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Review Article

The effect of complete dentures on edentulous patients' oral health-related quality of life in long-term: A systematic review and meta-analysis

Angela M. C. Martins[1,2], Ludmila S. Guimarães[1,2], Camila H. Campos[2,6], Erika C. Küchler[3], Daniele M. S. Pereira[4], Lucianne C. Maia[5], Leonardo S. Antunes[1,2,6], Lívia A. A. Antunes[1,2,6]

[1]Postgraduate Program in Dentistry, School of Dentistry, Fluminense Federal University, Niterói, [4]Center of Health Science, Central Library, Rio de Janeiro Federal University, [5]Department of Pediatric Dentistry and Orthodontics, School of Dentistry, Rio de Janeiro Federal University, Rio de Janeiro, Rio de Janeiro, [6]Postgraduate Program in Dentistry of Health Institute of Nova Friburgo, Fluminense Federal University, Nova Friburgo, [2]Department of Specific Formation, School of Dentistry, Fluminense Federal University, Nova Friburgo, [3]Ribeirão Preto Dental School, São Paulo University, São Paulo, Brazil

ABSTRACT

Background: To evaluate whether the long-term use of complete dentures (CD) into promotes significant changes in the oral health-related quality of life (OHRQoL) in edentulous patients.

Methods: A systematic review and meta-analysis was conducted. A broad search in Pubmed, Web of Science, Scopus, Cochrane Library, Grey Literature, clinical trials registers and manual search was done. The eligibility criteria were based on population, intervention, comparisons and outcome: (P) edentulous patients, (I) CDs rehabilitation, (C) OHRQoL after CD, (O) change in scores of OHRQoL. Two independent reviewers applied the eligibility criteria, collected qualitative data, performed methodological quality and evaluated the certainty of the evidence (grading of recommendations assessment, development and evaluation). The meta-analysis was analyzed in RevMan 5.4 with 95% confidence intervals (CIs) and $P < 0.05$.

Results: A total of 2452 records were identified. Twenty-four articles were included in qualitative synthesis. Nineteen studies were qualified as good, 3 as fair and 2 as poor quality. Twelve studies were included in quantitative analysis (meta-analysis). The use of CD did not improved OHRQoL in a period of 3 months through the assessment of the Geriatric Oral Health Assessment Index (GOHAI) instrument ($P = 0.55$; CI; 6.86 [−15.60, 29.31]), and Oral Health Impact Profile-14 (OHIP-14) ($P = 0.05$; CI; −14.91 [−29.87, 0.04]), with very low certainty of evidence. In a long term, 6 months, GOHAI instrument ($P < 0.00001$; CI; 16.22 [10.70, 21.74]), OHIP 20 ($P = 0.02$; CI; −11.09 [−20.54, −1.64]) and OHIP-EDENT ($P = 0.0004$; CI; −8.59 [−13.32, −3.86]) showed improvement on OHRQoL, with very low and low evidence of certainty, respectively.

Conclusion: CD has the strong potential to contribute to oral health-related quality of life in long-term.

Key Words: Complete denture, edentulous mouth, quality of life

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Address for correspondence:
Dr. Lívia A. A. Antunes, Department of Specific Formation, Fluminense Federal University, Nova Friburgo, RJ, Brazil. Rua Dr. Silvio Henrique Braune 22, Centro, Nova Friburgo, Rio de Janeiro 28625-650, Brazil.
E-mail: liviaazeredo@gmail.com

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INTRODUCTION

Tooth loss is still an unfortunate reality for many patients, especially for the elderly.[1] Edentulism has consequences such as reduction of the lower third of the face, decrease of vertical dimension, loss or reduction of masticatory movement, poor esthetics and phonetic problems.[2] Dietary restrictions and difficulty to eat certain foods are also mentioned by edentulous patients.[3-5] Typically, preference is given to foods that are easier to crush, which can compromise the nutritional needs of the individual, and thus affect general health.[6,7] Those alterations can impact oral health-related quality of life (OHRQoL) and compromise the psychosocial behavior of the individual.[8]

Osseointegrated implants have been used as a treatment for dental loss with high success rates. However, this treatment modality is not available for all patients due to general health, cost, and/or anatomical problems.[9] In spite of removable complete dentures (CDs) being a viable treatment option for the edentulous, they require an adequate bone ridge height to allow the retention and stability, thus efficiently recovering masticatory function.[3]

It is possible to notice a positive change in the behavior of these individuals after CDs oral rehabilitation with fully adapted, comfortable and aesthetic removable CDs. Patients regain self-esteem and general well-being, fit satisfactorily back into social esthetic standards and recover lost nutritional capacity.[10,11]

Thus, the objective of this systematic review and meta-analysis was to evaluate whether the scientific evidence of the long-term use of CD into promotes significant changes in the OHRQoL in edentulous patients.

MATERIALS AND METHODS

This systematic review was recorded on the systematic reviews database PROSPERO (CRD: 42016038907). The written was performed according to Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines (http://www.prisma-statement.org)[12] [Appendix 1] and checked according to a Measurement Tool to Assess Systematic Reviews 2 (AMSTAR-2)[13] [Appendix 2].

The following focused question was outlined according to the population, intervention, comparisons and outcomes (PICO): Do CDs influence the edentulous patients' OHRQoL in long-term?

Search strategy

The process to search primary studies was done up to June 28, 2020. The following electronic databases were assessed: Pubmed, Web of Science, Scopus and Cochrane Library. The search strategy included appropriate MeSH terms, keywords, and other free terms followed the syntax rules of each database. It was used Boolean operators (OR, AND) to combine searches [Table 1]. The grey literature was consulted through SIGLE (System of Information on Grey Literature) (http://www.opengrey.eu). To find additional studies, a hand search was performed on the reference lists of the retrieved studies.

Inclusion and exclusion criteria

The selection of studies was made by analysis of titles and abstracts that met the inclusion criteria. There was no restriction on language or year of publication. The inclusion criteria outlines articles according to the PICO and study design as follows:

- Population (P): Edentulous patients (both arches)
- Intervention (I): CDs rehabilitation
- Comparison (C): OHRQoL evaluation before and after CDs rehabilitation
- Outcome (O): Change in scores of OHRQoL evaluated in a follow up period of at least 3 months
- Study design (S): Clinical trial, controlled clinical trials, randomized-controlled trials, cohort studies.

The following the exclusion criteria were considered: (i) case reports, review articles, book chapters; (ii) studies in patients with medical conditions such as systemic diseases, syndromes and craniofacial anomalies, or who have special needs or were hospitalized; (iii) studies that used nonvalidated questionnaires; (iv) absence of a baseline evaluation or a baseline was not used to compare with the follow up; (v) absence of follow up; (vii) without results per groups; (vii) studies out theme proposed records.

Study selection

Two independent reviewers analyzed all articles (LAAA and LSG). To assess the agreement between authors, 10% of the publications were random selected in this literature research, and their classification was compared. Kappa statistic was employed and demonstrated good inter-examiner agreement (K = 0.90). Duplicate studies were excluded. If the title and abstract were not clear, the

Table 1. Search strategy

Electronic databases	Search strategy
PubMed	#1(Elderly[Title/Abstract]) OR (Seniors[Title/Abstract])) OR (Edentulous[Title/Abstract])) OR (Edentate[Title/Abstract])) OR (Edentulous Mouth[Title/Abstract]) OR (Tooth Loss[Title/Abstract])) OR (Complete edentulism[Title/Abstract])) OR (Mouth, Edentulous[MeSH Terms])) OR (Tooth Loss[MeSH Terms])
	#2(Complete Dentures[Title/Abstract]) OR (Conventional Dentures[Title/Abstract])) OR (Prostheses[Title/Abstract])) OR (New Denture[Title/Abstract])) OR (Denture, Complete[MeSH Terms])
	#3(Quality of Life[Title/Abstract]) OR (QoL[Title/Abstract])) OR (Oral health-related quality of life[Title/Abstract])) OR (OHRQoL[Title/Abstract])) OR (Oral health impact profile[Title/Abstract])) OR (Patient Satisfaction[Title/Abstract])) OR (OHIP-14[Title/Abstract])) OR (OHIP-20[Title/Abstract])) OR (OHIP-49[Title/Abstract])) OR (OHIP-Edent[Title/Abstract])) OR (GOHAI[Title/Abstract])) OR (Quality of Life[MeSH Terms])) OR (Patient Satisfaction[MeSH Terms])
	#1 and #2 and #3
Scopus	#1(TITLE-ABS-KEY (Edentulous) OR TITLE-ABS-KEY (Edentate) OR TITLE-ABS-KEY (“Tooth loss”) OR TITLE-ABS-KEY (“Complete edentulism”))
	#2(TITLE-ABS-KEY (“Complete dentures”) OR TITLE-ABS-KEY (“Conventional dentures”) OR TITLE-ABS-KEY (Prostheses))
	#3(TITLE-ABS-KEY (“Quality of life”) OR TITLE-ABS-KEY (QoL) OR TITLE-ABS-KEY (“Oral health-related quality of life”) OR TITLE-ABS-KEY (“Oral health impact profile”))
	#1 and #2 and #3
Web of Science	#1TOPIC:(Edentulous) *OR* TOPIC: (Edentate) *OR* TOPIC: (“Tooth loss”) *OR* TOPIC: (“Complete edentulism”) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*
	#2 TOPIC:(“Complete dentures”) *OR* TOPIC: (“Conventional dentures”) *OR* TOPIC: (Prostheses) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*
	#3TOPIC:(“Quality of life”) *OR* TOPIC: (QoL) *OR* TOPIC: (“Oral health-related quality of life”) OR TOPIC: (“Oral health impact profile”) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All year*
	#1 and #2 and #3
Cochrane library	Edentulous OR Edentate OR Tooth loss OR Complete edentulism in Title Abstract Keyword AND Complete dentures OR Conventional dentures OR Prostheses in Title Abstract Keyword AND Quality of life OR QoL OR Oral health-related quality of life OR Oral health impact profile in Title Abstract Keyword

OHRQoL: Oral health-related quality of life

article was read in full. If doubt remained, authors were contacted. If disagreements occurred, a third author (LSA) was called, aiming for a consensus.

Data extraction (qualitative data)

Two independent reviewers (LSG and AMCM) extracted relevant data presented in the articles. To characterize and demonstrate the methodological design, we presented the following in detail: Author/year of publication, country where the research was carried out, age of subjects, sample size, social dental index (questionnaire) used to assess the OHRQoL, form of application, type of study, groups compared and the time of follow up.

Another data extracted from the elected articles was average impact for the total scale and subscales before (baseline) and after the CD installation and its association with OHRQoL.

Evaluation criteria of study risk of bias

Methodological quality and risk of bias control were evaluated in accordance to the guidelines “Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Group” described by the National Institutes of Health.[14] This quality assessment tool allows classifying before-after studies with no control group and provides a standardized approach for evaluating the quality. The tools were designed to assist reviewers in focusing on concepts that are key for critical appraisal of the internal validity of a study.

Two reviewers (LSG and LAAA) independently assessed the quality of the included studies, which quality reviewers could select “yes,” “no,” or “cannot determine/not reported/not applicable” in response to each item on the tool. For each item in which “no” was selected, reviewers were instructed to consider the potential risk of bias that could be introduced by that flaw in the study design or implementation. “Cannot determine” and “not reported” were also noted as representing potential flaws. In general terms, a “good” study has the least risk of bias, and results are considered to be valid. A “fair” study is susceptible to some bias deemed not sufficient to invalidate its results. The fair quality category is likely to be broad, so studies with this rating will vary in their strengths and weaknesses. A “poor” rating indicates significant risk of bias. So, we established as

"good" studies those that presented up to 3 answers "no"; "fair" studies that presented from 3 to 5 answers of "no"; and "poor" studies that presented more than 5 answers of "no."

Meta-analysis (quantitative data)

For the meta-analysis, we pooled and extracted the mean and the standard deviation (continuous data) from the included studies. Subgroups were established prior to the overall analysis of the outcome, according to the time of follow-up of OHRQoL questionnaire. Each study was included in the analysis only once.

RevMan 5.4 software (Cochrane Central Executive Team, St Albans House, 57-59 Haymarket, London, United Kingdom) was used to analyze the data for heterogeneity and produce a graphical display of results. For forest plots, 95% confidence intervals (CIs) and *P* values were calculated. Heterogeneity among the results of studies and the quantification of inconsistency were evaluated using the I^2 test.[15] Values of I^2 >50%, I^2 25%–50% and I^2 <25% were considered high, moderate and low, respectively.[15] In the Forest plot, $P < 0.05$ was used to test for overall effect.

Co-variables that influence in the stability of the main outcomes of meta-analisys will be treated with sensibility analysis or meta-regression. Meta-regression consists of a form of sensitivity analysis in covariable meta-analysis. In meta-regression, the number of covariates to be included is limited to the number of studies considered in the meta-analysis. Ideally, one covariate should be used for every ten studies. If the sum of included studies of an outcome exceeded 10, funnel plots can also be generated to analyze the publication bias test.[16]

Grading of recommendations assessment, development and evaluation

Two reviewers (LSG and LAAA) independently analyzed the quality of the evidence (certainty in the estimates of effect) using the grading of recommendations assessment, development and evaluation (GRADE) approach. The domains evaluated in clinical studies are risk of bias, inconsistency, indirectness, imprecision and publication bias. The GRADE defines the quality of scientific evidence more clearly and objectively and can be classified as high, moderate, low or very low.[17]

RESULTS

Flowchart recommended by PRISMA guidelines[11] [Figure 1] describes the number of articles identified in each step of the study. A total of 2452 articles were found, of which 928 were duplicate articles and were removed. Of the 1524 remaining articles, 1460 were excluded after the application of eligibility criteria. Sixty-four articles were accessed in full and of these, 24 were elected for evaluation of methodological. No studies were found through the manual search in the references of the articles.

The characterization and methodological design extracted from the articles are presented in Table 2. The publications from 2003 and 2020 were assessed. The countries with most studies were Brazil[8,18-24] and India.[25-27] The population age ranged from 36 to 93 years old. The smallest sample was 15[22] volunteers and the biggest was 224.[28] Three studies[25,26,29] used Geriatric Oral Health Assessment Index (GOHAI), six studies[28,34-38] used Oral Health Impact Profile-14 (OHIP-14), three studies[30-32] used OHIP-20, two studies[28,33] used OHIP-49, and twelve studies[8,18-24,27,28,39,40] used OHIP for Edentulous (OHIP-EDENT) as the questionnaire tool. It was observed that in the last 5 years from 9 studies,[8,21-24,27,38-40] 8 papers[8,21-24,27,39,40] used the OHIP-EDENT. The most common study design was RCT comparing the CD group with another type of oral rehabilitation. The longest time of follow-up was 5 years[39] followed by 1 study that followed up for 2 years[22] and 4 studies[23,26,32,37] that followed up for 12 months.

From 24 studies,[8,18-40] only two[31,35] presented no significant changes on OHRQoL after new CD treatment. For GOHAI instrument, higher score is associated with a more positive oral health related quality of life,[29] while in the other OHRQoL questionnaires, such as OHIP-14, OHIP-20, OHIP-49 and OHIP-EDENT, lower score is associated with a more positive oral health related quality of life [Table 3].

Based on the checklist to assess the risk of bias, 19 studies were qualified as good,[8,19-24,26-33,37-40] 3 studies as fair[18,25,36] and 2 as poor[34,35] [Table 4]. The mainly problems were detected on questions 3, 5 and 7.

A meta-analysis was performed to evaluate the studies having comparable results. Some studies were not included in this meta-analysis due the authors reported the data in frequency,[18] median,[22] sum of rank,[34,35,40] and others have not yet provided the results of the mean impact of baseline or/and follow-up.[19,20,23,33,39]

A random-effect model was used when substantial high heterogeneity (I^2 >50%) was found in

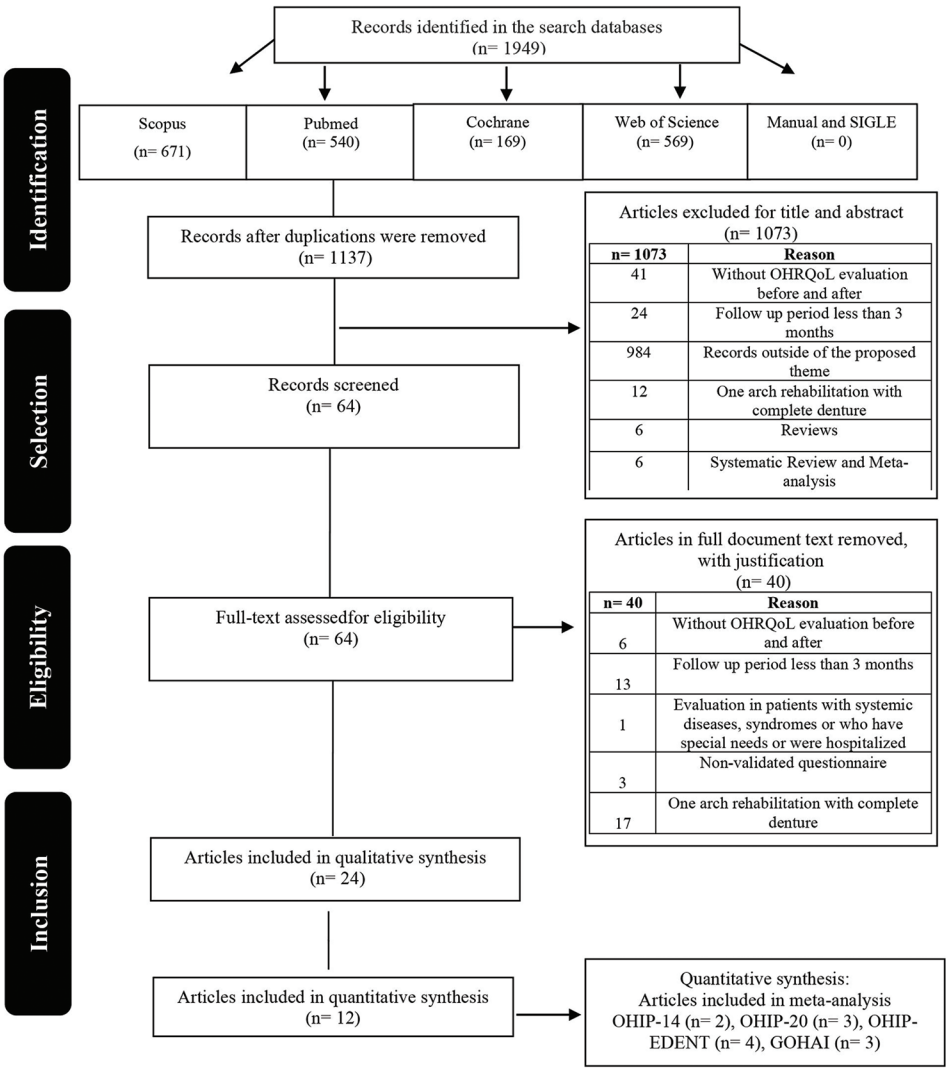

Figure 1: Flowchart for the search process in articles and selection using the Preferred Reference Items for Systematic Reviews (PRISMA).[11]

meta-analysis.[15] Forest plots were created according to the instruments: GOHAI at 3[26,29] and 6[25,26] months [Figure 2]; OHIP-14[36,38] at 3 months [Figure 3]; OHIP-20[30-32] [Figure 4] and OHIP-EDENT[21,24,27,28] at 6 months [Figure 5]. The meta-analysis showed no favorable outcome for the use of CD on improving OHRQoL in a period of 3 months through the assessment of the GOHAI instrument (P = 0.55; CI; 6.86 [−15.60, 29.31]), and OHIP-14 (P = 0.05; CI; −14.91 [−29.87, 0.04]). In a long term, 6 months, GOHAI instrument (P < 0.00001; CI; 16.22 [10.70, 21.74]), OHIP 20 (P = 0.02; CI; −11.09 [−20.54, −1.64]) and OHIP-EDENT (P = 0.0004; CI; −8.59 [−13.32, −3.86]) showed improvement on OHRQoL, with very low and low evidence of certainty, respectively.

This study did not have as many co-variables to perform the meta-regression or sensitivity analysis. Publication bias cannot be assessed once there were no subgroup analyses with at least 10 studies included in the meta-analysis.

The certainty of the evidence is shown in Table 5. It was considered very low when the GOHAI and OHIP-14 instruments were applied in 3 months after patients rehabilitated with new CDs. At 6 months, the certainty of the evidence was very low in the GOHAI and OHIP-20 questionnaires. In the subgroup analysis for the GOHAI instrument and in OHIP-EDENT, also at 6 months, the certainty of the evidence was considered very low and low respectively. Serious or very serious problems regarding the risk of bias, inconsistency and imprecision were detected in the studies included in this meta-analysis.

Table 2: Data characterization and methodological design from included articles (*n*=24)

Author/year	Country	Age	Total sample and CD group	Instrument/ application form	Type of studies	Comparision group	Follow up
Heydecke *et al.* (2003)[30]	Canada	65 to 75	Total: 55 CD: 30	OHIP- 20 Self-applied	RCT	Overdenture and CD	Baseline/6 months
Veyrune *et al.* (2005)[29]	France	40 to 81	Total: 25 CD: 25	GOHAI Interview	RCT	Before and after CD	Baseline and delivery/6 weeks and 12 weeks (3 months)
Forgie *et al.* (2005)[34]	Scotland and England	Mean age from 71 to 74 years	Total: 58 CD: 58	OHIP-14 Self-applied	CT	Before and after CD	Baseline/3 months
Scott *et al.* (2006)[35]	WD	Mean age 71 years	Total: 65 CD: 65	OHIP-14 Self-applied	CT	CD using two different confection methods	Baseline/3 months
Ellis *et al.* (2010)[31]	United Kingdom	40 to 80	Total: 54 CD: 26	OHIP-20 WD	Cohort	Mandibular overdentures and CD	Baseline/6 months
Michaud *et al.* (2012)[32]	Canada	64 to 85	Total: 255 CD: 128	OHIP-20 WD	RCT	Overdenture and CD	Baseline/6 months/12 months
Goiato *et al.* (2012)[18]	Brazil	WD	Total: 60 CD: 60	OHIP-EDENT WD	CT	Before and after CD	Baseline/3 months
Ha *et al.* (2012)[36]	Korea	65 to 93	Total: 439 CD: 178	OHIP-14K Self-reported	CT	PRP and CD	Baseline/3 months
Harris *et al.* (2013)[33]	Ireland	WD	Total: 122 CD: 65	OHIP- 49 WD	RCT	Overdenture and CD	Baseline/3 months/6 months
Dable *et al.* (2013)[25]	India	60 to 82	Total: 63 CD: 63	GOHAI WD	RCT	Before and after CD	Baseline/6 months
Viola *et al.* (2013)[19]	Brazil	37 to 86	Total: 70 CD: 70	OHIP-EDENT Interview	CT	Before and after CD	Baseline/3 months
Regis *et al.* (2013)[20]	Brazil	47 to 80	Total: 39 CD: 39	OHIP-EDENT Interview	RCT	CD using two different confection methods	Baseline/3 months/6 months
Kuo *et al.* (2013)[28]	Taiwan	65 and over	Total: 224 CD: 224	OHIP-49 OHIP-14S OHIP-14T OHIP-EDENT 36-item Short-Form (SF-36) Interview	CT	Before and after CD	Baseline/6 months
Cakir *et al.* (2014)[37]	Turkey	36 to 81	Total: 116 CD: 29	OHIP-14 Self-applied	RCT	Overdenture, FPP, PRP and CD	Baseline/12 months
Madhuri *et al.* (2014)[26]	India	Up to 50	Total: 42 CD: 42	GOHAI Interview	CT	Before and after CD	Baseline/3 months/6 months/12 months
Nuñez *et al.* (2015)[21]	Brazil	65 to 74	Total: 50 CD: 50	OHIP-EDENT WD	RCT	CD using two different confection methods	Baseline/1 month/6 months
Sivakumar *et al.* (2015)[27]	India	55 to 81	Total: 66 CD: 66	OHIP-EDENT Interview	CT	Before and after CD	Baseline/1 month/6 months
Cardoso *et al.* (2016)[8]	Brazil	49 to 75	Total: 50 CD: 25	OHIP-EDENT WD	CT	Before and after CD	Baseline/3 months
Degrandi *et al.* (2017)[38]	Uruguay	40 to 85	Total: 91 CD: 91	OHIP-14 Self-applied	CT	Before and after CD	Baseline/3 months
Marra *et al.* (2017)[39]	WD	WD	Total: 60 CD: 30	OHIP-EDENT WD	CT	Overdenture and CD	Baseline/5 years
Amagai *et al.* (2017)[40]	Japan	WD	Total: 62 CD: 62	OHIP-EDENT-J WD	RCT	CD+Simple dietary advice and CD+Denture care advice	Baseline/3 months
Alves *et al.* (2018)[22]	Brazil	50 to 82	Total: 15 CD: 15	OHIP-EDENT WD	CT	Before and after CD	Baseline/3 months/2 years

Contd...

Table 2: Continuation...

Author/year	Country	Age	Total sample and CD group	Instrument/ application form	Type of studies	Comparision group	Follow up
Tôrres *et al.* (2019)[23]	Brazil	WD	Total: 32 CD: 32	OHIP-EDENT WD	CT	Before and after CD	Baseline/3 months/6 months/12 months
Albuquerque *et al.* (2020)[24]	Brazil	50 to 79	Total: 50 CD: 50	OHIP-EDENT Interview	RCT	CD using two different confection methods	Baseline/3 months/6 months

WD: Without data; OHIP: Oral health impact profile; OHIP-EDENT: Oral health impact profile for assessing edentulous subjects; GOHAI: Geriatric oral health assessment index; OIDP: The oral impacts on daily performance; RCT: Randomized clinical trial; CT: Clinical trial; CD: Complete dentures; FPP: Fixed partial prosthesis; PRP: Partial removable prosthesis

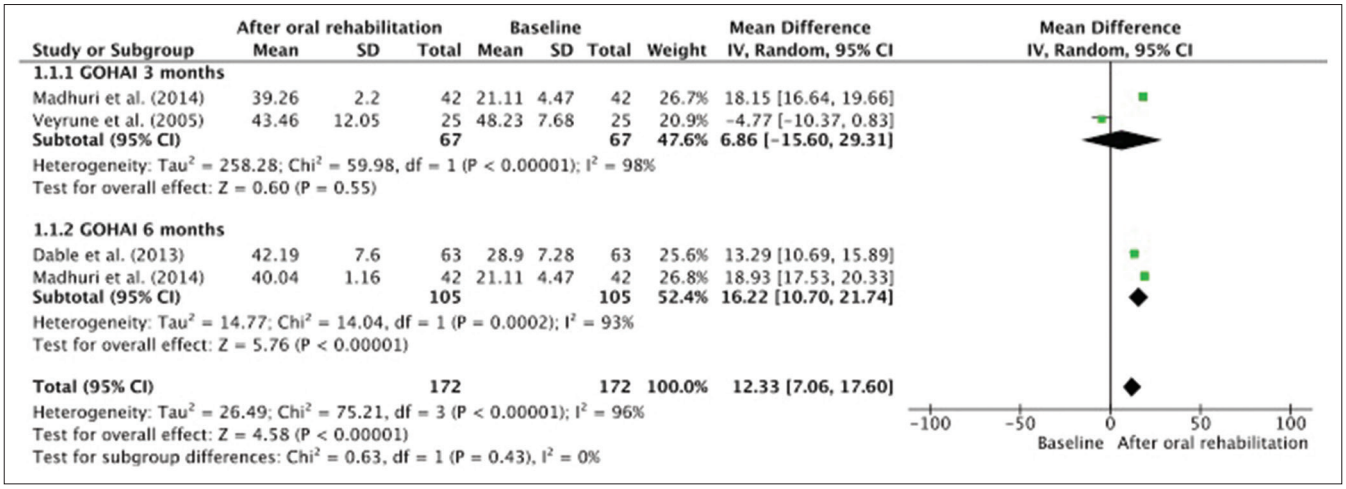

Figure 2: Forest plot of total scale of Geriatric Oral Health Assessment Index instrument regarding to time of follow-up (3 and 6 months).

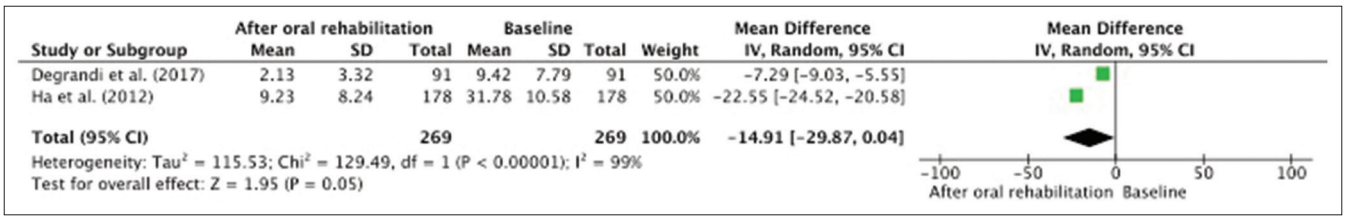

Figure 3: Forest plot of total scale of Oral Health Impact Profile-14 instrument regarding to time of follow-up (3 months).

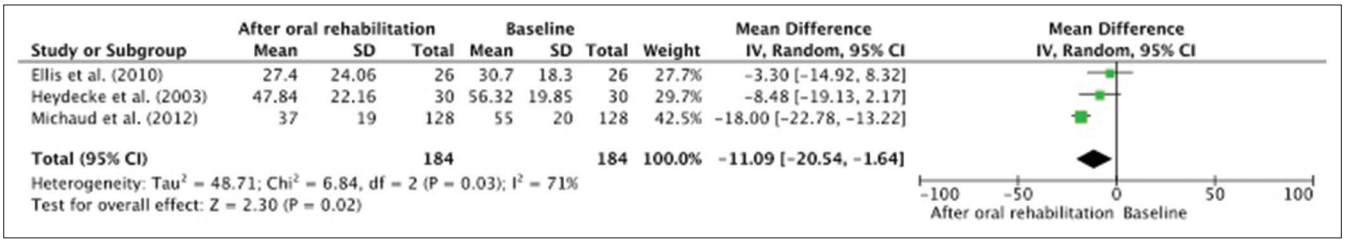

Figure 4: Forest plot of total scale of Oral Health Impact Profile-20 instrument regarding to time of follow-up (6 months).

DISCUSSION

Tooth loss is a major problem for people worldwide because tooth replacement does not always meet the basic needs of these patients. The consequences of edentulism can impact OHRQoL[41] and to compromise social life.[6,7] Also, there is a preference for soft foods, which compromises the overall health of these patients through inadequate ingestion of nutrients.

Table 3: Mean before and after complete dentures in edentulous patients and association with oral health-related quality of life (*n*=24)

Author/year	Questionnaire	Total scale	Subscale		Association of new
		Mean impact (SD)	Mean impact (SD)		CD and improvement on OHRQoL
Heydecke *et al.* (2003)[30]	OHIP- 20	Baseline=56.32 (19.85) 6 months=47.84 (22.16)	Baseline FL=11.56 (3.54) PP=15.48 (5.70) PD1=5.96 (3.01) PD2=10.88 (4.65) PD3=5.00 (2.53) SD=4.20 (1.55) HP=3.24 (1.64)	6 months FL=10.36 (4.44) PP=12.36 (6.10) PD1=4.60 (3.03) PD2=9.48 (5.60) PD3=4.40 (2.71) SD=3.88 (1.59) HP=2.76 (1.64)	Yes. Using OHIP-20, there were association of CD and OHRQoL in Physical pain and Psychological discomfort subscale
Veyrune *et al.* (2005)[29]	GOHAI	Baseline=48.23 (7.68) 6 weeks (1 month)=49.58 (7.16) 12 weeks (3 months)=43.46 (12.05)	WD		Yes. GOHAI demonstrated improvement of OHRQoL12 weeks after the participants received their CD.
Forgie *et al.* (2005)[34]	OHIP-14	WD	WD		Yes. The were significantly lower OHIP score after treatment with new CD.
Scott *et al.* (2006)[35]	OHIP-14	WD	WD		No. There were no significant changes in the OHIP scores after new dentures had been provided compared with before treatment.
Ellis *et al.* (2010)[31]	OHIP- 20	Baseline=30.70 (18.30) 6 months=27.40 (24.06)	WD		No. There were no significant changes between baseline and 6months.
Michaud *et al.* (2012)[32]	OHIP- 20	Baseline=55.00 (20.00) 6 months=37.00 (19.00) 12 months=35.00 (17.00)	WD		Yes. Results show that OHIP-20 change OHRQoL.
Goiato *et al.* (2012)[18]	OHIP-EDENT	WD	WD		Yes. The treatment was effective with respect to the patients OHRQoL.

Contd...

Table 3: Contd...

Author/year	Questionnaire	Total scale Mean impact (SD)	Subscale Mean impact (SD)			Association of new CD and improvement on OHRQoL
Ha *et al.* (2012)[36]	OHIP-14	Baseline=31.78 (10.58) 3 months=9.23 (8.24)	Baseline FL=5.65 (2.16) PP=5.06 (1.96) PD1=5.02 (2.16) PD2=5.75 (2.22) PD3=3.86 (2.18) SD=2.51 (2.13) HP=3.92 (2.17)		3 Months FL=2.25 (2.16) PP=2.44 (1.68) PD1=1.26 (1.58) PD2=1.46 (2.06) PD3=0.70 (1.12) SD=0.42 (0.96) HP=0.70 (1.39)	Yes. This study showed considerable improvement in the OHRQOL among the poor elderly population
Harris *et al.* (2013)[33]	OHIP - 49	WD	Baseline FL=35.57 (12.17) PP=28.82 (12.05) PD1=19.97 (9.04) PD2=26.64 (12.9) PD3=15.51 (11.11) SD=7.38 (7.83) HP=11.29 (8.93)	3 Months FL=36.67 (13.75) PP=26.20 (13.24) PD1=15.56 (10.20) PD2=26.45 (15.16) PD3=14.49 (12.00) SD=6.21 (7.43) HP=8.58 (9.67)	6 Months FL=20.39 (12.66) PP=18.94 (13.90) PD1=11.21 (11.01) PD2=17.40 (14.54) PD3=8.30 (10.54) SD=3.49 (6.34) HP=4.96 (9.10)	Yes. OHIP-49 demonstrated association 3 months after receiving CD. No further improvements on OHRQoL were found in 6 months on any of the measures
Dable *et al.* (2013)[25]	GOHAI	Baseline=28.90 (7.28) 6 months=42.19 (7.60)	WD			Yes. An improvement in GOHAI score was observed 6 months after the participants received their new CD.
Viola *et al.* (2013)[19]	OHIP-EDENT	WD	Baseline FL=8.11 (3.18) PP=5.11 (2.17) PD1=4.20 (2.32) PD2=5.84 (2.59) SD=1.41 (0.98) HP=1.85 (1.12)		3 Months FL=5.14 (1.96) PP=3.37 (2.02) PD1=2.30 (1.14) PD2=3.30 (2.26) SD=1.10 (0.48) HP=1.10 (0.48)	Yes. This study indicated that in all domains there were significant improvements in the OHIP scores with the new CD.
Regis *et al.* (2013)[20]	OHIP-EDENT	Baseline=11.70 (7.90) 3 months=WD 6 months=WD	Baseline WD	3 Months FL+PD2=2.50 (4.8) PD1+PD3=1.00 (2.00) SD=0.00 (0.00) PP+PD1=2.50 (3.00)	6 Months FL+PD2=2.00 (3.00) PD1+PD3=1.00 (1.00) SD=0.00 (0.00) PP+PD1=2.00 (2.80)	Yes. Considering total sample, new dentures improved OHRQoL at three and at 6 months (comparing to baseline).
Kuo *et al.* (2013)[28]	OHIP-49	Baseline=60.30 (35.09) 6 months=52.90 (36.19)	Baseline FL=15.29 (7.60) PP=10.24 (7.21) PD1=6.64 (4.91) PD2=10.42 (7.91) PD3=6.49 (5.42) SD=4.17 (3.98) HP=7.05 (5.60)		6 Months FL=12.45 (7.38) PP=9.43 (7.40) PD1=4.73 (4.24) PD2=9.95 (7.67) PD3=5.93 (5.31) SD=4.17 (4.06) HP=6.24 (5.37)	Yes. This study suggests that denture treatments are associated with improvements of OHRQoL.

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Table 3: Contd...

Author/year	Questionnaire	Total scale Mean impact (SD)	Subscale Mean impact (SD)			Association of new CD and improvement on OHRQoL
	OHIP-14S	Baseline=16.40 (10.63) 6 months=14.60 (10.61)	Baseline FL=2.70 (2.27) PP=2.20 (1.97) PD1=2.70 (2.00) PD2=2.50 (2.04) PD3=2.10 (1.94) SD=1.90 (1.77) HP=2.20 (2.16)		6 Months FL=2.40 (1.89) PP=2.10 (1.56) PD1=2.00 (1.77) PD2=2.30 (1.95) PD3=1.90 (1.79) SD=1.80 (1.73) HP=2.10 (2.00)	
	OHIP-14T	Baseline=17.40 (10.76) 6 months=15.10 (10.75)	Baseline FL=2.70 (2.27) PP=2.20 (1.86) PD1=3.30 (2.49) PD2=2.90 (2.18) PD3=2.10 (1.91) SD=1.90 (1.77) HP=2.40 (2.22)		6 Months FL=2.40 (1.89) PP=1.80 (1.68) PD1=2.20 (2.02) PD2=2.70 (2.07) PD3=1.80 (1.77) SD=1.80 (1.73) HP=2.30 (2.09)	
	OHIP-EDENT	Baseline=23.70 (13.46) 6 months=21.60 (14.73)	Baseline FL=5.90 (2.87) PP=4.10 (3.39) PD1=3.30 (2.49) PD2=3.70 (2.88) PD3=2.00 (1.94) SD=2.50 (2.49) HP=2.20 (2.01)		6 Months FL=5.10 (3.00) PP=4.30 (3.34) PD1=2.20 (2.02) PD2=4.00 (3.20) PD3=1.80 (1.75) SD=2.30 (2.40) HP=2.00 (1.91)	
Cakir *et al.* (2014)[37]	OHIP-14	Baseline=21.24 (2.82) 12 months=12.24 (2.80)	Baseline FL=16.02 (1.20) PP=18.22 (2.89) PD1=11.78 (3.07) PD2=23.67 (2.04) PD3=24.29 (8.96) SD=6.60 (2.54) HP=15.67 (6.70)		12 months FL=11.34 (3.98) PP=15.22 (8.67) PD1=10.75 (3.59) PD2=19.77 (4.60) PD3=11.22 (4.29) SD=5.45 (2.10) HP=8.44 (6.22)	Yes. A positive influence on OHRQoL was observed, mainly on FL, PD2 and HP.
Madhuri *et al.* (2014)[26]	GOHAI	Baseline=21.11 (4.47) 3 months=39.26 (2.20) 6 months=40.04 (1.16) 12months=40.19 (1.15)	WD			Yes. The insertion of CD was effective in increasing the OHRQoL.
Nuñez *et al.* (2015)[21]	OHIP-EDENT	Baseline=16.90 (8.00) 1 month=3.90 (4.50) 6 months=4.80 (6.30)	Baseline FL+PD2=4.50 (2.20) PD1+PD3=5.10 (2.80) SD=2.30 (2.60) PP+PD1=5.10 (2.80)	1 Month FL+PD2=1.70 (1.70) PD1+PD3=0.70 (1.30) SD=0.40 (1.20) PP+PD1=1.10 (1.50)	6 Months FL=1.80 (2.30) PD1+PD3=1.00 (1.90) SD=0.30 (1.90) PP+PD1=1.70 (2.10)	Yes. The reduction in OHRQoL impacts was significant for all OHIP-EDENT domains.

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Table 3: Contd...

Author/year	Questionnaire	Total scale Mean impact (SD)	Subscale Mean impact (SD)			Association of new CD and improvement on OHRQoL
Sivakumar *et al.* (2015)[27]	OHIP-EDENT	Baseline=15.55 (10.12) 1 month=5.71 (6.97) 6 months=2.70 (5.32)	Baseline FL=2.59 (1.97) PP=2.48 (2.07) PD1=1.89 (2.06) PD2=3.43 (2.66) PD3=2.20 (2.38) SD=1.68 (1.93) HP=1.29 (1.74)	1 month FL=1.20 (1.46) PP=1.64 (2.06) PD1=0.43 (0.89) PD2=1.52 (1.68) PD3=0.41 (0.87) SD=0.30 (0.99) HP=0.21 (0.80)	6 Months FL=0.50 (1.30) PP=0.50 (0.99) PD1=8.29 (0.76) PD2=0.79 (1.60) PD3=0.25 (0.77) SD=0.27 (0.70) HP=0.02 (0.02)	Yes. Elderly edentulous patients had an improved overall OHRQoL after CD therapy.
Cardoso *et al.* (2016)[8]	OHIP-EDENT	WD	WD			Yes. Elderly edentulous patients had an improved overall OHRQoL after CD therapy.
Degrandi *et al.* (2017)[38]	OHIP-14	Baseline=9.42 (7.79) 3 months=2.13 (3.32)	WD			Yes. There was a significant statistical improvement of the OHRQL as perceived by the surveyed patients.
Marra *et al.* (2017)[39]	OHIP-EDENT	Baseline=WD 5 years=30.36 (16.07)	Baseline FL=8.93 (3.57) PP=8.93 (3.57) PD1=7.14 (3.57) PD2=8.93 (3.57) PD3=8.93 (3.57) SD=8.93 (3.57) HP=7.14 (3.57)	5 years FL=5.36 (3.57) PP=5.36 (3.57) PD1=3.57 (1.79) PD2=4.46 (3.57) PD3=3.57 (1.79) SD=3.57 (3.57) HP=3.57 (0.00)		Yes. The results indicated that OHRQoL was significantly improved after treatment with new CD
Amagai *et al.* (2017)[40]	OHIP-EDENT-J	WD	WD			Yes. There were more significant improved dimensions of OHIP-EDENT-J in the intervention group than in the control group at the 3-month assessment.

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Table 3: Contd...

Author/year	Questionnaire	Total scale	Subscale			Association of new
		Mean impact (SD)	Mean impact (SD)			CD and improvement on OHRQoL
Alves *et al.* (2018)[22]	OHIP-EDENT	WD	WD			Yes. Differences in discomfort and chewing inability between the initial evaluation and 2 years into wearing the dentures were confirmed, demonstrating an improvement in patient OHRQoL
Tôrres *et al.* (2019)[23]	OHIP-EDENT	WD	WD			Yes. new complete dentures significantly improved the OHRQoL
Albuquerque *et al.* (2020)[24]	OHIP-EDENT	Baseline=12.40 (6.30) 3 months=6.70 (5.60) 6 months=5.00 (5.20)	Baseline 2 FL+PD2=3.50 (2.20) 3 PD1+PD3=2.80 (2.00) 4 SD=1.40 (1.50) 1 PP+PD1=4.70 (2.70)	3 months FL+PD2=2.20 (2.40) PD1+PD3=1.10 (1.40) SD=0.30 (0.60) PP+PD1=3.20 (2.10)	6 months FL+PD2=1.60 (1.90) PD1+PD3=0.70 (0.90) SD=0.00 (0.00) PP+PD1=2.80 (2.70)	Yes. Regardless of the technique, participants reported better OHRQoL in both follow-up periods (3 and 6 months after denture delivery)

WD: Without data; FL: Functional limitation; PP: Physical Pain; PD1: Psychological Discomfort; PD2: Physical Disability; PD3: Psychological Disability; SD: Social Disability; HP: Handicap; OHIP: Oral Health Impact Profile; OHIP-EDENT: Oral Health Impact Profile for assessing edentulous subjects.; GOHAI: Geriatric Oral Health Assessment Index; OIDP: The Oral Impacts on Daily Performance; OHRQoL: Oral health-related quality of life; CD: Complete dentures

Table 4: Quality assessment (n=24)

Author/year	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	Question 8	Question 9	Question 10	Question 11	Question 12	Quality Rating
Heydecke *et al.* (2003)[30]	Yes	Yes	Yes	Yes	Yes	Yes	No	Na	Nr	Yes	Yes	Na	G
Veyrune et al. (2005)[29]	Yes	Yes	Yes	No	No	Yes	Yes	Na	Yes	Yes	Yes	Na	G
Forgie *et al.* (2005)[34]	Yes	No	Yes	No	No	Yes	No	Na	Yes	Yes	No	Na	P
Scott *et al.* (2006)[35]	Yes	No	No	Yes	No	No	No	Na	Nr	Yes	No	Na	P
Ellis *et al.* (2010)[31]	Yes	Yes	No	Yes	Yes	Yes	No	Na	Yes	Yes	Yes	Na	G
Michaud *et al.* (2012)[32]	Yes	Yes	Yes	Yes	No	Yes	Yes	Na	Yes	Yes	Yes	Na	G
Goiato *et al.* (2012)[18]	Yes	Yes	Yes	Nr	No	Yes	Yes	Na	Nr	Yes	No	Na	F
Ha *et al.* (2012)[36]	Yes	No	No	Yes	No	Yes	No	Na	Yes	Yes	Yes	Na	F
Harris *et al.* (2013)[33]	Yes	Yes	Yes	Nr	Yes	Yes	No	Na	Nr	Yes	Yes	Na	G
Dable *et al.* (2013)[25]	Yes	Yes	Yes	No	No	Yes	No	Na	Yes	Yes	No	Na	F
Viola *et al.* (2013)[19]	Yes	Yes	Yes	Nr	No	Yes	No	Na	Ne	Yes	No	Na	G
Regis *et al.* (2013)[20]	Yes	Yes	Yes	Yes	Yes	Yes	No	Na	Yes	Yes	Yes	Na	G
Kuo *et al.* (2013)[28]	Yes	No	Yes	Yes	No	Yes	Yes	Na	Yes	Yes	Yes	Na	G
Cakir *et al.* (2014)[37]	Yes	Yes	Yes	Yes	Yes	Yes	No	Na	Yes	Yes	No	Na	G
Madhuri *et al.* (2014)[26]	Yes	No	Yes	Yes	Yes	Yes	Yes	Na	Yes	Yes	Yes	Na	G
Nuñez *et al.* (2015)[21]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Na	Yes	Yes	Yes	Na	G
Sivakumar *et al.* (2015)[27]	Yes	Yes	Yes	Yes	No	Yes	No	Na	Yes	Yes	Yes	Na	G
Cardoso *et al.* (2016)[8]	Yes	Yes	Yes	Yes	Yes	Yes	No	Na	Yes	Yes	No	Na	G
Degrandi *et al.* (2017)[38]	Yes	Yes	Yes	Yes	No	Yes	Yes	Na	Yes	Yes	Yes	Na	G
Marra *et al.* (2017)[39]	Yes	Yes	No	Yes	No	Yes	No	Na	Yes	Yes	Yes	Na	G
Amagai *et al.* (2017)[40]	Yes	Yes	Yes	Yes	Yes	Yes	No	Na	Yes	Yes	Yes	Na	G
Alves *et al.* (2018)[22]	Yes	Yes	No	Yes	No	Yes	No	Na	Yes	Yes	Yes	Na	G
Tôrres *et al.* (2019)[23]	Yes	Yes	Yes	Yes	No	Yes	No	Na	Yes	Yes	Yes	Na	G
Albuquerque *et al.* (2020)[24]	Yes	Yes	Yes	Yes	Yes	Yes	No	Na	Yes	Yes	Yes	Na	G

Questions: 1. Was the study question or objective clearly stated?; 2. Were eligibility/selection criteria for the study population prespecified and clearly described?; 3. Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?; 4. Were all eligible participants that met the prespecified entry criteria enrolled?; 5. Was the sample size sufficiently large to provide confidence in the findings?; 6. Was the test/service/intervention clearly described and delivered consistently across the study population?; 7. Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?; 8. Were the people assessing the outcomes blinded to the participants' exposures/interventions?; 9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?; 10. Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided P values for the pre-to-post changes?; 11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?; 12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?. CD: Cannot determine; Na: Not applicable; Nr: Not reported; Quality Rating: G: Good; F: Fair (acceptable); P: Poor

Table 5: Evidence profile

Certainty assessment							Number of patients		Effect		Certainty	Importance
Number of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Baseline	Follow-up	Relative (95% CI)	Absolute (95% CI)		
GOHAI (3 months)												
2	Randomised trials	Not serious	Very serious[a]	Not serious	Very serious[b]	none	67	67	-	MD 6.86 (−15.6-29.31)	⊕◯◯◯ Very low	Important
GOHAI (6 months)												
2	Randomised trials	Seriou[c]	Serious[d]	Not serious	Serious[e]	none	105	105	-	MD 16.22 (10.7-21.74)	⊕◯◯◯ Very low	Important
GOHAI measurements												
4	Randomised trials	Serious[c]	Not serious	Not serious	serious[e]	none	172	172	-	MD 12.33 (7.06-7.6)	⊕⊕◯◯ Low	Important
OHIP-14 (3 months)												
2	Randomised trials	Serious[f]	Very serious[a]	Not serious	Very serious[b]	None	269	269	-	MD -14.91 (−29.87-0.04)	⊕◯◯◯ Very low	Important
OHIP-20 (6 months)												
3	Randomised trials	Not serious	Serious[d]	Not serious	Very serious[b]	None	184	184	-	MD -11.09 (−20.54-−1.64)	⊕◯◯◯ Very low	Important
OHIP-EDENT (6 months)												
4	Randomised trials	Not serious	Serious[d]	Not serious	Serious[e]	None	390	390	-	MD -8.59 (−13.32-−3.86)	⊕⊕◯◯ Low	Important

Explanations: [a]Considerable heterogeneity across studies and there is no overlap of confidence intervals, [b]Small sample for continuous data and wide confidence interval, [c]Dable *et al.* (2013) was classified as fair quality, [d]Considerable heterogeneity across studies, [e]Small sample. f. Ha *et al.* (2012) was classified as fair quality. CI: Confidence interval; MD: Mean difference; OHIP: Oral health impact profile; OHIP-EDENT: Oral health impact profile for assessing edentulous subjects; GOHAI: Geriatric oral health assessment index

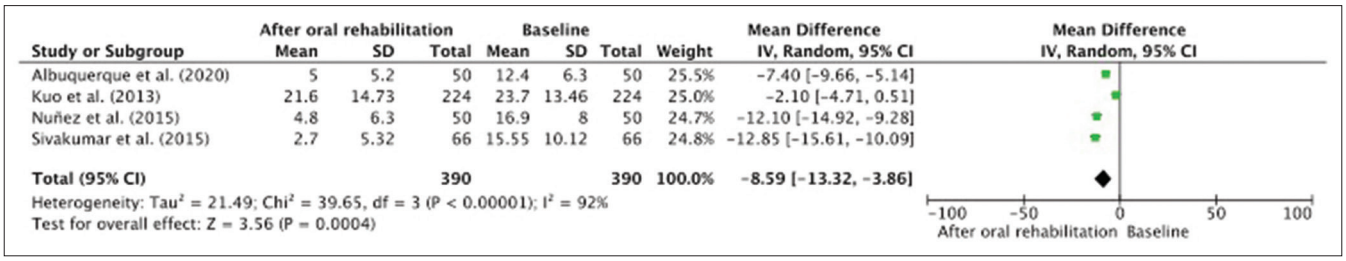

Figure 5: Forest plot of total scale of Oral Health Impact Profile for Edentulous (OHIP-EDENT) instrument regarding to time of follow-up (6 months).

Even though osseous implants present a great success rate, many patients are not able to be subjected to this type of treatment for many reasons.[9] Thus, CDs are a viable option of treatment for these cases. These prostheses recover the main functions of the stomatognathic system,[10] but it is necessary to present good retention and stability.[2] Evidence-based dentistry is important to provide a basis of solid evidence for all professionals who are committed to offering the best treatment option for their patients.

In this systematic review, the articles selected used diferent instruments to detect if new CDs were able to improve patients' OHRQoL. On qualitative analysis, excepting two articles,[31,35] 22 papers[8,18-30,32-34,36-40] concluded that the use CD improved the OHRQoL. CDs have been studied for many years, so a significant number of articles involving total prostheses and quality of life were found. A previous systematic[11] review selected 6 articles to evaluate whether treatment with new CDs improves OHRQoL in elderly patients. The present systematic review selected 24 articles. So, based on increased number of publications on this important clinical evaluation, an update a systematic review needs to be done.[42] This fact makes us realize the importance that this therapeutic option still presents in the dentistry scenario.

The addition of new synthesis methods, such as GRADE, improved the quality of the analysis and the clarity of the findings to answer the question if the new CD improves de OHRQoL. Added to it, this research was carried out in the most important databases, in the grey literature and manually in the bibliographic references of the selected articles. We also used common MeSH terms and keywords from articles published in the same field in order to minimize the possibility of not finding potentially eligible studies. Thus, the likelihood of risk of bias from this systematic review is low as also observed by AMSTAR-2 checklist.

The meta-analysis detected that greater follow-up (6 months) improved impact on OHRQoL in the long-term. These findings emphasizes that studies with greater follow-up are necessary to obtain an improvement in the long-term impact of OHRQoL. The study with longest time of follow-up was 5 years[39] followed by 1 study that follow-up for 2 years[22] and 4 studies[23,26,32,37] that follow-up for 12 months. The methodological design from the majority of the excluded papers presented no evaluation of the baseline or presented short or unspecified follow-up periods. The lack of baseline in many studies probably occurred due to the lack of use of total prosthesis by the volunteers at the initial time of the study. Early evaluation of the use of new prostheses may compromise the outcome, due to patient's neuromuscular adaptation.[43] Therefore, studies with a follow-up of <3 months were excluded.

The aim of this study was to search all available literature reporting the impact of new CD on OHRQoL. The possibility of combining patients' needs and desires with the professional's personal expertise in oral rehabilitation treatment planning should always be carried out based on the best scientific evidence available. Thus, it is important to evaluate the quality of evidence demonstrated by articles that propose to detect changes in OHRQoL after oral interventions.

Studies that met the eligibility criteria were submitted to a risk of bias analysis with a qualifier ("Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Group").[14] The qualifier items most frequently missing in the selected articles were sample size calculation (question 3 and 5) and the evaluation of the instruments' psychometric properties (question 7).

Sample size calculation in clinical trials is of great importance to ensure that the number of participants is large enough to have a high probability of detecting

true and clinically significant differences between groups or treatments. In this systematic review, ten studies[8,20,21,24,26,30,31,33,37,40] performed the sample size calculation, which indicates the need for greater care in future, research in relation to this important question.

In addition to the methodological problems found in articles, some studies presented their results in a nonreproducible way considering the evaluation of psychometric properties of instruments for evaluation of OHRQoL. Psychometric properties are essential requirements for measuring instruments. The main psychometric properties of a measuring instrument are validity, reliability and in the studies analyzing before and after a treatment, the responsiveness. Seven studies realized some of these evaluations.[18,21,26,28,29,32,38] Validity of an instrument can be defined as its ability to actually measure what it proposes to measure. The validity as mentioned above was guaranteed in all selected studies since all of them used validated instruments, including validation for the languages of their respective populations. Reliability is the first characteristic that an instrument must present. This refers to the degree to which the repeated application of an instrument on the same subject produces equal results, that is, indicates the reproducibility of a measure. Reliability should be contextualized in terms of stability and internal consistency.

Only four studies[21,26,28,29] realized test-retest of the OHRQoL instruments applied in their population. In this procedure, the same measuring instrument is applied at two times to the same group of people after a period of time to confirm the reliability of the instrument.

Internal consistency is perhaps the most widely used approach. It is understood as the degree of homogeneity in which the items designated to measure the same concept are interrelated. The most commonly used measurement for internal consistency is Cronbach's Alpha Coefficient. Three articles performed this measurement and the results were satisfactory.[18,21,28]

Responsiveness is the psychometric property that assesses the instrument's ability to detect changes and is used primarily in clinical work to test QoL changes during or after treatment. Responsiveness is an important characteristic of OHRQoL instruments, which are used as evaluative measures to assess the change pre-and post-treatment. This property is not well established in many studies that have measured OHRQoL, which is a significant omission given the increasing tendency to use OHRQoL measurements as outcomes in clinical trials and evaluation studies.[44] The absence of evaluation of this property is a worrying fact. In the present systematic review, only four articles[28,29,32,38] applied this measurement**.** This fact corroborates with Antunes *et al.*[44] in their systematic review evaluating changes in the OHRQoL of children and adolescents under 14 years old after oral health interventions, a moderate level of evidence was observed. One factor responsible for this level of evidence was that there were no evaluations of psychometric properties such as responsiveness.

To perform the meta-analysis was a challenge in this study. Results expressed as graphs and frequency, absence of information examiners calibration, made the comparison of the data of some articles impossible. It is important to emphasize that we tried to contact the authors, but we did not receive an answer. The difficulty to perform the meta-analysis was also especially high for the included studies that did not use the same quality-of-life assessment instrument. So, we chose to analyze in subgroups when it is possible to compile results from the same instrument at different follow-up times, as commonly performed in quality of life systematic review studies.[45] Despite these difficulties, the meta-analysis compiled the results of 12 included studies related to the OHIP-14,[36,38] OHIP-20,[30-32] OHIP-EDENT[21,24,27,28] and GOHAI[25,26,29] instrument.

There was a diversity of instruments used in the articles included in this systematic review. However, there is a specific instrument validated for elderly patients (OHIP-EDENT), which, if standardized for this type of study, would allow a comparison between the results obtained by several studies. This study observed twelve studies (50%) using OH IP-EDENT[8,18,19,20-24,27,28,39,40] as the questionnaire tool. We also observed an increasing tendency on use of this instrument once in the last 5 years from 9 studies,[8,21-24,27,38-40] 8 papers[8,21-24,27,39,40] used the OHIP-EDENT. Despite, the meta-analysis confirmation of an improve on OHRQoL using different instruments, we can perceive that the lack of standardization of the instrument hinders a more objective and efficient analysis of the results.

The meta-analysis of this study to affirm a favorable outcome for the use of CD on improving OHRQoL

in long-term; however very low certainty of evidence was observed in the GOHAI and OHIP-20 questionnaires analysis, and low certainty of evidence in the subgroup analysis for the GOHAI instrument and in OHIP-EDENT. It can be explained by the heterogeneity presented by some studies: Small follow-up periods,[8,18,19,34-36,38,40] applied the instrument by mail, did not explain how the questionnaire was applied[22,23,31,39,40] or did not use an expressive sample size[8,22,23,29,30,31,37,39] for this type of therapeutic option. The results of this review suggest that the exchange of unsatisfactory CDs for new ones has the strong potential to contribute to OHRQoL. However, based on the heterogeneity, risk of bias and low certainty of the evidence that some studies presented, well-designed studies are necessary due to the importance that CD still present in the contemporary dentistry.

CONCLUSION

CD has the strong potential to contribute to oral health-related quality of life in long-term.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

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Appendix 1: Prisma checklist

Section/topic	#	Checklist item	Reported on page
Title			
Title	1	Identify the report as a systematic review, meta-analysis, or both	1
Abstract			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number	1
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known	2
Objectives	4	Provide an explicit statement of questions being addressed with reference to PICOS	3
Methods			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated	2,3
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)	2
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators	3
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made	3
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis	3
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means)	4
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis	4
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies)	4
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified	4
Results			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram	4,5 4
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations	4,6,7,8,9, 10,11,12
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12)	4,13
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot	5, 7, 15
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency	5, 7, 15
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15)	5, 14
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16])	5
Discussion			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers)	7,15
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias)	15,16

Contd...

Appendix 1: Contd...

Section/topic	#	Checklist item	Reported on page
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research	17
Funding			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review	17

PICOS: Participants, interventions, comparisons, outcomes, and study design

Appendix 2: Quality assessment of the systematic review based on A Measurement Tool to Assess Systematic Reviews 2-checklist

Question	Answer possibilities	Classification
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes: The 4 elements of PICO are described somewhere in the report or the criteria of studies inclusion was clear No: Any element of PICO was not described or the criteria of studies inclusion was not clear	Yes
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Partial yes: The authors state they hag written protocolo or guide that included all the following itens: review question, a search strtegy, inclusion/exclusion criteria, a risk of bias assessment Yes: Partial yes plus should be specified meta-analysis/synthesis plan (if apropriatte); a plan for investigating causes of heterogeneity, justification for any deviation from the protocol No: Did not report about previous registered protocol	Yes
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes: The study report the type of studies included No: The study did not report the type of study included	Yes
4. Did the review authors use a comprehensive literature search strategy?	Partial yes: search in at least 2 databases, provide keyword/search strategy and justified publication restrictions Yes: Partial yes plus search in reference list of included studies, search in register studies, consulted experts, search in grey literature and conducted search in 24 months of competition review. No: Did not achieve the itens in partial yes	Yes
5. Did the review authors perform study selection in duplicate?	Yes: At least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include, or two reviewers selected a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder selected by one reviewer No: Did not answer this question	Yes
6. Did the review authors perform data extraction in duplicate?	Yes: At least two reviewers achieved consensus on which data to extract from included studies or two reviewers extracted data from a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder extracted by one reviewer No: Did not answer this question	Yes
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Partial yes: Provided a list of all potentially relevant studies that were read in full-text form but excluded from the review Yes: Justified the exclusion from the review of each potentially relevant study No: Did not report any detail about full-text assessed studies and excluded.	Yes
8 .Did the review authors describe the included studies inadequate detail?	Partial yes: Described not in detail populations, interventions, comparators, outcomes and research design Yes: Described the items of parities in detail plus timeframe for follow-up No: Did not describe populations, interventions, comparators, outcomes or research design	Yes
9. Did the review authors use a satisfactory technique for assessing the RoB in individual studies that were included in the review?	Partial yes: Use a nonstandard instrument but capable of detecting serious methodological flaw YES: Use a standard instrument for RoB No: Use a non-standard instrument not capable of detecting serious methodological flaws	Yes
10. Did the review authors report on the sources of funding for the studies included in the review?	Yes: Reported the sources of funding for individual studies included in the review or report that the reviewers looked for this information but it was not reported by study authors also qualifies No: Did not report sources of funding for individual studies included in the review and didn't looked for this information	Yes

Contd...

Appendix 2: Contd...

Question	Answer possibilities	Classification
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes: The authors justified combining the data in a meta-analysis; AND used an appropriate weighted technique to combine study results adjusting for heterogeneity if present; AND investigated the causes of any heretogenity No: Did not perform one or more criteria described above No: No meta-analysis was conducted	Yes
12.If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Yes: Included only low risk of bias studies (according each risk of bias scale used in systematic reviews)* or if the authors performed analyses to investigate possible impact of RoB on summary estimates of effect No: Did not perform one or more criteria described above No: No meta-analysis was conducted	Yes
13. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes: Included only the low risk of bias studies or a discussion of the likely impact of RoB was discussed No: Did not perform one or more criteria described above	Yes
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes: There was no significant heterogeneity or if present, the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review No: Did not perform one or more criteria described above	Yes
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Yes: Performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias No: Did not perform a statistical evaluation about publication bias No: No meta-analysis was conducted	Not aplicable
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes: The authors reported no competing interests or the authors described their funding sources and how they managed potential conflicts of interest No: The authors did not report anything about conflict of interest	Yes

RoB: Risk of bias; PICO: Population, intervention, comparisons and outcomes