DENT 655- Health Technology Assessment

A Health Technology Assessment Report on Mandibular Two-Implant Overdentures

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The views expressed in this report are those of the author(s) and do not necessarily reflect the views of the Faculty of Dentistry, McGill University. This report was developed for the course 'DENT 655- Health Technology Assessment' and assumes a call from general dentists to assist decision-making in dental offices, clinical and hospitals. All are welcome to make use of it. However, to help us estimate the impact, it would be deeply appreciated if users could inform us whether it has influenced policy decisions in any way.

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"Health technology assessment considers the effectiveness, appropriateness and cost of technologies. It does this by asking four fundamental questions: Does the technology work, for whom, at what cost, and how does it compare with alternatives?" (UK National Health Service R&D Health Technology Assessment Programme, 2003)

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Table of Contents

Abbreviations and Acronyms

CD	Complete Denture
IOD	Implant overdenture
PI	Plaque Index
CI	Calculus Index
MBL	Marginal Bone Loss
PD	Probing Depth
SBI	Sulcus Bleeding Index
OHIP	Oral Health Impact Profile
OHIP-EDENT	Short form of OHIP for edentulous persons
VAS	Visual analog Scale
OHRQoL	Oral Health Related Quality of Life
ISUP	Implant supported
IRET	Implant retained
RCT	Randomized controlled trial
Mand.	Mandibular
Max.	Maxillary

Executive Summary

The Issue: Given the increased use of dental implants to support mandibular dentures based on reputable scientific opinion recommending its use as the minimum standard of care for the edentulous patients, and the high treatment and maintenance costs associated with it, a review of the clinical efficacy and economic impact is needed to aid informed decision making by clinicians regarding its procurement and/or expanded use into clinical practice.

Objectives: The primary objectives of this Health Technology Assessment (HTA) were to assess clinical outcomes (clinician- and patient-based) of ball-type mandibular two-implant overdenture treatment in comparison to treatment with: 1) removable mandibular complete dentures, 2) different types of attachments for mandibular two-implant overdenture, and 3) different loading protocols of the mandibular overdenture. The secondary objective was to conduct a cost analysis for this technology from a Canadian clinician's perspective.

Methods: A systematic literature review covering Ovid MEDLINE® In-Process & Other Non-Indexed Citations, Ovid MEDLINE® without Revisions (1996 to January Week 4 2012), EMBASE, Web of Science and ProQuest and Health technology assessment databases (INAHTA, CRD, Cochrane, NICE, AETMIS, and CADTH) was conducted. Outcomes from 31 included peer-reviewed articles were divided into 'primary outcomes' including patient satisfaction, prosthodontic maintenance & complications, and peri-implant outcomes. All the other reported outcomes were categorized under 'other outcomes'.

A systematic review of the economic literature was conducted with the aim of assessing initial and maintenance costs from the clinician's perspective (in CAD $).

Clinical Efficacy: Of the 31 selected studies, 20 articles reported clinical efficacy based outcomes. The outcomes reported were classified into 'primary outcomes', which included prosthodontic maintenance & complications and peri-implant outcomes, as well as 'other outcomes' including: 1) implant success; 2) effects of loading time on implant success or prosthodontic maintenance requirements; 3) vertical retention forces; 4) masticatory function; 5) implant stability; 6) effects of IOD rotation; 7) occurrence of post-insertion pressure spots; 8) patients' preferences, 9) maximum bite force; and 10) soft tissue complications.

It was found that mandibular two-implant overdentures are associated with better peri-implant outcomes, greater vertical retention forces, less occurrence of post-insertion pressure spots, and lesser soft tissue complication as compared to all alternative treatments, including a removable CD, a bar type IOD, and a magnet type IOD. Moreover, the mandibular two-implant overdenture was found to be a superior treatment option when compared to a removable CD or a magnet type IOD in all other outcomes. However, no statistical difference was found between a mandibular two-implant overdenture and a bar-clip type IOD in other outcomes, including masticatory function, implant stability, and maximum bite force.

As for prosthodontic maintenance & complications, the ball-type mandibular two-implant overdenture requires significantly more maintenance and repair compared to a removable CD or a bar-clip IOD. Difference in loading time does not seem to affect the treatment outcome of the mandibular two-implant overdenture.

Patient based outcomes: Of the 31 selected studies, 17 articles reported patient-based outcomes. The primary outcome reported was patients' satisfaction. It was found that despite the higher cost of mandibular two-implant overdenture compared to removable CD, patients were more satisfied with the former. The satisfaction domains included the following: general satisfaction, comfort, stability, esthetics, ability to chew, ability to speak and clean, ability to chew six foods of varying textures, retention, denture fit, esthetics, and social functioning. However, compared to its bar-type IOD counterpart, one RCT reported that the patients' ratings of satisfaction for retention and stability of the ball-type mandibular two-implant overdenture decreased over time. Moreover, another cross-over study reported that when given the choice between a mandibular two-implant overdenture and a bar type IOD, more patients preferred the bar type over the ball type.

Economic review and analysis: The initial costs of the treatment as calculated from the included economic studies varied approximately between CAD $3,200 to $8,100 per patient. The variation in the costs can be explained due to the differences in costing approach used for the initial treatment. The maintenance costs ranged from approximately $130/year to $250/year per patient. The reported costs follow a clinician's perspective and the treatment charges to a patient for the treatment depend on other factors such as overhead costs.

Conclusions: A ball type two-implant mandibular over denture opposed by a removable maxillary complete denture is recommended as the minimum standard of care for edentulous patients because of the many advantages it provides over other treatment options. The increased cost of this treatment option is offset by the many advantages it provides to the

patient and the increased patient satisfaction and improved quality of life post-treatment. Loading time according to the studies included in this report has no direct effect on the treatment outcome. However, in patients with increased retention and stability requirements as well as patients with reduced access to care, a bar type IOD is more appropriate.

1. Introduction

1.1 Overview of the Technology

Historical Background

Dental implants in different forms are believed to have been used since Egyptian times. Although the currently used titanium root-form implants are a virtually serendipitous discovery from the 1950s by Dr. Per-Ingvar Brånemark of Gothenburg Sweden.[1] Since their introduction, dental implants, that are tooth-root analogue devices inserted into the jaw-bone (endosseous), have been increasingly used to support different types of dental prostheses, such as fixed partial dentures, fixed complete dentures and removable complete dentures.[2,3]

In 2002, two dental implants in the mandible to support removable complete dentures were advocated as the minimum standard of care for edentulous individuals by a panel of expert clinicians and scientists.[4] This consensus stemmed from a decade of longitudinal clinical studies that signify the clinical benefits and patient satisfaction with mandibular two-implant overdentures over conventional dentures.

Mandibular Two-Implant Overdentures

Two dental implants in the anterior mandible act as anchors for the mandibular dentures improving their retention and stability.[5,6] The connection between the implant and the denture can be constructed using various forms of attachment designs, such as, the ball attachment, the bar-clip attachment, the telescopic attachment and the magnet attachment.[7]

Some clinicians favor the use of bar retained IODs while others prefer ball attachment IODs for reasons of relatively low costs, relative ease of fabrication, and ease of implant cleaning by the patient.[8,9] Likewise, the debate continues on whether to load the implants with the denture at an early stage or to wait for a certain period prior to loading to allow osseointegration. These decisions may affect the outcomes of the treatment and have a sizable financial impact on the treatment and inevitably, the clinician and the patient.

Alternative Technologies:

Complete Denture: Though complete dentures have been used to treat edentulous patients for very long before other alternatives emerged, the current literature reports that mandibular complete dentures are in most cases a source of constant discomfort to patients. The common problems resulting from their use include decreased chewing ability, decreased self-confidence and decreased quality of life.[10]

Other Implant Supported Overdentures: Mandibular four-implant overdentures have been commonly used; however, 1, 3 and sometimes up to 6 implants have been used to support overdentures.[11,12] These alternative technologies are not considered as comparators to two-implant overdentures in this report.

Fixed Prosthesis for an Edentulous Mandible: Fixed prosthesis in the edentulous mandible requires a minimum of six implants.[13] The clinical efficacy is reported to be higher than two-implant overdentures, however, the initial and maintenance costs of providing fixed prosthesis is three times higher.[14] Furthermore, provision of fixed implant prostheses lack treatment simplicity when compared to two-implant overdentures.[13]

1.2 Context

This Health Technology Assessment (HTA) report was prepared as a decision-aid for clinicians who wish to adopt this technology or expand their current implant practices to incorporate two-implant overdenture as a possible treatment option for their edentulous patients. This report assumes a call from a panel of general dentists for a clinical (clinician-based and patient-based) and an economic evaluation of ball attachment mandibular two-implant overdentures.

2. Objectives

The primary objectives of this Health Technology Assessment (HTA) were to assess the clinical efficacy and patient satisfaction with ball attachment mandibular two-implant overdentures in comparison to other treatment options, including:

1. Removable mandibular complete dentures
2. Different types of attachments for mandibular two-implant overdentures
3. Different loading protocols of the mandibular overdenture.

We also conducted a cost estimation of ball attachment mandibular two-implant overdentures from a Canadian clinician's perspective (in CAD $).

3. Methods

3.1 Literature Search

A systematic search of peer reviewed literature was conducted for this review. An information scientist at McGill University (Angella Lambrou) helped in developing the search strategies with input from the review team.

Health technology assessment databases (INAHTA, CRD, Cochrane, NICE, AETMIS, and CADTH) were searched for existing health technology reports. In addition, the following bibliographic databases were searched: Ovid MEDLINE® In-Process & Other Non-Indexed Citations, Ovid MEDLINE® without Revisions (1996 to January Week 4 2012), EMBASE, Web of Science and ProQuest.

The search strategy for clinical efficacy and patient satisfaction related literature was conducted using the following keywords: (mandib* AND implant* AND denture* AND (2 OR two) AND (ball OR balls OR spherical OR unsplinted)). The search for economic literature was conducted using National Library of Medicine's MeSH (Medical Subject Headings) in MEDLINE and EMBASE.

3.2 Selection Criteria

- *Literature selection* was limited to data published in English between January 1, 2002 and January 25, 2012.
- *Study design:* Randomized clinical trials and non-randomized clinical studies were included. Case reports, editorials, letters, commentaries, conference abstracts, animal and in-vitro studies were excluded.

- *Intervention:* Mandibular two-implant overdenture with ball attachments opposed by a removable maxillary complete denture.
- *Comparators:*
  - A removable mandibular complete denture.
  - Different attachment types for the mandibular two-implant overdenture, namely, bar attachments, magnet attachments, self-aligning attachments and different commercial brands of ball attachments as reported in the literature.
  - Immediate, early and delayed-loading of ball attachment mandibular two-implant overdentures.

3.3 Selection Method

Two reviewers (NH, AS) independently screened the titles and abstracts of all citations retrieved during the literature search based on the selection criteria. Duplicate publications of the same trial were excluded. Inter- examiner calibration at the beginning of the abstract screening was carried out. A kappa value of 0.85 for literature on clinical efficacy and patient satisfaction and 1.00 for economic literature indicated high and consistent intra-examiner agreement. Full texts of articles that were considered potentially relevant by both the reviewers were extracted. The reviewers then independently evaluated the full texts of the selected articles, applied the selection criteria to them, and compared decisions for included and excluded studies. Disagreements were resolved through discussion until consensus was reached.

3.4 Data Extraction Strategy

A data extraction form (Appendix 1) was designed a priori and used to tabulate all relevant study characteristics and outcomes from the included studies. The two reviewers (NH, AS) then independently extracted data, and disagreements were resolved through discussion until consensus was reached.

3.5 Strategy for validity assessment of included studies:

The reviewers selected the Cochrane Collaboration tool for assessment of risk of bias to assess the internal validity (evidence of bias) of the included studies. The assessment includes domain-based evaluations (for more details, please refer to Chapter 8, Cochrane Handbook for Systematic Reviews of Interventions). Review Manager (RevMan) ([Computer program]. Version 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011) was used to conduct assessment of risk of bias.

3.6 Strategy for summarizing findings:

The findings from the included studies were tabulated under 'primary outcomes' and 'other outcomes' (Appendix 2). Primary outcomes included prosthodontic maintenance and complications, peri-implant outcomes, and patient satisfaction. Different parameters measured under each of these primary outcomes were reported in the tables.

'Other outcomes' identified from the included articles were tabulated separately and included the following: 1) implant success, 2) effects of loading time on implant success or prosthodontic maintenance requirements, 3) vertical retention forces, 4) masticatory function,

5) implant stability, 6) effects of IOD rotation, 7) occurrence of post-insertion pressure spots, 8) patients' preferences, 9) maximum bite force, and 10) soft tissue complications.

3.7 Strategy for estimating costs:

Costs may be divided into direct, indirect and overhead costs (see Figure 1 for relevant costs under each category). The cost analysis in this report is intended to provide information to clinicians pertaining to direct costs. Indirect and overhead costs are expected to differ between practices and thus are not estimated in this report.

Published economic studies that measure costs alongside clinical trials and report direct cost estimates were used to estimate average cost/patient for the initial treatment and the maintenance phase. Additionally, the cost estimation included data from clinical studies that report prosthodontic maintenance and complications. Details regarding maintenance visits/ complications were extracted from these studies and used in estimation of maintenance costs.

For cost calculations, historical exchange rates were used to convert other currencies to CAD$ for the year reported in the article.[15] Following this, inflation rate was applied from the starting year to the March 26, 2012. Average inflation rate data was obtained from Bank of Canada inflation calculator.[16]

Studies that reported chair-time as unit of measurement were used to calculate Canadian clinician's costs using Canadian census data for hourly wages after adjusting for inflation. Details have been described elsewhere.[17] The calculated hourly wages in 2012

Canadian dollars were $68.76/h for general dentists, $96.59/h for oral surgeons, $21.00/h for assistants, and $68.80/h for prosthodontists.

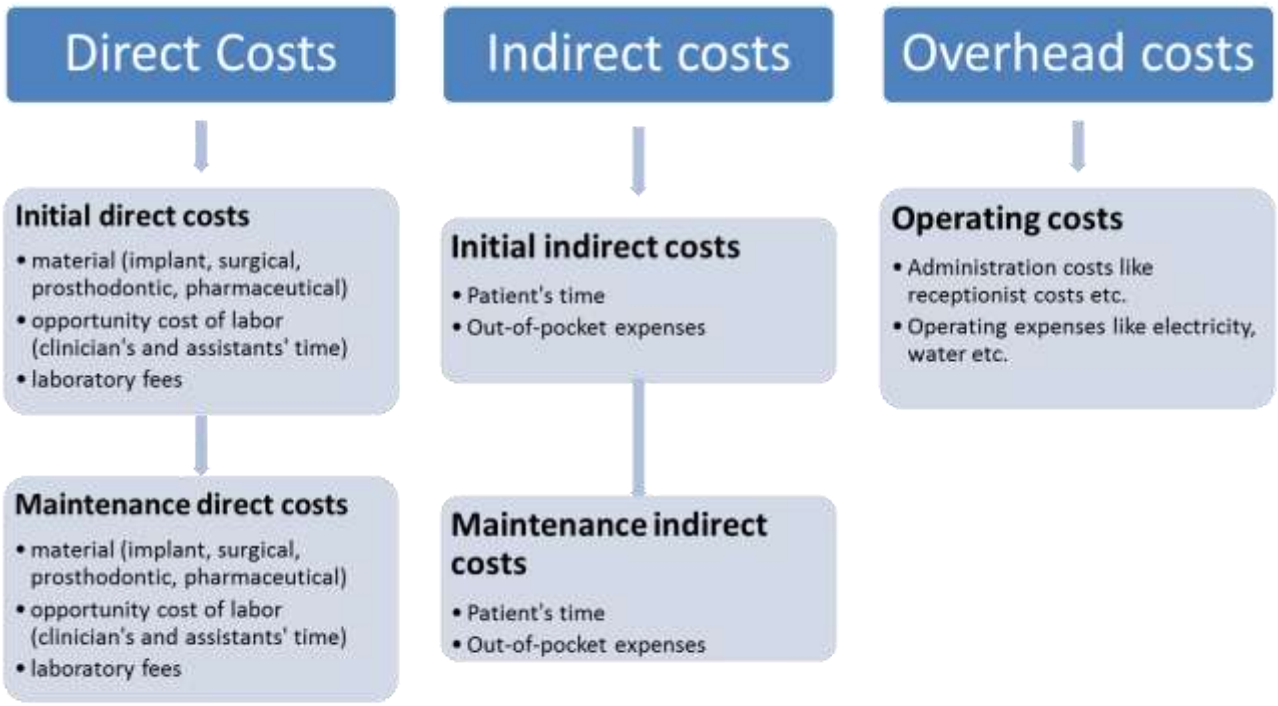

Figure 1. Classification of costs

In the narrative description of the studies, the methods of cost calculation within the study were described in brief and the study limitations were noted. The average direct costs calculated from the studies were tabulated (Annexure 4) as initial direct costs and maintenance direct costs.

4. Results

4.1 Quantity of Research available:

During the original literature search for clinical efficacy and patient satisfaction studies, 568 citations were identified (Figure 2). Of these citations, 54 full texts were retrieved and 31 articles were included in the final review. The primary reason for late exclusion of 23 studies was an inappropriate comparator intervention (such as mixed patient group of edentate and dentate maxillae or fixed prosthesis in the maxilla). Other reasons for exclusion were that the articles did not report a primary clinical study or that the results of the study were pooled for different interventions.

Out of the 31 selected studies, 20 articles reported clinical efficacy based outcomes and 17 reported patient based outcomes (Figure 3). The distribution of articles based on 'primary' outcomes is shown in Figure 4. The total distribution of article among "primary" and "other" outcomes is shown in Table 1. Twenty seven of the 31 articles included in the final review reported 'primary outcomes', 11 reported 'other outcomes' as well. Four of the 31 articles reported 'other outcomes' only resulting in a total of 15 articles reporting 'other outcomes'.

For the economic evaluation, 7 citations were identified during the original search. Five of these were included in the cost calculations. Apart from these studies, cost data were extracted from 3 other studies reporting prosthodontic complications and maintenance of ball attachment mandibular two-implant overdenture.

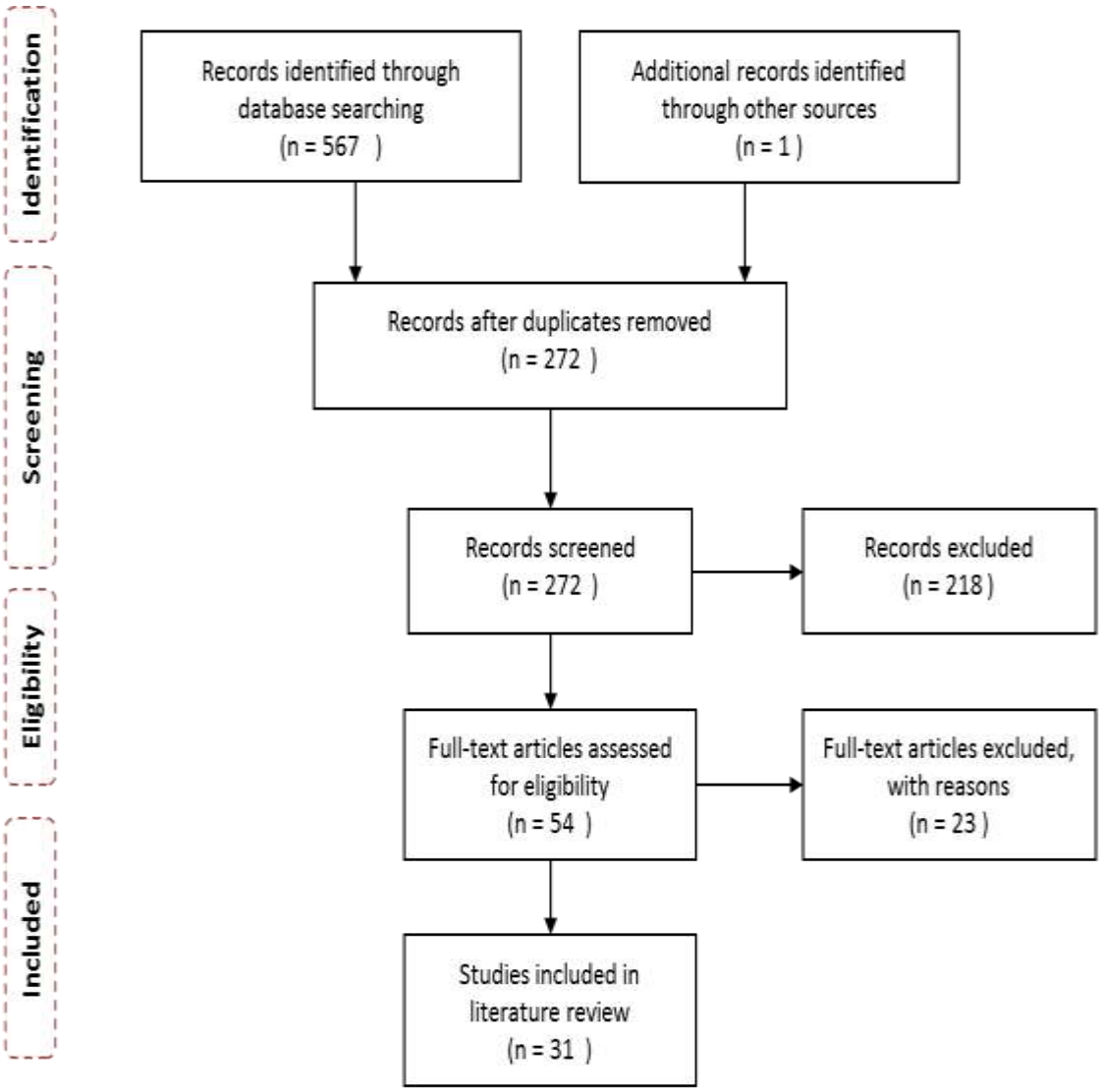

Figure 2. Flowchart of publication selection in the literature review (Studies on clinical efficacy and patient based outcomes)

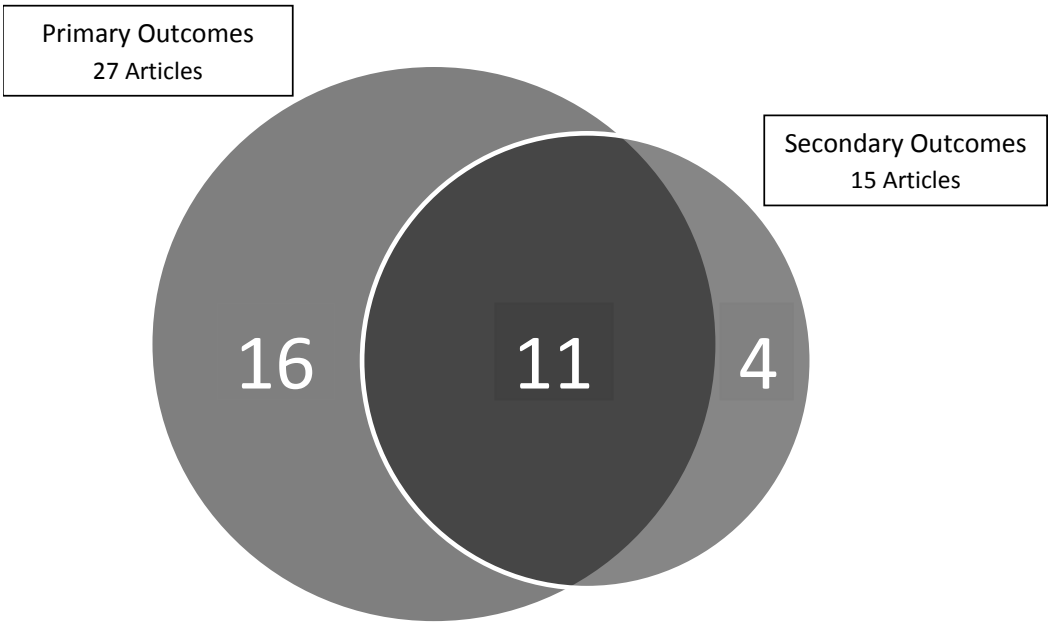

Figure 3. A venn Diagram showing the number of articles reporting primary outcomes, secondary outcomes, or both outcomes.

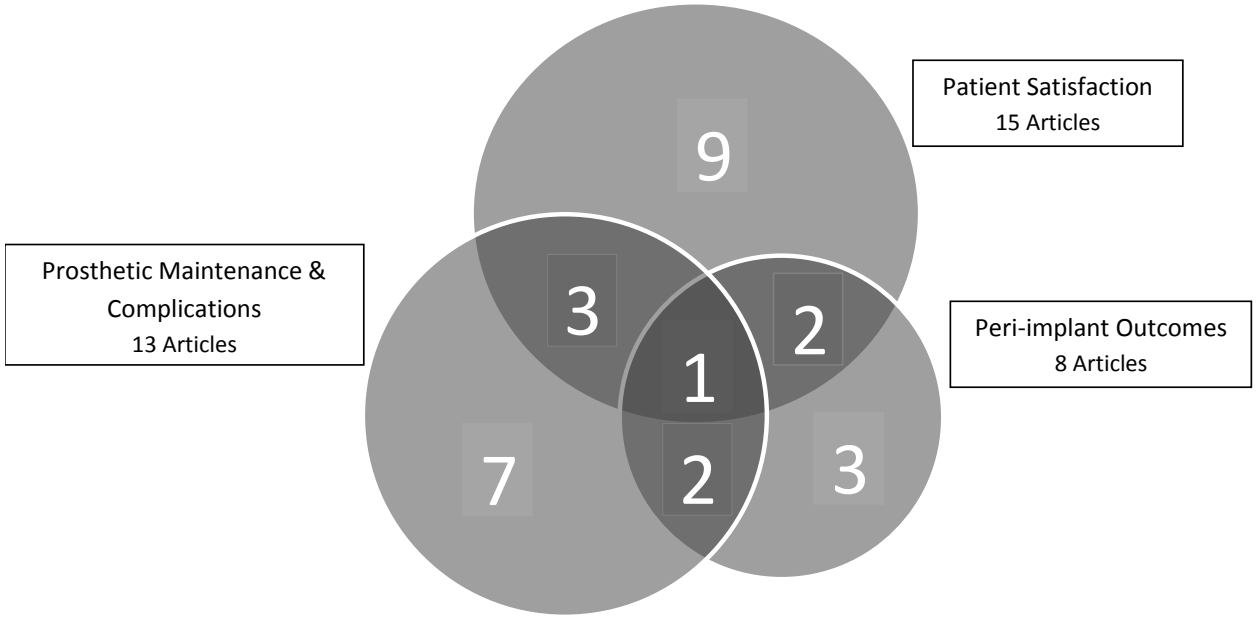

Figure 4. A venn diagram showing the number of articles reporting primary outcomes

4.2 Methodological quality of included studies:

The reviewers conducted a preliminary assessment of the internal validity (evidence of bias) of included studies following the Cochrane Collaboration tool for assessment of risk of bias. The assessment used domain-based evaluations, including reports of sample size estimation, parameters of quality and completeness of data reporting: sequence generation, allocation concealment, incomplete outcome data and selective outcome reporting (For more details, please refer to Chapter 8, Cochrane Handbook for Systematic Reviews of Interventions).

The 31 studies included in the literature review for this HTA report consists of 21 Randomized Clinical Trials (RCTs) and 10 non-RCTs. A decision was made to include the non-RCTs based on both insufficient number of RCTs on some outcomes, and the large sample size and impact of the non-RCTs included. However, after carefully reviewing the included studies, the reviewers decided not to report an assessment of risk of bias within this HTA report for the following reasons:

1- Based on the characteristics of the surgical intervention (dental implants) of all studies, "blinding" within these studies is not applicable. Consequently, an assessment of "blinding" cannot be done.

2- Two of the five domains (sequence generation and allocation concealment) do not apply to non-RCTs where no randomization is involved.

3- Attempts to assess risk of bias are often hampered by incomplete reporting of what happened during the conduct of the study. One option for collecting missing information is to contact the study investigators. Unfortunately, contacting authors of trial reports may lead to

overly positive answers (Cochrane Handbook, page 193) and is beyond the time constraints of this report.

4- It is desirable to ensure that reviewers themselves are unbiased while conducting an assessment of risk of bias. This can be done by blinding the reviewers to the authors/ titles of the studies being assessed. However, this is not possible for the studies included in this report as both reviewers were well acquainted with most articles prior to their inclusion in this report.

5- As many studies report multiple outcomes, a full validity assessment will ideally involve an assessment of the risk of bias at four levels (Cochrane Handbook): summarizing risk of bias for a study across each outcome, summarizing risk of bias for an outcome within a study (across domains), summarizing risk of bias for an outcome across studies, and summarizing risk of bias for a review as a whole (across studies and outcomes). This detailed approach requires expert collaboration that is beyond the scope of this report.

6- The presence of both RCTs and non-RCTs require complex assessment that is not the focus of this report. Moreover, the result of the assessment will not be used as bases for excluding studies from the report, so the reviewers will end up presenting all studies while providing a narrative discussion of risk of bias. This approach is discouraged by the Cochrane group (Cochrane Handbook).

Table 1. Studies included in the clinical review and outcomes measured.

Study I.D.	Primary Outcomes			Other Outcomes									
	Prosthodontic maintenance & complications	Peri-implant outcome	Patient Satisfaction	Implant Success	Effects of loading time on implant success and prosthodontic maintenance	Vertical retention forces	Masticatory function	Implant Stability	Effects of IOD rotation	Occurrence of post-insertion pressure spots	Patient's Preference	Maximum bite force	Soft tissue complicat-ions
Awad 2003			•										
Bilhan 2011 b			•										
Chaffee 2002	•												
Cooper 2008		•	•	•									
Cune 2004	•			•									
Cune 2005			•								•	•	
Cune 2010	•	•											
De Bruyn 2009	•	•	•	•									
Ellis 2009			•										
Fenlon 2002			•	•									
Kimoto 2009									•				
Klemetti 2003										•			
Lachmann 2007		•						•					
Liao 2010	•	•		•				•					
MacEntee 2005	•		•										
Mackie 2011	•		•		•								
Marzola 2007	•	•		•	•								
Naert 2004	•		•			•							•
Naert 2004a		•											
Pan 2008			•										
Rashid 2011			•										
Thomason 2003			•										
Timmerman 2004			•										
Turkyilmaz 2006	•												
Turkyilmaz 2007	•			•	•								
van der Bilt 2006							•						
van Kampen 2003	•												
van Kampen 2004							•						
van Kampen 2005		•											
Walton 2002	•		•										
Walton 2003	•												

4.3 Summary of findings from clinical review:

An outcome based summary of the findings from the articles included in the review is tabulated in Appendices 2 and 3.

4.3.1. Articles reporting primary outcomes:

Out of the 27 articles reporting primary outcomes (Figure 4), 15 reported patient satisfaction, 8 reported peri-implant outcomes, and 13 reported outcomes related to prosthodontic maintenance and complication (Table 1).

4.3.1.1. Patient Satisfaction (Table 7, Appendix 3)

Out of the 15 articles reporting patient satisfaction:

- Four studies compared the ball IOD to a control group of removable CD patients.[18-21] As compared to CD, IOD group exhibited significantly higher ratings of overall satisfaction using 100mm VAS, higher ratings of comfort, stability, ability to chew, and ability to speak and clean, as well as ability to chew six foods of varying textures. Moreover IODs were rated higher on OHIP-EDENT and OHIP except for psychological disability. Both edentulous males and females appear to be more satisfied with implant overdentures than with conventional dentures Females were less satisfied with complete dentures than males, but equally satisfied with their implant overdentures.[19] Awad et al. reported higher patients' ratings of aesthetics within the IOD group, whereas Rashid et al. found that ratings of denture aesthetics were similar in both groups (IOD and CD).[18,20] Edentulous seniors who received mandibular implant overdentures opposing a

removable maxillary complete denture rated their general satisfaction approximately 36% higher than a comparable group provided with a new set of complete dentures.

- Three articles included a comparison between a group of ball IOD and bar IOD patients.[22-24] Differences in mean of six scales constructed to measure denture complaints and VAS scores were not statistically significant between the two groups at initial evaluation and after 1, 2, 3, or 10 years of function. The ball abutment and bar abutment groups exhibited equivalent levels of patient satisfaction (pain, comfort, appearance, function, stability, speech, cleaning difficulty, and overall satisfaction). Additionally, MacEntee et al. reported that receiving new mandibular implant-supported dentures improved satisfaction ‘‘within subjects’’. The improvement was prompt, durable, substantial, and statistically significant regardless of the type of attachment used (bar or ball). However, the ball-spring attachment required substantially more repair.[23]

- Three studies reported satisfaction of patients treated with an IOD without a comparison group.[25-27] Patients reported decreased levels of satisfaction with respect to chewing when measured from baseline to 5 years after receiving the IOD. There was no change in general satisfaction and satisfaction related to phonetics. There was a marked positive change in facial attractiveness after delivering the IOD. Cooper et al. reported that the self-assessment of teeth revealed that most patients were greatly satisfied with their teeth at mandibular overdenture connection and then this satisfaction decreased till 5 years of follow-up (but level of satisfaction remained much higher than the baseline recordings).[25] De Bruyn et al. reported that patients were appreciative of the

work carried out by their dentist and they indicated a significant improvement in their well-being and quality of life.[26] According to the general health questionnaire ratings as reported by Fenlon et al., patients were more satisfied with IOD than when they wore CD, and also indicated better retention, better denture fit, better denture comfort, and better chewing ability. However, patients' ratings of appearance and social functioning after receiving the IOD treatment were not statistically significant.[27]

- Two articles reported satisfaction of patients treated with three types of IOD: ball, bar, and magnet.[28,29] VAS scores and the scores of general satisfaction on different scales were comparable for the bar and the ball types, and both were much higher than the magnet type IOD. The scores of physiognomy, neutral space, and aesthetics were not statistically significant for all three types of attachment. According to Naert et al. the ball attachment group exhibited better patient satisfaction scores after 10 years as compared to bar and magnet attachment groups.[30]

- One article reported satisfaction of three groups of patients treated with ball IOD, bar IOD, and 4-implant triple bar IOD.[31] Participants' general satisfaction with mandibular IODs and their opinion about phonetics, aesthetics, and social functioning were high after 8 years and were not dependent on treatment strategy. However, ratings for retention and stability of the overdenture in the ball attachment group decreased over time whereas in the single and triple-bar groups the ratings remained at the same level.

- One article compared ball IOD and self-aligning IOD.[32] The overall results of OHIP 14 scores indicated that the self-aligning IOD group was not statistically different than the

ball-socket attachment type. However, the sub-domains of OHIP other than the physical disability sub-domain, revealed that the self-aligning type is better than the ball type (p=0.049). For thirteen patients with below-average attachment space, functional limitation, psychological discomfort, physical disability, and psychological disability the total OHIP-14 scores were better for the self-aligning type compared to the ball type. The self-aligning attachment system for 2-implant–retained mandibular overdentures was equal or superior to traditional ball attachments in all domains of the OHIP-14.

- One article compared patient satisfaction between ball attachment and the magnet-attachment IOD patients.[33] The ball attachment IODs were superior to the magnet type in terms of: ease of cleaning, ability to speak, comfort, appearance, stability and ability to chew. Eleven out of 16 patients chose to keep the ball attachments.

4.3.1.2. Prosthodontic maintenance and complications (Table 8, Appendix 3):

Out of the 13 articles reporting prosthodontic maintenance and complications:

- Five studies included groups of patients treated with ball IOD without a control group,[8,26,34-36] amongst which 2 were immediate loading studies.[35,36] The follow up periods ranged from 1 to 3 years.

  - Chafee et al. reported that 6 out of 58 patients followed for three years required no adjustment while the other 52 patients required a total of 327 return visits of which 194 (59.3%) were unscheduled visits.[34] Denture adjustments accounted for 26% of all complications with 35 patients requiring 85 visits for adjustment of denture sore

spots/ ulcerations (mean 1.49 per patient; SD= 1.92; range 0-9; mean time to first adjustment 89.5 days, SD 297.17 days, range 2 days-37.7months). Ball housing complications accounted for 26.9% of all complications with 35 patients requiring 88 visits for inadequate retention (mean 2.51; SD= 1.72; mean time to first adjustment 9.86 months, range 1 day to 38 months). Three patients lost ball housings and 7 patients reported loosening of ball housings. Prosthetic tooth complications accounted for 9.1% of all complications with 13 patients requiring 27 visits (mean 0.44; SD=1.81, one of the patients was responsible for 14 visits; mean time to first adjustment 98.79 days; SD=234.81, range 27 to 1100 days). Eighteen patients required a total of 20 relines of the mandibular IOD (mean 0.34; mean time to first reline 16.49 months; SD=10.73, range 8 to 966 days); 4 patients required 12 repairs of mandibular. IOD (mean time to first repair 35.66 days; SD=171.86, range 93 to 1123 days); most repairs were because of a fractured midline. Sixteen patients required a total of 18 relines of the maxillary CD (mean 0.31; mean time to first reline 16.86 months; SD=11.93, range 34 to 969 days). No repairs were required for the maxillary CD. As for the abutment complications, 3 patients required 6 abutment tightening (mean time to first tightening was 22.78 days; SD=120.7; range 1 to 1140 days) and 2 patients required abutment replacement.

- Cune et al. followed up 18 patients for a period of one year.[8] Prosthetic complications and post-insertion maintenance were minimal. Three abutments loosened, one of which subsequently broke after 5 months of loading. Retightening of the attachment (gold matrix) was performed on seven occasions in 4 patients.

According to this study, short-term results indicate that mandibular IOD treatment by means of two ball-abutments, using Frialocs implants and prosthetic components, leads to good clinical results, both from the clinician's and patient's perspective. As for the peri-prosthetic complications of the ball abutments, stripping of the internal hexagon was noted in 2 balls and wear was seen in one ball. Post-prosthetic complications included a broken screw, loose ball abutment and loose matrix. Frequent retightening of matrix was done on follow-up visits.

- De Bruyn et al. followed-up patients for 33 months.[26] The study reported that retention of the IOD was perfect in 80% cases while 20% needed minor activation of attachments. Twenty percent of the IODs were repaired for damage (2 patients had a broken dentures; 2 patients had a damaged tooth; and 1 attachment needed replacement)

- Liao et al. and Marzola et al. followed up patients for 1 years and reported prosthodontic maintenance and complication of immediately loaded IODs.[35,36] In the first study, 2 patients showed loosening of the ball attachments at the 3 month follow-up exam, but after the screws were tightened the problem resolved and did not recur. No other prosthetic complications (e.g. denture fracture, denture reline, and retention adjustment) were noted throughout the study. In the second study, 10% patients needed adjustments for major prosthetic complications (denture fractures), 40% patients needed minor adjustments/ repairs related to ball abutments.

- Turkyilmaz et al. reported 2 articles in which patients were followed for 1 year and 2 years respectively.[37,38] These studies described the differences in prosthodontic maintenance and complications associated with early loading (1 week) and delayed loading (3 months) IOD patients. The time required for prosthesis fabrication was higher for delayed loading group than the early loading group. However, no significant difference in adjustments/ repairs was seen between both groups and the number of visits in both groups was similar. Moreover, significantly more adjustments/ repairs were reported for the 1st year than the 2nd year.

- Walton et al. also reported 2 articles for patients who were followed up for 1 and 3 years respectively.[24,39] These studies compared two groups of patients: one group was treated with a 2.25 ball abutment with titanium alloy cap (Nobel Biocare) while the other group was treated with round gold bar system (Nobel Biocare). No significant difference in the time to fabricate the prosthesis and adjust the overdenture post-insertion was reported. Significantly higher time and number of repairs in ball abutment group than bar abutment groups were reported. Almost three times as many bar-clip dentures (63%) were rated successful compared to the ball attachment design. More than three times as many ball attachment IODs (60%) required retreatment in the form of excessive repairs, and twice as many of the ball attachment design (8%) required replacement. The ball-socket attachment IOD was significantly more likely to require patrix tightening or matrix replacement, while the bar-clip design was more likely to require activation of the matrix.

- MacEntee et al. reported a comparison between a group of ball IOD and another with bar IOD.[23] The study followed up patients for 3 years, and found that most denture adjustments occurred during the 1st year (81% of total adjustments in 3 years period); mean no. of adjustments according to this study was similar between the two groups; repairs were more frequent than adjustments and were much higher in the ball-spring attachment group (6.7 repairs per person) compared to the bar-clip attachment group (0.8 per person on average). Almost all repairs (90%) occurred in the ball-spring group to correct problems with attachments.

- Mackie et al. followed up a group of patients for 8 years, and compared 6 Different types of matrices (Steri-Oss rubber, Straumann gold, Straumann titanium, Branemark gold, Southern plastic, and Southern gold/platinum) associated with ball attachment IOD.[40] It was found that attachment systems influence prosthodontic maintenance, particularly in regards to the type of matrices used. Mean number of maintenance events were as follows: Steri-Oss rubber matrices exhibited the highest number of maintenance events (32.2 ± 14.5 events) followed by Branemark gold matrices (28.8 ± 12.6 events). The lowest number of maintenance events was seen in Southern plastic matrices (8.7 ± 4.2). Straumann gold had the highest longevity of attachment which was much more than the Southern gold/ platinum matrices that were similar to Branemark gold and Southern plastic matrices. However, those were much higher in attachment longevity than Straumann titanium and Steri-Oss matrices. Mean time to reline OVDs was 3.37±2.06 years, and remaking of OVDs peaked by the 7th year (mean time to remake 5.81±2.04).

- Naert et al. followed up participants for 10 years and compared egg-shaped Dolder bars (Cendres et Metaux), magnet abutments (Model 1102 Dyna engineering), and ball abutments (model SDCB 115-17, Nobel Biocare).[30] The study found that prosthodontic complications related to wear and corrosion were maximum for the magnet attachment group followed by the bar attachment group. Ball attachments exhibited the least maintenance requirements (abutment tightening/ replacement).

- van Kampen et al. followed up patients for 3 months and reported prosthodontic maintenance and complications of magnet attachment (Dyna magnet ES, type extra strong, Dyna Dental Engineering) vs. ball abutment (Frialit-2, Friadent) vs. bar-clip attachment (round Dolder bar in conjunction with a metal omega-shaped IMZ clip, Friadent).[9] In this study, the magnet attachments exhibited significantly more complications related to wear (61%) than the ball (22%) and bar-clip abutments (0%) within the 3 month follow-up period.

4.3.1.3. Peri-implant outcomes (Table 9, Appendix 3):

Eight articles reported peri-implant outcomes:

- Four articles reported the outcomes associated with a ball IOD treatment without a control group (2 of those 4 were immediately loaded).[25,26,35,36] The follow up periods ranged from 1 to 5 years.

  - Cooper et al. reported measured parameters such as: (a) **crestal bone level changes** which were found to be statistically insignificant (0.62±0.53mm at 12 months; 0.51± 0.57mm at 30 months; and 0.66±0.81mm at 60 months), (b) **marginal bone level**

changes were statistically insignificant (+0.13±0.59mm at 12 months; +0.23± 0.66mm at 36 months; and 0.09±0.79mm at 60 months).[25] 34 of the 49 patients followed for 60 months had 0.0-0.5mm marginal bone loss; 4 patients had more than 1mm of bone loss in 5 yrs. (c) **peri-implant inflammation** and (d) **peri-implant sulcus depth changes** were found to be statistically insignificant when compared to baseline measurements.

- De Bruyn et al. reported the following sub-outcomes: (a) **marginal bone loss**, average marginal bone loss was 0.8mm (b) **pocket depth**, mean pocket depth 2.1mm (range 0.5-5mm) (c) **plaque index**, mean plaque index 0.9 (range 0-4) and (d) **bleeding index**, mean bleeding index was 0.8 (range 0-3).[26] 13 patients were free of bleeding, and the presence of plaque was highly correlated to bleeding ($p<0.02$).

- Liao et al. and Marzola et al. followed up patients for 1 years and reported the sub-outcomes of (a) **marginal bone loss**, which was found to be 1.12 ±1.10mm (b) **plaque index**, modified Plaque Index scores of 0 and 1were recorded throughout the study and (c) **radiographic bone loss (RBL)**, where it was found that Immediate loading of implants did not adversely affect bone remodeling.[35,36] The RBL changes average was 0.7 mm ± 0.5 mm after 1 year of function, which is within the value reported in the literature.

- Naert et al. and Van Kampen et al. compared the peri-implant outcomes of ball vs. bar vs. magnet IODs.[30,41] The first study followed-up patients for 10 years while the second followed the participants up for 3 months for each attachment type. The sub-outcomes

studied were: (a) **Plaque Index**, (b) **Bleeding Index**, (c) **change in attachment level (probing pocket depth + recession)**, (d) **Periotest values (implant mobility)**, (e) **marginal bone level**, and (f) **the Relationship between maximum bite force and marginal bone loss during healing of implants and functional loading**. None of the first five sub-outcomes studied were significantly different among the bar, ball and magnet groups. Moreover, the second study was not able to demonstrate a relationship between the level of maximum bite force and the amount of marginal bone loss.

- Cune et al. and Lachmann et al. compared the peri-implant outcomes of ball vs. bar IODs. The first study followed-up patients for 10 years while the second was a cross-sectional study.[22,42] The sub-outcomes studied were: (a) **Probing depth**, the mean probing depth over 10 years was lower for the ball attachment compared to the bar attachment type (b) **marginal bone loss**, over the 10 follow-up years there was no significant differences between the two groups studied in the marginal bone loss and bleeding index (c) **Plaque Index**, (d) **bleeding index**, (e) **probing depth**, (f) **sulcular fluid flow rate**, and (g) **microbiological concentration of different bacilli**. As for the Peri-implant probing depth; plaque and bleeding on probing scores; sulcular fluid flow rates; relative concentrations of Actinobacillus actinomycetemcomitans, Prevotella intermedia, Fusobacterium nucleatum, Porphyromas gingivalis, Tannerella forsythensis, and Treponema denticola: there was no significant difference between the two groups (ball vs. bar) of the cross-sectional study.

4.2.2. Articles reporting other outcomes (Table 10, Appendix 3):

Fifteen articles reported the 10 other outcomes as summarized in Tables 1 and 10:

- Seven articles reported implant success rates, which varied from 81.25% to 100% for follow-up periods ranging from 1 year up to 10 years.[8,22,25-27,35]

- Three articles reported effects of loading time on implant success or prosthodontic maintenance requirements with follow-up periods of 1, 2, and 8 years.[36,37,40] A 100% success rate was observed over a follow-up period of up to 2 years for implants that were immediately loaded, early loaded (1 week) or loaded after 3 months (delayed). Moreover, according to the results of a study that followed-up patients for 8 years, early loading protocols do not influence long-term prosthodontic maintenance requirements of un-splinted mandibular 2-implant overdentures.[40]

- Naert et al. described the differences in vertical retention forces between three groups (ball vs. bar vs. magnet IODs) followed for 10 years where it was found that ball retained overdentures showed the greatest vertical retention force after 10 years followed by bar and magnet attachments.[29]

- Two articles reported differences in masticatory function between three groups (ball vs. bar vs. magnet IODs) followed for 14 months.[43,44] Muscle activity was significantly lower for conventional mandibular dentures compared with implant overdentures. No significant differences in muscle activity were observed among the three attachment types. The masticatory function significantly improved after implant treatment with each of the 3 attachments. Overdentures with ball and bar-clip attachments exhibited slightly better masticatory performance than with magnet attachments. Subjects

chewed more efficiently after implant treatment. Swallowing threshold, however, was not significantly different among the three attachment groups;

- Two articles reported implant stability of ball IOD. One study had no control group whereas the other study, which was a cross-sectional study, compared ball IOD to bar IOD. It was found that ball and bar abutment groups did not exhibit any significant differences in implant stability, and the Periotest values were 4.25 ± (0.93), which meant good osseo-integration.[35,42]

- Kimoto et al. conducted a cross-sectional study that reported the influence of IOD rotation on satisfaction ratings of chewing ability, and the factors involved in the rotation of IODs.[45] 37/39 patients were aware of rotational movements that reduced their chewing ability compared to subjects of the non-rotation group. However, there was no statistical difference in general satisfaction or in the number of non-scheduled visits between the two groups. There was no relationship between general satisfaction and chewing ability.

- Klemetti et al. reported the occurrence of post-insertion pressure spots over a period of one year between ball IOD and CD patients.[46] Significantly fewer visits for adjustment related to post-placement pressure spots were required for mandibular IOD than for conventional mandibular prostheses (22 visits for IOD compared to 70 visits for the CD);

- Cune et al. reported both patients' preferences and the correlation of satisfaction with maximum bite force.[28] The study was a cross-over clinical study that compared ball IOD vs. bar IOD vs. magnet IOD, with a follow-up of 1 year. The correlation of satisfaction

with maximum bite force was not significant in this study. However, 10/18 patients strongly preferred bar-clip and 7/18 preferred ball-socket attachments over magnet-type attachment that was only preferred by 1/18 patient;

- Naert et al. reported soft-tissue complication over 10 years for patients who received either a ball-socket, a bar-clip or a magnet type IOD.[29] The magnet group revealed the maximum number of soft tissue complications (such as common ulcer) which increased over time. Ball group showed the fewest soft tissue complications.

4.4 Cost Estimates:

Of the included studies (see table 2), 3 were cost-effectiveness studies,[47-49] 1 was a cost-analysis,[50] and 1 was a cost-comparison study.[17] In addition, 5 studies included in the clinical review that reported prosthodontics maintenance/ complications were used for cost estimation of maintenance visits.

Table 2. Studies included in cost estimation

Primary economic evaluations included in cost estimation	Clinical studies (reporting Prosthodontic maintenance) included in cost estimation
Heydecke 2005	Chaffee 2002
Stoker 2007	MacEntee 2005
Takanashi 2004	Walton 2002
Zitzmann 2005	
Zitzmann 2006	

Heydecke et al. and Takanashi et al. have reported cost data from a randomized clinical trial that comprised of a conventional denture group (n=30) and a mandibular two-implant overdenture (n=30) group.[17,49] The direct costs were measured by micro-costing of the resources. This involved assessing resources such as clinician's time, assistant's time, materials, pharmaceuticals, laboratory work, and radiography for each patient. Market prices were used to estimate costs of disposable and re-usable materials, drugs, and laboratory costs. Costs of labor were estimated by multiplying the recorded clinician's/assistant's time and the wages for the dentist/ specialist/ assistant (estimated from Canadian census). Heydecke et al. obtained maintenance data for the 2nd year from two sources, namely, existing literature and expert clinicians. (Note: for the purpose of this report only costs reported from existing literature have been utilized for cost calculation). The experts stated approximate frequencies of maintenance, repairs, and replacements in a year. The cost data was used to conduct a cost-effectiveness analysis in which the effectiveness parameters were based on OHIP-20 scores. Takanashi et al. compared the costs of mandibular two-implant overdenture treatment to conventional denture treatment.

In 2007, Stoker et al. reported initial and 8 year follow-up costs for mandibular two-implant overdenture patients (n=103) from a randomized clinical trial.[50] The estimation of direct costs was based on the chair-time multiplied by hourly rates of the institution (Centre of Special Dental Care, Netherlands) where the patients were treated. These rates includes hourly rate for all providers, materials and equipment used, disposables, and costs of auxiliary assistants.

In 2006 and 2007, Zitzmann et.al reported cost-effectiveness analyses for mandibular two-implant overdentures (n=20) as compared to conventional dentures (n=20) with a time horizon of 6 months and 3 years respectively.[47,48] The initial direct costs were estimated based on the national dental tariff structure (Switzerland). These included costs of implant material, surgical and prosthodontics treatment, and laboratory fees. The effectiveness was estimated by patients' preferences based on VAS ratings.

Chaffee et al. recorded the prosthodontics complications over 3 years from a prospective study for mandibular two-implant overdenture treatment (n=58).[34] The study measured the clinician's time and the number of complications which was used to assess the laboratory and material cost.

MacEntee et al. followed a similar approach to Chaffee et al. for time and cost calculation.[23] The study compared prosthodontics complications between a ball attachment group (n=34) and a bar attachment group (n=34) over 3 years.

Walton et al. compared the time required for diagnosis, surgical procedure, fabrication and maintenance of prosthesis for a ball attachment group (n=45) and a bar attachment group (n=42) over a follow-up period of 1 year.[24] The study did not provide information about material, laboratory and other direct costs. Walton et al. reported higher costs for prosthetic repair in the ball attachment group.

The calculated costs (Annexure 4) indicate that the initial direct costs vary tremendously between different studies. The tabulated mean initial costs range from CAD $3,207 to CAD $8,127. Notably, the maintenance costs show lesser variation and may range (as calculated in

Annexure 4) from approximately $130/year to $240/year for the 1st year. The costs in the following years due to prosthodontics complications related to abutment and retentive mechanism has been shown to decrease while the costs related to denture reline and repairs are reported to increase.[23,34]

5. Discussion

5.1 Summary of findings:

Clinical Review

This HTA report on mandibular two-implant overdentures was generated to help dental practitioners in taking evidence-based decisions on the use of this health technology that have been encouraged to replace conventional dentures as the minimum standard of care for edentulous patients.[13]

The process of a health technology assessment involves prioritization of a specific technology followed by outlining precise research problems. Mandibular two-implant overdenture using ball attachments as the retentive mechanism was selected as the technology under consideration assuming a call from a panel of general dentists. To the authors' knowledge, this is the first HTA report on this specific health technology.

Based on the literature review and assessment of all the outcomes reviewed under this report, the ball attachment mandibular two-implant overdenture is a markedly better treatment choice for completely edentulous patients as compared to a removable CD. Awad et al. reported that patients are more satisfied with a mandibular two-implant overdenture compared to a removable CD. This satisfaction included general satisfaction, comfort, stability,

esthetics, ability to chew, ability to speak and clean, as well as ability to chew six foods of varying textures. Moreover, it is also worth mentioning that according to Pan et al. females were less satisfied with their complete dentures than males; but equally satisfied with their implant overdentures. The reviewers propose that this might be attributed to the fact that CDs maybe socially embarrassing due to their increased possibility of movement or dislodgment during social interactions, which might be even more embarrassing to female patients. Klemetti et al. reported that significantly fewer visits for adjustment related to post-placement pressure spots were required for a mandibular overdenture than for a conventional mandibular CD. Reviewers believe this to be related to the increased movement and greater border extensions of the removable CD compared to the IOD. The costs of IOD treatment are undoubtedly higher than CD treatment but so are the benefits. Thus, the reviewers believe that the adoption of this technology into clinical practice may also be contingent upon the patients' ability to pay.

When compared to different types of attachment systems, ball attachments prove to be a superior alternative to magnet attachment IODs. However, this is not always the case with the bar-clip attachment IOD. Although most studies have proven that the ball-type IOD is generally comparable to the bar-type in most clinical parameters, the bar type IOD was found to be superior to the ball type in factors such as patient's preference,[17] long-term retention and stability,[41] and the need for repairs and adjustments.[30,50,51] On an average, the bar IOD requires less repair and adjustments than the ball IOD. The reviewers believe that this could be attributed to the nature of attachment of the ball type that requires frequent repair and adjustment. Conversely, in a randomized clinical trial, Naert et al. reported the highest patient satisfaction and the lowest maintenance requirements (abutment tightening/ replacement)

with the ball-type attachment as compared to both the bar type and the magnet type IOD after a follow-up period of 10 years.[29] Ball type IOD is also reported to be superior to the bar-type in other factors, such as, vertical retention,[34] probing depth,[16] and soft-tissue inflammatory reactions.[34] Some of these could be attributed to the fact that bar-type IODs prevent proper cleaning under the bar which potentially leads to more plaque accumulation and consequently peri-implant complications. Nevertheless, Lachmann et al. reported that both the ball and bar type overdenture are statistically not different in the peri-implant probing depth, the plaque and bleeding on probing scores, the sulcular fluid flow rates, and the relative concentrations of a host of oral bacteria.[28] However, it should be noted that the Lachmann et al. study was a cross-sectional non-RCT study with a sample size of 10 patients divided into two groups (ball and bar) and the age of participants ranged from 66 to 76 years. Thus, the reviewers believe that further studies with a larger sample size and a wider age selection need to be conducted before adopting these results.

According to four studies included in this report, the loading protocol (immediate, early (1 week), and delayed (3 months)) has no effect on the success of implants or on the long-term prosthodontic maintenance requirements.[35-37,40] As reported by Mackie et al., the reviewers agree that even though the previous result may be true, more studies are required to reach a sound conclusion on the effect of loading time on implant success and prosthodontic maintenance requirements. Additionally, none of the included studies compared patient satisfaction in relation to loading time of the mandibular two-implant overdenture. Thus, studies that report patients' satisfaction as an outcome of loading time on mandibular two-implant overdenture are needed.

Mandibular IODs have a high success rate ranging from 93.9 to 100%.[8,22,25,26,35] When a single stage surgical protocol is adopted as reported by Fenlon et al., the success rate dropped to 81.25%.[27] The reviewers believe that these findings are consistent with the above findings on that implants supporting an overdenture have a high success rate regardless of the loading protocol followed, but the a single surgery protocol might have a negative impact on implant success. This, however, must be further investigated with other studies as the only study reporting this effect used a sample of 16 participants with an attrition rate of 56% at the end of the study, i.e. only seven participants were followed over the two-year period of the study.[27]

Furthermore, various studies followed different criteria to assess implant success/ survival.[51] This could partially account for the variance in success rates observed across studies. The commonly accepted criteria for implant success given by Albrektsson et al. in 1986 included assessment of survival rates, continuous prosthesis stability, radiographic bone loss, and absence of infection in the peri-implant soft tissues. Over the years, researchers have increasingly used self-defined criteria to incorporate prosthodontic parameters, esthetics and patient satisfaction.[51] Consequently, implant survival rates across different studies are not easily comparable and therefore, such a comparison was not undertaken by the reviewers. Nevertheless, the reported success rates are relatively high and the reviewers do not foresee any risks due to a lack of comparison across the reported studies.

However, proper functioning of an overdenture is not limited to implant success. The retentive mechanism and the denture itself are equally vital components in the effective performance of an overdenture. Both these components require frequent adjustments and

repairs as reported in most of the included studies. The most common reasons for failure of ball attachments are misalignment of the implants, and structural flaws in the matrix. Walton et al. emphasize that implants should be placed parallel to one another and to the path of insertion of the overdenture if un-splinted ball attachments are used.[39] To maintain the parallelism of implants, many researchers have propagated the use of surgical guides/templates or implant paralleling devices.[52]

Loss of retention of the overdenture retained with ball attachments occurs commonly due to wear of the patrix or matrix of the ball abutment.[53] A majority of the maintenance required for the patrix includes tightening of the loose component. However, the matrices often require replacement followed by activation.[40] Notably, a study by Mackie et al. indicated that the maintenance requirements vary with the commercial brands of ball attachments. With the rapid advancements in technology, manufacturers change implant components and introduce newer components which are quite often not subjected to clinical trials before being launched into the markets. The reviewers thereby advise the clinicians to be cautious before adopting a system into their clinical practice.

Cost estimation:

The cost analysis in this report was intended to provide rough estimates of direct costs/ patient for treatment and maintenance. Charges to a patient will depend on a multitude of factors such as overhead costs, market prices of materials, and profit to the clinicians. These factors vary between different regions and for the same reason are not included in this cost

estimation. Furthermore, the costs reported in the literature are usually calculated alongside clinical trials conducted in academic-teaching hospitals and may differ for private clinics.

We found that primary economic studies included in the cost estimation report a very diverse range of initial direct costs (see Annexure 4). These may be partially due to the costing approach used in each study. Heydecke et al. and Takanashi et al. have reported the use of a micro-costing approach in which individual resources are calculated for each patient and average values are taken.[17,49] On the other hand, Stoker et al. and Zitzmann et al. have used fixed dental tariffs set forth by the institution or the national board respectively. Using fixed tariffs has a potential limitation of under- or over-estimating the costs.

Moreover, the types of resources measured might have a similar impact on the estimated costs. For example, Walton et al. measured costs related to prosthodontics complications only in terms of time required for maintenance while most of the other studies included laboratory costs into the calculation.

Furthermore, the region (country) where the study was conducted may be an important determinant of the observed variations in costs. Three studies were conducted in Europe[47,48,50] while the other five studies were conducted in the United States.[17,23,24,34,49] By common knowledge, it is acknowledged that costs such as material prices and laboratory fees differ between countries and different regions of the same country. The authors believe that the resulting variation in total costs is an expected trend. However, since the number of cost studies is very few and the types of costs measured under each study are varied, a definitive pattern of cost variations cannot be effectively established in this report.

Most of the included studies consider prosthodontic maintenance under two broad headings: 1) adjustments, and 2) repairs. Adjustments have been defined as any treatment to the denture that did not involve the addition of new material or the replacement of broken or missing components or material. Repairs on the other hand are described as any treatment that requires addition of new material or replacement of a component or material. However, the assessment of whether a required maintenance is an adjustment or a repair may be subjectively influenced in some cases. For example, tightening of the retentive device may be considered an adjustment by a group of research and a repair by others.

In addition, most included economic studies provide inadequate cost data regarding management of implant failure cases. This may result in substantially additional costs in a private practice if re-treatment is considered. Additional procedures such as bone grafting may be required and carry added costs to both the clinicians and the patients.

5.2 Limitations of this HTA

To support a thorough evidence-based decision, a HTA report should encompass evidence related to safety, efficacy, patient-reported outcomes, real world effectiveness, cost, cost-effectiveness, social, legal, ethical, and political impacts. The literature review conducted to produce this report was unrestricted in terms of evidence and the authors' tried to include all possible peer-reviewed literature. However, some issues such as legal and socio-political issues related to the assessed technology are often published as opinion letters or as non-peer reviewed literature, if published at all. Incorporating such comprehensive evidence would require resources that were beyond the scope and time constraints of this expedited HTA

review. The defined research problems therefore covered clinical efficacy, real world effectiveness, patient based outcomes and cost estimation based on published peer-reviewed literature.

In contrast to systematic reviews and meta-analyses, HTA reports may incorporate a wide variety of outcomes to be reviewed. Health technology assessments are policy-oriented and may have a considerable impact on medical, economic, societal, and ethical consequences of health practices and technologies. This power of HTA reports requires scientists to identify and exclude potential confounders that may affect the validity of HTA reports.[54] Moreover, the source of evidence may not be restricted to a particular type of study design (for example, randomized clinical trials) such as the case of this report. While RCTs are the "gold standard" of internal validity for causal relationships, they are not necessarily the best method for answering all questions of relevance to an HTA. As stated by Eisenberg, even though RCTs are incomparable in their capacity, they should be complemented by other study designs in a health technology assessment to allow additional perspectives about a technology.(Goodman, 2004 #899) The reviewers' believe that unlike systematic reviews, the use of a 'single validity assessment tool' for assessing quality of a variety of published studies for a HTA report is debatable and hence was not included as a part of this report.

5.3 Generalizability of findings:

The reviewers (NH, AS) did not identify any literature pertaining to ethical, socio-political or legal issues related to ball attachment mandibular two-implant overdenture treatment. Therefore, the authors cannot report any such foreseeable risks with the use of this

treatment in different regions of the world. However, the included published literature reveals that the overdenture treatment is a globally accepted alternative to conventional denture.

The cost analysis was done from a Canadian perspective (in CAD$). However, costs may vary between different regions and this analysis is intended only to provide rough estimates to the clinicians.

6. Conclusions

This HTA clearly demonstrates that a ball-type mandibular two-implant overdenture has many benefits over alternative treatment options, such as, a removable complete denture and an implant overdenture with other attachment types (such as, bar-clip and magnet) in terms of patient satisfaction, peri-implant outcomes, and other outcomes such as vertical retention forces. We believe that adopting this health technology as a standard of care for edentulous patients with an upper removable complete denture is advisable. However, this technology is associated with more prosthodontic maintenance requirement compared to a bar-clip attachment overdenture. Moreover, patient satisfaction related to retention and stability decreases significantly over time for a ball attachment two-implant overdenture compared to a bar-clip two-implant overdenture. Thus, a mandibular bar-clip two-implant overdenture maybe the treatment of choice for patients having restricted access to care if they are able to maintain good oral hygiene and/ or patients with increased retention and stability requirements (atrophic ridges). This latter point, however, was reported in one RCT included in the review and its results needs to be further investigated by additional RCTs.

The loading protocol, i.e., immediate, early, or delayed loading does not affect the treatment outcome according to the studies included in this report. The increased cost associated with mandibular two-implant overdenture over a removable CD treatment option can be outweighed by the many benefits of the former treatment. These benefits include: higher levels of patient satisfaction, low peri-implant complications, moderate prosthodontic complications, good vertical retention, good stability, low soft-tissue complication, and better function and oral health–related quality of life over most other treatment options.

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Appendix 1: Data extraction form and guidelines

Table 3. Data extraction form

Study I.D.	Authors	Year	Title	Journal Name	Aims	Late Exclusion	Age range/ Population characteristics	Sample Size	Sample Gender	Study Design	Type of study I-RCT II-non-RCT	Methods used	**Comparator** [1= (C/C with C/2impl); 2= (ball vs. bar/magnet/etc.); 3=(immediate vs. delayed loading); 4=(others- specify)]	Outcomes and results	Evaluation period

Table 4. Data extraction guidelines

Study I.D	As produced by RevMan software
Authors	write the names of first 6 authors followed by et.al
Year	
Title	
Journal name	write full name, no abbreviations
Aims	as mentioned in the article
Late Exclusion (reasons)	not primary study, mixed population, no full text, duplicate, others specify
Age Range/ Population characteristics (if any)	population characteristics e.g. study included individuals who were edentulous for more than 2yrs./ 5 yrs. (to be written as edentulous>5yrs.)
Sample Size	mention complete sample size followed by sample size in each group e.g. 100 (n=50 for ball and n=50 for bar)
Sample Gender	Mention the number of females and males
Study Design (mention letters in bold)	Observational – e.g. **Des**criptive **Exp**erimental **Qual**itative – any type of qualitative study **Mix**ed Methods (if mentioned)
Type of Study	I-RCT ; II- Non-RCT
Methods used	mention all methods used to assess each outcome e.g. OHIP Questionnaire, radiographic evaluations, Periotest for implant mobility etc.
Comparator	1= complete/ conventional denture vs. mandibular two-implant overdenture opposed by conventional maxillary denture 2= ball attachment vs. other attachment systems e.g. bar, magnet 3= immediate vs. delayed loading 4=others- specify
Outcomes measured	free form coding (mention all outcomes and the relevant findings under each outcome) E.g. 1) For complications observed in the treatment mention the number of complications (out of total no.) or mention in percentages (implant success 96.7%), 2) ability to chew was found to be better with the IOD group (written as chewing ability IOD>CD) 3) Plaque accumulation was not significantly different in the ball and bar group (written as plaque (ball=bar, n.s.) [n.s.- not statistically significant]
Evaluation periods	mention at what points were the data recorded (e.g. pre-treatment and 6 months post- insertion OR immediate post- insertion and 5 yrs. post-insertion)

Appendix 2: Summary of included studies based on outcomes

Table 5. Articles reporting clinical efficacy based outcomes

Study (Year)	Study Type (Design)	Maximum Follow-up and % dropout (Attrition)	Sample Size	Female Count (%)	Age (years)	Intervention/ Comparator	Outcomes/ effects studied
Chafee 2002	Non- RCT (Descriptive prospective)	3 years 78 %	58	Not Reported	Range 35-75	Ball IOD/ No comparator	**Primary:** Prosthodontic maintenance & complications (+ time and costs of maintenance visits)
Cooper 2008	Non- RCT (Descriptive prospective)	5 years 17 %	59	29 (49.15)	Mean 58.3 Range 26-74	Ball IOD/ No comparator	**Primary:** Peri-implant outcomes **Other:** Implant Success
Cune 2004	Non- RCT (Descriptive prospective)	12 Months 0 %	18	13 (72.22)	Mean 60 Range 47.1-78.2	Ball IOD/ No comparator	**Primary:** Prosthodontic maintenance & complications; **Other:** Implant Success
Cune 2010	RCT (cross-over design)	10 years 22 %	18	1 (5.55)	Range 33-56	Ball IOD *vs.* Bar IOD	**Primary:** Peri-implant outcomes **Other:** Implant Success
De Bruyn 2009	Non- RCT (Descriptive prospective)	33 Months 24 %	34	13 (38.23)	Mean 63.6 Range 39-85	Ball IOD/ No comparator	**Primary:** Peri-implant outcomes, Prosthodontic maintenance & complications **Other:** Implant Success
Lachmann 2007	Non- RCT (Cross Sectional - age and gender matched groups)	Cross Sectional	10 (Ball, *n=5*; Bar, *n=5*)	8 (80.0)	Mean 71 Range 66-76	Ball IOD *vs.* Bar IOD	**Primary:** Peri-implant outcomes **Other:** Implant Stability
Liao 2010	Non- RCT (Experimental prospective)	1 year 0%	10	Not Reported	Mean 59.7 Range 43-78	Immediately loaded Ball IOD/ No comparator	**Primary:** Peri-implant outcomes, Prosthodontic complications; Other: Implant Success, Implant Stability

MacEntee 2005	RCT (stratified random sampling)	3 years 32%	100 (Ball, *n=34*; Bar, *n=34* after 3 years)	43 (63.23)	Mean 63 *(Ball)*; 61 *(Bar)*	Ball IOD *vs.* Bar IOD	**Primary:** Prosthodontic maintenance & complications.
Mackie 2011	RCT	8 years 36%	106	66 (66.26)	Mean 65.3 ± 7.4	6 Different types of matrices associated with ball Attachment are compared	**Primary:** Prosthodontic maintenance & complications **Other:** Effect of loading time on prosthodontic maintenance requirements
Marzola 2007	Non-RCT (Prospective experimental)	1 year 0%	17	11 (64.70)	Range 36-91	Immediately loaded Ball IOD/ No comparator	**Primary:** Peri-implant outcome (bone loss), prosthodontic maintenance **Other:** Effect of loading time on Implant success
Naert 2004	RCT	10 years 28%	36 (Ball, *n=12*; Bar, *n=12*; Magnet, *n=12*)	19 (52.78)	Range 36-85	Ball IOD vs. Bar IOD vs. Magnet IOD	**Primary:** Prosthodontic maintenance **Other:** Soft tissue complications, Vertical retention force
Naert 2004a	RCT	10 years 28%	36 (Ball, *n=12*; Bar, *n=12*; Magnet, *n=12*)	19 (52.78)	Range 36-85	Ball IOD *vs.* Bar IOD *vs.* Magnet IOD	**Primary:** Peri-implant outcomes
Turkyilmaz 2006	RCT	1 year 0%	20 (Early loading, *n=10*; Delayed loading, *n=10*)	12 (60.0)	Mean 62.4 ± 8.6 *(early)*; 62.3 ±7.1 *(delayed)*	Early loading (1 week) *vs.* Delayed loading (3 months) of Ball IODs	**Primary:** Prosthodontic maintenance & complications
Turkyilmaz 2007	RCT	2 years 0%	20 (Early loading, *n=10*; Delayed loading, *n=10*)	12 (60.0)	Mean 62.4 ± 8.6 *(early)*; 62.3 ±7.1 *(delayed)*	Early loading (1 week) *vs.* Delayed loading (3 months) of Ball IODs	**Primary:** Prosthodontic maintenance **Other:** Effect of loading time on Implant success
van der Bilt 2006	RCT (cross-over design)	14 months 0%	18	1 (5.55)	Range 33-56	Ball IOD *vs.* Bar IOD *vs.* Magnet IOD	**Other:** Masticatory function
van Kampen 2003	RCT (cross-over design)	3 months for each attachment 0%	18	1 (5.55)	Range 33-56	Ball IOD *vs.* Bar IOD *vs.* Magnet IOD	**Primary:** Prosthodontic maintenance (no. of repairs/ replacements)

van Kampen 2004	RCT (crossover design)	14 months 0%	18	1 (5.55)	Range 33-56	Ball IOD *vs.* Bar IOD *vs.* Magnet IOD	**Other:** Masticatory function and swallowing threshold
van Kampen 2005	RCT (cross-over design)	3 months for each attachment 0%	18	1 (5.55)	Range 33-56	Ball IOD *vs.* Bar IOD *vs.* Magnet IOD	**Primary:** Peri-implant outcomes
Walton 2002	RCT	1 year 4%	100 (Ball, *n=34*; Bar, *n=30* after 3 years)	41 (64.06)	Range 41.4-88.9	Ball IOD *vs.* Bar IOD	**Primary:** Prosthodontic maintenance (time and costs of maintenance visits)
Walton 2003	RCT	3 years 13%	100 (Ball, *n=45*; Bar, *n=42* after 3 years)	65 (65.0)	Range 41-89	Ball IOD *vs.* Bar IOD	**Primary:** Prosthodontic maintenance (no. of repairs/ replacements)

Table 6. Articles reporting patient based outcomes

Study (Year)	Study Design	Maximum Follow-up and %dropout	Sample Size	Female Count (%)	Age (years)	Intervention/ Comparator	Outcomes/ effects studied
Awad 2003	RCT	2 months 13%	60 (IOD, *n=30*; CD, *n=30*)	36 (60.0)	65-75 yrs.	Ball IOD *vs.* CD	**Primary:** Patient satisfaction
Bilhan 2011b	RCT (cross-over design)	Not Reported 8%	25	9 (36.0)	mean age= 57.3 yrs.	Ball IOD *vs.* Self-aligning IOD	**Primary:** Patient Satisfaction; **Other:** Available attachment space
Cooper 2008	Non- RCT (Descriptive prospective)	5 years 17 %	59	29 (49.15)	mean 58.3 (range 26 to 74)	Ball IOD/ No comparator	**Primary:** Peri-implant outcomes, Patient satisfaction **Other:** Implant Success
Cune 2005	RCT (cross-over design)	1 year 0%	18	1 (5.55)	33-56 yrs.	Ball IOD vs. Bar IOD vs. Magnet IOD	**Primary:** Patient Satisfaction **Other:** Patient preferences, and Maximum bite force
Cune 2010	RCT (cross-over design)	10 years 22 %	18	1 (5.55)	33-56 yrs.	Ball IOD *vs.* Bar IOD	**Primary:** Peri-implant outcomes, Patient satisfaction **Other:** Implant Success
De Bruyn 2009	Non- RCT (Descriptive prospective)	33 Months 24 %	34	13 (38.23)	Mean 63.6 Range 39-85	Ball IOD/ No comparator	**Primary:** Peri-implant outcomes, Prosthodontic maintenance & complications, and patient satisfaction **Other:** Implant Success
Ellis 2009	RCT (cross-over design)	6 Months 27 %	22	15 (68.18)	mean 65 yrs.	Ball IOD *vs.* Magnet IOD	**Primary:** Patient satisfaction
Fenlon 2002	Non- RCT (Descriptive prospective)	2 years 56 %	16	9 (56.25)	32-74 yrs.	Ball IOD/ No comparator	**Primary:** Patient satisfaction **Other:** Implant Success

Kimoto 2009	Non- RCT (Cross Sectional design)	Cross Sectional	79 (rotation group-37; non rotation group-42)	42 (53.16)	Rotation group (mean age-71.2); non rotation group (mean age-72.1)	Ball IOD/ No comparator	**Other:** Effects of IOD rotation (on patient satisfaction)
Klemetti 2003	RCT	1 year 0%	60 (IOD, *n=30;* CD, *n=30*)	Not reported	> 65 years of age	Ball IOD *vs.* CD	**Other:** Occurrence of post-insertion pressure spots
MacEntee 2005	RCT (stratified random sampling)	3 years 32%	100 (Ball, *n=34;*Bar, *n=34* after 3 years)	43 (63.23)	Mean ages (bar-clip group: 61 years; ball-spring group: 63 years)	Ball IOD *vs.* Bar IOD	**Primary:** Patient satisfaction, Prosthodontic maintenance & complications.
Naert 2004	RCT	10 years 28%	36 (Ball, *n=12*; Bar, *n=12*; Magnet, *n=12*)	19 (52.78)	36-85 years	Ball IOD vs. Bar IOD vs. Magnet IOD	**Primary:** Patient satisfaction
Pan 2008	RCT	1 year 10%	256 (IOD, *n=128*; CD, *n=128*)	142 (55.46)	72.3 ± 4.6 years	Ball IOD *vs.* CD	**Primary:** Patient satisfaction
Rashid 2011	Non-RCT (Descriptive prospective)	6 months 50%	102 (IOD, *n=55*; CD, *n=47* after 6 months)	58 (57.42); 1 missing	68.8 ± 10.4 years	Ball IOD *vs.* CD	**Primary:** Patient satisfaction

Thomason 2003	RCT	6 months 0%	60	36 (60.0)	65-75 years	Ball IOD *vs.* CD	**Primary:** Patient satisfaction
Timmerman 2004	RCT	8 years 6%	103 (Ball, *n=32*; Bar, *n=36*; 4-implant triple bar, *n=35*)	73 (70.87)	39-87 years	Ball IOD vs. Bar IOD vs. 4-implant triple bar IOD	**Primary:** Patient satisfaction
Walton 2002	RCT	1 year 4%	64 (Ball, n=34; Bar, n=30)	41 (64.06)	41.4-88.9yrs.	Ball IOD *vs.* Bar IOD	**Primary:** Patient satisfaction

Appendix 3: Summary of findings from included studies based on outcomes

Table 7. Articles reporting Patient Satisfaction outcomes

Author (Year)	Follow-up	Intervention/ Comparator	parameters measured	Results
Awad 2003	2 months	Ball IOD *vs.* CD	General satisfaction, comfort, stability, esthetics, ability to chew, ability to speak and clean, ability to chew six foods of varying textures, OHIP, OHIP-EDENT	Primary outcome: General satisfaction using 100mm VAS (IOD>CD); Other outcomes: comfort (IOD>CD), stability (IOD>CD), esthetics, ability to chew (IOD>CD), and ability to speak and clean), as well as ability to chew six foods of varying textures (IOD>CD); OHIP (IOD>CD except psychological disability); OHIP-EDENT (IOD>CD)
Bilhan 2011b	Not Reported	Ball IOD *vs.* Self-aligning IOD	OHRQoL, OHIP-14 scores, functional limitation, psychological discomfort, physical disability, psychological disability	OHIP 14 (I) overall results: self-aligning=ball; (II) subdomains: 1.physical disability (self-aligning>ball p=0.49); 2. no other sub domains had significant differences; (III) 13 patients with below-average attachment space: functional limitation, psychological discomfort, physical disability, psychological disability, total OHIP-14 scores (self-aligning>ball). The self-aligning attachment system for 2-implant–retained mandibular overdentures is equal or superior to traditional ball attachments in all domains of the OHIP-14
Cooper 2008	5 years	Ball IOD/ No comparator	Chewing ability, phonetics, general satisfaction	patients' assessment: chewing- no change (satisfaction of chewing decreased from baseline to 5 years); phonetics- no change; general satisfaction- no change; facial attractiveness- marked changes; self-assessment of teeth- increased after denture connection to implants and then decreased till 5 years of follow-up (but higher than initial recordings)

Cune 2005	1 year	Ball IOD *vs.* Bar IOD *vs.* Magnet IOD	VAS scores, denture complaints (general satisfaction, esthetics, physiognomy) correlation of satisfaction with maximum bite force	Scale scores: Max. CD: ball=bar=magnet; mand. IOD: bar=ball>>magnet; general satisfaction: bar=ball>>magnet; physiognomy: ball=bar=magnet; neutral space: ball=bar=magnet; esthetics: ball=bar=magnet VAS: ball=bar>>>magnet correlation of satisfaction with maximum bite force: not significant
Cune 2010	10 years	Ball IOD *vs.* Bar IOD	VAS scores, denture complaints (general satisfaction, esthetics, physiognomy) correlation of satisfaction with maximum bite force	mean scale and VAS scores not statistically significant between 1 and 10 years
De Bruyn 2009	33 Months	Ball IOD/ No comparator	Patients' opinions on satisfaction and treatment outcome	The patients were appreciative of the work carried out by their dentist and they indicated a significant improvement in their well-being and quality of life
Ellis 2009	6 Months	Ball IOD *vs.* Magnet IOD	chewing ability, stability, ease of cleaning, phonetics, patients' preferences	Ball> magnet (ease of cleaning, ability to speak, comfort, appearance, stability and ability to chew) 11/16 patients chose to keep the ball attachments
Fenlon 2002	2 years	Ball IOD/ No comparator	General satisfaction, retention, denture fit, comfort, chewing ability, esthetics, social functioning	General health questionnaire ratings (IOD better than CD); retention (IOD>CD); denture fit (IOD>CD); denture comfort (IOD>CD); chewing ability (IOD>CD); appearance (not significant); social functioning(IOD=CD; not significant)
MacEntee 2005	3 years	Ball IOD *vs.* Bar IOD	General satisfaction	Satisfaction level (IOD>CD baseline), (ball=bar)
Naert 2004	10 years	Ball IOD vs. Bar IOD vs. Magnet IOD	Chewing ability; prosthesis stability; comfort; appearance; speech; social behavior; general satisfaction	Ball attachment group exhibited the best patient satisfaction scores at 10 years as compared to bar and magnet attachment groups.
Pan 2008	1 year	Ball IOD *vs.* CD	General satisfaction, comfort, stability, ability to speak, chewing ability, aesthetics and ease of cleaning. (sex differences in satisfaction ratings)	Both edentulous males and females appear to be more satisfied with implant overdentures than with conventional dentures. Females may be less satisfied with conventional dentures than males; but equally satisfied with their implant overdentures.

Rashid 2011	6 months	Ball IOD *vs.* CD	General satisfaction, ability to clean, ability to speak, comfort, aesthetics, stability, ability to chew	Implant overdenture group exhibited significantly higher ratings of overall satisfaction, comfort, stability, ability to speak and ability to chew. Ratings of denture aesthetics were similar in both groups.
Thomason 2003	6 months	Ball IOD *vs.* CD	General satisfaction, comfort, stability, ability to chew, ease of cleaning	Edentulous seniors who received mandibular implant overdentures opposing a conventional denture rated their general satisfaction approximately 36% higher than did a comparable group provided with new conventional dentures.
Timmerman 2004	8 years	Ball IOD vs. Bar IOD vs. 4-implant triple bar IOD	General satisfaction, pain, denture retention	Participants' general satisfaction with mandibular implant-retained overdentures and their opinion about phonetics, aesthetics, and social functioning were high after 8 years and not dependent on treatment strategy. However, ratings for retention and stability of the overdenture' in the ball attachment group decreased over time whereas in the single and triple-bar groups the ratings remained at the same level.
Walton 2002	1 year	Ball IOD *vs.* Bar IOD	Patient satisfaction (pain, comfort, appearance, function, stability, speech, cleaning difficulty, and overall satisfaction)	The ball abutment and bar abutment groups exhibited equivalent levels of patient satisfaction.

Table 8. Articles reporting prosthodontic maintenance and complications			
Author (Year)	**Follow-up period**	**Intervention/ Comparator**	**Results**
Chaffee 2002	3 years	Ball IOD/ No comparator	6/58 pts. required no adjustment; 52/58 pts. required total visits: 327 ; 194 (59.3%) unscheduled visits; **Denture adjustments** (26% of all complications) **Ball housing complications** (26.9% of all complications) **Prosthetic tooth complications** (9.1% of all complications) **Reline/ repair of mand. IOD**: 18 pts.- 20 relines; 4pts- 12 repairs; most repairs- midline # **Reline/repair of max. CD**: 16 pts.- 18 relines; No repairs **Abutment complications**: 3 pts.- 6 tightening; 2 patients- abutment replacement
Cune 2004	12 Months	Ball IOD/ No comparator	18 pts. followed up for one year: prosthetic complications and post-insertion maintenance were minimal. Three abutments loosened, one of which subsequently broke after 5 months of loading. Retightening of the attachment (gold matrix) was performed on seven occasions in four patients. Short-term results indicate that mandibular implant overdenture treatment by means of two ball-abutments, using Frialocs implants and prosthetic components, leads to good clinical results, both from an objective and a subjective perspective. **Peri-prosthetic complications** - ball abutments: stripping and wear of the internal hexagon was noted in 2 and 1 balls respectively. **Post prosthetic complications** - broken screw, loose ball abutment and loose matrix.. Frequent retightening of matrix was done on follow-up visits.

De Bruyn 2009	33 Months	Ball IOD/ No comparator	Retention of denture was perfect in 80% cases, 20% needed minor activation of attachments; 20% dentures were repaired for damage (2 pts.-broken dentures; 2 pts.-damaged tooth; 1 attachment needed replacement)
Liao 2010	1 year	Immediately loaded Ball IOD/ No comparator	2 patients showed loosening of the ball attachments at the 3 month follow-up exam; after the screws were tightened the problem resolved and did not recur. No other prosthetic complications (e.g. denture fracture, denture reline, and retention adjustment) were noted throughout the study.
MacEntee 2005	3 years	Ball IOD *vs.* Bar IOD	Most denture adjustments occurred during 1st year (81% of total adjustments in 3 yrs.); mean no. of adjustments (ball=bar); repairs>adjustments; repairs (ball>bar) - 6.7 repairs per person in the ball-spring group, compared to 0.8 in the bar-clip group. Almost all repairs (90%) occurred in the ball-spring group to correct problems with the attachments
Mackie 2011	8 years	6 Different types of matrices associated with ball Attachment are compared	Attachment systems influence prosthodontic maintenance (including the mean number of maintenance events and longevity of the attachment), particularly in regards to the type of matrices used.; Mean time to reline OVDs- 3.37±2.06 years; remaking of OVDs peaked by 7 years (mean time to remake 5.81±2.04 years)
Marzola 2007	1 year	Immediately loaded Ball IOD/ No comparator	10% patients needed adjustments for major prosthetic complications (denture fractures). 40% patients needed minor adjustments/ repairs related to ball abutments.
Naert 2004	10 years	Egg-shaped Dolder bars vs. Magnet abutments vs. Ball abutments	Prosthodontic complications related to wear and corrosion were maximum for the magnet attachment group followed by the bar attachment group. Ball attachments exhibited the least maintenance requirements (abutment tightening/ replacement).

Turkyilmaz 2006	1 year	Early loading (1 week) vs. delayed loading (3 months)	The time required for prosthesis fabrication was higher for delayed loading group than the early loading group. However, the adjustment/ repair visits were not different for both the groups.
Turkyilmaz 2007	2 years	Early loading (1 week) vs. delayed loading (3 months)	Significantly more adjustments/ repairs are required in the 1st year than the 2nd year. No significant difference in adjustments/ repairs was seen between early and delayed loading groups.
van Kampen 2003	3 months	Magnet attachment vs. ball abutment vs. Bar-clip attachment	Magnet attachments exhibited significantly more complications related to wear (61%) than ball (22%) and bar-clip abutments (0%) within the 3 month follow-up period.
Walton 2002	1 year	2.25 ball abutment with titanium alloy cap (Nobel Biocare) vs. round gold bar system (Nobel Biocare)	No significant difference in the time to fabricate the prosthesis and adjust the overdenture post insertion was reported. Significantly higher time and number of repairs in ball abutment group than bar abutment groups were reported.
Walton 2003	3 years	2.25 ball abutment with titanium alloy cap (Nobel Biocare) vs. round gold bar system (Nobel Biocare)	Almost three times as many bar-clip dentures (63%) were rated successful compared to the ball attachment design. More than three times as many ball attachment IODs (60%) required retreatment in the form of excessive repairs, and twice as many of the ball attachment design (8%) required replacement. The ball attachment IOD was significantly more likely to require patrix tightening or matrix replacement, while the bar-clip design was more likely to require activation of the matrix.

Table 9. Articles reporting Peri-Implant outcomes				
Author (Year)	**Follow-up period**	**Intervention/ Comparator**	**Parameters measured**	**Results**
Cooper 2008	5 years	Ball IOD/ No comparators	Crestal bone level changes, Marginal bone level changes, peri-implant inflammation, sulcus depth	**Crestal bone level changes**: statistically insignificant **Marginal bone level changes**: statistically insignificant **Peri-implant inflammation**: statistically insignificant when compared to baseline measurements **peri-implant sulcus depth**: no significant changes as compared to baseline scores
Cune 2010	10 years	Ball IOD *vs.* Bar IOD	Probing depth, marginal bone loss	**Mean probing depth**: ball attachment< bar attachments; **Marginal bone loss and bleeding index**: not significant
De Bruyn 2009	33 Months	Ball IOD/ No comparators	Marginal bone loss, pocket depth, plaque index, bleeding index	Average **marginal bone loss** 0.8mm; mean **pocket depth** 2.1mm (range 0.5-5mm); mean **plaque index** 0.9 (range 0-4), mean **bleeding index** 0.8 (range 0-3); 13 patients were free of bleeding; presence of plaque highly correlated to bleeding ($p<0.02$)
Lachmann 2007	Cross Sectional	Ball IOD *vs.* Bar IOD	Plaque Index, bleeding index, probing depth, sulcular fluid flow rate, microbiological concentration of different bacilli	Peri-implant probing depth; plaque and bleeding on probing scores; sulcular fluid flow rates; relative concentrations of Actinobacillus actinomycetemcomitans, Prevotella intermedia, fusobacterium nucleatum, porphyromas gingivalis, Tannerella forsythensis, and Treponema denticola (ball=bar, n.s.)
Liao 2010	1 year	Immediately loaded Ball IOD/ No comparator	Marginal bone loss, plaque index	**Marginal bone loss**: 1.12 ±1.10mm; **Modified Plaque Index** scores of 0 and 1 throughout the study
Marzola 2007	1 year	Immediately loaded Ball IOD/ No comparator	Radiographic bone loss	Immediate loading of implants did not adversely affect bone remodeling. The RBL changes (average 0.7 mm ± 0.5 mm) after 1 year of function were within the value reported in the literature.

Naert 2004a	10 years	Ball IOD *vs.* Bar IOD *vs.* Magnet IOD	Plaque Index, Bleeding Index, change in attachment level (probing pocket depth + recession), Periotest values (implant mobility), and marginal bone level	None of the studied outcomes were significantly different among the bar, ball and magnet groups.
van Kampen 2005	3 months for each attachment type	Ball IOD *vs.* Bar IOD *vs.* Magnet IOD	Relationship between maximum bite force and marginal bone loss during healing of implants and functional loading	No significant differences in marginal bone loss were observed with different attachment types. The study was not able to demonstrate a relationship between the level of maximum bite force and the amount of marginal bone loss.

Table 10. Articles reporting 'other outcomes'				
Author (Year)	**Follow-up**	**Intervention/ Comparator**	**Effects measured**	**Results**
10.1 Effects of loading time on implant success or Prosthodontic Maintenance Requirements				
Mackie 2011	8 years	6 Different types of matrices associated with ball Attachment are compared	Effect of loading time on prosthodontic maintenance requirements	Early loading protocols do not influence long-term prosthodontic maintenance requirements of unsplinted mand. 2-implant overdentures
Marzola 2007	1 year	Immediately loaded Ball IOD/ No comparator	Effect of loading time on Implant success	100% implant success was reported.
Turkyilmaz 2007	2 years	Early loading (1 week) vs. Delayed loading (3 months) of Ball IODs	Effect of loading time on Implant success	100% implant success was achieved in both groups.
10.2 Vertical retention forces				
Naert 2004	10 years	Ball IOD vs. Bar IOD vs. Magnet IOD	Vertical retention force	Ball retained overdentures showed the greatest vertical retention force after 10 years followed by bar and magnet attachments

10.3 Masticatory function				
van der Bilt 2006	14 months	Ball IOD vs. Bar IOD vs. Magnet IOD	Masticatory function (Jaw-muscle activity) using surface electromyography (to measure electrical activity)	Muscle activity was significantly lower for conventional mandibular dentures compared with implant overdentures. No significant differences in muscle activity were observed among the three attachment types (ball, bar, and magnet). Subjects chewed more efficiently after implant treatment.
van Kampen 2004	14 months	Ball IOD vs. Bar IOD vs. Magnet IOD	Masticatory function and swallowing threshold	The masticatory function significantly improved after implant treatment with each of the 3 attachments. Overdentures with ball and bar-clip attachments exhibited slightly better masticatory performance than with magnet attachments. Swallowing threshold is not significantly different among the three attachment groups.

10.4 Implant Success/ Survival				
Cooper 2008	5 years	Ball IOD / No comparator	Implant survival	Implant survival rate: 95.9%
Cune 2004	12 Months	Ball IOD / No comparator	Implant success	1 year success rate: 93.9%
Cune 2010	10 years	Ball IOD *vs.* Bar IOD	Implant Success	Implant success rate: 100% in both the groups
De Bruyn 2009	33 Months	Ball IOD / No comparator	Implant survival	Implant survival rate: 97%
Fenlon 2002	2 years	Ball IOD / No comparator	Implant Success with single stage surgery	Implant success rate: 81.25%
Liao 2010	1 year	Immediately loaded Ball IOD/ No comparator	Implant Success	Implant success rate: 94%

10.5 Implant Stability				
Lachmann 2007	Cross Sectional	Ball IOD *vs.* Bar IOD	Implant Stability using Periotest device	Ball and bar abutment groups did not exhibit any significant differences in implant stability.
Liao 2010	1 year	Immediately loaded Ball IOD/ No comparator	Implant Stability using Periotest device	Periotest values - 4.25±0.93 (good osseointegration)

10.6 Effects of IOD Rotation				
Kimoto 2009	Cross Sectional	Ball IOD / No comparator	IOD rotation influence on satisfaction ratings of chewing ability, and the factors involved in the rotation of IODs	37/39 patients were aware of rotational movements; chewing ability (rotation<non-rotation); general satisfaction (rotation=non-rotation, n.s.); no relationship between general satisfaction and chewing ability; non-scheduled visits (rotation=non rotation, n.s.)

10.7 Occurrence of Post-insertion Pressure Spots				
Klemetti 2003	1 year	Ball IOD *vs.* CD	Other outcome (the occurrence of post-insertion pressure spots)	Significantly fewer visits for adjustment related to post-placement pressure spots were required for mandibular overdentures than for conventional mandibular prostheses (22 visits for IOD compared to 70 visits for the CD)

10.8 Patient's Preferences				
Cune 2005	1 year	Ball IOD vs. Bar IOD vs. Magnet IOD	Primary: Patient Satisfaction; Other: Patient preference, and maximum bite force	Preferences for type of attachment: Ball (7/18)=Bar (10/18)> magnet (1/18)

10.9 Maximum Bite Force				
Cune 2005	1 year	Ball IOD vs. Bar IOD vs. Magnet IOD	Maximum bite force	Correlation of satisfaction with maximum bite force: not significant

10.10 Soft Tissue Complications				
Naert 2004	10 years	Ball IOD vs. Bar IOD vs. Magnet IOD	Soft tissue complications	The magnet group revealed the maximum number of soft tissue complications (such as common ulcer) which increased over time. Bar attachments prevent proper cleaning under the bar which may cause soft tissue inflammatory reactions. Ball group showed the fewest soft tissue complications.

Appendix 4: Cost estimation

Table 12. Primary economic evaluations included in cost estimation

Study I.D.	Country	Original currency	Mean Initial direct costs	Mean maintenance direct costs	Follow-up	Types of costs calculated	
						Initial costs	Maintenance costs
Heydecke 2005	Canada	Year 1999 CAD $	$3,207/ Initial and maintenance costs for 1st year.	$241/ maintenance costs for 2nd year*	1 year	• Cost of labor • Materials • Medications • Laboratory fees • Radiography fees	
Takanashi 2004	Canada	Year 1999 CAD $	$3,207/ Initial and maintenance costs for 1st year		1 year		
Stoker 2007	Netherlands	Year 2000 Euro	NA	1456.20/8 years	8 years	NA	Cost of labor (prosthodontist, oral surgeon, oral hygienist) radiography fees
Zitzmann 2005	Switzerland	year 2000 CHF (Swiss Francs)	$7,938	NA	6 months	• Implant material • Surgical and prosthodontic treatment • Laboratory fees • New maxillary CD (if required) • Metal reinforcement of mandibular OVD (if required)	NA
Zitzmann 2006	Switzerland	year 2000 CHF (Swiss Francs)	$8,127	179/ 1st year 126/ 2nd year 120/ 3rd year	3 years	• Implant material • Surgical and prosthodontic treatment • Laboratory fees • New maxillary CD (if required) • Metal reinforcement of mandibular OVD (if required)	Treatment time, health care resource consumption (recorded for maintenance dental care in scheduled or unscheduled visits)

All costs are mean costs/patient in 2012 CAD $ (conversion rates for March 26, 2012 used)

*The Study calculated 2nd year maintenance costs from existing literature

Table 13. Studies (reporting Prosthodontic maintenance) included in cost estimation							
Study I.D.	**Country**	**Original currency**	**Mean Initial direct costs**	**Mean maintenance direct costs**	**Follow-up**	**Types of costs calculated**	
						Initial costs	**Initial costs**

Chaffee 2002	United States	US $ Year 2002 assumed	NA	$409.76/ 3 years	3 years	NA	Treatment time and laboratory costs for
							• Adjustments and repair to:
							  • Denture and denture teeth
							  • Ball housing
							  • Abutments
							• Remake dentures
							• Reline/ repairs of Maxillary CD

MacEntee 2005	Canada	US $ Year 2005 assumed	NA	$433.7/ 3 years	3 years	NA	Mean clinical time and laboratory fees for adjustments and repairs to: • Denture and occlusion • Abutment • Retentive mechanism (ball spring/ cap) • Miscellaneous components
Walton 2002	Canada	CAD $ Year 2002 assumed	NA	$182.9/ 1 year	1 year	NA	Time required for OVD adjustments to: • Denture contour • Retentive mechanism (ball spring/ housing) • Occlusal adjustment and abutment tightening Time required for OVD repairs to: • Retentive mechanism (ball matrix) • Reline dentures • Fractured/ lost denture teeth

All costs are mean costs/patient in 2012 CAD $ (conversion rates for March 26, 2012 used)

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