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Review

Mandibular complete denture versus single-implant overdenture: a systematic review of patient-reported outcomes

T. E. NOGUEIRA, D. R. DIAS & C. R. LELES *Department of Prevention and Oral Rehabilitation, School of Dentistry, Federal University of Goias, Goiania, Brazil*

SUMMARY **The single-implant mandibular overdenture (SIMO) has been proposed as an alternative for edentulous patients who are poorly adapted to their dentures due to low retention and stability of the conventional mandibular complete denture (CD). However, there is a lack of evidence regarding the effectiveness of SIMO, which can be measured by examining patient perception of treatment effects. The aim of this systematic review was to assess the comparative results of CD and SIMO treatments using patient-reported outcome measures. A literature search was carried out in PubMed, Scopus and Cochrane Central databases. The search included studies published up to July 2017. The focus question was: 'Do single-implant mandibular overdentures improve patient-reported outcomes compared to conventional complete dentures in edentulous patients?' Eligible studies were randomised clinical trials (RCT) and prospective studies. After initial screening for eligibility and full-text analysis, 11 studies were included for data extraction and quality assessment (five parallel-group RCTs, two crossover RCTs and four prospective studies). All studies reported marked improvement in satisfaction with the dentures and quality of life measures after SIMO treatment, irrespective of variations in implant treatment protocols and retention systems. Methodological considerations revealed a lack of evidence from RCTs on the comparative effectiveness of the two treatment strategies. Hence, although available evidence suggests considerable improvement in patient-reported outcomes following the insertion of a single implant to retain a mandibular denture, further well-designed comparative studies between SIMO and CD are required to improve the level of evidence and to support the indication of SIMO treatment in routine practice.**

KEYWORDS: **patient satisfaction, quality of life, overdenture, complete denture, patient-reported outcomes, systematic review**

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Background

Despite the significant decline in the prevalence and incidence of total tooth loss in the last decades at the global, regional and country levels (1), the continuing rate of decline in edentulism is projected to slow, compensated partially by population growth and ageing (2). Nevertheless, edentulism is still a relevant health problem and there are significant barriers to oral health care of older people. Poor socio-economic conditions of older people also contribute to their under-utilisation of oral health services even when these are available (3), which reinforces the need for accessible and cost-effective treatments that minimise the financial barrier in oral health care.

Conventional complete dentures are the most common treatment for edentulous subjects worldwide and, in general, edentulous patients treated with

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conventional complete dentures (CD) are well adapted to their dentures. Most of them, particularly older individuals, have expectations limited to well-functioning CDs and are less likely to be candidates for implant therapy (4). However, reports of impaired function, oral pain and discomfort are frequent, especially about the mandibular denture. Patient complaints and dissatisfaction with the dentures may be related to technical aspects of the treatment but may also be due to prognostic factors that are multifactorial and largely dependent on clinical, psychological and behavioural aspects of the patients (5). For these difficult clinical situations, especially for patients with edentulous mandible, implant-supported or implant-retained dentures are recommended to improve denture retention and stability and increase overall oral comfort, function and psychosocial well-being.

The mandibular overdenture retained by two implants has been recommended as the minimum standard of care for the edentulous mandible (6, 7). However, in recent years, the single-implant mandibular overdenture (SIMO) has been proposed as an alternative to more complex overdenture designs (8, 9). SIMO is assumed to be simpler and less costly than both the fixed-implant treatment and the overdenture retained by two implants. It is also considered a more feasible option for geriatric patients, who are less likely to adhere to complex implant interventions, because of its diminished functional demands and because of the favourable local bone condition in the symphyseal region, which ensures satisfactory primary implant stability (8).

Previous clinical studies showed satisfactory results of SIMO treatment using clinical outcomes such as implant survival rate, marginal bone loss and implant stability over time, as well as improved patient satisfaction and quality of life (10). The post-loading implant survival in 1- and 2-implant mandibular overdentures was compared in a meta-analysis, and no significant difference was observed between the two treatment modalities (11). Another review, which gathered evidence from clinical studies, suggested that SIMO could be a reliable alternative for elderly patients on the basis of implant survival, patient satisfaction and prosthodontic maintenance (12). However, it is difficult to make reliable comparisons across clinical studies because they differed greatly on the experimental design, use of different implant and retention systems, loading protocols and evaluation of distinct clinical outcomes.

There is sound evidence available about the positive impacts of the 2-implant mandibular overdenture on patient-reported outcomes, such as oral health-related quality of life and satisfaction, when compared to CD (13–15). Similarly, preliminary reports showed that there is no detrimental effect on denture maintenance, patient satisfaction, implant survival and peri-implant bone loss when the number of implants is reduced from two to one (16, 17). However, the incremental effect of SIMO is still poorly understood when CD, which is still the standard of care in the majority of health systems worldwide, is considered the reference for comparison. In addition, the impact of SIMO based on an assessment from the patient's perspective is critical to reveal whether this treatment truly improves a patient's health status and quality of life. Those two outcomes are crucial aspects of a patient-centred approach to oral health care.

The aim of this review was to assess the changes in patient-reported outcome measures between CD and SIMO treatment. The focus question was as follows: 'Do single-implant mandibular overdentures improve patient-reported outcomes compared to conventional complete dentures in edentulous patients?' The study hypothesis is that SIMO provides significant improvements for CD wearers when patient-reported outcomes are considered.

Methods

Search strategy

The 'Preferred Reported Items for Systematic Reviews and Meta-Analysis' (PRISMA) guidelines were used as a reference for reporting this systematic review (18). A broad systematic literature search was conducted in PubMed, Scopus and Cochrane Central focusing on clinical studies of edentulous subjects treated with SIMO. The last literature search was performed in July 2017.

The question and the search strategy were structured based on the 'PICOS' method: 'Population' – edentulous patients; 'Intervention' – single-implant mandibular overdenture; 'Comparator' – conventional mandibular denture; 'Outcome' – patient-reported outcomes; 'Study design' – randomized controlled trials (RCTs) and single-arm prospective studies. A detailed description of the search strategy containing

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MeSH terms, keywords, Boolean operators and their combinations for PubMed and Scopus is detailed in Table 1. No time frame was used to limit the number of eligible studies, and no language restriction was considered for this review.

Selection criteria

To be included in this systematic review, the study had to be preferably classified as a randomised controlled trial (RCT), but prospective studies with before–after comparisons were also considered, and all of them had to include at least 10 SIMO patients. RCTs had to include conventional denture wearers as an active comparator (control group), and single-arm prospective studies had to have assessed patients treated with conventional dentures as the baseline treatment. Moreover, one or more patient-reported outcomes had to be assessed in the study. The patient-reported outcomes are important because

Table 1. Electronic databases and search strategies according to the PICO question components

Database	Search strategy
PubMed	(P) #1 (mouth, edentulous[MeSH Terms]) OR mouth, edentulous[Title/Abstract]) OR mouth, toothless[Title/Abstract]) OR edentul*[Title/Abstract]) OR edentulous patients[Title/Abstract]) OR toothless patients[Title/Abstract]) OR jaw, edentulous[MeSH Terms]) OR jaws, edentulous[Title/Abstract]) (I) #2 (denture, overlay[MeSH Terms]) OR denture, overlay[Title/Abstract]) OR overdenture*[Title/Abstract]) OR implant overdenture[Title/Abstract]) OR mandibular overdenture[Title/Abstract]) OR single implant[Title/Abstract]) OR one implant[Title/Abstract]) OR midline implant[Title/Abstract]) OR median implant[Title/Abstract]) OR single implant overdenture[Title/Abstract]) OR single-implant overdenture[Title/Abstract]) (C) #3 (denture, complete[MeSH Terms]) OR denture, complete[Title/Abstract]) OR denture[Title/Abstract]) (O) #4 (quality of life[MeSH Terms]) OR quality of life[Title/Abstract]) OR patient satisfaction[MeSH Terms]) OR patient satisfaction[Title/Abstract]) OR satisfaction with the denture*[Title/Abstract]) OR patient outcome assessment[MeSH Terms]) OR patient outcome assessment[Title/Abstract]) OR research, patient-centered outcomes[Title/Abstract]) OR outcome assessment, patient[Title/Abstract]) OR patient*reported outcome*[Title/Abstract]) OR patient*centered outcome*[Title/Abstract]) OR patient*related outcome*[Title/Abstract]) OR patient*oriented outcome*[Title/Abstract]) OR treatment outcome[MeSH Terms] OR treatment outcome[Title/Abstract]) OR effectiveness, clinical[Title/Abstract]) OR patient*relevant outcome*[Title/Abstract]) OR clinical efficacy[Title/Abstract]) OR treatment effectiveness[Title/Abstract]) OR treatment efficacy[Title/Abstract]) OR rehabilitation outcome[Title/Abstract]) #1 AND #2 AND #3 AND #4
Scopus	(P) #1 'mouth, edentulous' OR 'mouth, toothless' OR edentul* OR 'edentulous patients' OR 'toothless patients' OR 'jaw, edentulous' OR 'jaws, edentulous' (I) #2 'denture, overlay' OR overdenture* OR 'implant overdenture' OR 'mandibular overdenture' OR 'single implant' OR 'one implant' OR 'midline implant' OR 'median implant' OR 'single implant overdenture' OR 'single-implant overdenture' (C) #3 'denture, complete' OR 'denture' (O) #4 'quality of life' OR 'patient satisfaction' OR 'patient outcome assessment' OR 'research, patient-centered outcomes' OR 'outcome assessment, patient' OR 'patient-reported outcome*' OR 'patient-centered outcome*'OR 'patient-related outcome*' OR 'patient-oriented outcome*' OR 'treatment outcome' OR 'effectiveness, clinical' OR 'patient-relevant outcome*' OR 'clinical efficacy' OR 'treatment effectiveness' OR 'treatment efficacy' OR 'rehabilitation outcome' #1 AND #2 AND #3 AND #4
Cochrane Central	(P) #1 edentulous mouth OR toothless mouth OR edentulous OR edentulism OR edentulous patients OR toothless patients OR edentulous jaw (I) #2 overdenture OR implant overdenture OR mandibular overdenture OR single implant OR one implant OR midline implant OR median implant OR single implant overdenture (C) #3 complete denture OR denture (O) #4 quality of life OR patient satisfaction OR patient outcome assessment R patient-centered outcomes OR patient-reported outcome OR patient-centered outcome OR patient-related outcome OR patient-oriented outcome OR treatment outcome OR clinical effectiveness OR patient-relevant outcome OR clinical efficacy OR treatment effectiveness OR treatment efficacy OR rehabilitation outcome #1 AND #2 AND #3 AND #4

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they are reports that come directly from patients about how they feel or function in relation to a health condition and its treatment without interpretation by healthcare professionals or anyone else (19). *In vitro* studies and reviews were excluded. In the case of multiple studies from a single cohort and with the same study design, we used the following criteria to decide which data to use in this review: if the publications from the same cohort reported different patient-reported outcomes (i.e. patient satisfaction in one and oral health-related quality of life in another), both of them were included; if the same outcome was reported in the multiple papers, only the publication with the longest follow-up was included.

After completing the PubMed and Scopus searches, two reviewers (DRD and TEN) independently read all titles and abstracts (when available) to identify eligible studies. The full-text versions were obtained for studies appearing to meet the inclusion criteria or when the titles and abstracts presented insufficient data to make a clear decision. The reviewers (DRD and TEN) then assessed the full-text version independently to judge whether the studies met the inclusion criteria. A specific protocol for full-text reading was formulated and used to record the rationale for making a decision. Disagreements between the reviewers were decided by discussion and a third review author (CRL) was consulted if necessary. Additionally, a manual search was performed in the reference lists of all selected articles, aiming to identify studies with titles that seemed relevant but that may have been missed through the PubMed, Cochrane CENTRAL and Scopus searches.

Data extraction and quality assessment

A data extraction form was designed and used by the two review authors (DRD and TEN) independently. The following information was extracted from the studies: first author, year of publication, study design, country, implant and retention system, surgical and loading protocols, number of patients and details of the outcomes reported, including method of assessment and time intervals. When any clarification or information was needed, the corresponding authors were contacted by e-mail.

Moreover, an adapted version of the Cochrane checklist for describing and assessing patient-reported outcomes in clinical trials (20) was used as a guide to assess the quality of the included studies.

Results

Eleven studies fulfilled the eligibility criteria and were included in the final list. Figure 1 presents a flow diagram, based on PRISMA guidelines, of the detailed data search used for this review, the identification and selection processes, the number of excluded studies and the reasons for exclusion. Three studies were excluded because they reported previous results of the same patient cohorts (21–23) from those already included.

Table 2 details the main characteristics of the selected studies. Studies differed widely with regard to the follow-up period (mean follow-up time of 21·8 months, range: 1–60 months), implant and retention systems used and the surgical and implant loading protocols. Three different methodological designs were identified in the included studies: five parallel-group trials (16, 17, 24–26), two crossover clinical trials (27, 28) and four prospective studies (single-group trials) (8, 29–31). In the selected studies, the sample size ranged from 10 to 158 participants, and patient-reported outcomes were assessed in 328 SIMO patients.

Tables 3 and 4 describe the assessment of the methods that were used for the evaluation of patient satisfaction and quality of life outcomes in the studies included in this review. The most common instruments used to measure patient-reported outcomes were rating scales to measure satisfaction with care (8, 16, 24–27, 29–31) and oral health-related quality of life instruments (17, 28, 30). Irrespective of the outcomes measured and related instruments, all studies showed satisfactory ability to detect changes between treatments and patient condition. However, the great variation in measurements and methods did not allow for the calculation of a common summary statistic for each study to describe the observed intervention effect.

In summary, all studies reported a positive effect on satisfaction and quality of life measures after rehabilitation with SIMO compared with the conventional denture treatment, which was the reference intervention. This improvement was found irrespective of variations in implant and prosthodontic procedures and materials. However, due to the absence of a standard outcome measure, a simple descriptive analysis

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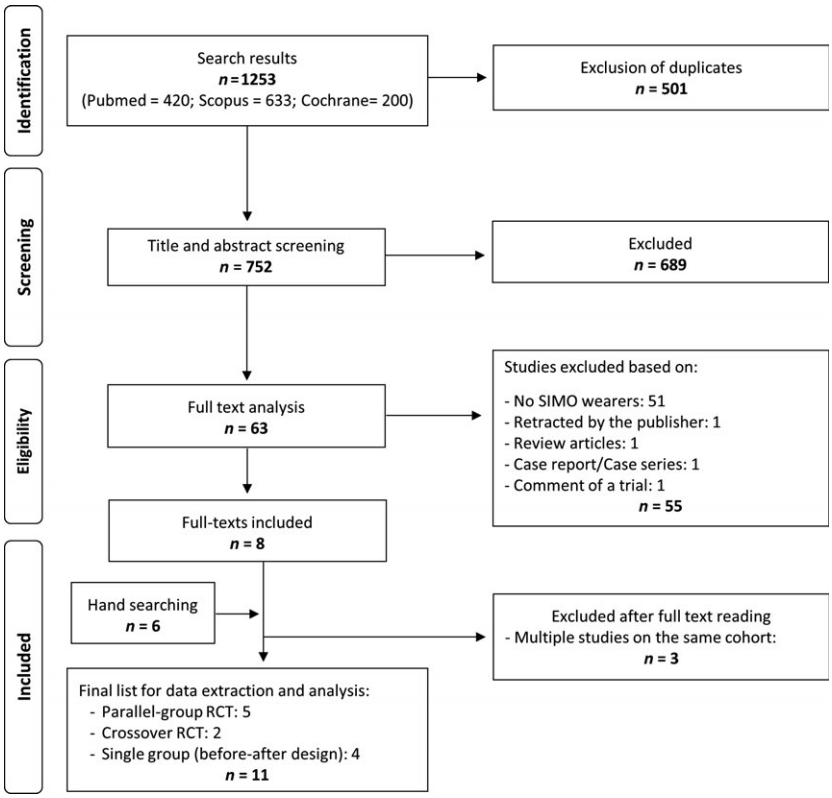

Fig. 1. Flow diagram of articles screened through the review process.

was performed by calculating the difference between initial and final measurements in order to identify the magnitude of change after SIMO treatment (Table 5).

Discussion

This systematic review summarised evidence from clinical studies regarding the effect of SIMO treatment on patient-reported outcomes after the insertion of a single implant to retain a mandibular overdenture in conventional denture wearers. Overall results suggest a significant improvement in patient satisfaction and a reduction in oral health-related quality of life impacts. Nevertheless, the heterogeneity among primary studies and the absence of randomised clinical trials comparing SIMO with CD may render meaningless any pooled estimate in a meta-analysis. Hence, this review is limited to a descriptive summary of the selected studies that described patient-reported outcomes, as well as an analysis of the main weaknesses and strengths of the methods used for outcome assessment in those studies.

Although the earliest reports identified in this topic were dated nearly two decades ago (8, 32), there are relatively few studies on SIMO, considering the high and growing number of publications in the implantology field. Furthermore, our literature search did not identify any results of randomised clinical trials that compared edentulous subjects receiving SIMO as the intervention and CD as the control treatment. However, a study protocol of an ongoing randomised controlled trial comparing SIMO and CD conducted by our research group was retrieved by our search and the results will possibly contribute to an answer for the focus question of this systematic review (33). Even though there were limitations of the studies included in this review, a clear superiority of SIMO compared to CD was observed when considering patient-reported outcomes. Conversely, previous studies that used patient-reported outcome measures also reported the non-inferiority characteristics of SIMO compared to the two-implant overdenture, suggesting that SIMO could also be a viable alternative for patients with higher surgical risks or impaired health conditions, such as very old patients, or in situations when simplification of the intervention is desirable due to financial restrictions (16, 17).

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Table 2. Main characteristics of the studies included in the systematic review

Authors/Year	Study design	Country	Implant system(s)	Retention system(s)	Surgical protocol	Loading protocol	Number of SIMO wearers	Follow-up period	Patient-reported outcome(s)	Instrument(s)
Cordioli *et al.*, 1997 (8)	Single-group design (CD→SIMO)	Italy	3i implant	O'ring/Ball attachment	2-stage	CL	21	Up to 5 years	Satisfaction (stability, retention, masticatory function, migrating pain, use of adhesive pastes)	VAS
Liddelow & Henry, 2010 (29)	Single-group design (CD→SIMO)	Australia	Branemark machined/ TiUnite implants	O'ring/Ball attachment	1-stage	IL	32	Up to 3 years	Satisfaction (pain, comfort, appearance, function, stability, speech, hygiene, overall satisfaction)	VAS
Harder *et al.*, 2011 (30)	Single-group design (CD→SIMO)	Germany	Camlog implant	Gold matrix/ Ball attachment	1/2-stages	EL	11	1 month	Chewing ability and OHRQoL	VAS and OHIP-49
Cheng *et al.*, 2012 (27)	Crossover design (locator vs. magnetic attachment)	China	Straumann standard implant	Magnetic and Locator attachments	1-stage	CL	13	3 months	Satisfaction (comfort level, speech, chewing ability, stability and retention, overall satisfaction)	VAS
Kronstrom *et al.*, 2014 (17)	Parallel-group design (SIMO vs. 2-implant overdenture)	Canada	Branemark TiUnite implant	O'ring/Ball attachment	1-stage	IL	11	1–3 years	OHRQoL	OHIP-Edent
Grover *et al.*, 2014 (28)	Crossover design (shortened vs. conventional dental arch)	India	Zimmer tapered implant	Magnetic attachment	1-stage	EL	10	Up to 3 months	OHRQoL	OHIP-49

(continued)

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Table 2. (continued)

Authors/Year	Study design	Country	Implant system(s)	Retention system(s)	Surgical protocol	Loading protocol	Number of SIMO wearers	Follow-up period	Patient-reported outcome(s)	Instrument(s)
Bryant *et al.*, 2015 (16)	Parallel-group design (SIMO vs. 2-implant overdenture)	Canada	Straumann implant	O'ring/Ball attachment	2-stage	EL	42	Up to 5 years	Overall satisfaction	VAS
Tavakolizadeh *et al.*, 2015 (25)	Parallel-group design (SIMO vs. 2-implant overdenture)	Germany/ Iran	Implantium implant	O'ring/Ball attachment	1/2-stages	IL	10	Up to 1 year	Satisfaction (overall satisfaction, social life, chew hard foods, comfort, fit)	VAS
Ismail *et al.*, 2015 (24)	Parallel-group design (ball vs. magnetic attachment)	Egypt/ Saudi Arabia	Dyna Dental implant	Ball and Magnetic attachment	2-stage	CL	10	Up to 2 years	Satisfaction and function complaints	5-point scale
Bhat *et al.*, 2016 (31)	Single-group design (CD→SIMO→2-IOD→3-IOD)	India	Snap Equinox implant	Dalla Bona attachment	2-stage	CL	10	1 month	Satisfaction (appearance, speech, chewing and self-confidence for the dentures; retention/ stability, comfort, pain and handling for the lower denture)	Grade scale up to 10
Passia *et al.*, 2017 (26)	Parallel-group design (IL-SIMO vs. CL-SIMO)	Germany	Camlog implant	Ball attachment	1/2-stages	IL or CL	158	4 months	Satisfaction (pain, comfort, appearance, function, cleaning, stability/fit and overall evaluation)	VAS

CD, conventional denture; IOD, implant overdenture; CL, conventional loading; IL, immediate loading; EL, early loading; OHRQoL, oral health-related quality of life; VAS, visual analogue scale; OHIP, Oral Health Impact Profile; OHIP-Edent, Oral Health Impact Profile for Edentulous.

Table 3. Quality assessment of the methods used for the evaluation of quality of life in the included studies

Authors/Year	What were the patient-reported outcome(s) measured?	Who completed the instruments?	How was the measurement scale?	Was the instrument used as originally proposed?	Was the instrument validated previously (reference provided?)	Was evidence of prior validation for use in this population presented?	Does the instrument have ability to measure change?
Harder *et al.*, 2011 (30)	Oral health-related quality of life	Not reported	Oral Health Impact Profile (OHIP-49) questionnaire [a 5-point scale (0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often and 4 = very often)]	Not reported	Yes	Yes	Yes
Kronstrom *et al.*, 2014 (17)	Oral health-related quality of life	Self-administered	Oral Health Impact Profile for Edentulous (OHIP-EDENT) questionnaire [five response alternatives ranging from a negative opinion ('very often') to a positive ('never')]	Yes	Yes	Yes	Yes
Grover *et al.*, 2014 (28)	Oral health-related quality of life	Self-administered	OHIP-49 questionnaire (no scale reported)	Unclear	No reference provided	No	Yes

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Table 4. Quality assessment of the methods used for the evaluation of patient satisfaction in the included studies

Authors/Year	What were the patient-reported outcome(s) measured?	Who completed the instruments?	How was the measurement scale?	Was the instrument used as originally proposed?	Was the instrument validated previously (reference provided?)	Was evidence of prior validation for use in this opulation presented?	Does the instrument have ability to measure change?
Cordioli *et al.*, 1997 (8)	Patient satisfaction based on oral comfort and function (prosthesis stability and retention, masticatory function, migrating pain and use of adhesive pastes)	Self-administered	VAS – unclear scaling	Yes	No (a reference was provided but do not describe a validation process)	No	Yes
Liddelow & Henry, 2010 (29)	Patient satisfaction based on oral comfort and function (general satisfaction, social life, mastication of hard food, comfort and fit)	Self-administered	VAS – 0–100 score	Yes	Yes	Yes	Yes
Harder *et al.*, 2011 (30)	Patient's perception of chewing ability of eight different hard and soft foods	Self-administered	VAS – no markings between the endpoints (interpreted as 0 and 100%)	Not reported	No	No	Yes
Cheng *et al.*, 2012 (27)	Patient satisfaction (comfort, speech, chewing ability, retention and stability and overall satisfaction)	Self-administered	VAS – 100-mm scale, from left (0) as completely unsatisfied and right (100) as completely satisfied	Not reported	No	No	Yes
Bryant *et al.*, 2015 (16)	Patient satisfaction (overall satisfaction with the lower denture)	Self-administered	VAS – 10-cm uninterrupted scale representing a continuum of feelings, with 'unsatisfied' at one end and 'satisfied' at the other	Not reported	No	No	Yes

(continued)

Table 4. (continued)

Authors/Year	What were the patient-reported outcome(s) measured?	Who completed the instruments?	How was the measurement scale?	Was the instrument used as originally proposed?	Was the instrument validated previously (reference provided?)	Was evidence of prior validation for use in this opulation presented?	Does the instrument have ability to measure change?
Tavakolizadeh *et al.*, 2015 (25)	Patient comfort and function (general satisfaction, social life, mastication of hard and soft foods and fit)	Self-administered	VAS – 100-mm line anchored at the beginning and end by opposing statements ('not at all satisfied' to 'extremely satisfied')	Yes	Yes	Yes	Yes
Ismail *et al.*, 2015 (24)	Patient satisfaction and complaints	Unclear	Scale ranging from 1 to 5 – Level of satisfaction: very good, good, satisfactory, sufficient, not satisfactory; Complaints: no, mild, moderate, severe, very severe complaints	Yes	No (a reference was provided but do not describe a validation process)	No	Yes
Bhat *et al.*, 2016 (31)	Patient satisfaction	Unclear	Questionnaire (eight questions, without figures or line designs, maximum score of 10)	Not reported	No	No	Yes
Passia *et al.*, 2017 (26)	Patient satisfaction (pain, comfort, appearance, function, cleaning, stability/fit and overall evaluation)	Self-administered	VAS – no markings between the endpoints (interpreted as 0 and 100%)	Yes	No (a reference was provided but do not describe a validation process)	No	Yes

VAS, visual analogue scale.

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Table 5. Estimates of the magnitude of change (before–after difference) in patient-reported outcome between initial (complete denture phase) and last measurements in the individual studies for patients treated with single-implant mandibular overdentures

Patient satisfaction	Baseline	Last follow-up	Difference*
Bhat *et al.* (31)†	2·4	3·9	15·0
Bryant *et al.* (16)†	38·1	68·8	30·7
Cheng *et al.* (27)†	85·0	97·0	7·4
Ismail *et al.* (24)†	1·3	3·7	48·0
Liddelow & Henry (29)†	≈30	≈83	53·0
Tavakolizadeh *et al.* (25)†	2·7	7·1	44·0
Cordioli *et al.* (8)	§	§	—
Harder *et al.* (30)‡	§	§	—
Passia *et al.* (26)	§	§	—
OHIP score	Baseline	Last follow-up	Difference (points)
Harder *et al.* (30)	49·0	25·0	24·0
Kronstrom *et al.* (17)	50·8	83·2	32·4
Grover *et al.* (28)	§	§	—

*0–100 converted scale.
†General satisfaction.
‡Satisfaction with chewing ability.
§No summary data available.

Four included studies were classified as prospective studies, designed as single-group trials in which all study participants received the same intervention and then were followed over time to have their response observed in a before–after comparison of measured outcomes. Despite its simplicity, inferences from single-arm trials are limited due to the inability to distinguish between the effect of the treatment and the difficulty with interpreting the response without a frame of reference for comparison (34). Conclusions drawn from these studies may be considered preliminary evidence of the efficacy and safety of SIMO treatment. Even though the selected studies reported relatively small sample sizes, most of them were powerful enough to detect differences, mainly for within-group comparison of single-group studies. These differences could be detected because of the marked increase in patient satisfaction after SIMO treatment when compared to CD. On the other hand, the small sample sizes limit the ability to test the effect of specific patients' conditions on clinical and radiographic outcomes, and the detection of significant general and local risk factors.

Besides the wide spectrum of outcome measures in implant and prosthodontic interventions, this review focused on outcomes directly reported by the patient. Patient-reported outcomes include any evaluation obtained directly from patients through interviews, self-completed questionnaires, diaries or other data collection tools such as hand-held devices and web-based forms (19). The measuring instrument must be standardised and show external validity to reduce bias and provide comparable results among different studies. Currently, there is an increasing focus in clinical studies on placing patients at the centre of healthcare research and on evaluating clinical care. The goal is to improve the patient's experience and ensure that research is both robust and of maximum value for the use of health interventions and products (35). Patient-reported outcomes are also suggested to be of more importance in the future compared to any other outcomes – for example, clinical, physiological or caregiver-reported outcomes – because patient feedback and change in patient behaviour are essential to improve treatment adherence and satisfaction with care (36).

In general, we observed a lack of information regarding the use of data collection instruments among studies, the absence of references related to the respective validation process, how the instrument was used (self-completed or interview) and how the resulting data were analysed. One study reported the Oral Health Impact Profile (OHIP) as a questionnaire to measure patient satisfaction (17); whilst it is known that OHIP does not measure any positive aspects of oral health and excludes perceptions of satisfaction with oral health, changes in oral health, prognosis or self-reported diagnoses and all impacts in the OHIP are conceptualised as adverse outcomes (37).

This systematic review highlighted the need for additional evidence derived from rigorously designed and delivered randomised clinical trials, as well as subsequent reports containing high-quality descriptions of all aspects of the study methodology. Such studies and reports would enable a systematic appraisal and interpretation of results, which could provide sound evidence about the effectiveness of SIMO compared to other treatments and about the improvement of patient-reported outcomes for poorly adapted CD wearers.

Conclusions

The available evidence suggests a considerable improvement in patient-reported outcomes following

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the insertion of a single implant to retain a mandibular denture. The results observed in the selected studies also suggest that the instruments used to measure patient-reported outcomes were able to detect the changes between treatments; however, poor reporting and lack of standardised instruments and scale measures make it difficult any attempt to combine data from these studies in a meta-analysis. To add evidence and support the indication of SIMO, further studies specifically designed to compare SIMO and CD are needed.

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Correspondence: Cláudio Rodrigues Leles, Faculdade de Odontologia, Universidade Federal de Goiás, Praça Universitária S/N. Setor Universitário. CEP 74605-220, Goiânia, Goiás, Brasil.
E-mail: claudio_leles@ufg.br

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