. From a total of 10, six studies with 588 participants \( n = 322 \) implant overdentures; \( n = 266 \) conventional dentures were included in the meta-analysis. Participants’ general satisfaction with their prostheses was assessed using 100 mm VAS or Likert-type response scales. Standardized mean differences were positive in all of the studies (Fig. 3). The pooled ES was \( 0.80 \) \( [z = 3.56, 95\% \text{ confidence intervals } [CI] 0.36–1.24, P = 0.0004] \) in favor of the implant overdenture treatment. The \( P \)-value for heterogeneity \( (\chi^2 = 31.63, df = 5) \) was \( P < 0.00001 \) and \( I^2 = 84% \) (Fig. 3, analysis 1.1.1). Two studies [Kapur et al. 1999; Allen et al. 2006] had a 95% CI that included an ES of zero. The overall
<table>
<thead>
<tr>
<th>Trial</th>
<th>First author</th>
<th>Location, date of study</th>
<th>Sample size</th>
<th>Ages</th>
<th>Intervention randomized number</th>
<th>Outcomes, instruments</th>
<th>Follow up Period and % dropout after randomization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Boerrigter et al. (1995b)</td>
<td>the Netherlands, 1995</td>
<td>157</td>
<td>35–84</td>
<td>IOD, n = 93</td>
<td>General satisfaction</td>
<td>12 months</td>
</tr>
<tr>
<td>2</td>
<td>Bouma et al. (1997)</td>
<td>the Netherlands, 1997</td>
<td>90</td>
<td>55 ± 11</td>
<td>CD, n = 64</td>
<td>Validated questionnaires</td>
<td>12 months</td>
</tr>
<tr>
<td>3</td>
<td>Kapur et al. (1999)</td>
<td>United States, 1999</td>
<td>102</td>
<td>48–75</td>
<td>IOD, n = 40</td>
<td>Psychological well being</td>
<td>6, 24 months</td>
</tr>
<tr>
<td>4</td>
<td>Awad et al. (2000a, 2003a)*</td>
<td>Canada, 2000, 2003</td>
<td>102</td>
<td>35–65</td>
<td>CD, n = 62</td>
<td>GARS-D, Psychosocial Well-Being</td>
<td>2 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IOD, n = 54</td>
<td>Oral health-related quality of life</td>
<td>2 months</td>
</tr>
<tr>
<td>5</td>
<td>Awad et al. (2003b)*</td>
<td>Canada, 2003</td>
<td>60</td>
<td>65–75</td>
<td>CD, n = 30</td>
<td>General satisfaction</td>
<td>2 months</td>
</tr>
<tr>
<td>6</td>
<td>Thomason et al. (2003)</td>
<td>the Netherlands, 2003</td>
<td>121</td>
<td>IOD 56.9 ± 11.6</td>
<td>IOD, n = 61</td>
<td>Oral health-related quality of life</td>
<td>6 months, % 1 CD, % 22 IOD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CD, n = 30</td>
<td>General satisfaction</td>
<td>% 20 CD, % 10 IOD</td>
</tr>
<tr>
<td>7</td>
<td>Meijer et al. (2003)</td>
<td>the Netherlands, 2003</td>
<td>118</td>
<td>≤ 80</td>
<td>IOD, n = 60</td>
<td>Oral health-related quality of life</td>
<td>3 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CD, n = 56</td>
<td>General satisfaction</td>
<td>22%</td>
</tr>
<tr>
<td></td>
<td>Allen et al. (2006)</td>
<td>United Kingdom, 2006</td>
<td>118</td>
<td></td>
<td>IOD, n = 62</td>
<td>General satisfaction</td>
<td>22%</td>
</tr>
</tbody>
</table>

**Table 1. Summary of included manuscripts**

<table>
<thead>
<tr>
<th>Trial</th>
<th>First author</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Boerrigter et al. (1995b)</td>
<td>Better post-treatment scores for the IOD than the CD group for general satisfaction (P &lt; 0.001).</td>
</tr>
<tr>
<td>2</td>
<td>Bouma et al. (1997)</td>
<td>Significant improvement in the average values of dental health-related quality of life measures for both groups (P &lt; 0.001), except for the HSCL subscale on somatic complaints. Score of 0 before treatment for up to 43% of the analyzed data. No within group difference for general quality of life measured by LASA. No significant between groups differences for all measures.</td>
</tr>
<tr>
<td>3</td>
<td>Kapur et al. (1999)</td>
<td>No significant post treatment between group difference for patient satisfaction, although higher for the IOD group.</td>
</tr>
<tr>
<td>4</td>
<td>Awad et al. (2000a, 2003a)*</td>
<td>Significant improvement from mean OHIP baseline to post-treatment scores for the IOD (P &lt; 0.05) in all subscales, including functional limitations, physical pain, psychological discomfort, physical disability, social disability and handicap. In contrast, pre/post treatment improvements in the conventional group only for functional limitation and physical disability items. Significant mean post treatment scores between the groups for all seven OHIP domains (P &lt; 0.05).</td>
</tr>
<tr>
<td>5</td>
<td>Heydecke et al. (2005)</td>
<td>Less post treatment looseness in eating, speaking, yawning and kissing in IOD than CD (P &lt; 0.001). Participants wearing implant overdentures had better sexual activity scores than did those in the conventional denture group. Moderate (r = 0.5–0.7) correlation between total OHIP 49 scores and perceived prosthesis looseness.</td>
</tr>
<tr>
<td>6</td>
<td>Thomason et al. (2003)</td>
<td>Significant between-group difference only in the physical pain domain for OHIP-49. Significant differences between the two groups for total score, functional limitations, physical pain and physical disability with the OHIP 20. CD group: Pre/post-treatment differences using the OHIP-49 for the total score, functional limitation and physical disability. IOD group: Significant pre/post treatment differences with the OHIP-20 in all domains, including total score and in all domains except psychological disability using the OHIP-49.</td>
</tr>
<tr>
<td>7</td>
<td>Meijer et al. (2003)</td>
<td>Significant between group difference (P &lt; 0.001) according to patient satisfaction at 1, 5 and 10 years follow-up. Mean satisfaction score of CD group (including 40% who later received implants) lower than IOD. Comparative post-treatment OHIP means in both groups. Both groups showed significant improvements in OHIP scores from baseline to 3 months after treatment (P &lt; 0.001). The ES of the change in the OHIP score was 1.1 for the IOD group and 1.0 for the CD group. The pre/post treatment change scores significantly higher for the IOD receivers than for those who refused IOD and received CD (P &lt; 0.001).</td>
</tr>
<tr>
<td>8</td>
<td>Allen et al. (2006)</td>
<td>Significant post-treatment between group difference in general satisfaction (P = 0.005). Significant pre-post treatment difference for both groups (P &lt; 0.001). Magnitude of change greater for IOD group (22.4 mm mean difference).</td>
</tr>
</tbody>
</table>

*Rows include trials with multiple publications reporting on different outcomes. IOD, overdenture retained by implants; CD, conventional denture; General satisfaction term used to explain overall denture satisfaction; PPS, preprosthetic surgery and conventional denture; ARS-D Groningen Activity Restriction Scale-Dentistry; HSCL, Hopkins Symptom Check List; LASA Linear Analogue Self-Assessment Method, one-item version.
standardized mean difference for the general population recruited via newspaper advertisements was 0.81 \( [z = 4.95 \ (95\% \ CI \ 0.49–1.13 \ P < 0.00001] \), test for heterogeneity \( P = 0.70, I^2 = 0\% \) [Fig. 3, analysis 1.1.2]. For participants who were referred to specialist clinics because of their poor oral condition or severe problems with their dentures, the overall standardized mean difference was 0.95 \( [z = 2.31 \ (95\% \ CI \ 0.14–1.75 \ P = 0.02] \), test for heterogeneity \( P < 0.00001, I^2 = 92\% \) [Fig. 3, analysis 1.1.3]. In one study (Kapur et al. 1999), in which participants were controlled diabetic patients referred from medical centers, the overall standardized mean difference was 0.30 \( [z = 1.19, \ 95\% \ CI \ 0.19 to 0.80, \ P = 0.23] \) [Fig. 3, analysis 1.1.4].

### Effect of type of mandibular prosthesis on oral health-related quality of life

The summary results of the studies evaluating the impact of mandibular prosthesis on oral health-related quality of life are presented in Table 1.

#### Table 2. Methodological quality summary: review authors’ judgments about each methodology quality item for each included study

<table>
<thead>
<tr>
<th>Trial</th>
<th>Adequate sequence generation</th>
<th>Allocation concealment</th>
<th>Report on withdrawals and dropout</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boerrigter et al. (1995b)</td>
<td>+</td>
<td>?</td>
<td>+</td>
</tr>
<tr>
<td>Bouma et al. (1997)</td>
<td>+</td>
<td>?</td>
<td>+</td>
</tr>
<tr>
<td>Kapur et al. (1999)</td>
<td>+</td>
<td>?</td>
<td>+</td>
</tr>
<tr>
<td>Awad et al. (2000a, 2003a)</td>
<td>+</td>
<td>?</td>
<td>+</td>
</tr>
<tr>
<td>Heydecke et al. (2005)</td>
<td>+</td>
<td>?</td>
<td>+</td>
</tr>
<tr>
<td>Awad et al. (2003b)</td>
<td>+</td>
<td>?</td>
<td>+</td>
</tr>
<tr>
<td>Thomason et al. (2003)</td>
<td>+</td>
<td>?</td>
<td>+</td>
</tr>
<tr>
<td>Meijer et al. (2003)</td>
<td>+</td>
<td>?</td>
<td>+</td>
</tr>
<tr>
<td>Allen et al. (2006)</td>
<td>+</td>
<td>?</td>
<td>+</td>
</tr>
</tbody>
</table>

*Rows include trials with multiple publications reporting on different outcomes.*  
+ adequate; ?, not reported; –, inadequate.

Fig. 2. Methodological quality graph: review authors’ judgements about each methodology quality item presented as percentages across all included studies.

Fig. 3. Meta analysis of randomised trials comparing mandibular implant overdentures with conventional dentures on patient rating of satisfaction.
The meta-analysis includes only the studies using the oral health-related quality of life as the outcome. Thus, we included only studies using OHIP as the measurement instrument, and excluded two others (Bouma et al. 1997; Heydecke et al. 2005). The instruments used in these two studies were: The Groningen Activity Restriction Scale-Dentistry, the Psychological Well Being Scale for Denture Patients, the Hopkins Symptom Check List, the Linear Analogue Self-Assessment and the Social Impact Questionnaire. These instruments have been used to measure the impact of oral prostheses on individuals’ psychosocial well-being, general quality of life and on social and sexual activities.

For all three trials combined, the pooled ES was \( P = 0.74, I^2 = 5% \) was rejected [Fig. 4, analysis 1.2.2]. The trial of Allen et al. [2006] showed an almost null result [Fig. 4, analysis 1.2.3].

**Effect of type of mandibular prosthesis on perceived general health**

The lack of evidence in this field was conspicuous. We found only one article [Heydecke et al. 2003a] in which perceived general health was measured with a generic instrument, The Short Form (SF-36). Based on a reverse scoring system, they found no difference between the conventional denture and the implant overdenture groups on any of the SF-36 subscales. Because this was the only article using a reverse scoring method, further processing of the data was not performed.

**Publication bias**

We were unable to find studies [published or not published] in which negative effects were found. The funnel plot is not included in this report, because less than 10 RCTs are available. In these situations, the test for asymmetry is not powerful enough to distinguish chance from real asymmetry [Higgins & Green 2008].

**Discussion**

This meta-analysis yielded two principal findings: firstly, the results of this meta-analysis demonstrate that mandibular implant overdentures might be a more effective treatment for edentulous individuals than conventional dentures, based on patient ratings of satisfaction or oral health-related quality of life. However, there is still uncertainty about the true magnitude of the effect.

Secondly, there is a lack of evidence concerning the impact of mandibular implant overdentures on perceived general health.

To our knowledge, this is the first systematic review and meta-analysis on this topic, in which only randomized-controlled trials were included. The strengths of this study include the sole use of randomized-controlled trials and the inclusion of patient-based outcomes. Unbiased evidence obtained from systematic reviews of individual randomized trials is needed to estimate the effect of healthcare interventions and to determine whether there are differences in their effects. However, some limitations should be considered when interpreting these results. Despite our extensive search strategy, the number of included randomized-controlled trials was limited. This could partly have been caused by the fact that some trial results may not have been reported due to negative findings. Furthermore, our analysis was limited by any flaws in the methodological quality of the included trials, which could threaten the...
internal validity of the study and introduce the risk of bias. In fact, this meta-analysis revealed substantial statistical heterogeneity. However, it is not surprising to find this incompatibility in quantitative results as the studies in any meta-analysis will necessarily be clinically heterogeneous [Hardy & Thompson 1998]. Trials included in this meta-analysis differed in patient recruitment, patient characteristics, the duration of follow-up, the extent of withdrawals and the handling of losses to follow-up. Other sources of heterogeneity could also be a result of ignoring the quality of component trials [Schulz et al. 1995]. We used a component approach to assess the trial quality in this study, because the use of composite scales has been reported to be problematic for several reasons, including items not related to the internal validity of the trial [Jüni et al. 1999].

Although randomized-controlled trials are the accepted gold standard in the evaluation of the effectiveness of healthcare interventions, they are not immune to bias. In fact, several studies have shown that trial quality has an impact on the ES [Moher et al. 1998]. It is reported that poorly concealed treatment allocation is associated, on average, with an exaggeration of treatment effects by 20–40%. Trials that are not double blinded also result in larger ES [Schulz et al. 1995]. The quality assessment of studies included in this meta-analysis indicated unreported allocation concealment in all of the publications. We recontacted the authors to clarify the level of allocation concealment. Based on the explanations of allocation concealment by those who responded, it appears likely that the allocation concealment was adequate in these trials, even though these details did not originally conform to Cochrane guidelines. Furthermore, in none of the included trials was double blinding carried out. However, the quality of randomized-controlled trials in implant research must be assessed considering the nature of the condition. In other words, loss of dentition is a chronic condition, and therapies for complete tooth loss are palliative. As with all palliative care, the aim is to improve the function, quality of life and patient satisfaction. Therefore, patient-based outcomes are most appropriate outcomes, and blinding is often not possible. This means that no implant studies can be considered to meet the quality ‘gold standard’, because of the criterion is that the study should be double blinded. Therefore, the results of implant studies should be interpreted with caution, because of this risk of bias. In addition, overestimation of the results should be considered.

Three systematic reviews that include a variety of study designs [Fitzpatrick 2006, Strassburger et al. 2006, Thomson et al. 2007] addressed the impact of implant prostheses on patient-based outcomes, including patient satisfaction and quality of life. The latest [Thomson et al. 2007], carried out by the European Workshop on Evidence-Based Reconstructive Dentistry, concluded that the magnitude of the treatment effect is greater for mandibular implant overdentures than for conventional dentures. However, the other two reviews indicated that complete dentures are still a good treatment choice for people who are able to adapt to these devices [Fitzpatrick 2006, Strassburger et al. 2006]. These authors also concluded that implant overdentures are more beneficial to patients with advanced alveolar bone resorption and those with several denture problems. However, the Fitzpatrick [2006] review does not meet the criteria of standard systematic reviews. In this article, the search strategy, results and conclusions appear to be drawn from selective analyses. Strassburger et al. [2006] reviewed the influence of all types of prosthodontic treatments on patient satisfaction ratings and oral health-related quality of life. They included a variety of study designs and did not limit their research question to any specific treatment. Although their results show that edentate individuals benefit more from the use of implant-supported prostheses in the edentulous mandible, the authors suggest that implant prostheses should be provided with priority to those patients in whom conventional therapy has failed. Because of this recommendation, in this meta-analysis, we planned and carried out subgroup analyses of trials with participants who had major problems with their dentures. We expected that participants with high levels of impairment and who were referred for specialist care are not likely to be representative of a general population, both in terms of the size of the treatment effect and in terms of the level of treatment expectations.

Our meta-analysis revealed that, although the overall ES was greater with mandibular implant overdentures, the magnitude of effect varied considerably among studies.

This heterogeneity should not be ignored. The meta-analysis shows that two of the six studies [Kapur et al. 1999, Allen et al. 2006] differed from the rest, because they found no between-treatment differences in patient satisfaction ratings. The difference in the patient characteristics (diabetic or maladaptive patients) could be one of the explanatory factors. Subgroup analyses restricted to trials with recruitment of individuals with severely impaired conditions indicated that the ES increases (0.95), but statistical heterogeneity remains. Inclusion of participants with high levels of impairment may increase the potential for selection bias in that population. However, several prospective and retrospective studies demonstrated that this group may show the greatest satisfaction or improvement in oral health-related quality of life in view of their existing oral condition [Strassburger et al. 2006].

As with the oral health-related quality of life, the overall ES improved and heterogeneity disappeared only when studies with participants from the general population, recruited via newspaper advertisements, were included. It should be noticed that two of these studies (Awad et al. 2000a, 2003b) were carried out in the same research center using almost identical protocols but different age groups. Therefore, this could explain why their results are so similar.

It is suggested that conclusions should not be drawn on the summary results when there are small numbers of trials available with many clinical differences. In such situations, ideas about the sources of heterogeneity could be considered as hypotheses for further studies [Thompson 1994]. Therefore, we should be cautious about drawing definitive conclusions and clinical practice guidelines from these results. However, they can be integrated with clinical judgments and expertise, patients’ expectations and values as well as considerations of cost-effectiveness, for clinical decision making [Eddy 2005].

This review confirms the results of Strassburger et al. [2006] that a limited number of studies, as well as a lack of
sensitive and non-generic instruments for measuring perceived general health, have hindered the transfer of knowledge in this field. Naito et al. [2006] have also addressed this issue in their review of the association between oral health status and health-related quality of life. Thus, there is a need for adequately powered and properly designed clinical trials as well as more sensitive general health instruments to assess and compare the general and oral health quality of life of edentulous people wearing various types of prostheses.

In order to reduce the influence of chance effects in estimating treatment differences in meta-analyses, we support the use of individual patient data (IPD) or raw data (Clarke & Stewart 2001). We were impressed with the very supportive attitudes and offers of assistance when we contacted trialists involved in clinical implant research to request additional information about their trials. Therefore, we are planning a future meta-analysis using aggregate data from trialists. These IPD reviews are less prone to bias and can better ensure the quality of disseminated information.

Conclusions

The available evidence points to better patient-based outcomes with mandibular implant overdentures. However, with regard to the magnitude of treatment effects, the results of this meta-analysis are inconclusive. We need additional meta-analyses on well-conducted randomized-controlled trials that include relevant economic assessments as a priori outcome to inform policy makers, insurers and the public in their decisions on adoption of implant therapies.

Implications for further research

As stated previously, there is a need for more well-conducted randomized-controlled trials to assess the real magnitude of effect of mandibular implant-retained overdentures on patient satisfaction and oral health-related quality of life. Furthermore, there is a need for further studies investigating the cost effectiveness of this technology.

Sensitive and appropriate general health and quality-of-life measures should be used in these studies. Some authors have advocated that mandibular implant overdentures should be provided only for patients with major problems with their conventional prostheses. Although the subgroup analysis in this trial indicates a positive impact of this treatment for the general population, it would be interesting to test this hypothesis in groups of patients whose conditions differ (e.g., those with severe resorption vs. normal resorption, those with no problems with their conventional dentures vs. those with severe problems) using a stratified randomization strategy and a long-term follow-up period.

We emphasize the need for adequate reporting of results using the CONSORT guidelines (http://www.consort-statement.org/), as well as the inclusion of numbered data to demonstrate treatment effects for facilitating and improving the quality of published meta-analyses.

Role of the funding source and potential conflict of interest

No external funding sources directly supported this meta-analytic study. One of the reviewers [E. E] is completing a PhD based on a randomized-controlled trial in which this particular question is addressed. The corresponding author is the Principal Investigator on two of the included randomized-controlled trials that were funded over the past 17 years by University/Industry grants from The Canadian Institutes of Health Research and Straumann Canada Ltd and by the Canadian Medical Research Council and Nobelpharma Canada Inc. The corresponding author had full access to all data and final responsibility for the decision to submit this report for publication.

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References


Appendix A: Search strategy developed for Medline (via PubMed) and revised appropriately for each search database

Search: #1

denture OR (complete denture) OR (complete lower dental prosthesis) OR (dental prosthesis) OR (implant supported) OR (implant overdenture) OR (overdenture) OR (dental implantation) OR (dental implant)
Search: #2

(health) OR (general health) OR (oral health) OR (patient satisfaction) OR (quality of life) OR (outcome assessment) OR (outcome and process assessment) OR (treatment outcome) OR (health status) OR (health status indicator) OR (public health) OR (mental health) OR (oral hygiene) OR (SF36) OR (OHIP) OR (physical activity scale)

Query Translation

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</table>

Search #3: (#1) AND (#2)

The above search was run with the Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision); PubMed format

1. randomized controlled trial [pt]
2. controlled clinical trial [pt]
3. randomized [tiab]
4. placebo [tiab]
5. clinical trials as topic [mesh: noexp]
6. randomly [tiab]
7. trial [ti]
8. #1 or #2 or #3 or #4 or #5 or #6 or #7
9. humans [mh]
10. #8 and #9