

Systematic Review of the Evidence Supporting Intra-Oral Maxillofacial Prosthodontic Care

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Abstract - *The literature on maxillofacial prosthodontics may be considered to be dominated by articles describing case reports or case series. Prospective, well-controlled clinical trials are scarce owing to the inherent difficulty of performing such trials in patients suffering from oral cancer. The aim of this study was to perform a systematic review of the literature relating to intra-oral maxillofacial prosthodontics based on the principles of evidence-based dentistry. A detailed report of the findings is presented and critically assessed and a discussion of the outcome in respect to the various confounding factors is carried out. Finally, suggestions for future research in the field of maxillofacial prosthodontics are made.*

KEY WORDS: Maxillofacial prosthodontics, Oral cancer, Dental implantation

INTRODUCTION

Oral cancer is a disease which is malignant and life-threatening. Post-operative rehabilitation and the associated follow-up can extend up to several years especially if adjuvant procedures are included in the rehabilitation process. The principal objectives of the rehabilitative treatment, regardless of the restorative modality followed, remain the same as in conventional, non-cancer cases, i.e. the restoration of basic oral functions (e.g. eating, speaking and swallowing) to an acceptable level. The choice of restorative approach (surgical and/or prosthetic) should, ideally, rely upon evidence-based practice combined with personal skills although this is not always the case^{1,2}.

A Quality of Life (QoL) deficit may be defined as the gap existing between one's physiological, psychological, social and functional status and one's ideal standard. QoL measures are intrinsically subjective and based on each patient's perceptions³. Functional status refers to the ability of a person to perform daily task related to self-care, mobility, physical activity and roles inside work environment or family⁴. The number of measures available for evaluating quality of life usually indicates the level of functioning and disability. On the other hand, patients themselves see their subjective satisfaction rather than their level of functioning as being more important⁵. Therefore, the determination of the quality of life of the head and neck cancer patient should involve the assessment of both the general factors of psychosocial functioning and physical well being as well as the specific functional aspects of the upper aero-digestive tract and the oral cavity. It is clear that the functional assessment criteria and tests used, contribute to the estimation of the latter.

Measuring the quality of life of oral cancer patients through functional assessments tests and standardised general and disease-specific questionnaires should be a vital part in a well-designed evidence based study on intra-oral maxillo-

facial prosthodontics^{6,7}. The ideal would be that these patients would complete the same type of questionnaires prior to the diagnosis of cancer so that there can be a comparison and statistical analysis of the data given before and after the incident of the disease. Regrettably, this has not been hitherto reported. Several studies on quality of life, however, have advocated a comparison of the results from the group of cancer patients with those from a matched control group⁸. Another approach to the investigation of quality of life is analysing the results from the questions administered to the patients before the surgical treatment with the results obtained when patients completed the treatment and during a follow-up period⁹. A third approach is that of assessing the quality of life of patients before and after the fabrication of a prosthesis¹⁰.

Functional assessment carries with it the inherent concept of accountability. Therefore, it should be easier for the maxillofacial prosthodontist to decide which treatment would generate the most successful outcome for the patient. In addition, accountability to the referral source and any possible third-party payers in the health industry is achieved, as may be the ability to judge the quality and effectiveness of care provided^{6,11}.

Evidence-based practice is closely connected to the need for a valid list of functional assessment criteria, as the latter is a powerful means for establishing the effectiveness of individual patient treatment. Evidence-based dentistry is achieved through careful examination of well-conducted controlled trials and the application of their results onto each separate case. Therefore the necessity for Randomised Control Trials (RCTs) that focus on treatment evaluation is apparent. However, RCTs are expensive to conduct, difficult to blind, often require limited inclusion criteria or are ethically impossible to undertake¹². This being the case, particularly for RCTs on oral cancer patients, one has to seek the next best study design to rely on for evidence.

The aim of this study was to carry out a systematic review of the research literature on intra-oral prosthesis prescribed for patients following surgical removal of

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Table 1. *The combination of MeSH terms (in capitals) and free-text words (in lower case) used in the electronic database search.*

1	exp MAXILLOFACIAL PROSTHESIS/
2	exp MAXILLOFACIAL PROSTHESIS IMPLANTATION/
3	exp PALATAL OBTURATORS/
4	maxillofacial\$. mp.
5	maxillofacial\$. mp.
6	mandibular\$. mp.
7	palatal\$.mp.
8	(implant\$ or prosthesis\$ or obturator\$). mp.
9	(4 or 5 or 6 or 7) and 8
10	1 or 2 or 3 or 9

maxillofacial tumors, utilizing an evidence based practice approach. The selected papers that fulfilled the inclusion criteria of this review were then assessed for their quality and statistical significance of their findings and screened for evaluation of treatment outcomes.

MATERIALS AND METHODS

The Cochrane Library (including the Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effectiveness (DARE), Controlled Clinical Trials Register (CCTR) and Medline (from 1993 to May 2002) were searched. A combination of MeSH (Medline Subject Headings) terms and free text terms was used when searching each database. The strategy shown in *Table 1* was used for Medline (Ovid), and adapted accordingly for the Cochrane Library. A handsearch of the *Journal of Prosthetic Dentistry* was carried out covering the issues from 1993 onwards. The results were checked against the electronic search to demonstrate the sensitivity of the electronic search strategy. Papers were restricted to English language. All databases were searched from 1993 onwards. This cut-off point was chosen for several reasons. Firstly, this field of dentistry has developed rapidly in the past 10 years. This is partially attributable to the fact that studies on implant placement in this group of patient are relatively new. Thus, the introduction of implants to this specific area of dentistry has led to a great deal of research in the past ten years. Secondly, this specific year was chosen in order to contain the volume of the literature into a manageable size.

The type of studies included in the review comprised:

- Systematic reviews
- Randomised Controlled Trials
- Quasi-Experimental Studies
- Before-and After-Design Studies
- Cross-sectional Studies
- Cohort Studies
- Case Control Studies.

All of these study designs on maxillary, mandibular, implant-or non-implant – supported intraoral prosthesis/es were retrieved.

The exclusion criteria included those studies reporting on:

- case series and case reports
- materials and pigments used to fabricate these prosthesis
- reports on histological aspects of osseointegration of oral implants
- studies that assessed oral and psychological function

without taking into consideration the prosthetic treatment modality used

- surgical procedures alone for oral reconstruction of cancer patients

Each publication was first classified according to the inclusion criteria using the abstract. When the abstract was not available or failed to provide sufficient information, a reprint of the paper was obtained and read. Once studies on maxillary, mandibular, implant-or non-implant-supported intraoral prosthesis fabricated after ablative oral tumour surgery were identified, they were all put together and any duplicates were excluded.

To enable this review to draw useful conclusions on the retrieved articles, a quality assessment of each article was performed. The rationale behind the decision for assessment of papers was the fact that differences in quality between studies may indicate that the results of some studies are more biased than the results of others¹³. Every paper that fulfilled the selection criteria and was determined to be relevant to the aim of the study was assessed using the quality assessment criteria checklist suitable for its design (*Table 2*). The criteria were selected in a manner that a “yes or no” answer was needed for each of them. If unclear or insufficient information was provided on a specific criterion, then a “no” answer was chosen. A total score for each study was calculated by dividing the number of positively scored criteria by the total of quality criteria used for the paper, the outcome being expressed as a percentage.

The types of qualitative and quantitative studies reviewed are listed in *Table 3*.

RESULTS

The search in the Cochrane Library (including CDSR, DARE and CCTR) failed to yield any studies related to the subject of this review. The final search in MEDLINE produced 1889 papers. The abstracts were assessed and the relevant papers were narrowed down to 85. These included all study designs on intraoral maxillofacial prosthesis. Copies of the papers were obtained. Before reading the papers, their references were screened for relevant non-retrieved papers. The search produced another 50 papers. Their abstracts were read and it was decided to retrieve only 31 of them. All the retrieved papers were read. The handsearch of the *Journal of Prosthetic Dentistry* did not produce any studies that were not already identified either as relevant or not relevant by the electronic search. Out of a total of 116 papers, 23 (19.8%) were identified as relevant. *Table 4* presents the

Table 2. *Quality assessment criteria list.*

FOR RCTs AND QUASI-EXPERIMENTAL STUDIES

1. Was the assignment to the treatment groups really random? (Y/N)
2. Was the treatment allocation concealed? (Y/N)
3. Were the groups similar at baseline in terms of prognostic factors? (Y/N)
4. Were the eligibility criteria specified? (Y/N)
5. Were outcome assessors blinded to the treatment allocation? (Y/N)
6. Was the care provider blinded? (Y/N)
7. Was the patient blinded? (Y/N)

FOR BEFORE- and AFTER- DESIGN STUDIES

1. Does the paper address a clearly focused issue? (Y/N)
2. Are the tables/graphs adequately labelled and understandable? (Y/N)
3. Are the inclusion/exclusion criteria given? (Y/N)
4. Were all the important outcomes and results considered? (Y/N)
5. Is there a suitable statistical analysis employed in this study? (Y/N)
6. Can the results be applied to the local situation? (Y/N)

FOR COHORT STUDIES

1. Was follow-up long enough for the outcomes to occur? (Y/N)
2. Are the groups assembled at a similar point in their disease progression? (Y/N)
3. Is there sufficient description of the groups and the distribution of prognostic factors? (Y/N)
4. Is the intervention/treatment reliably ascertained? (Y/N)
5. Were the groups comparable on all-important confounding factors? (Y/N)
6. Was outcome assessment blind to exposure status? (Y/N)

FOR CASE-CONTROL STUDIES

1. Is the case definition explicit? (Y/N)
2. Were interventions and other exposure assessed in the same way for cases and controls? (Y/N)
3. Was an appropriate statistical analysis used (matched or unmatched)? (Y/N)
4. Has the disease state of the cases been reliably assessed and validated? (Y/N)
5. Are the cases and controls comparable with respect to potential confounding factors? (Y/N)

FOR CROSS-SECTIONAL STUDIES

1. Does this paper address a clearly focused issue? (Y/N)
2. Is the population studied appropriate? (Y/N)
3. Is confounding and bias considered? (Y/N)
4. Are tables/graphs adequately labelled and understandable? (Y/N)
5. Were all-important outcomes/results considered? (Y/N)

Table 3. *Types of qualitative and quantitative tests used in the retrieved studies.*

	<i>Cohort studies</i>	<i>Case control studies</i>	<i>Cross-sectional studies</i>	<i>Before-after-design studies</i>
Qualitative tests	Cheek and tongue function test. Questionnaires on food scale and prosthesis function. Speech intelligibility test.	Tongue function test. Questionnaires on food scale, prosthesis quality and quality of life. Speech intelligibility test.	Visual analogue scale for prosthesis function. Questionnaires on masticatory function, prosthesis function and quality of life. Perceptual test of hypernasality. Food comminution test.	Speech intelligibility test
Quantitative tests	Area of occlusal contact test. Chewing gum method test. Bite force test. Number of teeth/tooth stops.	Masticatory force test. Number of occlusal contacts. Maximum mouth opening test.	Acoustic analysis of hypernasality test.	None used.

Table 4. *Classification of the results of electronically searched databases by type of relevant studies.*

<i>Study design</i>	<i>Systematic reviews</i>	<i>Randomised control trials</i>	<i>Quasi-experimental studies</i>	<i>Cohort studies</i>	<i>Case-control studies</i>	<i>Cross-sectional studies</i>	<i>Before-after studies</i>	<i>Total</i>
Number of retrieved papers	0	0	0	10 (43.5%)	5 (21.8%)	6 (26%)	2 (8.7%)	23 (100%)

results of the search related to relevant study designs while *Table 5* lists the results of mean quality assessment results of each study type.

Six cross-sectional studies¹⁴⁻¹⁹ were identified, the earliest been published in 1994 and the latest in 2000. There

was a detailed report on the prostheses used for rehabilitation in five out of six studies. Treatment outcome for the oral cancer patient rehabilitated with a prosthesis was evaluated in five out of six papers (83%) using mainly qualitative assessment tests in the form of questionnaires and scales. Only one paper reported the use of a quanti-

Table 5. Results of quality assessment of types of study.

Type of study	Mean score (%)
Cohort	56.4
Case-control	64
Before-and-after	75
Cross-sectional	93.3

Table 6. List of factors with a significant/non-significant impact on outcome of treatment.

Type of factor	List of factors	Reference(s)
Significant factors	Age	16,37,38
	Marital status	3
	Smoking	39
	Site/extent of resection and oncological stage of lesion	3,5,14,38,40-44
	Site of implant placement	39,45-48
	Type of surgical reconstruction	26,29,32,35,36,41,42,49,50-52
Non-significant factors	Type of prosthetic reconstruction	14,15,17,21,23,25,28,49,53,54
	Gender	16
	Economic/social background	3
	Radiotherapy	31,38,43,44,55-58
	Hyperbaric oxygen therapy	19,55,56,59,60
	Implant system used	30,61

tative test in the functional assessment of the rehabilitated oral cancer patients¹⁸. Quality assessment of the six papers revealed a score of 5/5 (100%) for four out of the six while the remaining two scored a total of 4/5 (80%).

Five of the retrieved papers were of a case-control study design²⁰⁻²⁴. The earliest year of publication was 1994 and the latest was 1999. In three (60%) of the studies, the control group comprised "healthy" individuals. The term "healthy" referred to the absence of any detected malignancies or surgical defects in the oral cavity of the individuals involved and not to their general health status, on which no further data were given. In the remaining two papers, the control group was oral cancer patients for whom a surgical or restorative approach different from that of the cases had been chosen. Generally, matching between cases and controls in terms of confounding factors was either incomplete or non-existent. The outcomes of the treatments were evaluated in all five of the retrieved case-control studies. Quantitative assessment tests were utilized in only one²⁰ of the five studies whereas qualitative assessment was performed in all five studies. Quality assessment of the papers was conducted using the criteria list in *Table 2*. According to this list, four (80%) papers scored a total of 3/5 (60%) and one scored a total of 4/5 (80%) in the quality assessment process. The results of the quality testing are listed in *Table 3*.

Two papers were identified as before-after-design studies²⁵⁻²⁶. In both studies every participant was examined twice, with or without his/her prosthesis in place, and each acting together as the case and the control. Treatment outcome evaluation was performed in both studies using a qualitative assessment test (intelligibility of speech). Quality assessment was performed using the criteria list for before-after design studies depicted in *Table 2*. According to this list, one paper scored a total of 3/6 (50%)²⁶ whereas the other scored a total of 6/6 (100%)²⁵.

Ten papers described cohort studies²⁷⁻³⁶. The ideal situa-

tion of having the same follow-up period for both groups being observed existed in only four (40%) of the studies. Half of the papers reported having performed treatment outcome evaluation in which qualitative or quantitative tests were employed. The quality assessment for each study was performed using a well-established criteria list for cohort studies (*Table 3*). There was a large range in scores among the papers. Two papers (20%) scored a total of 2/6 (33%) while four (40%) scored a total of 3/6 (50%). Three studies (30%) had a total quality score of 4/6 (66%) and only one paper scored 100% in the quality assessment process.

The results of this review have determined that some factors would appear to have a significant effect on outcome of treatment while others were not found to be significant; this list is presented in *Table 6*.

DISCUSSION

An electronic search of the literature was conducted using four databases but only papers in the English language were included in the study owing to lack of resources for translation of the non-English papers. This means that there could have been well-controlled studies that were not retrieved and included in this review thus introducing a bias to the integrity of the review. Another problem in systematic reviews in general is the inability to locate studies that concluded with non-significant results. It is perceived to be more likely for a study that proves to have statistical significance between cause and result to be more likely to be published. This is in effect a publication bias. Studies of poor quality may produce different and possibly biased results.

Therefore, it was considered appropriate to incorporate a quality appraisal in this systematic review. The checklist for the assessment was based on the National Health Service Centre for Reviews and Dissemination (CRD) guidance for those carrying out or commissioning reviews. Each item on these checklists received equal weight. The

disadvantage to this approach is that studies with only few yet crucial flaws would still be ranked among the better studies.

While acknowledging this limitation, *Table 5* lists the differences in the mean quality assessment results: cohort studies with 56.4%, case-control studies 64%, before-after-design studies with 75% and cross-sectional studies with the highest mean score of all, 93.3%. Studies with a cohort design are higher in the hierarchy of observational studies and the fact that the quality score of this type of studies is the lowest indicates the difficulty in designing, stratifying and executing an unbiased, well-controlled prospective study with oral cancer patients. In fact, nine out of ten cohort studies were structured in a way that their groups were not comparable for confounding factors. All the case-control studies in this review did not take confounding factors into consideration and one third of the cross-sectional ones did not consider bias introduced from these variables.

On the other hand, before-after-design studies have, by nature, an inherent way of avoiding biases from confounding variables since each patient acts as both the case and the control with the only difference being the application of intervention studied. This is a strong reason why these studies scored high in the quality assessment.

The fact that 66% of the cross-sectional studies in this review accounted for confounding factors is a contribution to the high quality score that this type of studies achieved.

It could well be argued that perhaps the fact that oral cancer is highly malignant in nature contributes to an increased patients' dropout rate. This, plus other patient-related variables can have a confounding effect on the outcome, and thereby influence the results of a study.

The treatment provided to the oral cancer patient is shown to influence the quality of life of the patient and this can be detected if an evaluation of the treatment's outcome is performed. Although more research is needed, it is clear that certain factors have been shown to have a significant impact on the outcome of treatment (*Table 6*).

More research is therefore required to draw positive conclusions on the effect that these factors can have on the treatment and, furthermore, to determine the statistical power of such factors.

In this review, the majority of the papers described the use of qualitative assessment tests, mainly questionnaires, as a mean of treatment evaluation. Although the use of questionnaires is a well-documented means of assessing quality of life, the questionnaires used in these studies were not standardised, but were custom-made questionnaires with no further details available to the reader as to the nature or type of the included items. This is a major disadvantage as it prohibits any comparison or analysis between quality of life's assessment results obtained in different studies.

The size of the study groups in each of the papers assessed was, statistically speaking, small. In small studies, therefore, the controlling of variables through stratification in an attempt to rule-out bias can lead to even smaller size; in effect, the smaller the number of the participants, the weaker the significance of the results.

This is a critical point and highlights the difficulty in carrying out a Cochrane review on this topic, as it covers a variety of diseases, a variety of interventions and, inevitably variety in philosophies among multidisciplinary teams.

The results of this systematic review of the literature suggest that future work on the field of intra-oral maxillofacial prosthodontics should concentrate on the effort to obtain stratified groups of patients, free from bias owing to potential confounding factors, adequate blinding and large, if possible, number of participants. The latter would clearly involve multi-centred trials and to achieve this, co-operation of different treatment centres is essential if multi-centre, well-controlled randomised trials are to be produced.

ADDRESS FOR CORRESPONDENCE

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