Standard of care for the edentulous mandible: A systematic review

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Statement of problem. Implant therapies have increased the range of prostodontic options for the treatment of edentulism. Considering both dentist- and patient-mediated outcomes, a universal treatment intervention for the treatment of the edentulous mandible has not been demonstrated.

Purpose. The purpose of this study was to test the null hypothesis that there is no single standard of care for the edentulous mandible as defined by a specific treatment modality.

Material and methods. A review of the literature was undertaken seeking evidence of a superior intervention for the treatment of the edentulous mandible. A search of the English language peer-reviewed literature was completed using Medline and Google Scholar for the period from 1995 to 2005, focusing on evidence-based research. This was supplemented with a hand search of selected dental journals and textbooks. Longitudinal retrospective studies, longitudinal prospective studies, longitudinal experimental clinical studies, nonrandomized controlled studies, and randomized controlled clinical trials were included for review using a general linear hierarchical classification of studies. Articles that did not focus exclusively on treatment interventions for mandibular edentulism or on the effects of such therapies on the patient were excluded from further evaluation. The search period included articles that were published before the criteria for evidence-based literature were established, but this was not necessarily used to exclude an article. The last search was conducted on September 25, 2005.

Results. The literature demonstrates that the functional demands of edentulous patients are highly variable and that patient treatment responses are individual, vary significantly, and are influenced by psychosocial forces. The literature further demonstrates that patient acceptance of specific treatment modalities is modified by social and cultural influences, financial means, and adaptive capacity. Additionally, patient acceptance of a particular treatment modality is influenced by the educational background, knowledge, and experience of the dental health care provider, as well as by a host of other socioeconomic, regional, cultural, age, and gender influences.

Conclusions. Within the limits of this review, there is no evidence for a single, universally superior treatment modality for the edentulous mandible. Better designed, long-term studies are required to further explore differences in patient acceptance to each treatment intervention for the edentulous mandible. (J Prosthet Dent 2006;95:71-8.)

CLINICAL IMPLICATIONS

This investigation supports the view that each treatment modality can produce a successful outcome for the treatment of the edentulous mandible in a chosen individual. Clinicians should avoid applying one universal treatment intervention. Choice of treatment modality should evaluate both dentist- and patient-mediated factors, including treatment and maintenance costs.

Treatment of the edentulous mandible using a conventional complete removable denture is a common clinical undertaking, yet at times it can be a difficult and challenging intervention. Patient expectations for such a treatment intervention are understandably high, yet the predictability of the outcome is generally regarded by most practitioners as variable. A general Medline search using the key words “standard of care” reveals that the term is often found in general use within specialty areas of the medical and dental literature. These results are suggestive of the view that specialty areas of medicine, in particular, are attempting to establish one specific treatment intervention for the management of a specific diagnostic entity. Despite the widespread use of the term, definitions for standard of care specific to prostodontics are difficult to find. A general reference was found in Webster’s medical dictionary. This definition for standard of care is in 2 parts: (1) A diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance; and (2) In legal terms, the level at which the average, prudent provider in a given community would practice. It refers to the manner in which a similarly qualified practitioner would have managed the patient’s care under the same or similar circumstances. The medical malpractice plaintiff must establish the appropriate standard of care and demonstrate that the standard of care has been breached.


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The 2002 McGill Consensus Conference concluded that the evidence available at the time suggested the restoration of the edentulous mandible with a conventional denture is no longer the most appropriate first-choice prosthodontic treatment. The attendees produced a consensus statement that the first-choice standard of care for the edentulous mandible was an overdenture retained by 2 implants.

In the current evidence-based research environment, the McGill consensus statement on overdentures and standard of care for the edentulous mandible requires review. At approximately the same time of the reporting of the consensus statement that “the 2-implant overdenture should become the first choice of treatment for the edentulous mandible,” guidelines for the critical appraisal of evidence-based literature were increasingly reported and encouraged. Additionally, the initial heading in the McGill Consensus Statement on Overdentures—“Mandibular 2-implant overdentures as first-choice standard of care for edentulous patients”—appears to be contradictory, since “first choice” concedes that more than one treatment intervention exists, and yet Webster’s definition for “standard of care” is suggestive of a single standard.

Zarb expressed a need for ongoing clinical research with both dentist- and patient-mediated concerns driving the best possible treatment outcomes for the aging patient group. This concern was expressed in an earlier symposium where scientists, clinicians, and editors reviewed reporting standards for outcomes using success and survival criteria. This symposium produced a consensus for reporting outcomes for dental implants, along with a consensus statement that redefined the determinants necessary to identify successful treatment outcome measures for implants supporting functional dental prostheses, including both patient- and dentist-mediated concerns.

It is generally regarded that a major principle of prosthodontic treatment is the ability of the prosthodontist to make the most correct diagnostic and treatment decisions. Once determined, treatment should be implemented and undertaken within a culture of prosthodontic scholarship and patient-mediated outcomes. Patients may choose a treatment option that is perceived as supporting a superior intervention were sought.

MATERIAL AND METHODS

Broad systematic searches of the English peer-reviewed dental literature were undertaken to seek appropriate definitions for “standard of care” and for evidence of clinical studies with outcome measures for all available treatment modalities for the edentulous mandible. Key phrases included edentulous mandible, dental implants, dental prosthesis, quality of life, and clinical trial. No exclusion criteria were applied to the initial electronic search. Medline and Google Scholar searches were conducted for the period from 1995 to September 25, 2005. The following journals were hand searched for this review: The Journal of Prosthetic Dentistry, International Journal of Prosthodontics, and International Journal of Oral & Maxillofacial Implants.

The titles and abstracts (when available) of all articles identified through the electronic searches were reviewed and assessed for suitability. The retrieved articles were then subjected to inclusion and exclusion criteria. Longitudinal retrospective studies, longitudinal prospective studies, longitudinal experimental clinical studies, nonrandomized controlled studies, and randomized controlled clinical trials were included for review using a general linear hierarchical classification of studies. Articles that did not focus exclusively on treatment interventions for mandibular edentulism or on the effects of such therapies on the patient were excluded from further evaluation. Preference was given to randomized controlled trials (RCTs) and evidence-based clinical studies comparing separate treatment modalities. If an article was identified involving a comparative clinical trial, the full text was obtained and reviewed. Data supporting a superior intervention were sought.

RESULTS

A total of 244 articles were identified through the Medline and Google Scholar search. Abstracts from these articles were reviewed to ensure that the articles met the inclusion criteria. A total of 47 articles met initial inclusion criteria and were then read in their entirety. Seven RCTs and 32 prospective and retrospective clinical trials of varying levels of evidence were reviewed. Data relative to prosthetic performance demonstrated that most patients are satisfied with the performance of conventional mucosal-borne dentures. For patients experiencing functional problems with conventional dentures, data relative to prosthetic performance
comparing conventional dentures to implant-supported prostheses demonstrated superior patient acceptance and performance for implant-supported prostheses. Patient preference material demonstrated considerable population variation that might be influenced by many variables.

**DISCUSSION**

**Conventional complete mandibular denture**

Until recently, the complete tissue-supported removable denture has been regarded as the prosthesis of choice for the treatment of the edentulous mandible. This was due largely to the absence of a viable alternative. There are still no reliable methods to predict the outcome of complete denture treatment, and there are many problems relating to treatment with complete dentures. Clinical experience confirms the observation that there is considerable variation among individuals with respect to patient adaptation to complete dentures, despite the fact that complete dentures have been shown to be a poor functional masticatory replacement for complete natural dentitions. Regardless of these observations, most patients are satisfied with their complete dentures. It is interesting to note that patients and clinicians do not usually agree when evaluating individual prostheses; patients generally report higher satisfaction levels for conventional dentures. Despite the variety of edentulous patient populations that have been studied, for the person at the appropriate age and oral circumstance, general health, and socioeconomic status, a complete removable denture may be a safe, predictable, and cost-effective treatment to restore an edentulous mandible.

**Two-implant-retained overdenture**

Since the advent of predictable osseointegrated implants in the early 1980s based on the concept of the fixed implant-supported prosthesis, the long-term success of this protocol in the management of complete mandibular edentulism has been well established. The inevitable progression to implants as a supporting, stabilizing, and retention mechanism for the implant-retained complete mandibular overdenture occurred in the mid-1980s. Numerous studies and clinical trials have demonstrated the viability, safety, superior functional performance, and patient satisfaction with the implant-retained and tissue-supported mandibular overdenture, when compared to the traditional removable denture.

Among many factors considered and compared when studies align conventional denture treatment and implant-retained treatment, cost comparisons are inevitably cited as a high priority consideration in the choice of treatment options. Schmitt and Zarb concluded that there was a need for less invasive, less expensive, less complex, and equally effective treatment options, such as the implant-supported and retained overdenture, for the management of the maladaptive edentulous patient.

A recently published cost comparison between a 2-implant-retained overdenture using a single-stage surgical procedure and unsplinted retainers, and a conventional denture treatment, including both direct and indirect costs to the patient, confirmed an implant-to-conventional total cost ratio of 1.8 compared to a ratio of 2.4 for direct costs alone. The cost and performance information for these 2 types of prosthetic treatment concepts may permit practitioners and their patients to make more valid informed decisions.

Feine and Carlsson define a mandibular 2-implant-retained overdenture treatment modality, heralding it as the “gold standard” for the treatment of the edentulous mandible. This textbook claims to provide compelling evidence for the efficacy of this rehabilitative treatment modality based on a thorough review of the current literature. The review by leading experts considered the impact of the 2-implant-retained overdenture on function, nutrition, and overall quality of life, while at the same time considering patient preferences and expectations, treatment planning, prosthetic management, and predicted costs.

Attard and Zarb supported the consensus finding with a measure of qualification regarding the chosen study population. The study population was selected for treatment due to a history of maladaptive prosthetic experience with conventional dentures and followed for a period ranging from 10 to 19 years. The authors concluded that the first choice of treatment for patients with mandibular denture problems, able to tolerate a removable prosthesis, should be an implant-retained overdenture.

**Complete mandibular implant-supported fixed prosthesis**

The long-term outstanding success of the fixed implant-supported mandibular prosthesis has been well established and documented. A prospective study evaluating implant treatment in the edentulous mandible presented excellent results over more than 20 years for the fixed implant-supported mandibular prosthesis. Although numerous prospective studies have been published over the years supporting the efficacy of this treatment modality, economic, time, and resource constraints preclude many edentulous patients from receiving this more expensive and prosthodontically demanding fixed prosthesis. It has long been generally regarded that the 3 modalities for the treatment of the edentulous mandible—conventional complete denture, implant-retained overdenture, and fixed implant-supported mandibular prosthesis—have a linear cost.
progression from least costly to most costly, due to the increased number of implants used and the increasing prosthetic complexity required for a fixed implant-supported prosthesis. Studies comparing the implant-retained overdenture with the fixed implant-supported prosthesis have found little or no significant difference when testing for objective function measure and subjective patient satisfaction. Some older (over 50 years), long-term denture wearers express a preference for the overdenture solution.

The cost differential has precluded many edentulous patients from receiving the more technically challenging and expensive fixed treatment alternative. Implant-retained overdentures would appear to have an economic advantage over the fixed implant-supported prosthesis alternative, yet it has been demonstrated that this is clearly not the only reason why patients choose one treatment alternative over another. The cost differential between an implant-retained overdenture and a fixed implant-supported prosthesis has been recently challenged by Palmqvist et al. In this prospective randomized clinical study, the authors compared a new implant-supported fixed prosthesis to an implant-retained overdenture in the edentulous mandible using 3 implants (Branemark; Nobel Biocare AB, Goteborg, Sweden). Patients in the fixed group were treated using 4 angled implants (All-in-One; Nobel Biocare, Goteborg, Sweden) and restored using a computer-numeric, controlled-milled, titanium framework, with acrylic resin denture teeth extending from first molar to first molar in the mandibular arch. The authors determined that a fixed implant-supported prosthesis in the edentulous mandible could be provided at approximately the same cost as an implant-retained overdenture. The authors concluded by stating that there was no rational reason for a fixed implant-supported prosthesis in the edentulous mandible to be more expensive to the patient than an overdenture.

**Dentist- and patient-mediated preferences**

A survey by Kronstrom and Carlsson demonstrated that the use of implant-retained overdentures in Sweden was rare compared with fixed implant-supported prostheses in the treatment of edentulous mandibles. It was clear from this study that treatment strategies differ internationally and regionally regarding the choice of a fixed prosthesis, or an overdenture, when restoring the edentulous mandible. This review found significant associations between diagnostic mistakes and a lack of or inadequate information about complications that actually occurred. The reality of the treatment tools at the disposal of the prosthodontist, coupled with the broad socioeconomic spectrum and varying treatment needs and expectations of edentulous patients, create challenging circumstances when advising appropriate treatment solutions. At all times, treatment solutions should be patient-mediated, directed at meeting these needs and expectations and resolving the problems confronting edentulous patients. It should be widely
accepted that principals of prosthodontic treatment demand that prosthodontists pursue the safest, least invasive, least costly, least complex treatment solutions to meet the reasonable needs and expectations of edentulous patients. The need for mechanical and biological stability, longevity and low maintenance for the life of the prosthetic device is required. As biological architect, bioengineer, contractor, and fabricator, this can impose considerable demands on the prosthodontist to fashion a satisfactory solution while at the same time maintaining a high standard of bioethics. Once this treatment decision is agreed on, the complex discipline that is the prosthodontic treatment is reduced to expert clinical technique and materials manipulation essential to producing the best possible functional and aesthetic outcome dictated by the circumstances. In this context, prosthodontics can arguably be the most complex and demanding specialty of dentistry.

It would seem that complete-denture prosthodontics has been a legitimate treatment modality for more than 2 centuries, and removable prosthodontic techniques and materials have been the traditional focus of scholarship, study, and research by the prosthodontic community. Through education, practicing dentists were made aware that patient needs and expectations have been met with a removable prosthesis. The outcomes of the years of reported clinical experience and research have resulted in a realization that many patients cannot be successfully treated with a complete removable denture, and it has been suggested that it may be possible to identify this population with greater predictability using the American College of Prosthodontists diagnostic classification system. It does not appear that this classification system has been derived from evidence-based research using defined success and survival criteria. It is not a validated system since interexaminer reliability, intraexaminer reliability, prognostic capacity, or communication utility have yet to be analyzed.

Many studies comparing a conventional removable denture treatment and a 2-implant-retained overdenture either chose a patient population in which all subjects were experiencing persistent problems wearing conventional dentures, or failed to define the previous denture experience of patients chosen for the study population. Better designed, long-term (>5years) RCTs with a study population of sufficient numbers randomly selected from a broad community base have a better chance of determining differences in patient acceptance of each treatment intervention. Such RCTs should define acceptable criteria for both patient- and dentist-mediated outcomes, and include a measure for maintenance requirements, economic benefit, and impact on patient’s quality of life for each treatment modality.

The McGill Conference attendance was by invitation, seeking opinions on overdentures and comparing this to treatment with conventional dentures. The choice of treatment interventions considered by the symposium attendees appeared to be limited to conventional dentures and implant-retained overdentures and, therefore, was not wholly representative of the entire spectrum of prosthodontic opinion regarding all available interventions for treatment of the edentulous mandible. In addition, it was unclear whether the symposium clearly defined standard of care, the chosen study population, and success and survival criteria when reviewing the literature.

It is generally perceived that predictable long-term treatment outcomes are best achieved when decision making and treatment recommendations are founded on evidence-based results from RCTs. The RCT design is regarded as the gold standard to establish reliable conclusions about the effectiveness of interventions, especially if it is assumed that possible differences between alternative interventions are small. The organizers of the McGill Conference stated that strong emphasis was given to evidence from RCTs. Recent literature reviews concluded that few RCTs in prosthodontics are reported in accordance with contemporary guidelines for adequate reporting of trials. Recently published studies challenge the findings and conclusions of the McGill consensus.

This challenge to the McGill consensus findings has come from several directions and has gathered momentum in the literature during 2005. The principle challenges have been related to cost and global demographics. The designers of some RCTs that compared treatment interventions for the edentulous mandible have noticed that recruiting patients to participate in these studies has been difficult, especially when the randomization process has denied choice for subjects. When subjects were given a choice of implant-supported prostheses, the well-informed population was evenly divided with respect to an overdenture or fixed prosthetic solution. A range of reasons for each choice was found. It appears that an essential ingredient in patient-mediated success outcomes for satisfaction could be choice. Perhaps the prosthodontic standard of care for treatment of the edentulous mandible is to offer choice.

The clinical trial undertaken by Palmqvist et al to compare implant-supported fixed prostheses and overdentures in the edentulous mandible encountered problems with the recruitment of a suitable study population. It is worthy of note that the authors experienced great difficulty enlisting patients to participate in this RCT, in spite of the fact that the treatment fees were heavily subsidized. One common reason for a subject’s unwillingness to participate was an inability to choose in advance the type of prosthodontic treatment they would
receive. Several candidates could not accept the removable alternative.

Much of the literature reviewed by the author and referenced in this paper does not conform to strict evidenced-based criteria. Study populations not randomly representative of the general edentulous population could prejudice conclusions regarding treatment recommendations for the edentulous mandible. It is not possible in these circumstances to draw data-driven conclusions to support one specific treatment intervention as being superior to another for the universal treatment of the edentulous mandible. Universally accepted criteria for standard of care for prosthodontic interventions have not been defined or established. Defining the standard of care for all patients with an edentulous mandible in terms of a single treatment modality, without defining the type of patient or specific clinical circumstance, is too simplistic and suggestive of the view that any alternative treatment is inferior, less acceptable, or misconstrued in some circumstances as being of a poor standard or even negligent. This unchallenged information regarding the standard of care for the edentulous mandible in the hands of a person with training in legal litigation, but no health care training and experience or understanding of the biological process, could lead to difficult litigation defense for the providers of such interventions, and ultimately, unfavorable long-term outcomes for patients. Courts in Australia are determining the standard of care in claims of professional negligence and using published clinical guidelines and evidence-based literature to make such determinations. It is clear that the dental literature is read not only by the dental profession but also by the legal profession. Caution is advised with the use of the term standard of care until universally accepted criteria are established for its use by the prosthodontic community.

Those who contributed to the original 2002 McGill consensus statement on overdentures should be heralded as pioneers for their work in attempting to establish a standard of care for the edentulous mandible. The McGill consensus statement on overdentures should be viewed as a milestone, as well as a desirable stepping stone in the pursuit of a universally acceptable standard of care for all edentulous patients. Criteria for assessing intervention outcomes have been established, and prosthodontic clinical research is strongly encouraged to quantify patient-mediated outcomes as well as the traditional dentist-mediated outcomes for success.

As a group, prosthodontists could be seen as leaders in the field of implant dentistry. As opinion leaders and clinical specialists, prosthodontists must be mindful of falling into the trap of presenting treatment solutions to patients from a dentist-mediated perspective and neglecting the patient-mediated aspect of seeking appropriate treatment solutions. Clearly, training and competence with a particular treatment modality can prejudice advice to patients. Any treatment solution that does not meet the expressed wishes and expectations of patients, regardless of the research-driven predictability of the outcome or the competence and skill with which the treatment is undertaken, has the potential to fail. Prosthodontists are cautioned not to succumb to prosthodontic prejudices and blindly apply a single particular treatment modality to the restoration of all edentulous clinical situations. It is worth reiterating that patient-mediated determinants for success have been recommended for inclusion in any success measure.

Experience clinical prosthodontists are aware of the consequences of failure, for it is an unusual occurrence to fully satisfy the needs of all edentulous patients with a prosthesis. From this experience flows the understanding that there is considerable variability within the human community with respect to needs, expectations, and responses to treatment. A prosthodontist should provide patients with sufficient information regarding treatment options and likely outcomes to allow patients to make adequately informed decisions regarding their needs. Appropriate information regarding all treatment options should be presented in such a manner that each treatment modality being considered is weighted in a balanced perspective relevant to the patient’s stated needs and expectations. Further, all treatment advice should be in keeping with the clinical findings and biological constraints of the particular treatment situation.

CONCLUSIONS

Within the scope of the systematic review, there is no strong evidence supporting a single standard of care in the edentulous mandible as defined by a specific treatment modality. There is evidence to suggest that patient choice has a greater influence on a successful outcome than operator preference for a treatment modality. From the available evidence, it could be ventured that the standard of care in the edentulous mandible is the intervention judged by the well-informed patient, in consultation with an appropriately trained and experienced dental health care provider, to best meet the needs and circumstances of the patient.

REFERENCES

Immediately loaded implants supporting fixed prostheses in the edentulous maxilla: A preliminary clinical and radiologic report


**Purpose:** To evaluate the survival rate of immediately loaded ITI sand-blasted, large-grit, acid-etched (SLA) solid-screw dental implants in the edentulous maxilla after 8 months of loading.

**Materials and Methods:** Twenty-eight patients (mean age 63 years) with edentulous maxillae each received 6 implants and 1 implant-supported fixed provisional prosthesis within 24 hours after surgery. After a mean healing time of 15 weeks, the patient received a definitive, screw-retained, implant-supported fixed prosthesis. A total of 168 implants were placed. Clinical parameters were registered after 1 month of loading with the implant-supported fixed prostheses as well as 8 months after implant placement. Radiologic examinations and assessments were made at implant placement and after 8 months.

**Results:** The mean marginal bone level at implant placement was 1.6 mm (range 0 to 5.1; SD 1.1) apical of the reference point (the implant shoulder). The mean marginal bone level at the 8-month follow-up was 3.2 mm (range 0.4 to 5.9; SD 1.1) apical of the reference point. Three implants failed during the healing period.

**Discussion:** The improved results in the present study might be a result of the positive effect of splinting the implants immediately after placement.

**Conclusion:** ITI SLA solid-screw implants immediately loaded (ie, loaded within 24 hours of placement) and supporting fixed prostheses had successful survival rates after 8 months. The present results constitute a solid baseline for future follow-up studies.—*Reprinted with permission of Quintessence Publishing.*