Received: 23 May 2018 | Accepted: 26 May 2018

DOI: 10.1111/clr.13299

CONSENSUS REPORT

WILEY CLINICAL ORAL IMPLANTS RESEARCH

Group 3 ITI Consensus Report: Patient-reported outcome measures associated with implant dentistry

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Abstract

Objectives: The aim of Working Group 3 was to focus on three topics that were assessed using patient-reported outcome measures (PROMs). These topics included the following: (a) the aesthetics of tooth and implant-supported fixed dental prostheses focusing on partially edentulous patients, (b) a comparison of fixed and removable implant-retained prostheses for edentulous populations, and (c) immediate versus early/conventional loading of immediately placed implants in partially edentate patients. PROMs include ratings of satisfaction and oral health-related quality of life (QHRQoL), as well as other indicators, that is, pain, general health-related quality of life (e.g., SF-36).

Materials and methods: The Consensus Conference Group 3 participants discussed the findings of the three systematic review manuscripts. Following comprehensive discussions, participants developed consensus statements and recommendations that were then discussed in larger plenary sessions. Following this, any necessary modifications were made and approved.

Results: Patients were very satisfied with the aesthetics of implant-supported fixed dental prostheses and the surrounding mucosa. Implant neck design, restorative material, or use of a provisional restoration did not influence patients' ratings. Edentulous patients highly rate both removable and fixed implant-supported prostheses. However, they rate their ability to maintain their oral hygiene significantly higher with the removable prosthesis. Both immediate provisionalization and conventional loading receive positive patient-reported outcomes.

Conclusions: Patient-reported outcome measures should be gathered in every clinical study in which the outcomes of oral rehabilitation with dental implants are investigated. PROMs, such as patients' satisfaction and QHRQoL, should supplement other clinical parameters in our clinical definition of success.

KEYWORDS
clinical research, clinical trials, patient-centered outcomes, prosthodontics, systematic reviews

INTRODUCTION

The objectives of Group 3 of the 6th ITI Consensus Conference were to provide statements and recommendations for clinicians and researchers relating to patient-reported outcome measures (PROMs). Three systematic reviews on different topics were carried out in which implant prostheses were assessed by patients using PROMs. Each review was written up as manuscript. Group 3 met to discuss the results of each review; consensus statements and clinical recommendations stemming from each review were then discussed and agreed upon, then presented to a plenary session for discussion and final agreement.

The three systematic reviews are as follows:

1. Patient-reported outcome measures focusing on aesthetics of implant- and tooth-supported fixed dental prostheses: A systematic review and meta-analysis
   Julia G. Wittneben, Daniel Wismeijer, Urs Brägger, Tim Joda, Samir Abou-Ayash
2. Patient-reported outcome measures of edentulous patients restored with implant-supported removable and fixed prostheses: A systematic review
   Coral J. Yao, Cong Cao, Michael M. Bornstein, Nikos Mattheos
3. Immediate loading vs. early/conventional loading of immediately placed implants in partially edentulous patients from the patients' perspective: A systematic review.
   Guy Huynh-Ba, Thomas W. Oates, Mary Ann H. Williams

1 | REVIEW

1. Patient-reported outcome measures focusing on aesthetics of implant- and tooth-supported fixed dental prostheses: A systematic review and meta-analysis. Wittneben et al. (2018).

1.1 | Preamble

The aim of this review was to summarize the existing evidence on the aesthetic outcome of implant-supported and tooth-supported fixed dental prostheses (FDPs) in partially edentulous patients according to PROMs. Secondary outcomes were to analyze the influence of restorative material, implant neck design, and the implementation of a provisional phase focusing on PROMs.

In all, 16 publications on implant-supported FDPs, including 19 relevant study cohorts, were identified and met the review inclusion criteria. No publications on tooth-supported FDPs met the inclusion criteria; thus, a comparison could not be performed. However, the group was able to produce consensus statements and clinical recommendations from the studies on implant-supported FDPs.

1.2 | Consensus statements

1.2.1 | Consensus statement 1

The aesthetics of implant-supported FDPs are highly rated by patients (VAS 90; 95%CI: 87.9–92.2).

**This statement was supported by: two RCTs, eight prospective cohort studies, four retrospective studies and two cross-sectional studies, including 867 patients in total.*

1.2.2 | Consensus statement 2

Mucosal aesthetics of implant supported FDPs are highly rated by patients (VAS 87; min. 73–max. 92).

**This statement was supported by: one RCT, three prospective cohort studies and one cross-sectional studies, including 315 patients in total.*

1.2.3 | Consensus statement 3

Implant neck design, that is, tissue or bone level, has no influence on patients' ratings of aesthetics: VAS 93 (95% CI: 89–96) versus VAS 89 (95% CI: 86–92)

**This statement was supported by: two RCTs, five prospective cohort studies and two cross-sectional studies, including 443 patients in total.*

1.2.4 | Consensus statement 4

Individual restorative materials have no influence on patient ratings of the aesthetics of implant supported FDPs.

**This statement was supported by: two RCTs, five prospective cohort studies, two retrospective studies and two cross-sectional studies, including 556 patients in total.*

1.2.5 | Consensus statement 5

The use of a provisional restoration had no effect on patients' ratings of the aesthetics of definitive restorations on implant supported FDPs.

**This statement was supported by: two RCTs, five prospective cohort studies and two cross-sectional studies, including 359 patients in total.*

1.2.6 | Consensus statement 6

No studies were found that reported on PROMs for tooth-supported FDPs in partially edentulous patients.

1.3 | Clinical Recommendations

1.3.1 | Can we satisfy the patient's aesthetic concerns with implant-supported fixed dental prostheses (FDPs)?

It is possible to achieve high patient satisfaction with aesthetics. It is also possible to achieve highly rated mucosal aesthetics around implants. Hence, implant-supported FDPs can be recommended.

**Based on consensus statements 1 and 2*

1.3.2 | Does the selection of tissue or bone level implants influence the patient's perception regarding aesthetics?

The individual implant choice of implant-supported FDPs has no influence on ratings of aesthetics. Therefore, the choice of implant type supporting FDPs should be based on factors other than patient ratings of aesthetics.

**Based on consensus statement 3.*

1.3.3 | Does the restorative material have an impact on the patient's perception regarding the aesthetic outcome?

The type of restorative material used in implant-supported FDPs did not influence patient ratings of aesthetics. Therefore, the choice of restorative material for implant-supported FDPs should not be based on PROMs.

**Based on consensus statement 4.*

1.3.4 | Do patients perceive an added benefit on the final aesthetic result when a provisional is used for an implant supported FDP?

The choice of implementation of a fixed implant-supported provisional should not be only based on PROMs. Regardless, according to the 2014 ITI Consensus Statement, the use of provisional implant-retained restorations in the aesthetic zone is recommended.

**Based on consensus statement 5*

1.4 | Recommendations for future research

1. Standardized reliable and valid questionnaires with similar scoring methods should be used.

2. Patient ratings should be collected without influence from the clinician performing the treatment.

2 | REVIEW

Patient-reported outcome measures of edentulous patients restored with implant-supported removable and fixed prostheses: A systematic review. Yao et al. (2018).

2.1 | Preamble

The aim of this review was to summarize the scientific evidence on implant supported removable and fixed prostheses for edentulous populations and to compare Patient-Reported Outcome Measures such as satisfaction, impact of prosthesis on oral health-related quality of life or any other PROMs reported within this field. In all, 13 studies met the inclusion criteria. Most studies reported different measures of patients' satisfaction and oral health-related quality of life PROMs. However, due to lack of standardization and high heterogeneity, no meta-analysis or collective quantitative analysis of the results was possible. On the basis of the existing evidence on all studied parameters, neither prosthetic design—fixed or removable—was rated by patients as consistently superior, with the exception of the ability to practice oral hygiene, which is perceived by patients to be superior with removable implant supported prostheses.

2.2 | Consensus Statements

2.2.1 | Consensus statement 1

PROMs are not commonly used in clinical implant research. There are currently no guidelines on what PROMs are most appropriate for implant dentistry.

**This statement was based on 13 investigations, including one RCT, seven prospective and five retrospective studies.*

2.2.2 | Consensus statement 2

The timing of PROMs assessment in the literature is inconsistent and often limited to one time point.

**This statement was based on 13 investigations, including one RCT, seven prospective and five retrospective studies.*

2.2.3 | Consensus statement 3

Reporting of patients' characteristics and sampling techniques in PROMs research is inadequate, which could limit the ability to draw conclusions in implant dentistry.

**This statement was based on 13 investigations, including one RCT, seven prospective and five retrospective studies.*

2.2.4 | Consensus statement 4

There are no differences in PROMs between Implant supported Overdentures (IOD) and Implant-supported Fixed Complete Dentures (IFCD), except for perceived maintenance of oral hygiene, which is rated higher with IODs.

**This statement was based on 13 investigations, including one RCT, seven prospective and five retrospective studies. The oral hygiene superiority of IOD is based on five investigations, including one RCT, three prospective and one retrospective studies.*

2.3 | Clinical Recommendations

2.3.1 | Should PROMs supplement clinical implant patient care?

Patient perceptions of psychosocial state, functional limitation, pain and discomfort, and expectations should be assessed before implant treatment. Clinicians are advised to use PROMs when assessing clinical outcomes.

**Based on Consensus statement 1*

2.3.2 | Should the assessment of PROMs be conducted prospectively?

Before implant treatment, a baseline assessment of patient perception of oral health-related quality of life and satisfaction should be recorded.

After treatment completion, the assessment of PROMs should be conducted prospectively at appropriate intervals, case dependent.

**Based on Consensus statement 2.*

2.3.3 | Based on PROMs, should clinicians rehabilitate fully edentulous patients with Implant-supported Overdentures (IOD) or Implant-supported Fixed Complete Dentures (IFCD)?

The decision of whether to rehabilitate a patient with fixed or removable implant prostheses cannot be based solely on PROMs. Such decisions should be guided by the specific anatomy, clinical parameters, as well as the patient's needs and wishes.

In cases in which either treatment is feasible, proper assessment of patients' expectations and desires before treatment is critical prior to deciding between fixed or removable prosthesis.

**Based on Consensus statement 4*

2.3.4 | Do patients perceive differences in their ability to maintain oral hygiene with IFCDs and IODs?

Patients report that it is easier for them to maintain oral hygiene with an implant overdenture (IOD) than with an implant fixed conventional denture (IFCD); therefore, the IOD may be preferable for certain patients.

*Based on Consensus statement 4

2.4 | Recommendations for future Research

1. More well-designed studies are needed to be able to statistically compare the ratings of PROMs for implant fixed complete dentures (IFCDs) and implant overdenture (IOD) treatment are needed.
2. Guidelines for assessing PROMs in clinical research are needed to help clinical researchers select the most appropriate outcomes and measurement instruments.
3. The use of standard PROMs instruments in every relevant well-designed study will enable more powerful and useful analytic approaches.

3 | REVIEW

Immediate loading vs. early/conventional loading of immediately placed implants in partially edentulous patients from the patients' perspective: A systematic review. Huynh-Ba et al. (2018).

3.1 | Preamble

The aim of this review was to summarize the scientific evidence on immediate and early/conventional loading of immediately placed implants and to compare them according to the results of patient-reported outcomes of satisfaction, quality of life, and other aspects of treatment. Nine studies were identified and met the selection criteria. However, due to the small number of studies and the heterogeneity of the data, a meta-analysis could not be carried out. Regardless, patient satisfaction ratings were high for both loading strategies, and both resulted in improvement in OHRQoL scores.

3.2 | Consensus statements

3.2.1 | Consensus statement 1

From the patient's perspective, there is no difference between immediate provisionalization and conventional loading. Both treatment modalities can achieve similar positive patient-reported outcomes.

This statement was based on: one RCT and two controlled clinical trials.

3.2.2 | Consensus statement 2

Based on PROMs, no evidence was found to address early loading of immediately placed implants.

This statement was based on the fact that no study was identified reporting on early loading of immediately placed implants.

3.2.3 | Consensus statement 3

Positive patient-reported outcomes can be achieved following immediate implant placement with immediate provisionalization in a single edentulous space in maxillary anterior and premolar sites.

From an occlusion standpoint, most studies reported immediate provisional restoration with no contact in centric occlusion or eccentric movement.

This statement was based on: one RCT, two controlled clinical trials and five single cohort studies.

3.2.4 | Consensus statement 4

The placement of an immediate implant-supported provisional restoration demonstrated a significant improvement in OHIP-14 score.

This statement is based on two single cohort studies

3.2.5 | Consensus statement 5

From the patient's perspective, the outcome of immediate implant-supported provisional restorations in contiguous edentulous spaces has yet to be determined.

This statement was based on the fact that no study was identified reporting PROMS for contiguous edentulous spaces.

3.2.6 | Consensus statement 6

Limited evidence is available to support immediate provisionalization based on PROMs.

This statement is based on the fact that only a third of the studies used standardized and validated tools to report PROMs.

3.3 | Clinical recommendations

3.3.1 | Based on patients' perspectives, what loading protocol can be recommended following immediate implant placement in single edentulous spaces?

Both immediate provisionalization and conventional loading can be recommended to provide patient benefit. Clinicians' preferences, expertise, specific case- and patient-related factors should be included to make this determination.

This is based on Consensus statements 1 and 4.

3.3.2 | When immediate provisionalization of immediately placed implants in single edentulous spaces is chosen, what occlusal scheme should be favoured?

Positive patient ratings have been associated with immediate provisional restoration having no contact in centric occlusion and eccentric movements. Therefore, the clinical recommendation is to

have no contact in centric occlusion and eccentric movements for immediate implant-supported provisional restorations.

**This is based on Consensus statement 3.*

3.4 | Recommendations for future research

- The choice of which PROMs to use should be restricted to those most appropriate for the study question that have been previously validated.
- At a minimum, PROMs data should be gathered at 2 time points: at baseline and at a designated point post-treatment. Ideally, multiple assessments are desirable to discriminate short-versus long-term treatment effects.
- More well-controlled randomized trials are needed to determine the appropriate standard of care with regard to loading protocols based on clinical and patient-reported outcome measures.

CONCLUSIONS

Understanding how patients respond to implant treatment is essential. The use of patient-reported outcome measures can provide the patient perspective for both practice and research objectives. The results of these reviews, in which patient-reported outcome measures were used, have provided evidence to assist clinicians when planning treatment and discussing therapeutic options with their implant patients.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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How to cite this article: Feine J, Abou-Ayash S, Mardini MA, et al. Group 3 ITI Consensus Report: Patient-reported outcome measures associated with implant dentistry. *Clin Oral Impl Res*. 2018;29(Suppl. 16):270–275. https://doi.org/10.1111/clr.13299