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## **Interventions for replacing missing teeth: different times for loading dental implants** Volume (1), 2007, [no page #] [Reviews]

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## Abstract <sup>^</sup>

**Background:** To minimize the risk of implant failure, osseointegrated oral implants are conventionally kept load-free during the healing period. During healing removable prostheses are used, however many patients find these temporary prostheses rather uncomfortable and it would be beneficial if the healing period could be shortened without jeopardizing implant success. Nowadays immediate and early loaded implants are commonly used in mandibles of good bone quality. It would be useful to know whether there is a difference in success rates between immediately or early loaded implants compared with conventionally loaded implants.

**Objectives:** To test the null hypothesis of no difference in the clinical performance between osseointegrated implants loaded at different times 1 year after loading.

**Search strategy:** The Cochrane Oral Health Group's Trials Register, The Cochrane Central Register of Controlled Trials, MEDLINE and EMBASE were searched. Handsearching included several dental journals. Authors of all identified trials, an internet discussion group and 55 oral implant manufacturers were contacted to find unpublished randomized controlled trials

(RCTs). The last electronic search was conducted on 2 February 2004.

**Selection criteria:** All RCTs of root-form osseointegrated oral implants having a follow up of at least 1 year comparing the same osseointegrated root-form oral implants loaded at different times.

**Data collection and analysis:** Data were independently extracted, in duplicate, by two reviewers. Authors were contacted for details of randomization and withdrawals and a quality assessment was carried out. The Cochrane Oral Health Group's statistical guidelines were followed.

**Main results:** Seven RCTs were identified and five trials including 124 patients in total were suitable for inclusion. Implants have been either immediately loaded after insertion (2 to 3 days), early loaded (6 weeks) or conventionally loaded (3 to 8 months) in edentulous mandibles of adequate bone quality and shape. On a patient, rather than per implant basis, there were no statistically significant differences for prosthesis failures, implant failures and marginal bone loss on intra-oral radiographs.

**Authors' conclusions:** While it is possible to successfully load oral implants immediately after their placement in mandibles of adequate bone density and height of carefully selected patients, it is yet unknown how predictable this approach is. More well designed RCTs are needed to understand how predictable immediate and early loading are. Such trials should be simply designed and should be reported according to the CONSORT guidelines (<http://www.consort-statement.org/>). It is suggested that priority should be given to trials assessing the effectiveness of immediately loaded implants rather than early loaded ones.

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## Issue protocol first published [^](#)

2002 Issue 4

## Date new studies found and included or excluded [^](#)

09 February, 2004

## Issue first published [^](#)

2003, Issue 1

## Plain language summary [^](#)

Some people may be able to have dentures attached to dental implants immediately instead of waiting months, but more research is needed to be

sure.

When people have dental implants in their jaws, they wait several months for the bone around the implants to heal before a denture is attached (using removable dentures in the meantime). If the denture could be loaded onto the implant immediately, people might be able to start chewing comfortably within days. The review found some evidence from trials in people with healthy lower jaws that immediate or early loading with dentures (in 6 weeks) had similar outcomes to waiting several months. However, more research is needed to be sure that immediate or early loading is safe and effective, in upper and lower jaws, and for whom.

## Background<sup>^</sup>

Missing teeth and supporting oral tissues have traditionally been replaced with dentures or bridges to restore the ability of patients to eat and speak and improve appearance. However, in several instances, patients are not satisfied with the function of removable dentures and it is not always possible to place a fixed bridge if the number of remaining abutment teeth is insufficient. Since the seventies, osseointegrated dental implants have offered an alternative ([Branemark 1977](#)). They are surgically inserted into the jaw bones to support a dental prosthesis and are retained because of the intimacy of bone growth onto their surface (osseointegration). Dental implants have undoubtedly been one of the most significant scientific breakthroughs in dentistry over the past 30 years.

Primary implant stability and lack of micromovements are considered to be two of the main factors necessary for achieving predictable high success of osseointegrated oral implants ([Albrektsson 1981](#)). A successful osseointegrated oral implant is anchored directly to bone, however, in the presence of movement a soft tissue interface may encapsulate the implant ([Brunski 1979](#)) causing its failure. To minimize the risk of soft tissue encapsulation, it has been recommended to keep the implants load-free during the healing period (3 to 4 months in mandibles and 6 to 8 months in upper jaws) ([Branemark 1977](#)).

In general, during the healing period removable prostheses are used, however many patients find these temporary prostheses rather uncomfortable and it would therefore be beneficial if the healing period could be shortened without jeopardizing implant success. In 1990 the first longitudinal clinical trial was published suggesting that implants could be loaded immediately or early in the mandibles of selected patients ([Schnitman 1990](#)). Nowadays immediate and

early loaded implants are commonly used particularly in mandibles of good bone quality (Branemark 1999). Some authors also advocate that the use of some specific implant surface preparation is able to reduce the healing time (Roccuzzo 2001).

It would be useful to know whether there are differences in success rates between immediately or early loaded implants compared with conventionally loaded implants and if there are some surface modifications able to promote a faster bone healing (for the role of the surface characteristics the reader is referred to another Cochrane systematic review (Esposito 2002)). It is likely that the effect of loading at different times would become apparent during the first year of loading and therefore it was decided to make all comparisons at 1 year after loading.

## **Objectives** [^](#)

To test the null hypothesis of no difference in the clinical performance between the same osseointegrated implants loaded at different times.

## **Criteria for considering studies for this review** [^](#)

### Types of studies [^](#)

All randomized controlled trials of root-form osseointegrated oral implants having a follow up of 1 year of loading.

### Types of participants [^](#)

Patients who are having osseointegrated root-form oral implants.

### Types of intervention [^](#)

Trials comparing the same osseointegrated root-form oral implants loaded at different times.

### Types of outcome measures [^](#)

- \* Prosthesis failure if secondary to implant failure.
- \* Implant mobility and removal of stable implants dictated by progressive marginal bone loss.
- \* Radiographic marginal bone level changes on intraoral radiographs taken with a parallel technique.

## **Search methods for identification of studies** [^](#)

See: methods used in reviews.

For the identification of studies included or considered for this review, we developed detailed search strategies for each database to be searched. These were based on the search strategy developed for MEDLINE (OVID) but revised appropriately for each database. The search strategy used a combination of controlled vocabulary and free text terms based on the following:

1. exp Dental Implants/
2. exp Dental Implantation/ or dental implantation
3. exp Dental Prosthesis, Implant-Supported/
4. ((osseointegrated adj implant\$) and (dental or oral))
5. dental implant\$
6. (implant\$ adj5 dent\$)
7. (((overdenture\$ or crown\$ or bridge\$ or prosthesis or restoration\$) adj5 (Dental or oral)) and implant\$)
8. "implant supported dental prosthesis"
9. ("blade implant\$" and (dental or oral))
10. ((endosseous adj5 implant\$) and (dental or oral))
11. ((dental or oral) adj5 implant\$)
12. OR/1-11

The above search was run with phases 1 and 2 of the Cochrane Sensitive Search Strategy for RCTs as published in Appendix 5b.2 of the Cochrane Reviewers Handbook 4.2.0 (updated March 2003) and amended by the Cochrane Oral Health Group as follows:

1. RANDOMIZED CONTROLLED TRIAL.pt.
2. CONTROLLED CLINICAL TRIAL.pt.
3. RANDOMIZED CONTROLLED TRIALS.sh.
4. RANDOM ALLOCATION.sh.

5. DOUBLE BLIND METHOD.sh.

6. SINGLE BLIND METHOD.sh.

7. CROSS-OVER STUDIES.sh.

8. MULTICENTER STUDIES.sh.

9. ("multicentre stud\$" or "multicentre trial\$" or "multicenter stud\$" or "multicenter trial\$" or "multi-centre stud\$" or "multi-centre trial\$" or "multi-center stud\$" or "multi-center trial\$" or "multi-site trial\$" or "multi-site stud\$").ti,ab.

10. MULTICENTER STUDY.pt.

11. latin square.ti,ab.

12. (crossover or cross-over).ti,ab.

13. (split adj (mouth or plot)).ti,ab.

14. or/1-13

15. (ANIMALS not HUMAN).sh.

16. 14 not 15

17. CLINICAL TRIAL.pt.

18. exp CLINICAL TRIALS/

19. (clin\$ adj25 trial\$).ti,ab.

20. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.

21. PLACEBOS.sh.

22. placebo\$.ti,ab.

23. random\$.ti,ab.

24. RESEARCH DESIGN.sh.

25. or/17-24

26. 25 not 15

27. 26 not 16

28. 16 or 27

### **Searched databases**

The Cochrane Oral Health Group's Trials Register (to 26 January 2004).

The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library Issue 1, 2004).

MEDLINE (1966 to 2 February 2004).

EMBASE (1980 to 2 February 2004).

The most recent electronic search was undertaken on 2 February 2004.

The most recent search for unpublished material was undertaken on 14 March 2004.

We checked the bibliographies of all identified RCTs and relevant review articles for studies outside the handsearched journals.

### **Language**

There were no language restrictions.

### **Unpublished studies**

We wrote to all the authors of the identified RCTs, to more than 55 oral implant manufacturers; we used personal contacts and we asked on an internet discussion group ([implantology@yahoogroups.com](mailto:implantology@yahoogroups.com)) in an attempt to identify unpublished or ongoing RCTs.

### **Handsearching**

Details of the journals being handsearched by the Oral Health Group's ongoing programme are given on the web site: <http://www.cochrane-oral.man.ac.uk/>

The following journals have been identified as being important to be



handsearched for this review: British Journal of Oral and Maxillofacial Surgery, Clinical Implant Dentistry and Related Research, Clinical Oral Implants Research, Implant Dentistry, International Journal of Oral and Maxillofacial Implants, International Journal of Oral and Maxillofacial Surgery, International Journal of Periodontics and Restorative Dentistry, International Journal of Prosthodontics, Journal of the American Dental Association, Journal of Biomedical Materials Research, Journal of Clinical Periodontology, Journal of Dental Research, Journal of Oral Implantology, Journal of Oral and Maxillofacial Surgery, Journal of Periodontology, Journal of Prosthetic Dentistry. Where these have not already been searched as part of the Cochrane Journal Handsearching Programme, the journals were handsearched by one reviewer.

## **Methods of the review**<sup>^</sup>

The titles and abstracts (when available) of all reports identified through the electronic searches were scanned independently by two reviewers. For studies appearing to meet the inclusion criteria, or for which there were insufficient data in the title and abstract to make a clear decision, the full report was obtained. The full reports obtained from all the electronic and other methods of searching were assessed independently by two reviewers to establish whether the studies did meet the inclusion criteria or not. Disagreements were resolved by discussion. Where resolution was not possible, a third reviewer was consulted. All studies meeting the inclusion criteria then underwent validity assessment and data extraction. Studies rejected at this or subsequent stages were recorded in the table of excluded studies, and reasons for exclusion recorded.

### **Quality assessment**

The quality assessment of the included trials was undertaken independently and in duplicate by the two reviewers as part of the data extraction process.

Three main quality criteria were examined:

(1) Allocation concealment, recorded as:

(A) Adequate

(B) Unclear

(C) Inadequate.

(2) Treatment blind to outcomes assessors, recorded as:

(A) Yes

(B) No

(C) Unclear.

(3) Completeness of follow up (is there a clear explanation for withdrawals and drop outs in each treatment group?) assessed as:

(A) None

(B) Yes

(C) No.

After taking into account the additional information provided by the authors of the trials, studies were grouped into the following categories:

(A) Low risk of bias (plausible bias unlikely to seriously alter the results) if all criteria were met.

(B) Moderate risk of bias (plausible bias that raises some doubt about the results) if one or more criteria were partly met (when authors responded that they had made some attempts to conceal the allocation of patients, to blind the assessors or to give an explanation for withdrawals, but these attempts were not judged to be ideal, these criteria were categorized as 'partly').

(C) High risk of bias (plausible bias that seriously weakens confidence in the results) if one or more criteria were not met as described in the Cochrane Reviewers' Handbook 6.7.

Further quality assessment was carried out to assess the randomization procedure, sample size calculations, the definition of exclusion/inclusion criteria, adequate definitions of success criteria and comparability of control and treatment groups at entry. The quality assessment criteria were pilot tested using several articles.

### **Data extraction**

Data were extracted by two reviewers independently using specially designed data extraction forms. The data extraction forms were piloted on

several papers and modified as required before use. Any disagreement was discussed and a third reviewer consulted where necessary. All authors were contacted for clarification or missing information. Data were excluded until further clarification was available or if agreement could not be reached.

For each trial the following data were recorded:

- \* Year of publication, country of origin and source of study funding.
- \* Details of the participants including demographic characteristics and criteria for inclusion.
- \* Details of the type of intervention.
- \* Details of the outcomes reported, including method of assessment, and time intervals.

### **Data synthesis**

For dichotomous outcomes, the estimates of effect of an intervention were expressed as relative risks together with 95% confidence intervals. For continuous outcomes, mean differences and standard deviations were used to summarize the data for each group.

Clinical heterogeneity was to be assessed by examining the types of participants, interventions and outcomes in each study. Meta-analyses were done only if there were studies of similar comparisons reporting the same outcome measures. Relative risks were to be combined for dichotomous data, and weighted mean differences for continuous data, using a random effects model. Data from split mouth studies were combined with data from parallel group trials with the method outlined by Elbourne ([Elbourne 2002](#)). The significance of any discrepancies in the estimates of the treatment effects from the different trials was to be assessed by means of Cochran's test for heterogeneity, and any heterogeneity investigated.

It was planned to undertake sensitivity analyses to examine the effect of randomisation, allocation concealment and blind outcome assessment on the overall estimates of effect. In addition, the effect of including unpublished literature on the review's findings was also to be examined, however there were insufficient studies to undertake this.

The following subgroup analyses were planned, however there were insufficient studies in the meta-analysis to undertake this:

(1) Whether implants were placed in mandibles or maxillae.

(2) Whether implants were placed in partially or fully edentulous jaws.

(3) Whether implants were placed in the anterior or posterior jaw.

(4) Different number of inserted implants (for instance overdentures supported by two versus overdentures supported by four implants).

(5) Whether turned (machined) or implants with a roughened surface were used.

(6) Whether the trial was supported by implant manufacturer(s) or not.

## Description of studies<sup>^</sup>

See 'Characteristics of included studies' table.

See 'Characteristics of excluded studies' table.

### Characteristics of the trial settings and investigators

Of the seven eligible trials ([Polson 2000](#); [Chiapasco 2001](#); [Tawse-Smith 2002](#); [Payne 2002](#); [Romeo 2002](#); [Cannizzaro 2003](#); [Romanos 2004](#)), one trial ([Polson 2000](#)) was excluded due to insufficient data presented and another was judged not to be a RCT ([Cannizzaro 2003](#)). Of the five included trials ([Chiapasco 2001](#); [Payne 2002](#); [Tawse-Smith 2002](#); [Romeo 2002](#); [Romanos 2004](#)): two were conducted in Italy ([Chiapasco 2001](#); [Romeo 2002](#)), two in New Zealand ([Tawse-Smith 2002](#); [Payne 2002](#)) and one in Germany ([Romanos 2004](#)). Four trials had a parallel group study design and one a split-mouth study design ([Romanos 2004](#)). All trials were conducted at university dental clinics. Three trials received support from industry ([Tawse-Smith 2002](#); [Payne 2002](#); [Romanos 2004](#)). All studies included only adults.

We have been informed by Ignace Naert that a randomized clinical trial was ongoing during 2003 at the Catholic University of Leuven, Belgium ([Naert 2003](#)). However, we were not supplied with any additional information.

### Characteristics on interventions

Three different loading protocols were investigated:

(A) The immediate loading protocol in which implants are loaded the same

day they are placed or a few days later ([Chiapasco 2001](#); [Romeo 2002](#); [Romanos 2004](#)).

(B) The delayed loading protocol in which implants are loaded a few weeks/months after placement ([Tawse-Smith 2002](#); [Payne 2002](#)).

(C) The conventional loading protocol in which implants are loaded 3 or more months in the mandible and 6 or more months in the maxilla (all trials).

### **(A) Immediate loading**

[Chiapasco 2001](#) and [Romeo 2002](#) compared four implants in each mandible immediately loaded after insertion (2 to 3 days) with four implants conventionally loaded after 4 to 8 months.

[Romanos 2004](#) in a split-mouth design compared three implants distal to the canines loaded the same day with temporary restorations with three implants on the contralateral side conventionally loaded at 3 months.

### **(B) Delayed loading**

[Tawse-Smith 2002](#) and [Payne 2002](#) compared two implants in each mandible early loaded at 6 weeks with two implants conventionally loaded at 12 weeks.

Five different implant systems were used:

(1) Branemark(R) (Nobel Biocare AB, Goteborg, Sweden) Mark II type turned titanium grade 1 screws ([Chiapasco 2001](#)).

(2) Southern(R) (Southern Implants Irene, South Africa) sand-blasted acid-etched titanium grade 4 screws ([Tawse-Smith 2002](#)).

(3) Steri-Oss(R) (Steri-Oss, Yorba Linda, California, USA) HL series, 3.8 mm in diameter acid-etched titanium grade 4 screws ([Tawse-Smith 2002](#)).

(4) ITI(R) SLA (Institut Straumann AG, Waldenburg, Switzerland) solid sand-blasted large-grit acid-etched titanium grade 4 screws ([Romeo 2002](#); [Payne 2002](#)).

(5) Ankylos(R) (Degussa Dental, Hanau-Wolfang, Germany) grit-roughened titanium grade 2 screws ([Romanos 2004](#)).

Conventionally loaded Branemark and Ankylos implants were used

according to a submerged (two-stage) procedure, i.e. the implants were covered by the mucosa during the healing phase (3 to 8 months), thus a second surgical intervention was necessary to connect the abutments (posts) to the implants. Southern, Steri-Oss and ITI implants were placed according to a non-submerged (one-stage) protocol, i.e. the abutments are directly connected to the implants, thus a second operation was avoided.

Removable overdentures were retained by clip attachments to a bar supported by four implants (Chiapasco 2001; Romeo 2002), or were retained by two unsplinted ball attachments (Tawse-Smith 2002; Payne 2002). Temporary resin bridges were fabricated and then replaced by final metalloceramic restorations in one trial (Romanos 2004).

### **Characteristics of outcome measures**

Prosthesis failures, implant failures and bone level measurements were recorded in all studies. However, in three trials (Chiapasco 2001; Romeo 2002; Romanos 2004) peri-implant bone level measurements were performed on panoramic radiographs and they were not included in the present analyses.

All trials reported on implants functionally loaded for 2 years.

## **Methodological quality<sup>^</sup>**

### **Allocation concealment**

The method of allocation concealment was considered adequate for one trial (Payne 2002), unclear for two trials (Tawse-Smith 2002; Romanos 2004). No allocation concealment was used in two trials (Chiapasco 2001; Romeo 2002).

### **Blinding**

In four studies patients could not be blinded, but outcome assessors were blinded (Chiapasco 2001; Tawse-Smith 2002; Payne 2002; Romeo 2002). Such information was supplied by the authors. In one trial the assessor could not be blinded (Romanos 2004).

### **Completeness of follow up**

Only two withdrawals occurred in one study in the conventional loading group before 1 year of loading (Payne 2002). Reason for these withdrawals was emigration.

## Sample size

No a priori sample size calculation was performed in any of the trials.

## Randomization

In two trials ([Tawse-Smith 2002](#); [Payne 2002](#)) the randomization was generated using a table of random numbers and was considered adequate. The randomization procedure was judged to be inadequate for two trials where this was done by 'drawing lots' for the allocation group by another person other than the operator ([Chiapasco 2001](#); [Romeo 2002](#)). The randomization procedure remained unclear after author's reply in one study ([Romanos 2004](#)).

## Inclusion and exclusion criteria

All trials used quite strict inclusion criteria and included only ideal patients but this choice is understandable since it is common sense to load implants immediately or early only in selected cases. All implants were placed in edentulous mandibles and were at least 10 mm long.

### *Main inclusion criteria*

- Completely edentulous mandible ([Chiapasco 2001](#); [Tawse-Smith 2002](#); [Payne 2002](#); [Romeo 2002](#)).
- 13 to 15 mm of residual anterior mandibular bone or more ([Chiapasco 2001](#); [Tawse-Smith 2002](#); [Payne 2002](#)).
- 10 mm of residual anterior mandibular bone or more ([Romeo 2002](#)).
- 11 mm of residual posterior mandibular bone in height and 6 mm in width or more ([Romanos 2004](#)).
- Elderly patients (55 to 80 years) ([Tawse-Smith 2002](#); [Payne 2002](#)).
- Bilaterally free-end lower jaws distal to canines or premolars ([Romanos 2004](#)).

### *Main exclusion criteria*

- Any evidence of current or previous smoking ([Tawse-Smith 2002](#); [Payne 2002](#)).

- Smoking more than 10 cigarettes per day ([Chiapasco 2001](#)).
- Smoking more than 20 cigarettes per day ([Romeo 2002](#)).
- Any systematic disease likely to compromise implant surgery ([Chiapasco 2001](#); [Tawse-Smith 2002](#); [Payne 2002](#); [Romeo 2002](#); [Romanos 2004](#)).
- Previously bone grafted bone jaws ([Tawse-Smith 2002](#); [Payne 2002](#)).
- Previously irradiated jaws ([Chiapasco 2001](#); [Tawse-Smith 2002](#); [Payne 2002](#); [Romeo 2002](#); [Romanos 2004](#)).
- Bone quality type IV (very soft bone) according to the classification of [Lekholm 1985](#) detected at the time of surgery ([Chiapasco 2001](#); [Tawse-Smith 2002](#); [Payne 2002](#); [Romeo 2002](#)).
- History of bruxism ([Tawse-Smith 2002](#); [Payne 2002](#)).
- Severe clenching or bruxism ([Chiapasco 2001](#); [Romeo 2002](#)).
- Severe maxillomandibular skeletal discrepancy ([Chiapasco 2001](#); [Romeo 2002](#)).

### **Success criteria**

All studies used validated success criteria.

### **Comparability of control and treatment group at entry**

In general, the various groups were comparable at entry with the exception of [Tawse-Smith 2002](#) where the early loaded implants (both Steri-Oss and Southern) seemed to be shorter than those in the conventionally loaded groups. The clinical significance, if any, of this finding is difficult to interpret.

There was disagreement on one of the five included studies for each of the three methodological quality items rated by the two assessors. In all cases we were unable to calculate kappa due to a constant value for one assessor for one item and unsymmetrical tables for the other two. There was 80% agreement between assessors for all three items.

The agreed quality of the included trials after having incorporated the information provided by the authors is summarized in 'Additional table 1'. For each trial we assessed whether it was at low, medium or high risk of bias. Four



studies were rated as at high risk of bias and only one study of low risk of bias ([Payne 2002](#)).

## Results <sup>^</sup>

In total 376 implants were originally placed in 124 edentulous mandibles in the five trials. Of the placed implants, 116 were immediately loaded, 72 were early loaded and 188 were conventionally loaded. During the follow up considered in this review (1 year of function) 11 implants failed. One of the failed implants was immediately loaded, seven were early loaded and three conventionally loaded. Of the 136 placed restorations, only six (or four depending on the success criteria adopted) failed. They were all in one study ([Tawse-Smith 2002](#)) and five (or three) were early loaded.

The meta-analysis for prosthesis failures, implant failures and marginal bone level changes at 1 year are presented in MetaView 'Comparisons 01 to 02'.

### **Immediate loading versus conventional loading(Outcome 01)**

Three trials were included ([Chiapasco 2001](#); [Romeo 2002](#); [Romanos 2004](#)) and all were assessed as at high risk of bias.

- One trial ([Chiapasco 2001](#)) with a parallel design compared four immediately loaded (2 to 3 days) Branemark implants with four conventionally loaded (4 to 8 months) implants supporting overdentures in totally edentulous mandibles of adequate shape and quality for 2 years. Ten patients were originally included in each group. No baseline differences were apparent for sex, age, and length of the implants used between the two groups. No withdrawals occurred during the period considered for this review (1 year). One implant failed in each group. Considering the patients as the unit of analyses, there was no statistically significant difference for prosthesis or implant failures between the different loading strategies after 1 year of function (Comparison 01, Outcomes 01 and 02).

- One trial ([Romeo 2002](#)) with a parallel design compared four immediately loaded (2 days) ITI SLA implants with four conventionally loaded (3 to 4 months) implants supporting overdentures in totally edentulous mandibles of adequate shape and quality for 2 years. Ten patients were originally included in each group. No withdrawals occurred during the period considered for this review (1 year). One implant failed for peri-implantitis in the conventionally

loaded group. Considering the patients as the unit of analyses, there was no statistically significant difference for prosthesis or implant failures between the different loading strategies after 1 year of function (Comparison 01, Outcomes 01 and 02).

- One trial ([Romanos 2004](#)) with a split-mouth design compared three immediately loaded (same day) Ankylos implants with three contralateral conventionally loaded (3 months) implants in mandibles partially edentulous distal to the canines or premolars for 2 years. Twelve patients were originally included. No baseline differences were apparent for bone quality between the contralateral sites. No withdrawals occurred during the period considered for this review (1 year). No implant failed. Considering the patients as the unit of analyses, there was no statistically significant difference for prosthesis or implant failures between the different loading strategies after 1 year of function (Comparison 01, Outcomes 01 and 02).

A meta-analysis of these trials could only be conducted for implant failure, although the relative risk for [Romanos 2004](#) was not estimable. There was no significant difference in implant failure with RRrandom effects 0.63 (95% CI 0.09 to 4.67), however this was based only on three failures in a total of 40 patients and the two included trials were both assessed as at high risk of bias.

### **Early loading versus conventional loading (Outcome 02)**

Two trials were included ([Tawse-Smith 2002](#); [Payne 2002](#)), one was assessed at high risk of bias ([Tawse-Smith 2002](#)), the other at low risk of bias ([Payne 2002](#)).

- One trial ([Tawse-Smith 2002](#)) with a parallel design compared two early loaded (6 weeks) Southern or Steri-Oss implants with two conventionally loaded (12 weeks) implants supporting overdentures in totally edentulous mandibles of adequate shape and quality for 2 years. Twelve patients were originally included in each of the four groups (Southern early loaded, Steri-Oss early loaded, Southern conventionally loaded, Steri-Oss conventionally loaded). There were no apparent baseline differences in bone quality and quantity between the two groups. However, the implants of both the Steri-Oss and Southern early loaded groups were shorter than those in the conventionally loaded groups. In the article Steri-Oss implants were described as having a turned surface, but after having analyzed the surface of one implant, kindly provided by the authors, it was realized that the implant surface was chemically treated. No withdrawals occurred during the period considered for this review (1 year). Seven Steri-Oss implants failed in five

patients of the early loaded group versus one Steri-Oss implant failed in the conventionally loaded group. No implants failed in the Southern groups. Most of the failed implants were placed by a surgeon who only placed some Steri-Oss implants. Considering the patients as the unit of analyses, there were no statistically significant differences for prosthesis failures, implant failures and marginal bone loss between the implants loaded at different time points after 1 year of function (Comparison 02, Outcomes 01, 02, 03).

- One trial ([Payne 2002](#)) with a parallel design compared two early loaded (6 weeks) ITI SLA implants with two conventionally loaded (12 weeks) implants supporting overdentures in totally edentulous mandibles of adequate shape and quality for 2 years. Twelve patients were originally included in each groups. There were no apparent baseline differences in gender, bone quality and quantity between the two groups. Two withdrawals occurred from the conventionally loaded group during the period considered for this review (1 year). No implant failed. Considering the patients as the unit of analyses, there were no statistically significant differences for prosthesis failures, implant failures and marginal bone loss between the implants loaded at different time points after 1 year of function (Comparison 02, Outcomes 01, 02, 03).

A meta-analysis was conducted for marginal bone level changes. There was no significant difference for marginal bone level changes with WMDrandom effects -0.04 (95% CI -0.15 to 0.07) and this was based on one trial assessed as at low risk of bias and one trial assessed as at high risk of bias.

## Discussion<sup>^</sup>

The question of whether implants could be immediately loaded after their insertion has relevant clinical implications since the treatment period could be drastically reduced for the benefit of the patients. The main outcome for these type of studies is the success of the prosthesis since implant loss may not always jeopardize prosthesis success. It was decided to consider only a relatively short follow up (1 year) since it was felt that other confounding factors such as the implant characteristics and the quality of maintenance might have an important influence on longer follow-up periods.

No statistically significant differences for prosthesis success, implant success and marginal bone levels were observed when different loading regimens were applied. It should be recognized that no trials undertook a priori sample size calculation. The number of trials and patients was definitively too low to draw any reliable conclusions. For instance in the early loaded group

with Steri-Oss implants seven implants in five patients failed out of 24 implants (12 patients) (Tawse-Smith 2002). Since those overdentures were supported by two implants, the loss of a single implant should have determined the failure of the entire treatment. The author of the study (Tawse-Smith 2002), acting as one of the referees of this review, argued that it is possible to have a successful treatment only with one implant as observed in two of their patients. While this may be true, it is not a common procedure and many clinicians and patients may not be fully satisfied with the result. If we consider an overdenture supported by a single implant as a failure, then the loss of five overdentures out of 12 may have some important clinical implications. On the other hand, other confounding factors might have played a determinant role in the final outcome such as the surgical skill of one operator who just placed Steri-Oss implants and that accounted for almost all the failures or the presence of shorter implants in the early loaded group. Other aspects that should be considered are the role of the implant characteristics (i.e. surface roughness, shape and materials) and the timing of loading (immediate versus early loading). However, there is too little reliable data at present to provide evidence-based recommendations.

From a methodological perspective, the allocation concealment process was not properly conducted in four out of five trials included in this review. This meant that four of the five included trials were assessed as at high risk of bias. This aspect of trial designing and reporting needs to be improved since it has been shown that randomized controlled trials (RCTs) where allocation concealment procedures were inadequately conducted tended to overestimate treatment effects (Schulz 1995a; Schulz 1995b).

The generalization from the results of the included trials to clinical practice should be made with extreme caution. In these trials, the inclusion criteria were strict and only patients known to be ideal candidates for implant treatment were carefully selected (mandibles with good bone quality and height). On the other hand, it has been shown that in selected patients it is possible to load immediately oral implants with good success rates. However, the actual effectiveness of immediate and early loading protocols when compared to conventional loading remains to be established.

## **Authors' conclusions** <sup>^</sup>

### Implications for practice <sup>^</sup>

While it is possible to successfully load oral implants immediately after their placement in mandibles of adequate bone density and height of carefully

selected patients, it is yet unknown how predictable this approach is.

### Implications for research<sup>^</sup>

More well designed randomized controlled trials (RCTs) are needed to understand how predictable the protocols for immediate and early loading are. Such trials should be simply designed and reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Moher 2001) (<http://www.consort-statement.org/>). It is suggested that priority should be given to trials assessing the effectiveness of immediately loaded implants rather than early loaded ones.

### Potential conflict of interest<sup>^</sup>

None known.

### Acknowledgements<sup>^</sup>

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### Characteristics of included studies<sup>^</sup>

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## **Characteristics of excluded studies** [^](#)

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## **Characteristics of ongoing studies** [^](#)

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Table. No caption available.

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## **Additional tables** [^](#)

Table 01

## **Analyses** [^](#)

Comparison 01

Comparison 02

## **Sources of support** [^](#)

### External sources of support [^](#)

- \* The Hjelmar Svensson Foundation SWEDEN
- \* Swedish Medical Research Council (9495) SWEDEN
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### Internal sources of support [^](#)

- \* Sahlgrenska Academy at Goteborg University SWEDEN
- \* University Dental Hospital of Manchester UK

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Comparison 01 Immediate versus conventional loading, Outcome 01  
Prosthesis failure

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Comparison 01 Immediate versus conventional loading, Outcome 02 Patients  
with implant failure

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Comparison 02 Early versus conventional loading, Outcome 01 Prosthesis  
failure

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Comparison 02 Early versus conventional loading, Outcome 02 Patients with  
implant failure

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Comparison 02 Early versus conventional loading, Outcome 03 Marginal bone  
level changes

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Table 01. Results of quality assessment after correspondence with authors

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Comparison 01. Immediate versus conventional loading

## Comparison 02. Early versus conventional loading

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### **Contribution of Reviewer(s)** <sup>^</sup>

Conceiving, designing and co-ordinating the review (Marco Esposito (ME)).

Developing search strategy and undertaking searches (ME, Paul Coulthard (PC)).

Screening search results and retrieved papers against inclusion criteria (ME, PC).

Appraising quality and extracting data from papers (ME, Helen Worthington (HW)).

Writing to authors for additional information (ME, HW).

Data management for the review and entering data into RevMan (HW, ME).

Analysis and interpretation of data (ME, HW).

Writing the review (ME).

Providing general advice on the review (PC, HW, Peter Thomsen (PT)).

Performing previous work that was the foundation of current study (ME, HW, PC).

### **Most recent changes** <sup>^</sup>

We have updated the review and added three new included studies (Payne 2002; Romeo 2002; Romanos in press).

We have added to the Methods of the review section the following possible subgroup analyses to be conducted in the future if appropriate data become available:

- (1) Whether implants were placed in mandibles or maxillae.
- (2) Whether implants were placed in partially or fully edentulous jaws.
- (3) Whether implants were placed in the anterior or posterior jaw.



(4) Different number of inserted implants (for instance overdentures supported by two versus overdentures supported by four implants).

(5) Whether turned (machined) or implants with a roughened surface were used.

(6) Whether the trial was supported by implant manufacturer(s) or not.

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### References to studies included in this review <sup>^</sup>

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Romanos GE. Immediate loading of implants in the posterior mandible. A 2-year prospective study. *Journal of Periodontology* 2004; Vol. in press.

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## **References to ongoing studies <sup>^</sup>**

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Naert I, et al. Personal communications. [[Context Link](#)]

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ORAL HEALTH; Oral & Maxillofacial surgery; Implants/prostheses; Humans; Bone Density; \*Dental Implantation, Endosseous; Dental Implants; Mandible/pg (physiology); Materials Testing; Randomized Controlled Trials; Time Factors; \*Tooth Loss/sg (surgery)

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