Comparing patient-based outcomes related to neutral zone and conventional mandibular dentures: a systematic review.

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Geerts G,[1] Khan S.[2]

SUMMARY

Introduction: neutral zone mandibular dentures are considered to be superior to conventional complete dentures.

Aim

To synthetize evidence regarding patient-based outcomes of treatment with complete mandibular dentures following static or dynamic methods of establishing denture shape.

Objective

To answer the question: "In edentulous patients, what is the effect of neutral zone dentures on oral health-related quality of life and preference as compared with conventional dentures?"

Methods

Medline, Wiley, Cochrane Central Register of Controlled Trials, Proquest, Elsevier, Trip and Science Direct databases were searched for clinical studies, using a specific search strategy.

Results

From a total of 103 records, 9 studies (participants n=270) were included in the review, based on specific selection criteria. Reports on oral health-related quality of life and preference produced conflicting results. Most patients reported improvement in retention, stability, comfort, chewing, speech with fewer recall visits for neutral zone dentures. High level of heterogeneity in study design, patient-based outcomes, instruments and statistical analysis was encountered, preventing meta-analysis. Quality of most studies was low, with small sample sizes (range: n=5-128), short follow-up periods (5 days-2 months), and high level of selection, performance and detection bias.

Conclusion

Results should be interpreted within the context of little and low-level scientific evidence.

ACRONYMS:

CD: complete dentures

NZ: neutral zone method

OHRQoL: oral health-related quality of life

PBOs: patient-based outcomes

RoBm: risk of bias

INTRODUCTION

Conventional complete dentures (CD) have been the most common and only treatment modality for rehabilitation of edentulousness until the introduction of dental implants. Implant-retained or implant-supported prostheses have been proven to be superior to conventional CDs in terms of patient-based outcomes (PBOs).[1] However, implant therapy may be out of reach of patients due to a variety of reasons. This group of patients is and will continue to be dependent on traditional CDs to restore form and function. It is assumed that these patients would benefit if dentures were made to be as stable and comfortable as possible.

The neutral zone (NZ) concept has been defined as "the potential space between lips and cheeks on the one side, and tongue on the other side; that area or position where forces between tongue and cheeks and lips are equal".[2] As early as 1746, Fauchard advocated that the inside and outside form and shape of dentures should be considered carefully in order to avoid conflict with lips, cheeks and tongue (in: Lott and Levine, 1966).[3] Today, there is a high level of international consensus that teeth should be arranged in a neutral position and that arch form should assist stability during function.[4]

While experts may agree, there appears limited scientific evidence based on patient feedback on the clinical benefits of CDs made according to a dynamic NZ method (NZD) over a biometric, static method of determining arch form and shapes of dentures. To date, no systematic review of clinical studies comparing PBOs of the mandibular NZD versus a conventional mandibular CD has been done. Therefore, the efficacy of NZDs compared with CDs has yet to be established.

The aim of this systematic review was to synthesize scientific data related to PBOs of mandibular CDs fabricated according to the NZ concept as compared with conventional methods.

1. **Greta Geerts** *BChD, PG Dip* Implantology, *MChD, PhD* Prosthodontist / Associate Professor / Senior Lecturer, Department of Restorative Dentistry, University of the Western Cape, Tygerberg Campus, Fransie van Zyl Drive, Parow 7505
2. **Saadika Khan** *BChD, PDD, MSc, PhD* Dentist / Senior Lecturer, Department of Restorative Dentistry, University of the Western Cape, Tygerberg Campus, Fransie van Zyl Drive, Parow 7505 +27 21 9373000 skhan@uwc.ac.za

Contributions

1. **Greta Geerts.** Conceptualization 100%, Researcher 50%, Writing 50%
2. **Saadika Khan** Researcher 50%, Writing 50%

Corresponding author
Professor Greta Geerts Tel +27 21 9373095
email ggeerts@uwc.ac.za

The objectives of this systematic review were:

1. To identify clinical studies comparing PBOs of mandibular NZDs versus conventional CDs
2. To extract and compare data based on PBOs of both types of dentures from studies included in the review
3. To perform a meta-analysis should the nature of the data identified from the clinical studies allow this to be done.

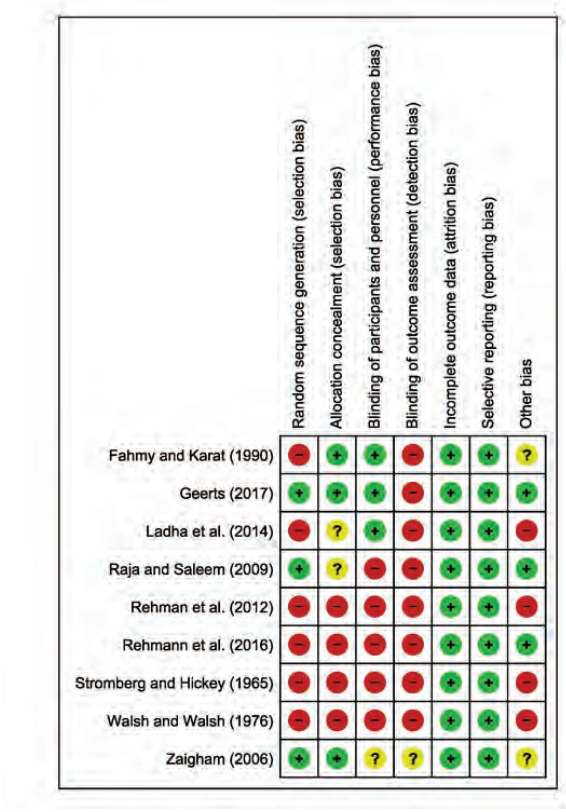

Figure 2: Risk of bias graph
+ = low risk of bias
- = high risk of bias
? = unclear risk of bias

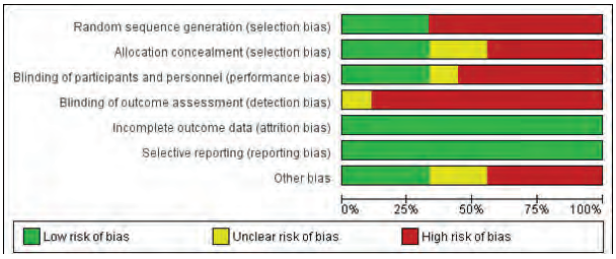

Figure 3: Risk of bias table

Hence, the following research question was developed: In edentulous adult patients, what is the effect of NZD on oral health-related quality of life (OHRQoL), patient satisfaction, and preference as compared with that of conventional mandibular CDs?

METHODS

A protocol was developed to include all aspects of a systematic review: a search strategy, selection criteria (Table 1), the use of customized study eligibility and data extraction forms, assessment of risk of bias (RoB) using the Cochrane tool,[5,6] and statistical analysis by calculating risk ratios for outcomes using 95% confidence intervals. The protocol was registered with the Biomedical Research Ethics Committee at the University of the Western Cape (BM/17/4/9).

Search and Selection Strategy

Online searches were conducted for primary and ongoing studies to identify literature on the topic of NZ as a treatment strategy for edentulous adult patients. Two reviewers (GG and SK) independently and systematically searched for studies using the databases Medline, Wiley, Cochrane Central Register of Controlled Trials, Proquest, Elsevier, Trip and Science Direct. Medical subject headings (MESH terms) were applied in databases which allowed this function. Key terms were combined using Boolean operators and search strategies were developed for each database using database specific functions. For Pubmed, the search terms were: Neutral zone AND complete dentures and the following article types were selected: Case Reports, Clinical Study, Clinical Trial, Clinical Trial Phase I, Clinical Trial Phase II, Clinical Trial Phase III, Clinical Trial Phase IV, Comparative Study, Controlled Clinical Trial, Multicenter Study, Observational Study, Pragmatic Clinical Trial, Randomized Controlled Trial. A similar search strategy was developed and modified according to the requirements of each database to ensure inclusion of all relevant studies. If databases allowed it, the following filters were applied: publication dates (1930-2017), species (human), ages (18+ years). No language filters were activated. Similar articles listed for each reference were also searched for possible inclusion. Based on titles and abstracts, a first selection of articles was done. Full texts of these selected articles were retrieved. Eligibility of these articles was determined using the customized eligibility tool. Reference lists of included studies were searched for additional records. Where full texts were unavailable, authors were contacted. Efforts were also made to obtain English versions of studies reported in other languages either by requesting them from the authors or using language experts to translate key findings. At every level of selection, consensus was reached between the two reviewers, adopting a lenient approach towards inclusion of records.

Data extraction

The two reviewers independently reviewed all included full-articles extracting the following data using the standardized data extraction sheet: authors, title, date, country, publication type, study method, estimate of bias, sample (number, age, sex), interventions, outcomes, statistical analyses, results, conclusions, funding sources, ethics clearance, comments and correspondence required.[5] Extraction sheets were compared. Differences were discussed until consensus was reached. Where more than one article reported different aspects of the same study, these were combined as a single study. Data from the included and excluded studies were summarized in tables of included and excluded studies respectively.

Qualitative analysis

The two reviewers independently evaluated the included studies for RoB using the Cochrane's 'Risk-of-bias assessment tool'.[5,6] Risk of bias was assessed across the following components: Sequence generation and allocation concealment to prevent selection bias; Blinding of participants, personnel and outcomes assessors to reduce performance bias; Incomplete outcome data to eliminate attrition bias; Selective outcome reporting to reduce selective outcome reporting bias; and other sources of bias, such as those related to specific study designs, early stoppage, fraudulent or extreme baseline imbalances. Risk of bias for each component was scored as 'high', 'low' or 'unclear'. Bias was summarized in RoB graphs for each study in the Review Manager Software program.[5]

Data synthesis and management

Results from the included studies were reported separately according to the interventions, controls, and reported outcomes. No imputation of missing data was carried out and as all outcomes were reported, authors were not contacted for these. Although a meta-analysis of outcomes across studies was anticipated, the included studies had different designs and reported outcomes differently. Hence, individual study results could not be pooled in a meta-analysis.

Table 1: Selection criteria for study eligibility

	Inclusion criteria (all criteria had to be present)	Exclusion criteria (any of the criteria present resulted in exclusion)
Type of study	Clinical study (n>5)	Clinical study (n<5) Narrative reviews Systematic reviews
Type of participants	Human Male and female ≥18 years of age Requesting replacement CD	Animal <18yrs of age
Type of interventions	NZD with or without piezographically shaped flanges	No NZD
Type of comparisons	PBOs from NZD and conventional CD, including patients' existing dentures	No comparison between interventions
Type of PBOs	Primary outcomes: OHRQoL, preference, patient satisfaction Secondary outcomes: stability, retention, comfort, speech, chewing, need of recalls as reported by patients	No PBOs

CD = conventional mandibular denture
NZD = neutral zone mandibular denture
PBOs = patient-based outcomes
OHRQoL = oral health-related quality of life

RESULTS

Results of the search are indicated in the PRISMA flow chart (Figure 1). One hundred and fifty nine records were generated: 157 records from online search engines and two records found later on reference lists from included full-texts. A total of 56 duplicate records were removed, leaving 103 records which were assessed for eligibility. After reading titles and abstracts, a further 79 records were excluded. Full texts of the remaining 24 records were retrieved. A total of 10 articles, reporting results of 9 studies, were used for this review. There were no deviations from the protocol during the search.

The nine studies were placed in three different groups according to NZ methodology. In Group 1, NZDs were made using a NZ impression including piezographically shaping of flanges. In Group 2, NZDs were made without piezographically shaping of flanges. Group 3 included methods of Groups 1 and 2. Because of the different NZ techniques followed for these studies, it was decided not to combine results from studies in different groups.

There were seven studies in Group 1, reporting on a total of 137 patients.[7-14] Their follow-up periods were 1, 2, 4, 8 (x2) weeks. Two studies did not report a follow-up period. Two studies reported on OHRQoL using two different versions of the OHIP, with conflicting results.[12,14] Geerts (2017) (OHIP-20, n=37) reported no significant

Table 2: Characteristics of included studies

Study	Methods	Statistics	Participants	Intervention	PBOs	Results	Instrument
Fahmy & Kharat (1990) Saudi Arabia Clinical study	Cross-over Follow-up 2 weeks post-insertion	No stats for preference	Total:10 Gender: not reported Age: not eported	1. new conventional CD 2. new NZD (Group 1)	Preference	10/10 preferred NZ denture (better comfort and speech, none mentioned mastication as reason for preference).	No instrument given for preference
Geerts (2017) South Africa Clinical study	Cross-over Sequence randomized Follow-up 2 months post-last recall	Power analysis, Paired t-test, Fisher exact test, GLM, treatment effect size.	Total:37 Gender: 22 female Age: 62.3 (47-85)	1.new conventional CD 2. new NZD (Group 1)	OHRQoL Preference	Preference: 15/35 NZ. 8/35 CD and 14/35 none. Statistically no difference in preference or OHRQoL. Treatment effect size = small	OHIP-20 Preference: NZD, CD None. Treatment ES
Ladha et al. (2014) India Clinical study	Cross-over Follow-up: 2 months for each denture	Kruskal-Wallis with non-parametric Mann-Whitney tests, ($p<0.05$)	Total: 10 Gender: 1 Female Age group; 60-80 yrs. Advanced ridge resorption	1. old denture (A) 2. swallowing (SNZ) & phonetic (PNZ) NZ (Group 1)	Satisfaction Aesthetics Stability Retention Comfort Speech Chewing Soreness Food entrapment	For mandibular denture: Satisfaction, retention, stability, speech, comfort, chewing, statistically better for SNZ and PNZ as compared to A. No difference between SNZ and PNZ No difference for soreness among 3 groups. Statistical difference in food entrapment between A and SNZ. Preference: higher for SNZ	16-item questionnaire with VAS scale answers (5-point Likert scale 0-4)
Rehmann et al.(2016) Germany Clinical study	1 cohort Follow-up: 4 weeks of wearing denture	Sign test	Total: 21 Gender: 10 females Age: mean 71 (+-19yrs)	1.unsatisfactory "new" CD 2. NZD (Group 1)	Satisfaction Denture function Mastication Stability.	Stat sign improvement in OHRQoL for NZ Masticatory test: no sign. change. 18/21 patients reported improved general stability and stability with chewing. 14/21 patients reported improved stability during speech.	OHIP-G14 Scale: stability clearly improved, improved, unchanged, deterioration

Rehmann et al.(2012) Germany Clinical study	1 cohort Follow-up: not reported.	no	Total: 5 Age: mean 61yrs Gender: not reported	1.unsatisfactory old dentures 2.NZD (Group 1)	Stability Pressure sores	4 patients: improvement in general, while chewing and speaking. 1 patient unchanged. Perceived sores: similar improvement	Scale: clearly improved, improved, unchanged, deterioration.
Walsh and Walsh (1976) South Africa Clinical study	1 cohort Prospective Randomization not reported. Follow-up: 1 week.	no	Total: n=30 Age: not reported Gender: not reported	1.Old CD (unacceptable by patients but technically acceptable) 2.new NZ denture (Group 1)	Stability Recalls	28/30: improvement in stability. 1/30 no improvement. 1/30 impossible to adapt. 9/30 needed recall (no control)	Scale: Improvement. No improvement. Impossible to adapt. Number of patients needing recalls.
Zaigham (2006) Pakistan Clinical study	2 Cohorts (12 x 2) Comparative Duration: not reported	Student t-test	Total: 24 Gender: not reported Age: not reported	1.selective impression technique denture 2.NZD (Group 1)	Secondary outcome: Preference	In discussion: All patients preferred NZ (no data in results)	No scale/category given
Raja and Saleem (2009) Pakistan Clinical study	4 Cohorts Follow-up 40 days after insertion Randomized sampling	t-test, chi square, Fisher's Exact Test (p<=0.05)	Total: 128 Gender: 39 females Age: mean for 4 groups = 55.8-58.3yrs	1.CDs 2. NZ dentures Duration of edentulousness: 2 groups (Group 2)	Satisfaction	Statistically less recalls for NZ dentures for patients who were edentulous for>2yrs.	Patient satisfaction expressed by number of post-insertion visits.
Stromberg and Hickey (1965) USA Clinical study	Cross-over Follow-up: 5 days (3 measurements: day 1, day 3, day 5)	no	Total: n=5 Gender: 3 female Age: not reported	1.NZ + manually formed flanges 2.NZ + piezographically formed flanges (Group 3)	Preference	100% preference for manually formed dentures	No scoring details for "preference" given

difference in OHIP-scores between NZD and CD, while Rehmann et al. (2016) (G-OHIP-14, n=21) found significant differences.[12,14] Three studies (total n=71) reported on patient preference.[8,9,13] A total of 49 preferred NZDs, eight preferred CDs and 14 had no preference. Only one study had results statistically analyzed and found no significant difference in preference.[13] This study was also the largest with the longest follow-up period (at least eight weeks as compared with two weeks and unknown). One study reported on satisfaction (n=10) with a significantly higher satisfaction for NZDs.11 Of the studies that reported on stability (total n=66), 50 out of 56 patients reported improvement for NZDs,[7,10,12] and one study (n=10) reported a significant improvement for NZDs.[11] Only one study (n=10) reported a statistically improved patient-reported retention, chewing, satisfaction, comfort, speech for NZDs.[11] Walsh (1976) (n=30) reported that nine patients needed recalls for NZDs, as compared with 21 for CDs.[7]

Group 2 had one study, reporting on 128 patients, with a follow-up period of 40 days.[15] "Number of recalls" was used as a measurement for patient satisfaction. This study reported statistically less recalls for NZDs for patients who were edentulous for longer than two years.

Group 3 also had one study, reporting on five patients, followed-up over five days, who all preferred manually formed flanges as compared with piezographically shaped flanges.[16]

For Group 1, lengths of follow-up periods were 1, 2, 4, 8 (x2) weeks. Two studies did not report a follow-up period. For Groups 2 and 3, follow-up periods were 5 ½ weeks and five days respectively.

In Group 1, there were four prospective single-cohort studies where PBOs of existing dentures were compared with the new NZDs.[7,11,10,12] One study was prospective with two cohorts, receiving either a new CD or NZD.[9] There were two cross-over trials with all patients receiving both new CDs and NZDs.[8,13,14] Four of the seven studies did not report statistical analysis.[7-10]

There was one study in Group 2, with cohorts receiving either a NZDs or CD.[15] These two cohorts were further divided into "period of edentulousness < or > than two yrs".

The study in Group 3 was a cross-over with all patients being tested with both the manually formed and physiologically formed flanges.[16]

The study characteristics of all included studies are summarized in Table 2. It must be noted that, regarding outcomes, only PBOs were extracted. Some studies also reported on clinician-based outcomes, but these outcomes are not reported since they fell outside the scope of the review. Excluded studies are recorded in Table 3, together with reasons for exclusion.

For each included study, RoB was assessed as being 'low', 'high' or 'unclear' following Cochrane guidelines.[5,6] Results are shown in a RoB graph and RoB summary (Figures 2 and 3). A detailed explanation of the results is as follows:

ALLOCATION (SELECTION BIAS)

Three of the nine studies were reported as randomized.[7,13-15] For sequence generation: Three out of nine studies used some sequence to include patients into the study (Figures 2 and 3). One study drew lots, one used random tables and another used computer generated numbers. Where participants were asked to join the study or were included on the basis of their experiencing problems with old dentures, these were recorded as studies with a high risk of bias. Three of the studies used an allocation technique (directing the patient to a specific treatment group) eliminating selection bias. In two of the studies, allocation was unclear.[9,11,15]

BLINDING (PERFORMANCE BIAS AND DETECTION BIAS)

Blinding of either participants and/ or personnel was ensured in three of the nine studies (Figures 2, 3). Blinding of participants only may thus be considered as in a single-blinded cross-over clinical trial.[8,11,13,14] But this process was unclear in one of the studies.[9] For all the included studies, the outcomes assessors were not blinded and these were all judged as having a high risk of bias.

INCOMPLETE OUTCOME DATA (ATTRITION BIAS)

All studies did not report the analysis to be completed by the "intention-to-treat" principle, nor did any of the studies lose any patients, thus results were not negatively affected. Moreover, all pre-specified outcomes (even though these were not pre-specified as primary or secondary outcomes) were reported, thus all the studies were judged to have a low risk of bias as there was no missing data (Figures 2 and 3).

Table 3: Characteristics of excluded studies

	Study	Reason/s for Exclusion
1.	Afroz et al. (2012)	Patients had oral submucous fibrosis
2.	Astorga et al. (2013)	Participants' characteristics suggested this study be excluded
3.	Barrenäs and Odman (1989)	Not NZ impression – only piezographically generated polished surfaces
4.	Comut and Somohano (2015)	Case report, which initially formed part of inclusion criteria, but this later changed
5.	Darwish et al. (2015)	The study did not include the NZ as intervention or control, and patients had implants
6.	Kursoglu et al. (2007)	The study was excluded on the basis of the NZ not being the intervention or control and the study type or design also not meeting the inclusion criteria
7.	Liu et al. (2015)	The study had the specific design but the NZ not the intervention or control
8.	Makzoumé (2004)	The conventional denture was not the control
9.	Miller et al. (1998)	No patient-based outcomes
10.	Mustafa (2015)	No NZs or patient-based outcomes
11.	Patil (2010)	The study was excluded on the basis of the NZ the intervention or control and the participants not meeting the inclusion criteria
12.	Pilon et al. (1985)	The study did not meet the type or design criteria
13	Porwal et al. (2016)	The study met the design criteria but not having the neutral zone denture as the intervention or control suggests exclusion
14	Tambe et al. (2014)	The NZ and characteristics of participants ensured exclusion of this study.

NZ = neutral zone mandibular denture

SELECTIVE REPORTING (REPORTING BIAS)

All included studies pre-specified and reported all outcomes; but only the Geerts (2017) study pre-specified these as primary and secondary outcomes.[13,14] Most of the studies were not registered or approved by a review board, but because these studies reported all the outcomes as specified in the protocol, these were still judged as having a low risk of bias.

OTHER POTENTIAL SOURCES OF BIAS

Studies were judged as having a low risk of bias if there were no reason to suggest any other potential sources of bias.[12-15] Four other studies were judged as having a high risk of bias due to the poor design, small sample sizes, no blinding and/or no randomization and because no ethical approval was obtained.

DISCUSSION

This SR was developed to answer the question: "In edentulous adult patients, what is the effect of NZDs on OHRQoL, patient satisfaction, and preference as compared with that of conventional mandibular CDs?" Following the search strategy, nine studies were included in an effort to answer the question. The nine studies showed high levels of heterogeneity in terms of study design, sample (size, gender), type of PBOs, instruments used to measure PBOs and RoB. Therefore, the answer to the question is: There exists no strong evidence on the beneficial effects of NZDs over conventional CDs when analyzing PBOs.

The nine selected studies were placed in one of three groups according to NZ technique used. In Group 1, four of the seven studies reported frequencies and/or ratios which were not statistically analyzed.[7-10] Three studies did a statistical analysis of some PBOs but used different instruments to measure these.[11-14] Only two studies used validated instruments for measuring OHRQoL, but reached conflicting results, with Geerts (2017)[14] reporting no difference in OHRQoL between NZDs and CDs, while Rehmann et al. (2016)[12] did identify differences.[12-14] The reason might be that the study design differed, with Geerts (2017)[14] being a prospective cross-over study, while the Rehmann et al. (2016)[12] study was a cohort study with the new NZD being compared with the patients' existing dentures, made outside trial conditions. In the Ladha et al. (2014)[11] study, the main focus was comparing PBOs using a 16-item questionnaire using a 5-point Likert scale.[11] This questionnaire was not provided. Hence, validity and reliability of the data could not be determined. Two different methods of making NZDs (swallowing and phonetics) performed statistically better than the CDS in satisfaction, retention, stability, comfort, speech and chewing hard food. However, they were compared with the patients existing dentures that were made outside the confines of the trial. Hence, for both the Ladha et al. (2014)[11] and Rehmann et al. (2016)[12] studies, the fact that existing dentures were used as control may have caused bias towards a positive outcome for the NZDs. It has been reported that simply making new dentures already improves OHRQoL, regardless of technique used.[31] Another prospective single cohort study in Group 1 using the existing denture was by Walsh and Walsh (1976).[7] The same argument can be used here to explain bias towards the positive results for NZDs as compared with CDs.

One study in Group 1 was prospective, using two cohorts, one receiving new CDs and one receiving new NZDs, but there was no other information on PBOs other than that all patients who received the NZDs preferred it (to the old dentures).[9]

Groups 2 and 3 each had one study. The study in Group 2 was a prospective cohort with all patients receiving both a CD and NZD. However, the only PBO reported on was the number of recalls as a measure for satisfaction.[15] The study in Group 3 was a cross-over study, but compared functionally shaped with manually shaped flanges.[16] No literature could be found confirming a positive cause-effect relationship between number of recalls and patient satisfaction. The authors did not have a conventional denture as control – both dentures were NZ dentures. However, it was decided to include this study in the review for the following reason: Piezographically contoured flanges is one of the variables of the other two groups. This study showed that piezographically developed flanges did not influence retention as compared with manually shaped flanges, while all patients preferred the manually shaped flanges. This could be clinically relevant and should be investigated further because not having to dynamically shape flanges as part of the NZ procedures reduces clinical chair time.

Quality of the evidence of the research is dependent on several factors. By completing a RoB assessment, quality is evaluated and addressed. The quality of the evidence is an indication of the integrity of the study. The ethics in conducting a clinical study encompasses several aspects too, but the details of design and conducting the study and obtaining the expected data is equally important. It has been reported that developing a protocol and registering it with an Ethics review board or in trial registries and even publishing it, ensures rigor.[5] The quality of the study is determined by the study design; and details must be such that

results may be generalizable to larger populations. Randomized controlled trials and cross-over trials are of higher quality than cross-sectional and cohort studies. But if an RCT does not have all the steps such as 'sequence generation,' 'blinding' or 'allocation concealment' these maybe downgraded and considered of poorer quality. The results may not be considered reliable and valid. Most of the included studies followed some guidelines to protect against bias even though all the details were not reported. These were judged by using the Cochrane's RoB tool.[5] For example, completing power calculation to estimate sample size will reduce RoB. Sample sizes of the included studies ranged from five to 128, but only one study reported a power calculation.[13,14]

The use of different study designs, methodologies, validated and unvalidated instruments and "results" not supported by data, prevented comparisons and the completion of meta-analysis among the studies. For example, Raja (2009) and Zaigham (2006) used subjective grading systems, also lacking calibration and reliability.[9, 15]

CONCLUSION

The nine studies incorporated in this SR showed a high level of heterogeneity in terms of study design, types of PBOs and instruments used to measure these PBOs.

The quality of the majority of clinical studies was low, with small sample sizes, short follow-up periods and presence of high level of selection, performance and detection bias.

Little high-level scientific evidence exists on the benefit of dynamic over static methods to determine mandibular CD form and shape.

Declaration

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