

Invited Review Paper Pre-Implant Surgery

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What is the quality of the evidence base for pre-implant surgery of the atrophic jaw?[☆]

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Abstract. This review aimed to evaluate the level of evidence for bone augmentation preimplant surgery for atrophic jaws in studies which measure outcome. Medline, Embase, Cochrane library and online journal searches were performed with a defined search strategy and the abstracts screened against selection criteria. The resultant papers were sorted by study design using the Cochrane study design algorithm, analysed for clinical/statistical homogeneity and graded with the Oxford Centre of Evidence-based Medicine levels of evidence. The initial online Medline search yielded 1194 results and the Embase search yielded 490 results. Using the selection criteria, 10 studies were identified. Additionally, 5 articles were identified from bibliography and online searches, giving a total of 15 studies for grading. All 15 studies were graded as level 4 evidence. No meta-analysis of outcomes was possible with the low level of evidence and degree of heterogeneity found. The best grade of recommendation that can be made for a particular preimplant surgical bone augmentation procedure, from these level 4 studies, is Grade C. Benchmarking studies by assessing quality of evidence can be helpful to inform future study designs with respect to reporting study outcomes with a higher level of evidence.

Preimplant surgery can be defined as surgery to allow for favourable endosteal implant placement of optimal size and position. This ensures the best possible implant-associated prosthetic rehabilitation and applies to any situation where implants may be required to restore dental function and appearance. This includes patients that are edentulous, partially dentate and patients with hard or soft tissue deficits due to disease, trauma or deformity. This review focuses on bone augmentation of the atrophic jaw, the commonest indication for preimplant surgery.

Following the introduction of endosteal implants, a large volume of literature has been published in relation to preimplant surgery and many assertions have been made. The quality of this literature varies and it is sometimes difficult to draw firm conclusions or to make recommendations for best practice in preimplant surgery. Recommendations about interventions should be based on well-designed studies, Keywords: preimplant surgery; preprosthetic surgery; surgery; oral; endosteal implants; dental implants; osseointegrated implants; evidence-based medicine; review; rehabilitation; procedures; maxillofacial.

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implying that the quality of individual studies needs to be assessed and in such a way that is seen to be valid. One such method is to use the Oxford Centre of Evidence-based Medicine (CEBM) levels of evidence²³ (Tables 1 and 2).

The aim of this review was to apply the CEBM system to evaluate the level of evidence for bone augmentation preimplant surgery for atrophic jaws in studies that measure outcome. The intent was to benchmark the best studies to date in this area against a recognised system of measuring strength of evidence. It was not the

^{*} This paper was prepared at the invitation of the executive committee of the International Academy for Oral and Facial Rehabilitation⁶.

| Table 1. | Centre | of | Evidence | Based | Medicine | criteria | for | levels | of | evidence | for | therapeutic |
|------------|----------------------|----|----------|-------|----------|----------|-----|--------|----|----------|-----|-------------|
| interventi | ions ²³ . | | | | | | | | | | | |

| Level | Therapy | | | | | | | |
|-------|---|--|--|--|--|--|--|--|
| 1a | Systematic review (with homogeneity [*]) of randomised controlled trials (RCTs) | | | | | | | |
| 1b | Individual RCT (with narrow Confidence Interval) | | | | | | | |
| 1c | All or none [§] | | | | | | | |
| 2a | Systematic review (with homogeneity [*]) of cohort studies | | | | | | | |
| 2b | Individual cohort study (including low quality RCT; e.g., <80% follow-up) | | | | | | | |
| 2c | 'Outcomes' research; ecological studies | | | | | | | |
| 3a | Systematic review (with homogeneity [*]) of case-control studies | | | | | | | |
| 3b | Individual case-control study | | | | | | | |
| 4 | Case-series (and poor quality cohort and case-control studies ^{§§}) | | | | | | | |
| 5 | Expert opinion without explicit critical appraisal, or based on physiology, | | | | | | | |
| | bench research or "first principles" | | | | | | | |

*By homogeneity the authors mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. Studies displaying worrisome heterogeneity should be tagged with '-' at the end of their designated level.

[§] Met when all patients died before the treatment became available, but some now survive on it; or when some patients died before the treatment became available, but none now die on it.

^{§§} By poor quality cohort study the authors mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study the authors mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.

Table 2. Grades of recommendation from Centre for Evidence Based Medicine²³.

| A | consistent level 1 studies |
|---|---|
| В | consistent level 2 or 3 studies or extrapolations from level 1 studies |
| С | level 4 studies or extrapolations from level 2 or 3 studies |
| D | level 5 evidence or troublingly inconsistent or inconclusive studies of any level |

intention to carry out a meta-analysis on reported outcomes from studies selected in this review, unless they were studies providing high levels of evidence.

Material and methods

Medline, Embase and Cochrane library searches were performed in May 2006 using a modification of the search strategy of the Cochrane review by COULTHARD et al.⁹ to include a search for the term 'bone graft' in line 37 (Fig. 1). On the advice of a librarian from the British Medical Association, modifications were made to line 11 of the search changing '(ANIMAL not HUMAN)sh.' to 'ANI-MAL/not HUMAN/', and line 33 was changed from 'prosthes*' to 'prosthes#s'. Where the websites were enabled, the following 42 journals were searched for the keywords 'prospective', 'randomized'/ 'randomised' and 'implant': Adv Dent Res, Ann Perio, Ann Plast Surg, Arch Oral Biol, Br Dent J, Br J Oral Max Surg, Br J Plast Surg, Chin J Dent Res, Clin Impl Dent Rel Res, Clin Oral Impl Res, Clin Oral Investig, Compendium, Crit Rev Oral Biol Med, Dent Clin N Amer, Eur J Dent Educ, Eur J Oral Sci, Eur J Plast Surg, Implant Dent, Int J Oral Max Impl, Int J Oral Max Surg, Int J Prosthod, J Am Dent Ass, J Clin

Period, J Craniofac Surg, J Craniomax Surg, J Dent, J Dent Res, J Evid-based Dent Pract, J Oral Impl, J Oral Max Surg, J Oral Rehabil, J Periodont, J Prosthet Dent, J Prosthodont, Odontol, Oral Biosci Med, Oral Health & Prevent Dent, Oral Max Surg Clin N Am, Oral Oncol, Oral Radiol, Oral Surg Oral Med Oral Path Oral Rad & Endo, Quintessence International.

The abstracts and, where necessary, full-text articles were then screened on two separate occasions by one reviewer (TKB) applying the following selection criteria, which were devised by the authors: randomised controlled clinical trials, longitudinal cohort studies, case controls and case series both prospective and retrospective; patients with atrophic or severely atrophic jaws: maxilla, mandible or both; patients undergoing bony augmentation surgery; follow-up duration of ≥ 3 years³⁵; ≥ 10 subjects; minimum outcome measures including a report on either (or both) of the following: implant loss and/or implant failure and prosthesis failure due to implant failure.

The subset of studies fulfilling the selection criteria were then divided into studies of preimplant surgery for the maxilla or for the mandible and graded using the Oxford Centre for Evidence-based Medicine Levels of Evidence 2001 (Tables 1 and 2^{23} . The 'therapy' level of evidence CEBM template was judged to be the appropriate classification for preimplant surgery studies. For this purpose, it was necessary to classify each non-randomised study as a case series, case-control or cohort study using the Cochrane design algorithm for studies of healthcare interventions³⁰. It was then necessary to evaluate the quality of each cohort or casecontrol study according to CEBM definitions. The four main CEBM parameters (Table 1, superscript \S) that determine whether a case-control or cohort study is good quality are that: comparison groups should be clearly defined; exposures and outcomes should be measured in the same standard (ideally blinded) objective way in both exposed and non-exposed individuals; known confounders should be identified or appropriately controlled (the minimum confounders considered of sufficient importance to be reported in the published studies were: smoking status, age, gender, radiotherapy or chemotherapy treatment, application of an atrophic jaw classification); the follow-up of patients should be sufficiently long and complete (the authors interpreted this definition as if it was stated that: the subjects were recruited consecutively; with explanations as to why any subjects were

Table 3. The following methodological or outcome data were charted.

- Edentulous or partially edentulous status of subjects
- Number of subjects and implants placed
- Type of preimplant surgery performed
- 1 or 2 stage implant placement i.e. immediate with bone augmentation (1 stage) or interval implant placement following bone augmentation healing (2 stage)
- Delayed or immediate implant loading
- Bone graft failure
- Type of implant system used
- Type of prosthetic rehabilitation
- Mean bone graft height loss (magnification-adjusted orthopantomogram)
- Mean implant marginal bone loss (using the long cone paralleling technique)
- Use of resonance frequency analysis in objectively recording implant stability
- Method of calculating implant survival/success rates (e.g. absolute/life table/Kaplan–Meier analysis¹⁴)
- Statistical analyses used and whether these were patient-based or implant-based
- Patient satisfaction or quality of life data

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