

Patient-reported outcome measures of digitally versus conventionally constructed removable dentures: a systematic review protocol

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ABSTRACT

Objective: This review will evaluate patient-reported outcome measures of treatment with digitally fabricated versus conventionally manufactured removable dental prostheses in partially or completely edentate adults.

Introduction: Compared with conventionally manufactured dental prostheses, digitally fabricated prostheses may simplify and reduce the number of clinical steps and minimize errors in the production of prostheses without compromising occlusal accuracy and fit. This may, in turn, improve patient satisfaction, ability to speak, esthetics, stability, and oral health status. Determining evidence of patient-reported outcomes will assist the dental practitioner when communicating patient expectations.

Inclusion criteria: This review will consider experimental and quasi-experimental study designs, including randomized and non-randomized controlled trials, comparative or non-comparative clinical studies, prospective or retrospective trials, longitudinal clinical studies, clinical reports, and technique articles. The review will include patient-reported outcome measures from fully or partially edentulous adult participants who received either conventionally or digitally fabricated dental prostheses.

Methods: The following databases will be searched for scientific, peer-reviewed literature: EBSCO (Academic Search Complete, CINAHL, Dentistry and Oral Sciences), MEDLINE (PubMed), ScienceDirect, and Cochrane Central Register of Controlled Trials. The search strategy will include terms relevant to the intervention, which will be adapted for each bibliographic database, in combination with database-specific filters, where available. The language restriction will be English and Dutch. All included studies will be critically appraised and data will be extracted for synthesis. If possible, a meta-analysis will be conducted. The Grading of Recommendations, Assessment, Development and Evaluation approach will be followed to evaluate the certainty of evidence.

Systematic review registration number: PROSPERO CRD42018094357

Keywords: computer-aided design; computer-aided manufacture; conventional dentures; oral health-related quality of life; patient-reported outcome measures

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Introduction

A digitally fabricated denture is defined by the *Glossary of Prosthodontic Terms* as a removable complete or partial denture created with automation by using computer-aided design (CAD), computer-aided manufacturing (CAM), and computer-aided engineering in lieu of conventional processes.¹ The workflow can be fully digital or it may

involve analogue steps, such as conventional impressions or a try-in with reline visit. If analogue steps are present, the workflow is then considered partially digital. The definitive prosthesis is fabricated by means of one of two methods: additive or subtractive manufacturing.² Although early literature on CAD/CAM workflows for complete dentures (CDs) date back to the mid-1990s, the concept of CAD/CAM technology and workflows for CDs became a clinical reality only after the publication of a “proof of concept” article by Goodacre *et al.* in 2012, as cited in Clark *et al.*³ Since then, commercially available digital denture companies and workflows have grown in

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number and improvements on existing products have been continuously launched onto the market. A review of in-vitro studies shows clinically acceptable values for occlusal trueness and adaptation of digital CDs.⁴ Likewise, for removable partial dentures (PDs), workflows can be fully or partially digital. Because of the complexity of their designs, metal frameworks for PDs are mostly made using additive technology. Accuracy of fit of frameworks for PDs differs according to scanning techniques, but is reported to be within clinically acceptable values.⁵

Patient-centered outcomes research focuses on preferences, needs, and subjective, clinically relevant outcomes as reported by participants, in contrast to physician-centered outcomes of health care interventions.⁶ These outcomes are also called patient-reported outcome measures (PROMs) and have important implications for clinical practice, research, and policy.⁷ They allow clinicians to evaluate efficacy of treatment protocols from the patient's perspective.⁸ Examples of PROMs are patient acceptability of treatment, pain and discomfort, or health-related quality of life. Oral health-related quality of life (OHRQoL) is a multidimensional construct that provides a subjective assessment of the patient's oral health, functional and emotional well-being, expectations, and satisfaction.⁹ Evidence on OHRQoL and patient satisfaction after rehabilitation with conventionally manufactured prostheses is abundant. For edentulous patients, OHRQoL is positively affected after rehabilitation with CDs.¹⁰ For partially edentulous patients, OHRQoL is positively affected in the short term.¹¹ A systematic review by Kattadiyil *et al.* reported that dissatisfaction with overall outcomes, inadequate retention, and esthetic concerns were the most common complaints with digitally fabricated CDs.¹² A limitation of this systematic review is the low number of studies ($n = 2$) that reported on patient satisfaction. In addition, the Kattadiyil *et al.* systematic review searched publications up to September 2016. Rapidly developing CAD and CAM technologies and the inclusion of conventional prostheses as a comparator warrants a different and updated systematic review. There appears to be limited literature on how different denture manufacturing processes affect patient experience.

The focus of this study will be the rehabilitation of completely or partially edentulous patients by means of removable prostheses. Satisfaction scores appear to be higher for dentures made partially or

completely with digital techniques compared with conventional techniques.¹³⁻¹⁵ However, some studies have found no statistically significant difference in satisfaction between digital CDs and previous conventionally manufactured CDs.^{16,17} A prospective cross-over clinical study, using the German version of the Oral Health Impact Profile (OHIP), found no significant difference between conventionally and digitally manufactured complete dentures.¹⁸ Cristache *et al.* reported an improvement of the Oral Health Impact Profile for Edentulous Patients ([OHIP]-EDENT) of participants who had received a 3D functional completed denture, but the study did not include a cohort that received new conventionally manufactured dentures.¹⁹

A preliminary search of PROSPERO, MEDLINE (PubMed), the Cochrane Central Register of Controlled Trials, and JBI Evidence Synthesis was conducted and no current or in-progress systematic reviews on the topic were identified. The overall aim of this proposed systematic review is to determine the PROMs following rehabilitation of fully or partially edentulous adults by means of digitally fabricated versus conventionally manufactured removable dentures.

Review question

For adult patients who are partially or completely edentulous (Participants), how do digitally (Intervention) versus conventionally (Comparator) manufactured removable dentures affect PROMs (Outcome)?

Inclusion criteria

Participants

This review will consider studies that include adults (18 years or older) who are partially or completely edentulous and have been rehabilitated with removable prostheses. Patients who received maxillofacial prostheses, overdentures, or prostheses supported or retained by dental implants will be excluded.

Intervention

This review will consider studies that evaluate treatment with removable complete or partial prostheses manufactured by means full or partial digital workflows. To be included in the intervention, the treatment protocol needs to include one or more of steps of the digital workflow for the design and manufacture of removable prostheses. These steps can be: digital impressions by means of intra-oral scanning;

extra-oral scanning of conventional impressions; extra-oral scanning of conventional casts; intra-oral scanning of jaw registration; digital articulation; the use of CAD software to design a virtual prosthesis or components of the prosthesis; and the use of CAM software to fabricate a full prosthesis or components of a prosthesis by means of additive or subtractive technology.

Comparator

This review will consider studies that compare the intervention with treatment using removable complete or partial prostheses manufactured by means of conventional methods. The steps of the conventional construction of removable prostheses are clinical intra-oral impressions using impression material supported by an impression tray; the use of stone casts; clinical jaw registration using record bases and rims; manual articulation of casts in an articulator; manual production and shaping of denture components using wax or equivalent material; manual set-up of denture teeth; clinical try-in wax denture replica; clinical try-in of casts framework; and investing and casting of frameworks and wax trial dentures.

Outcomes

This review will consider studies reporting on the following PROMs as their main outcomes: Oral Health Impact Profile (OHIP), OHIP-EDENT; Oral Impacts on Daily Performance (OIDP) tool, General Oral Health Assessment Index (GOHAI); patient satisfaction (Patient Satisfaction Questionnaire short form [PSQ-18] and Dental Satisfaction Questionnaire [DSQ]); and other self-reported outcome measures including Visual Analogue Scale (VAS). The effect measure will be before and after treatment (immediately and at different follow-up periods).

Types of studies

This review will consider experimental and quasi-experimental study designs, including randomized and non-randomized controlled trials, comparative clinical studies, prospective and retrospective trials, longitudinal clinical studies, clinical reports, and technique articles.

Methods

The proposed systematic review will be conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)

checklist²⁰ and the *JBI Manual for Evidence Synthesis*.²¹

The systematic review is registered with PROSPERO (CRD42018094357).

Search strategy

An initial limited search of PubMed was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for MEDLINE (PubMed), ScienceDirect, Cochrane Central Register of Controlled Trials (see Appendix I) and EBSCO (Academic Search Complete, CINAHL, Dentistry And Oral Sciences). For the definitive search, the search strategy, including all identified keywords and index terms, will be adapted for each included database and/or information source. The reference lists of all included sources of evidence will be screened for additional studies. Studies published in English and Dutch will be included as the main author is fluent in both languages. Sources of unpublished and gray literature will not be searched.

Study selection

Following the search, all identified citations will be collated and uploaded into Rayyan (Qatar Computing Research Institute, Doha, Qatar) and duplicates removed. Following a pilot test, titles and abstracts will then be screened by two independent reviewers for assessment against the inclusion criteria. Potentially relevant studies will be retrieved in full and their citation details imported into Rayyan. The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers. Reasons for exclusion of full-text papers that do not meet the inclusion criteria will be recorded and reported in the systematic review. Any disagreements that arise between the reviewers at each stage of the selection process will be resolved through discussion. The results of the search and the study inclusion process will be reported in full in the final systematic review and presented in a PRISMA flow diagram.²⁰

Assessment of methodological quality

Eligible studies will be critically appraised by two independent reviewers at the study level using standardized critical appraisal instruments from JBI for experimental.^{22,23} Authors of papers will be

contacted to request missing or additional data for clarification, where required. Any disagreements that arises between the reviewers will be resolved through discussion. The results of the critical appraisal will be reported in a table with accompanying narrative.

All studies, regardless of its results or of its methodological quality, will undergo data extraction and synthesis (where possible).

Data extraction

Data will be extracted by two independent reviewers using the modified data extraction tool (see Appendix II). The extracted data will include specific details about the year of publication, location of study, study design, number of participants, sex of participants, age, status of edentulism, types of prosthesis, materials used for the prosthesis, techniques used to design or manufacture the dentures, OHR-QoL, satisfaction, fit, cost, time, and funding sources of the study. These data will be recorded in Excel (Redmond, Washington, USA) spreadsheets. Any disagreements that arise between the reviewers will be resolved through discussion. Authors of papers will be contacted to request missing or additional data, where required.

Data synthesis

Studies will, where possible, be pooled with statistical meta-analysis using STATA v.17 (Stata Corp LLC, Texas, USA). Effect sizes will be expressed as final post-intervention mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Clinical heterogeneity will be assessed by considering the variability in clinical studies (eg, differences in digital workflows, OHR-QoL instruments) and study factors (randomization concealment, blinding of outcome assessment, losses to follow-up, treatment type, co-interventions).

Statistical heterogeneity will be tested using the χ^2 test (significance level: 0.1) and the I^2 statistic (0% to 40% = might not be important; 30% to 60% = may represent moderate heterogeneity; 50% to 90% = may represent substantial heterogeneity; 75% to 100% = considerable heterogeneity).²⁴ If high levels of heterogeneity among the trials exist ($I^2 \geq 50\%$ or $p < 0.1$), the study design and characteristics in the included studies will be analyzed. We will use subgroup analysis or sensitivity analysis to explain the source of heterogeneity.

Statistical analyses will be performed using random or fixed effects models as described by Tufanaru *et al.*²⁵ Where statistical pooling is not possible, the findings will be presented in narrative format, with tables and figures to aid in data presentation, where appropriate.

A funnel plot will be generated using STATA to assess publication bias if there are 10 or more studies included in a meta-analysis. Statistical tests for funnel plot asymmetry (Egger test) will be performed, where appropriate.

Assessing certainty in the findings

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach will be followed to grade the certainty of evidence. A Summary of Findings (SoF) will be created using GRADEpro GDT (McMaster University, ON, Canada). The SoF will present the following information, where appropriate: absolute risks for the treatment and control, estimates of relative risk, and a ranking of the quality of the evidence based on the risk of bias (sequence generation, allocation concealment, blinding, incomplete outcome data, and selective outcome reporting), directness, heterogeneity, precision, and risk of publication bias of the review results. These judgments will be made independently by two reviewers at the study level. The outcomes reported in the SoF will be: OHRQoL, satisfaction, and other PROMs.

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Author contributions

Both GG and FK contributed to conceptualization and design, methodology, writing, original draft review, editing, and final approval of this manuscript.

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Appendix I: Search strategy

MEDLINE (PubMed)

Search conducted on February 2, 2022.

The following search strategy was used: (((("Randomized Controlled Trial" [Publication Type]) OR (Randomized Controlled Trial[Title/Abstract])) AND ("Computer-Aided Design"[Mesh] OR "Imaging, Three-Dimensional"[Mesh] OR "Printing, Three-Dimensional"[Mesh] OR "Computer generated"[Title/Abstract] OR "Computer* aided*"[Title/Abstract] OR "Three dimensional printing"[Title/Abstract])) AND ("Patient Satisfaction"[Mesh] OR "Patient Satisfaction"[Title/Abstract])) AND ((("Edentulous" [Title/Abstract] OR ("Complete denture*"[Title/Abstract]) OR ("Jaw, Edentulous" OR "Mouth, Edentulous" OR "Denture, Complete" OR "Denture, Complete, Upper" OR "Denture, Complete, Lower"[MeSH Terms])) which resulted in 10 hits.

| | Query | Results retrieved |
|----|--|-------------------|
| 1. | ("Edentulous"[Title/Abstract] OR ("Complete denture*"[Title/Abstract]) OR ("Jaw, Edentulous" OR "Mouth, Edentulous" OR "Denture, Complete" OR "Denture, Complete, Upper" OR "Denture, Complete, Lower"[MeSH Terms])) | 27,639 |
| 2. | "Patient Satisfaction"[Mesh] OR "Patient Satisfaction"[Title/Abstract] | 117,889 |
| 3. | "Computer-Aided Design"[Mesh] OR "Imaging, Three-Dimensional"[Mesh] OR "Printing, Three-Dimensional"[Mesh] OR "Computer generated"[Title/Abstract] OR "Computer* aided*"[Title/Abstract] OR "Three dimensional printing"[Title/Abstract] | 135,953 |
| 4. | ("Randomized Controlled Trial" [Publication Type]) OR (Randomized Controlled Trial[Title/Abstract]) | 591,740 |
| 4. | #1 AND #2 AND #3 AND #4 | 10 |

Filters applied: Dutch, English, Humans.

Appendix II: Draft data extraction instrument

| Study ID | Title | Author | Year of publication | Location of study | Study design | Number of participants | Sex | Age | Type of edentulism | Type of prosthesis: PD/CD | Materials used for prosthesis | Techniques for impressions/ jaw registration/ mounting of teeth/try-in/ fabrication (lost wax technique, subtractive, additive) | PROM instrument | Statistical tests | Results |
|----------|-------|--------|---------------------|-------------------|--------------|------------------------|-----|-----|--------------------|---------------------------|-------------------------------|---|-----------------|-------------------|---------|
| | | | | | | | | | | | | | | | |

CD, complete dentures; ID, identification; PD, partial dentures; PROM, patient-reported outcome measures.

PROOF