

Effect of soft denture liners on complete denture treatments: A systematic review

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Abstract

Purpose: This systematic review examined the effectiveness of soft denture relining (SDR) materials.

Study selection: A comprehensive search of MEDLINE, Cochrane Library, and ICHUSHI was conducted up to July 26, 2020. Target outcomes were patient satisfaction, oral health-related quality of life (OHRQOL), masticatory ability (MA), denture functional duration, residual ridge resorption (RRR), and microbial contamination. An organization specializing in literature searches performed the reference searches, and two reviewers independently selected the literature sources, extracted the data, and assessed the risk of bias. The reviewers resolved any disagreements concerning the assortment of literature sources through discussion. SDR included acrylic- and silicone-based materials, which were evaluated separately.

Results: Reviewers selected 7, 5, 11, 1, 4, and 6 studies to assess patient satisfaction, OHRQOL, MA, functional duration, RRR, and microbial contamination, respectively. The results confirmed that SDR improved patient satisfaction, OHRQOL, MA, and RRR. However, the functional duration of SDR material is shorter than that of hard denture relining (HDR) or acrylic resin material. Furthermore, SDR material is more susceptible to microbial contamination in the long term. The risk of bias for the included studies tended to be high because of specific issues (difficulty in blinding SDR versus HDR).

Conclusions: For patients who wear complete dentures, SDR often provides beneficial outcomes such as pain reduction and recovery from MA. However, caution should be exercised regarding their use owing to insufficient functional duration and the possibility of microbial contamination during long-term use.

Keywords: Soft relining material, Reline, Systematic review, Complete denture, Treatment outcome, Denture reline

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1. Introduction

The function and esthetics of edentulous jaws and multiple tooth defects are often restored using removable dentures (hereafter, dentures). The internal surface of the denture base must fit the denture-bearing mucosa to restore function and esthetics[1]. Denture use can cause disharmony between individuals and dentures due to age-related residual ridge resorption (RRR)[2], denture deterioration, wear of artificial teeth, and changes in the conditions

of the remaining teeth. Long-term use of ill-fitting denture bases or deformed or broken dentures can overload the mucosa and remain-

WHAT IS ALREADY KNOWN ABOUT THE TOPIC?

» Complete dentures fabricated with soft denture relining (SDR) materials offer comfort by reducing local stress, promoting mucosal healing, and evenly distributing the functional load. Despite these potential advantages, the use of SDR materials is relatively recent and lacks solid clinical evidence.

WHAT THIS STUDY ADDS?

» SDR materials improve patient satisfaction, oral health-related quality of life, masticatory ability, and residual ridge resorption, compared with hard materials, for denture relining. However, short longevity and potential susceptibility to microbial contamination should be considered regarding the clinical application of SDR materials.

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ing teeth, thereby inducing pathological changes and destruction of the tissues of the oral maxillofacial system. Furthermore, ill-fitting dentures can introduce pressure and easily lead to denture base breakage[3].

Relining or rebasing can improve the fit between the denture and the mucosa, which can help overcome denture–mucosal surface incompatibility. To date, dentures relined with conventional hard materials have failed to satisfy patients with mucosal trauma, bone undercutting, RRR, or parafunctional habits[4–6]. Conventional complete dentures fabricated using long-term soft denture relining (SDR) materials tend to be more comfortable because they relieve local stress concentrations, promote the mucosal healing effect[7–9], and provide an even functional load over the complete denture-bearing mucosa[10–12].

Recently, SDR materials have been approved as health-insurable treatments for denture relines in Japan. SDR materials are primarily used in complicated cases in which pain during mastication cannot be avoided with a hard denture base. In the Japanese health insurance system, SDR is approved only for patients with edentulous mandibles, who are classified as difficulty level IV (difficult) by the Japanese Society of Prosthetic Dentistry Classification I-1, and those who cannot avoid pain during mastication with hard denture base materials[13]. Difficulty level IV (difficult) in patients with edentulous mandibles is a condition in which one of the following criteria is applicable: the residual ridge crest of the first molar is lower than the mucobuccal fold, the cross-sectional morphology of the residual ridge is flat or concave, the mucosa is very thin, or oral dyskinesia is identified.

Two types of SDR materials are commonly used: acrylic- and silicone-based (auto- or heat-polymerized). Although fluorine-, isoprene rubber-, and polyolefin-based SDR materials have been used in the past, they are no longer employed in clinical use because of problems with adhesion to the denture base resin and their material properties. Polydimethylsiloxane[11–16] with hydroxyl or vinyl groups[17] is the main component of silicone-based SDR material. A special adhesive is applied to the concave surface of the denture to increase the adhesive strength between the denture base and SDR material because of the structural differences with the polymethyl methacrylate denture base resin[18,19]. The disadvantages of SDR materials include loss of softness over time, plaque formation, microbial growth, and fungal colony formation by *Candida albicans*[7–9,20].

Acrylic-based SDR materials have viscoelastic properties, whereas silicone-based SDR materials have elastic properties and can help avoid pain during mastication by relaxing occlusal forces[21]. Acrylic-based SDR materials tend to undergo changes in viscoelasticity over time and gradually lose their loosening effect, whereas silicone-based SDR materials exhibit negligible changes in their physical properties over time and have high durability for denture relining[22].

Relining is not a temporary repair or adjustment of dentures; instead, it is a procedure used to adjust the contact between the internal surface of a denture and the denture-bearing mucosa after the denture has been used for a certain period. Conventional hard denture relining (HDR) materials were the only choice for long-term denture relining before SDR materials were approved for use. However, evidence of the clinical use of SDR materials in denture relining is lacking. Thus, the collection and review of existing studies are

necessary to compare the performances of SDR and HDR materials for long-term use. The advantages and disadvantages of acrylic- and silicone-based SDR materials can be explained. However, limited evidence is available regarding the treatment outcomes of each type of SDR material. In addition, the benefits and disadvantages of acrylic- and silicone-based SDR materials remain unclear, and no relevant criteria have been suggested for their selection. Therefore, the effectiveness of denture relining using SDR materials, compared with that using HDR materials, in patients with complete dentures was evaluated in this systematic review.

2. Material and Methods

2.1. Search strategy method and focused questions

This systematic review was performed in accordance with the guidelines recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) statement[23]. The review protocol was structured according to the Medical Information Network Distribution Service (Minds) Practice Guideline Development Manual 2017[24]. The scope of this systematic review was registered in PROSPERO (PROSPERO no. CRD 42021282206)[25].

This review examined the effect of relining the SDR materials in patients with complete dentures. The following review questions were formulated using the participant, intervention, comparison, and outcome (PICO) approach[26]. Participants were patients who wore complete dentures. The intervention consisted of denture relining using two long-term SDR materials: acrylic and silicone. Tissue conditioners for short-term use were excluded from the SDR materials. The results of the SDR materials were compared with those of HDR materials or acrylic resin for denture base (hereinafter abbreviated as acrylic resin denture). The following six clinical questions (CQ) were formulated using the PICO approach to determine whether SDR materials were more effective than HDR materials for denture relining[27]:

1. Does the use of SDR materials improve patient satisfaction, compared with the use of HDR materials, in relines or acrylic resin dentures? (Patient satisfaction)
2. Does the use of SDR materials improve oral health-related quality of life or reduce pain, compared with the use of HDR materials, in relines or acrylic resin dentures? (Oral health-related quality of life [OHRQOL])
3. Does the use of SDR materials improve masticatory ability, compared with the use of HDR materials, in relines or acrylic resin dentures? (Masticatory ability [MA])
4. Does the use of SDR materials prolong the functional duration of dentures, compared with the use of HDR materials, in relines or acrylic resin dentures? (Longevity)
5. Does the use of SDR materials reduce residual ridge resorption, compared with the use of HDR materials, in relines or acrylic resin dentures? (Residual Ridge Resorption [RRR])
6. Does the use of SDR materials reduce or inhibit microbial growth, compared with the use of HDR materials, in relines or acrylic resin dentures? (Microbial contamination)

Table 1 lists the outcomes of each clinical question.

Table 1. List of outcomes for each clinical question

Outcome	
CQ1	Patient satisfaction by VAS, and patient preference
CQ2	Number of oral pain spots, pain awareness, pain perception, OHIP (Components and Overall), and physical pain
CQ3	Masticatory performance, chewing frequency, chewing time, EMG, mandibular movement, maximum occlusal force, and perceived chewing ability
CQ4	Functional duration (Longevity)
CQ5	Residual ridge resorption, residual ridge resorption around the root plate, changes in mucosa blood flow, and patient's subjective assessment
CQ6	<i>C. albicans</i> count, <i>C. non-albicans</i> count, <i>Gram-positive cocci</i> , <i>Gram-positive bacteria</i> , <i>Fung</i> , and total microbe count

VAS: visual analog scale, EMG: electromyogram, CQ: clinical question, OHIP: oral-health impact profile

2.2. Search methods and literature selection criteria

A comprehensive search of MEDLINE, the Cochrane Library, and ICHUSHI (a Japanese medical bibliographic database of the Japan Medical Abstracts Society) was conducted for articles published up to July 26, 2020. The search string comprised a combination of key-words (Medical Subject Headings [MeSH]) and free-text terms, and linkage was performed using Boolean operators (OR and AND). All the processes were linked to the Japan Medical Library Association to ensure independence. The search formulas used for the MEDLINE database are listed in **Table 2**.

Human clinical literature was selected as evidence. The following inclusion criteria were applied for literature selection: clinical research published in peer-reviewed journals; systematic reviews; meta-analyses; randomized controlled trials (RCTs); quasi-RCTs; prospective and observational studies (retrospective or prospective cohort studies and case-control studies); publications available in English; and no restrictions on the lengths of follow-up periods. Case reports, *in vitro* studies, and animal studies were excluded. Only the most recent publication was included in cases of possible duplication. Finally, the references to all selected full-text literature sources were searched for relevant studies. A manual search process was adapted based on the bibliographies of the selected literature.

2.3. Screening procedures

Two prosthodontic specialist reviewers (CQ1 and -5: Kensuke Nishio and Fumi Yoshioka, CQ2 and -6: Tomohiro Ishii and Yoko Hasegawa, CQ3: Takafumi Watanabe and Yuichiro Nishiyama, CQ4: Yusuke Sato and Kazuhiro Yoshida) independently performed literature retrieval and screened titles and abstracts to identify studies eligible for selection based on the inclusion and exclusion criteria.

For each CQ, the two reviewers listed the selected studies. The lists were then compared, and a definitive consensus for the inclusion of literature for each CQ was reached by discussing each literature source. Discussions between the two reviewers resolved discrepancies during the screening and selection processes. If discrepancies were not resolved, a third reviewer (Hajime Minakuchi and/or Yoko Hasegawa) appointed by the first two reviewers was consulted to reach a consensus.

Subsequently, all literature for which a consensus was reached for each CQ was collected as full text, and the same peer reviewers conducted independent assessments. Only studies with sufficient data were included in the analysis, and discrepancies were resolved through discussion.

2.4. Data extraction and synthesis

Two reviewers from each CQ team independently extracted data using a standardized form. General information collected for each study included authors, title, year of publication, journal name, study aims, study design, level of evidence, number of participants, complications, follow-up period, and outcomes. Information regarding each outcome was extracted from the included studies.

Data were pooled into evidence tables to evaluate and identify variations in the study characteristics and outcomes, and a descriptive summary was generated. This enabled the detection of similarities and differences between studies, and the determination of the suitability of further synthesis or comparison methods.

2.5. Quality assessment

Two reviewers independently assessed the quality and risk of bias of the data extraction process. The risk of bias in this systematic review was evaluated based on the guidelines listed by the Ministry for Guideline Development 2017[24] (**Table 3A**). Discrepancies were resolved through discussions. The quality of each included RCTs, controlled clinical trials (CCTs), and observational studies was evaluated using the Cochrane Collaboration's tool to assess the risk of bias[28]. This instrument is based on the following components that define study quality and evaluate the risk of bias: selection bias (random sequence generation and allocation concealment), performance bias (blinding), detection bias (outcome assessment), attrition bias (intention to treat [ITT] analysis, incomplete outcome data), and other sources of bias (selective outcome reporting bias, stopped early trial for benefits, and other sources of bias). The Minds Manual for Guideline Development 2017 addresses the same domains to assess the risk of bias in observational studies, such as selection[24], performance, detection, and case attrition. The bias was rated on a 3-point scale (high risk, -2; medium/suspicious, -1; or low risk, 0) for each domain, depending on the reviewers. The risk of bias was summarized considering the assessments for each domain and synthesizing them into an overall judgment of the study's risk of bias: Mostly -2 indicates very serious risk (-2), mixed judgment indicates serious risk (-1), and mostly 0 indicates no risk (0). This process was divided into RCTs and observational studies.

Considering the purpose of this systematic review, no inferential statistical analyses were performed. The selected studies did not provide all required general information; in some studies, the information was provided only narratively. The lack of information and the heterogeneity of the selected studies made it impossible to conduct a complete meta-analysis. Multiple studies selected for each outcome were combined to evaluate the body of evidence, and

Table 2. Search formula for each research question

CQ1 Does the use of soft denture relining (SDR) materials improve patient satisfaction compared to using hard denture relining (HDR) in relines or acrylic resin denture? (Patient satisfaction)

#1	Denture Liners[MeSH Terms]
#2	denture*[Title] AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#3	relin*[Title] AND material*[Title]
#4	#1 OR #2 OR #3
#5	Denture Liners[MeSH Terms] AND (Acrylic Resins[MeSH Terms] OR Silicones[MeSH Terms] OR "PL 732" [Supplementary Concept])
#6	(soft[Title] OR hard[Title] OR acryl*[Title]) OR silicone[Title] OR polyolefin[Title] OR resilient[Title]) AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#7	#5 OR #6
#8	#4 AND #7 AND (English[Language] OR Japanese[Language])
#9	Patient Satisfaction[MeSH Terms] OR Consumer Behavior[MeSH Terms] OR (patient*[Title/Abstract] AND satisf*[Title/Abstract])
#8 AND #9	

CQ2 Does the use of SDR materials improve oral health-related quality of life or reduce pain compared to the use of HDR in relines or acrylic resin denture? (Oral health-related quality of life)

#1	Denture Liners[MeSH Terms]
#2	denture*[Title] AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#3	relin*[Title] AND material*[Title]
#4	#1 OR #2 OR #3
#5	Denture Liners[MeSH Terms] AND (Acrylic Resins[MeSH Terms] OR Silicones[MeSH Terms] OR "PL 732" [Supplementary Concept])
#6	(soft[Title] OR hard[Title] OR acryl*[Title]) OR silicone[Title] OR polyolefin[Title] OR resilient[Title]) AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#7	#5 OR #6
#8	#4 AND #7 AND (English[Language] OR Japanese[Language])
#9	Quality of Life[MeSH Terms] OR "quality of life"[Title/Abstract] OR QOL[Title/Abstract]
#10	#8 AND #9
#11	Pain[MeSH Terms]
#12	#8 AND (#9 OR #11)

CQ3 Does the use of SDR material improve masticatory ability compared with the use of HDR in relines or acrylic resin denture? (Masticatory ability)

#1	Denture Liners[MeSH Terms]
#2	denture*[Title] AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#3	relin*[Title] AND material*[Title]
#4	#1 OR #2 OR #3
#5	Denture Liners[MeSH Terms] AND (Acrylic Resins[MeSH Terms] OR Silicones[MeSH Terms] OR "PL 732" [Supplementary Concept])
#6	(soft[Title] OR hard[Title] OR acryl*[Title]) OR silicone[Title] OR polyolefin[Title] OR resilient[Title]) AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#7	#5 OR #6
#8	#4 AND #7 AND (English[Language] OR Japanese[Language])
#9	Mastication[MeSH Terms] OR masticat[Title/Abstract] OR chewing[Title/Abstract]
#8 AND #9	

CQ4 Does the use of SDR prolong the denture's functional duration compared to that when using HDR in relines or acrylic resin denture? (Longevity)

#1	Denture Liners[MeSH Terms]
#2	denture*[Title] AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#3	relin*[Title] AND material*[Title]
#4	#1 OR #2 OR #3
#5	Denture Liners[MeSH Terms] AND (Acrylic Resins[MeSH Terms] OR Silicones[MeSH Terms] OR "PL 732" [Supplementary Concept])
#6	(soft[Title] OR hard[Title] OR acryl*[Title]) OR silicone[Title] OR polyolefin[Title] OR resilient[Title] AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#7	#5 OR #6
#8	#4 AND #7 AND (English[Language] OR Japanese[Language])
#9	longevity[Title/Abstract]
#10	#8 AND #9
#11	(#8 AND "Time Factors"[MeSH Terms]) NOT #10

CQ5 Does the use of SDR material reduce residual ridge resorption compared with the use of HDR in relines or acrylic resin denture? (Residual ridge resorption)

#1	Denture Liners[MeSH Terms]
#2	denture*[Title] AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#3	relin*[Title] AND material*[Title]
#4	#1 OR #2 OR #3
#5	Denture Liners[MeSH Terms] AND (Acrylic Resins[MeSH Terms] OR Silicones[MeSH Terms] OR "PL 732" [Supplementary Concept])
#6	(soft[Title] OR hard[Title] OR acryl*[Title]) OR silicone[Title] OR polyolefin[Title] OR resilient[Title] AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#7	#5 OR #6
#8	#4 AND #7 AND (English[Language] OR Japanese[Language])
#9	Alveolar Bone Loss[MeSH Terms] OR Alveolar[Title/Abstract] OR Resorption[Title/Abstract] OR Bone Loss[Title/Abstract]
#10	#8 AND #9

CQ6. Does the use of SDR material reduce or inhibit microbial growth compared with the use of HDR in relines or acrylic resin denture? (Microbial contamination)

#1	Denturelineers[MeSH Terms]
#2	Denture Liners[MeSH Terms]
#3	denture*[Title] AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#4	relin*[Title] AND material*[Title]
#5	#1 OR #2 OR #3
#6	Denture Liners[MeSH Terms] AND (Acrylic Resins[MeSH Terms] OR Silicones[MeSH Terms] OR "PL 732" [Supplementary Concept])
#7	(soft[Title] OR hard[Title] OR acryl*[Title]) OR silicone[Title] OR polyolefin[Title] OR resilient[Title] AND (liners[Title] OR liner[Title] OR lining[Title] OR relin*[Title])
#8	#4 AND #7 AND (English[Language] OR Japanese[Language])
#9	Stomatitis[MeSH Terms] or Mucositis[MeSH Terms] or Candida[MeSH Terms] or CandidaSilicon SDL[MeSH Terms] or Mycoses [MeSH Terms]
#10	#8 AND #9

Electronic searches of MEDLINE, Cochrane Library database, and ICHUSHI were performed. Literature published between January 1, 1970 and October 26, 2020 was considered.

the strength of the evidence was assessed using the grading of recommendation assessment, development, and evaluation (GRADE) approach. The certainty of the evidence is summarized in the final grading statement listed in **Table 3B**. In addition, four domains of evidence synthesis and evaluation were assessed, as follows: indirectness, allocation concealment, imprecision, and others (e.g., publication bias)[29–32]. This process may have contributed to a lower rating of the certainty of evidence. The approach used to evaluate the evidence for the observational studies was similar to that used for the RCTs. For the observational studies, the rating of the strength of the body of evidence begins at "weak."

3. Results

3.1. General outcomes

Figure 1 and the Supplementary files present flowcharts of the literature screening and selection process. The final electronic database search yielded 580 literature sources. Based on a review of the titles and abstracts of these sources, 51 were selected for the second round of evaluation. In the second round, the entire texts of the selected literature sources were screened and evaluated. Finally, 34 literature sources were selected for the systematic review, as listed in **Table 4**.

Table 3A. Risk of bias assessment and evidence intensity level. Risk of bias assessment, domain name of bias (Cochrane bias risk tool v.2.0).

Bias name (Minds 2017 Domains)	RCTs	Observational study
Selection bias	Bias arising from the randomization process, (e.g., allocation concealment)	Differences in background factors between the groups being compared
Performance bias	Blinding of participants and personnel	Systematic difference in the interventions or care approaches implemented between the groups being compared
Detection bias	Blinding of outcome assessment	Inappropriate outcome measurement
Attrition bias	Incomplete outcome data, bias from missing data, and ITT analysis not conducted	Incomplete outcome data, bias from missing data, and ITT analysis not conducted
Other bias	Selective outcome reporting, early study discontinuation bias, and other potential biases	Adjustment for inadequate confounding, and other biases (Bias attributed to selective outcome reporting)

ITT: intention-to-treat, RCT: randomized controlled trial

Table 3B. Evidence intensity and meaning

Evidence intensity	Meaning
A (Strong)	There is a high level of confidence in the estimated effect. Further research is unlikely to change the conclusion.
B (Moderate)	There is a moderate level of confidence in the estimated effect. Further research may have an impact on the conclusion.
C (Weak)	There is a limited level of confidence in the estimated effect. Further research is likely to have a significant impact on the conclusion.
D (Very weak)	There is very little confidence in the estimated effect. Any estimate is uncertain.

3.2. Patient satisfaction

Since all evidence in the literature confirmed that SDR materials improve patient satisfaction, SDR can be considered to effectively improve patient satisfaction, especially in cases with complete mandibular dentures. Whether silicone- or acrylic-based SDR materials most improved patient satisfaction could not be determined.

Six of the seven studies[33–39] selected for evidence used acrylic resin dentures as the control material[33,34,36–39], and the results of SDR materials were for mandibular dentures. Furthermore, efficacy was determined after using SDR materials for a short period. Even for the longest study duration, the evaluation was performed six months after denture relining with SDR materials, which does not constitute a recommendation for efficacy regarding the long-term use of SDR materials.

The GRADE profiles of patient satisfaction are shown in **Table 5**. Most outcomes were judged to have weak or very weak evidence, which can be attributed to the study designs, making the blinding of SDR and HDR material/acrylic resin dentures difficult. Other factors, such as the small number of included studies per outcome, absence of statistical analysis, and lack of cost-of-insurance (COI) descriptions in the literature, were evaluated as having a high risk of bias. However, the effect of SDR on maxillary dentures has not yet been reported; therefore, further studies are required.

3.3. Oral health-related quality of life (OHRQOL) or reduction in pain

Oral pain relief is an important factor in OHRQOL. Relining with SDR material significantly reduced mandibular pain; however, no change was observed in the maxilla[38,40]. The oral-health impact profile (OHIP), which is a measure of OHRQOL, improved after relining with SDR material, suggesting that relining relieves psychological discomfort and physical pain in patients. These effects were validated using mandibular relines[41–43].

The GRADE evidence profiles of the changes in OHRQOL are presented in **Table 6**. Most outcomes had weak or very weak evidence. The strength of the evidence was also reduced by the small number of literature sources per outcome and by the fact that the evidence was not collected from RCTs. Overall, the risk of performance bias in the selected studies was high, owing to the difficulty in blinding SDR materials versus HDR materials/acrylic resin dentures. Moreover, the lack of COI descriptions and statistical analyses associated with case attrition increases the risk of bias.

3.4. Masticatory ability (MA)

Evaluation methods for MA involve the assessments of masticatory performance[36,44–48], maximum occlusal force[37,44,45,49], electromyography (EMG)[44,45,49,50], mandibular movement[44,45,49], chewing time[37], chewing frequency[37], and perceived chewing ability[39,51]. However, methods that evaluate maximum bite force, EMG, mandibular movement, chewing time, and chewing frequency are indirect examination methods for MA assessment, and their relationship with MA is currently unclear. Therefore, we considered only literature that described direct examination methods, such as the evaluation of masticatory performance and masticatory score.

The use of silicone-based SDR materials on denture relines for short periods (within three months) was advantageous for improving MA. This finding was similar to that of a systematic review by Palla et al.[49]. However, the effects of long-term use or use of acrylic-based SDR materials remain uncertain.

The GRADE evidence profiles for MA are presented in **Table 7**. Most outcomes were considered to have weak or very weak evidence owing to similar reasons as those for the outcomes of CQ1 and CQ2, such as study design and difficulty in blinding SDR materials versus HDR materials/acrylic resin dentures. However, the evidence for masticatory performance and mastication scores was moderate, suggesting that denture relines made of SDR materials are likely to

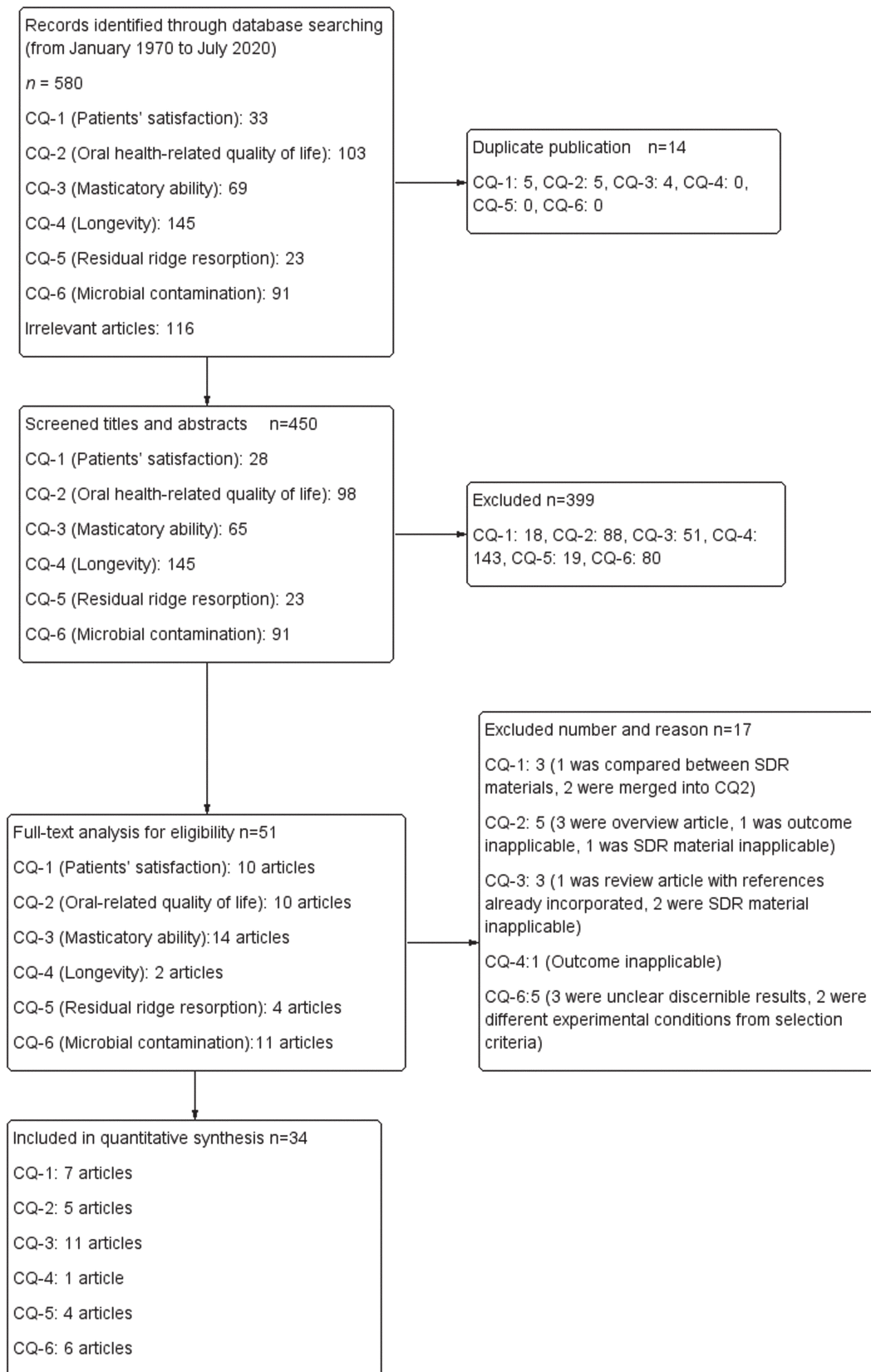


Fig. 1. Flow diagram for literature screening and selection. SDR: soft denture relining.

Table 4. List of evidence related to clinical questions

CQ	Authors	Study Design	Outcome	Edentulism of participants	Evaluated jaw	Number of participants (dropped out)	Control	Intervention	Number of control (dropped out)	Number of intervention (dropped out)	Follow-up period	Summarized results
CQ1	Kimoto S et al. 2014[39]	RCT	Patient satisfaction (VAS)	Maxilla and mandible	Both maxilla and mandible	74(12)	Acrylic resin denture	Acrylic SDR	37(7)	37(5)	2 months	General, chewing and speaking satisfaction were significantly higher in intervention patients than in control patients.
	Kimoto S et al. 2008[38]	RCT	Patient satisfaction (VAS)	Maxilla and mandible	Both maxilla and mandible	74(7)	Acrylic resin denture	Acrylic SDR	37(2)	37(5)	3 days (no mention of maximum)	The intervention group showed significantly higher satisfaction ratings related to chewing, cleaning, retention, and esthetics in mandibular dentures than the control group.
	Murata H et al. 2002[37]	quasi-RCT	Patient satisfaction (VAS)	Mandible	Mandible	10	-	Acrylic SDR and Silicone SDR	-	10	1 week	The VAS results for the patients' assessment of satisfaction with intervention were significantly higher than those with control material.
	Hosoi N et al. 2003[35]	Review	Patient satisfaction (VAS)	-	-	-	Acrylic HDR	Acrylic SDR and Silicone SDR	-	-	-	-
CQ2	Kimoto S et al. 2003[36]	RCT (cross-over)	Patient preference	Maxilla and mandible	Both maxilla and mandible	28	Acrylic resin denture	Silicone SDR	28	28	3 months	72% of the patients preferred the SDR compared to acrylic resin dentures.
	Schmidt WF et al. 1983[34]	Case-control study	Patient preference	Maxilla and mandible	Both maxilla and mandible	65(22)	-	Silicone SDR	-	87(22)	6 years	Nearly all the patients strongly preferred or slightly preferred SDR than acrylic resin denture if a new denture were to be made.
	Mäkilä E et al. 1979[33]	Case-control study	Patient preference	Maxilla and mandible	Mandible	37	-	Silicone SDR	-	37	30 months	73% of the patients stated that they were very satisfied or satisfied with SDR.
	Kimoto S et al. 2007[40]	RCT	Number of pain spots	Maxilla and mandible	Both maxilla and mandible	74(7)	Acrylic resin denture	Acrylic SDR	37(5)	37(2)	3 days	The number of sore spots in the mandibular support and border areas for the permanent intervention group were significantly less than those for control groups.
CQ3	Kimoto S et al. 2008[38]	RCT	Patients' pain	Maxilla and mandible	Both maxilla and mandible	74(7)	Acrylic resin denture	Acrylic SDR	37(5)	37(2)	3 days	The pain rating of intervention group was significantly lower than that of the control group.
	Pisani MX et al. 2012[43]	quasi-RCT	OHIP-EDENT	Maxilla and mandible	Mandible	45(13)	-	Silicone SDR	-	45(13)	3 months	All four domains showed significant differences between before and after intervention. After three months of relining, participants reported significant improvement of their OHRQoL.
	Krunić N et al. 2016[42]	RCT	OHIP-EDENT	Maxilla	Maxilla	24	Acrylic HDR	Silicone SDR	12	12	3 months	SDR of maxillary complete dentures had a significant positive impact on the quality of life of patients.
	Furokawa S et al. 2020[41]	RCT	Psychological discomfort (OHIP component)	Mandible	Both maxilla and mandible	31(8)	Acrylic resin denture	Silicone SDR	16(6)	15(2)	3 months	The pain thresholds were significantly higher in the SDR group than control group. The physical pain and psychological discomfort scores were significantly lower in the SDR group.
CQ3	Kimoto S et al. 2003[36]	RCT (cross-over)	Masticatory performance	Maxilla and mandible	Both maxilla and mandible	28	Acrylic resin denture	Silicone SDR	28	28	3 months	Masticatory performance with SDR material was significantly higher than control denture at 2 and 3 months after completing adjustments of the denture.
	Kimoto S. et al. 2006[44]	RCT (cross-over)	Masticatory performance, maximum occlusal force, EMG, mandibular movement	Maxilla and mandible	Both maxilla and mandible	28(8)	Acrylic resin denture	Silicone SDR	28(8)	28(8)	3 months	The intervention group showed better masticatory performance than control group and 2 months after the completion of denture adjustments, although the differences were not significant at 1 month. The masticatory performance of SDR improved significantly over time after 2 and 3 months compared to after 1 month than control.

Table 4. Continued

CQ	Authors	Study Design	Outcome	Edentulism of participants	Evaluated jaw	Number of participants (dropped out)	Control	Intervention	Number of control (dropped out)	Number of intervention (dropped out)	Follow-up period	Summarized results
	Kimoto S. <i>et al.</i> 2010[47]	RCT	Perceived chewing ability	Mandible	Mandible	74(12)	Acrylic resin denture	Acrylic SDR denture	37(6)	37(6)	2 months	SDR applied to mandibular complete dentures does not significantly impact the perceived chewing ability of edentulous patients when compared to control denture.
	Shinomiya M. <i>et al.</i> 2007[45]	RCT	Masticatory performance, maximum occlusal force, EMG, mandibular movement	Mandible	Mandible	53	Acrylic resin denture	Acrylic SDR and Silicone SDR	27	26	2 months	SDR wearers showed significantly higher masticatory performance as compared to the control group ($P < 0.01$), no difference between groups.
	Kimoto S. <i>et al.</i> 2010[51]	RCT	Masticatory performance, and mandibular movement	Mandible	Mandible	74(29)	Acrylic resin denture	Acrylic SDR denture	37(15)	37(14)	2 months	No significant difference in the masticatory performance between control and intervention groups.
	Kimoto S. <i>et al.</i> 2014[39]	RCT	Perceived chewing ability	Maxilla and mandible	Both maxilla and mandible	74(12)	Acrylic resin denture	Acrylic SDR denture	37(7)	37(5)	2 months	No significant difference in mastication index and in chewing foods between intervention and control groups.
	Tata S. <i>et al.</i> 2012[46]	quasi-RCT (two-phases)	Masticatory performance	Maxilla and mandible	Both maxilla and mandible	20	Acrylic resin denture	Silicone SDR	20	20	2 weeks	A 5% improvement was seen in the masticatory performance of patients with intervention compared to control.
	Kar S. <i>et al.</i> 2019[48]	quasi-RCT (two-phases)	Masticatory performance	Maxilla and mandible	Both maxilla and mandible	30	Acrylic resin denture	Acrylic SDR denture	30	30	16 weeks or 4 months	Masticatory performance improved significantly after intervention. Masticatory performance was maximum at 4 week and gradually declined until the 16th week but was still better than masticatory performance in control group.
	Murata H. <i>et al.</i> 2002[37]	quasi-RCT	Maximum bite force, chewing time, chewing frequency	Mandible	Mandible	10	-	Acrylic SDR and Silicone SDR	-	10	1 week	Patients with acrylic SDR has higher bite force than silicone SDR. The maximum bite force among dentures with SDR were significantly higher in all subjects than those with hard resin except for one subject provided with a temporary liner.
	Pisani M. X. <i>et al.</i> 2013[50]	quasi-RCT	EMG	Maxilla and mandible	Mandible	50(6)	Acrylic resin denture	Acrylic SDR denture	25(3)	25(3)	3 months	Relining with hard and soft materials increased electromyographic activity and improved masticatory function.
	Palla E. <i>et al.</i> 2015[49]	Review	Masticatory performance, maximum occlusal force, EMG, mandibular movement	Maxilla and mandible	Both maxilla and mandible	-	-	-	-	-	3 months	SDR provided denture wearers with increased masticatory function compared to conventional denture base materials. Use of long-term silicone liners significantly improved the mastication parameters.
CQ4	Kimoto S. <i>et al.</i> 2013[52]	RCT	Functional duration	Mandible	Mandible	67	Acrylic resin denture	Acrylic SDR denture	35	32	75 months	The group using SDR had twice the risk of having shorter denture-survival times than those using acrylic resin dentures.
CQ5	Babu BD, <i>et al.</i> 2014[54]	RCT	Mandibular residual ridge resorption	Maxilla and mandible	Both maxilla and mandible	28	Acrylic resin denture	Acrylic SDR denture	14	14	12 months	The use of SDR significantly reduced the residual ridge resorption in complete denture wearers as compared to control denture over a period of 1 year.
	Kocabalkan E. <i>et al.</i> 2005[55]	RCT	Changes in mucosal blood flow	Mandible	Mandible	20	Acrylic resin denture	Acrylic SDR denture	10	10	6 months	Blood flow in the canine region returned to almost normal levels 6 months after beginning to wear control dentures. However, blood flow values did not return to the levels recorded before denture insertion in SDR group.

Table 4. Continued

CQ	Authors	Study Design	Outcome	Edentulism of participants	Evaluated jaw	Number of participants (dropped out)	Control	Intervention	Number of control (dropped out)	Number of intervention (dropped out)	Follow-up period	Summarized results
CQ6	Kimoto K. et al. 2013[52]	RCT	Patients' subjective assessment	Mandible	Mandible	67	Acrylic resin denture	Acrylic SDR	35	32	75 months	In controls, the only reason for replacing or reattaching dentures was "loose dentures." In the intervention group, seven patients replaced or reattached their dentures because of loose dentures and seven patients replaced or reattached their dentures because of staining and roughness of the resilient liner.
	Badawy MS, et al. 1992[53]	quasi-RCT	Mandibular residual ridge resorption around the root plate	Maxilla (complete denture), Mandible (overdenture)	Mandible	14	Acrylic resin denture	Acrylic SDR	7	7	12 months or 1 year	The intervention group had less reduction in alveolar bone density around the anterior or posterior abutments than the control group.
	Mäkilä E. et al. 1977[58]	Cohort study	Number of adherent microbes	Maxilla and mandible	Both maxilla and mandible	39	Acrylic resin denture	Silicone SDR	39(maxilla)	39(mandible)	2 weeks to 5 1/2 years average of 1 year and 5 months	Fungal growth was detected in 85% of the mandibular dentures and in 44% of the maxillary dentures.
	Valentini F. et al. 2013[57]	RCTs (cross-over)	Number of adherent microbes	Maxilla	Maxilla	30(3)	Acrylic HDR	Acrylic SDR and Silicone SDR	30(3)	30(3)	21 days	The surface roughness of SDR material increased in patients with denture stomatitis compared to patients with healthy denture-wearing soft tissues, and it is thought that the longer the period of use, the more likely it is that the surface becomes rougher.
	Mutluay M. M. et al. 2010[14]	Cohort Study	Number of adherent microbes	not mentioned	not mentioned	14	-	Silicone SDR	-	14	1 year	Eleven of the 14 patients examined after wearing the dentures for 1 year carried populations of yeasts. Six of the patients had more than one yeast species.
	Bal B. T. et al. 2008[56]	RCT (three-phases)	Number of adherent microbes	Maxilla	Maxilla	17	Acrylic resin denture	Acrylic SDR and Silicone SDR	17	17	14 days	SDR materials are not resistant to adhesion and possible surface damage caused by oral bacteria, and therefore their use should be limited to short-term periods.
	Mutluay M. M. et al. 2008[59]	Cohort Study	Number of adherent microbes	not mentioned	not mentioned	33	-	Silicone SDR	-	33	12 months	Except for cases showing extensive fungal colonization, the observed changes in clinical performance did not necessitate remaking of the SDR dentures.
	Pereira-Cenci T. et al. 2010[20]	quasi-RCT (cross-over)	Number of adherent microbes	Mandible	Mandible	21(2)	Acrylic resin denture	Acrylic SDR and Silicone SDR	21(2)	21(2)	14 days	Surface roughness increased mainly after 14 days, except for the acrylic resin. Higher counts in total streptococci, Actinomyces, and total microorganisms were observed after 7 and 14 days.

CQ: clinical question, SDR: soft denture relining, HDR: hard denture relining, OHIP: oral-health impact profile, EDENT: edentulous patients, VAS: visual analog scale, RCT: randomized controlled trial

Table 5. Grade evidence profile: Changes in patient satisfaction by relining with a soft denture relining (SDR) material

Outcome	Study design/ number of studies	Risk of bias	Allocation concealment	Imprecision	Indirectness	Others (e.g., publication bias)	Evidence intensity
Acrylic SDR							
Patient satisfaction by VAS (Mandible)	RCT/2 quasi-RCT/1	–1	0	0	0	–1	Weak (C)
Patient preference (Mandible)	RCT/1	–1	–1	–1	0	–1	Very weak(D)
Silicone SDR							
Patient satisfaction by VAS (Mandible)	quasi-RCT/1	–1	–1	–1	0	–1	Very weak (D)
Patient satisfaction by VAS (Mandible)	quasi-RCT/1	–1	–1	–1	0	–1	Very weak (D)
Patient preference (Mandible)	RCT/1	–1	–1	–1	0	–1	Very weak (D)
Patient preference (Mandible)	Case-control study/2	–1	0	0	0	–1	Very weak (D)

The outcomes are shown according to the SDR material type (acrylic and silicone-based). OHIP: oral-health impact profile, VAS: visual analog scale, RCT: randomized controlled trial.

facilitate mastication.

3.5. Functional duration

Only one study provided evidence to clarify the survival of comprehensive denture relines[52]. Dentures relined with acrylic-based SDR materials tended to have shorter functional durations than those relined with acrylic denture bases.

The GRADE evidence profiles for functional duration are presented in **Table 8**. The evidence was evaluated as weak because of the small number of studies and high risk of bias. The high risk of bias can be attributed to the difficulty in establishing blinding because both the operator and patient knew which materials (SDR or acrylic resin dentures) were used. Additionally, the literature was obtained from a single-center study, and the COIs were not stated.

3.6. Residual ridge resorption (RRR)

As outcomes directly related to RRR have yet to be established, we evaluated changes in bone resorption[53,54], mucosal blood flow changes[55], and denture fitness (subjective assessment)[52]. The evidence was provided by one literature source, which indicated that in mandibular complete dentures, the rates of RRR[54] and bone resorption[53] were significantly lower for acrylic-based SDR materials than those for hard denture base materials during the 12-month observation period, suggesting that the use of SDR materials was more effective than that of HDR materials/acrylic resin dentures. The use of SDR materials was inferred to be advantageous in terms of RRR, compared with the use of HDR materials, for denture relining. Further, no clear difference was evident between SDR and HDR materials/acrylic resin dentures in terms of blood flow change/compatibility[52,55].

The GRADE evidence profiles for the changes in RRR are presented in **Table 9**. The evidence was very weak because one RCT or quasi-RCT provided evidence for each outcome, and the RRR was not evaluated directly. In addition, the risk of bias was high because the COI has not been reported in the literature; therefore, only one outcome (resorption of the residual ridge) was determined to be weak[54].

3.7. Microbial contamination

All RCTs[20,56,57] included in the systematic review were for the short-term use of three weeks or less, with only non-RCTs or observational studies providing evidence for long-term use[14,58,59]. Dentures relined with SDR materials for short-term use showed a trend toward lower microbial growth than those relined with HDR materials. SDR material showed a trend toward lower microbial growth than the hard denture base material when all outcomes were combined, although this was not a statistically significant effect. For each microorganism type, a stronger trend toward lower numbers of *Candida albicans* (*C. albicans*) and gram-positive cocci was identified in the SDR material than that in the hard denture base material. In contrast to its results for short-term use, the SDR material was more susceptible to microbial contamination than hard materials (HDR materials/acrylic resin dentures), although all studies on long-term use were observational.

The GRADE profiles of microbial contamination are presented in **Table 10**. In many cases, the evidence was weak or very weak because case attrition bias was present among the included studies, and COI was not described. However, some assumptions in the literature regarding this CQ differ from those of other CQs. Blindness (e.g., a certain space under the denture base to which the reline material was applied) was established, and clinical research was subsequently conducted. In addition, microbial growth was easily influenced by each patient's underlying disease status, and a significant case-reduction bias, such as discontinuation of the experiment caused by the use of antimicrobial agents, was identified.

3.8. Risk of bias and evidence (Tables 5–10)

In all studies, the risk of bias due to the differences between SDR and HDR materials/acrylic resin dentures was obvious for both operators and patients. In most cases, blinding is impossible. In addition, some studies did not mention COI, lacked statistical analysis associated with case attrition, or did not describe any statistical analysis. Although most evaluations were based on individual differences in the subjects' underlying diseases and oral hygiene statuses, some literature sources that described studies with high risks of bias were included in the analysis.

Table 6. GRADE evidence profile: Changes in oral health-related quality of life or reduction in pain due to relining with a soft denture relining (SDR) material

Outcome	Study design/ number of studies	Risk of bias	Allocation concealment	Imprecision	Indirectness	Others (ex. publication bias)	Evidence intensity
Acrylic SDR							
Number of pain spots (Maxilla)	RCT/1	−1	−1	−1	0	−1	Weak (C)
Number of pain spots (Mandible)	RCT/1	−1	−1	−1	0	−1	Weak (C)
Pain awareness (Maxilla)	RCT/1	−1	−1	−1	0	−1	Weak (C)
Pain perception (Mandible)	RCT/1	−1	−1	−1	0	−1	Weak (C)
Silicone SDR							
Physical pain	RCT/1	−1	−1	−1	0	0	Weak (C)
Chewing-related (OHIP component)	RCT/1	−1	−1	−1	0	−1	Weak (C)
Psychological discomfort (OHIP component)	RCT/2	−1	0	0	0	0	Medium (B)
Social impairment (OHIP compo- nent)	RCT/1	−1	−1	−1	0	−1	Weak (C)
Maintenance and hygiene (OHIP component)	RCT/1	−1	−1	−1	0	−1	Weak (C)
Overall OHIP	RCT/1	−1	−1	−1	0	−1	Weak (C)
Oral pain/discomfort (OHIP com- ponent)	Cohort study/1	−1	−1	−1	0	−1	Very weak (D)
Mastication-related complaints (OHIP component)	Cohort study/1	−1	−1	−1	0	−1	Very weak (D)
Psychological discomfort and impairment (OHIP component)	Cohort study/1	−1	−1	−1	0	−1	Very weak (D)
Social impairment (OHIP compo- nent)	Cohort study/1	−1	−1	−1	0	−1	Very weak (D)
Overall OHIP	Cohort study/1	−1	−1	−1	0	−1	Very weak (D)

The outcomes are shown according to the SDR material type (acrylic and silicone-based). VAS: visual analog scale, RCT: randomized controlled trial.

Table 7. Grade evidence profile: Changes in masticatory ability by relining with a soft denture relining (SDR) material

Outcome	Study design/ number of studies	Risk of bias	Allocation concealment	Imprecision	Indirectness	Others (e.g., publication bias)	Evidence intensity
Acrylic SDR							
Mandibular movement	RCT/2	−1	−2	0	0	−1	Weak (C)
Maximum occlusal force	RCT/1, quasi-RCT/1	−1	−1	−1	0	−1	Weak (C)
Occlusal force	RCT/1, quasi-RCT/1	−1	−1	−1	0	−1	Weak (C)
Masticatory performance	RCT/2, quasi-RCT/1	−1	0	0	0	−1	Medium (B)
Mastication score	RCT/2	−1	0	0	0	−1	Medium (B)
Chewing time	quasi-RCT/1	−2	0	−2	0	−1	Very weak (D)
Chewing frequency	quasi-RCT/1	−2	0	−2	0	−1	Very weak (D)
Silicone SDR							
EMG	RCT/1, quasi-RCT/1	−2	−2	−1	0	−1	Very weak (D)
Occlusal force	RCT/2, quasi-RCT/1	−1	−1	−1	0	−1	Weak (C)
Mastication score	RCT/3, quasi-RCT/1	−1	0	0	0	−1	Medium (B)
Mandibular movement	RCT/2	−1	−2	0	0	−1	Weak (C)
Chewing time	quasi-RCT/1	−2	0	−2	0	−1	Very weak (D)
Chewing frequency	quasi-RCT/1	−2	0	−2	0	−1	Very weak (D)

The outcomes are shown according to the SDR material type (acrylic and silicone-based). Acrylic SDR: acrylic-based soft denture relining, Silicone SDR: silicone-based soft denture relining, RCT: randomized controlled trial.

Table 8. GRADE Evidence Profile: Changes in denture durability by relining with a soft denture relining (SDR) material

Outcome	Study design/ number of studies	Risk of bias	Allocation concealment	Imprecision	Indirectness	Others (e.g., publication bias)	Evidence intensity
Acrylic SDR							
Longevity period	RCT/1	−1	0	−1	0	−1	Weak (C)

Acrylic SDR: acrylic-based soft denture relining, RCT: randomized controlled trial

Table 9. Grade evidence profile: Change in reduce residual ridge resorption by relining with a soft denture relining (SDR) material

Outcome	Study design/ number of studies	Risk of bias	Allocation concealment	Imprecision	Indirectness	Others (e.g., publication bias)	Evidence intensity
Acrylic SDR							
Resorption of the residual ridge	RCT/1	−1	−1	−1	0	0	Weak (C)
Resorption of the residual ridge around the root plate	quasi-RCT/1	−1	−1	−1	0	−1	Very weak (D)
Changes in mucosa blood flow	RCT/1	−1	−1	−1	−1	−1	Very weak (D)
Patient's subjective evaluation	RCT/1	−1	−1	−1	−1	−1	Very weak (D)

Acrylic SDR: acrylic-based soft relining, RCT: randomized controlled trial

Table 10. GRADE evidence profile: Change in the inhibition of microbial growth by relining with a soft denture relining (SDR) material

Outcome	Study design/ number of studies	Risk of bias	Allocation concealment	Imprecision	Indirectness	Others (e.g., publication bias)	Evidence intensity
Acrylic SDR							
<i>C. albicans</i> count	RCT/2, nonRCT1	−1	0	0	0	−1	Weak (C)
<i>C. non-albicans</i> count	RCT/2	−1	0	0	0	−1	Weak (C)
<i>Gram-positive cocci</i>	RCT/2, nonRCT1	−1	0	0	0	−1	Weak (C)
<i>Gram-positive bacteria</i>	RCT/2	−1	0	0	0	−1	Weak (C)
Total bacteria count	RCT/2	−1	0	0	0	−1	Weak (C)
Silicone SDR							
<i>C. albicans</i> count	RCT/3	−1	0	0	0	−1	Weak (C)
<i>C. non-albicans</i> count	RCT/3	−1	0	0	0	−1	Weak (C)
<i>Gram-positive cocci</i>	RCT/3	−1	−1	0	0	−1	Weak (C)
<i>Gram-positive bacteria</i>	RCT/3	−1	0	−1	0	−1	Weak (C)
Total bacteria count	RCT/3	−1	0	0	0	−1	Weak (C)

The outcomes are shown according to the SDR material type (acrylic and silicone-based). Acrylic SDR: acrylic-based soft relining, Silicone SDR: silicone-based soft relining, RCT: randomized controlled trial.

4. Discussion

In denture relining procedures performed for long-term use, relining with HDR materials was common before the introduction of SDR materials. This systematic review compared the effectiveness of SDR materials for denture relining in complete denture wearers based on each outcome. SDR materials were superior to HDR materials/acrylic resin dentures in terms of patient satisfaction, OHRQOL, MA, RRR, and short-term microbial growth suppression. However, the functional duration and long-term microbial growth outcomes were worse for the SDR materials than those for the HDR materials.

In this systematic review, common problems cited in the literature that served as evidence for each CQ were the limited number of RCTs and the high risk of bias. The risk of bias assessment showed that the evidence lacked allocation concealment and blinding, which could be attributed to the obvious difference between SDR and HDR or the acrylic resin denture base for denture relining. Furthermore, adequate control of confounding factors was lacking, as each case

had a different underlying disease, residual ridge morphology, and insufficient follow-up or duration.

4.1. SDR material for denture relines

Commercially available long-term SDR materials can be classified as acrylic- or silicone-based. Vinyl resin and polyolefin SDR materials are also established; however, none of the selected evidence supported the use of vinyl resin or polyolefin as SDR materials. Flexible polymeric materials exhibit both elasticity (rubber properties) and viscosity (clay properties), and the ratio of these properties varies depending on the material used[11,37,60]. Silicone-based SDRs exhibit low viscosity and elastic properties, whereas acrylic-based SDRs exhibit both elastic and viscous properties, making them viscoelastic. Acrylic-based SDRs have a greater loosening effect on the occlusal forces than silicone-based SDRs. Acrylic-based SDRs tend to lose their original flexibility and deteriorate over time because of the elution of plasticizers and water absorption. In contrast, silicone-based SDR materials are characterized by low elution and water absorption;

therefore, they exhibit little change in physical properties over time and have high longevity[61]. The adhesive strengths of heat-cured silicone- and acrylic-based SDRs to denture base resins were higher than those of chemically cured materials. However, many chemically cured silicone-based SDR materials commonly used at the chairside are additives with inferior adhesion to the denture base[61]. Both acrylic- and silicone-based SDRs are viscoelastic and expected to have loosening effects; however, each material has unique characteristics[61].

Therefore, in this systematic review, evidence in the literature was classified according to material type. However, the number of studies on each CQ was small, and the reliability of the evidence was low because the outcomes were evaluated using references that only used silicone/acrylic-based SDRs.

4.2. Previous reviews for soft denture relines

A literature review (systematic and narrative reviews) on denture relines included eleven references; four of these references were systematic reviews[16,49,62,63]. Only Chaves *et al.*[62] discussed HDR, whereas the other three studies discussed SDR[16,49,63], excluding narrative reviews. One systematic review corresponded to CQ3[49] and discussed the effects of soft denture liners on the masticatory performance of complete denture wearers. Two other systematic reviews[16,63] focused on the adhesion between the denture base and SDR materials, with *in vitro* studies comprising the majority of the cited literature. The others were narrative reviews[11,15,64–67]. Thus, to the best of our knowledge, this systematic review is the first to summarize clinical studies on SDR and examine its effectiveness.

4.3. Patient satisfaction and OHRQOL

Patient satisfaction with complete dentures depends on various factors, such as the patient's age, personality, previous denture-wearing experience, expectations, esthetics, residual ridge morphology and anatomy, denture quality, method of construction, dentist's experience, and dentist–patient relationship[52,68,69]. Older adults and patients who have used dentures for a long time often experience significant bone resorption in the residual ridge or thinning of the residual ridge mucosa, making complete denture rehabilitation difficult. Furthermore, older adults often find the adaptation to new dentures difficult, and even if a theoretically correct denture could be made and worn, it may not be acceptable to some patients. Therefore, for patients with difficult complete dentures, relining the denture with SDR is effective and has the same elasticity as the oral mucosa to relieve masticatory pressure[70], provide appropriate occlusion, and adjust the denture base edges instead of fabricating a new denture[71]. In addition, its application in maxillofacial prosthetics and adaptability to the undercut area of the residual ridge are expected to have a maintenance effect[11,65,66].

Kimoto *et al.*[51] found that the use of SDRs reduced the occlusal force-bearing support areas and stress concentrations at the denture base edges. Furthermore, they found that SDRs were more effective than HDRs in reducing the effects of denture bases. They also reported that using SDRs resulted in fewer pressure wounds in the supporting areas that bear the burden of occlusal forces and at the edges of the denture base where stresses are concentrated[51].

4.4. Masticatory ability (MA)

MA evaluation was performed with multiple outcomes. Masticatory values increased for both silicone- and acrylic-based SDR materials; however, masticatory performance was slightly higher for silicone-based SDR[36,44,46] than that for acrylic-based SDR[45,48,51]. This finding was similar to that of a systematic review by Palla *et al.*[49]. However, occlusal force, chewing time, and chewing frequency tend to be slightly better for acrylic-based SDR materials than those for silicone-based SDR materials[37]. Acrylic-based and silicone-based SDR materials exhibited stronger viscoelastic and elastic properties, respectively; however, determination of which SDR was superior proved difficult. The maximum study period in all selected studies was three months; therefore, acrylic-based SDR material may differ from silicone-based SDR material in terms of aging because acrylic-based SDR material is more prone to elasticity loss after long-term use. Nevertheless, SDR improved MA better than HDR or acrylic resin denture bases. Tissue conditioners are elastic materials; however, they have been reported to be less effective than SDR materials in improving MA[37]. The elastic modulus of the tissue conditioners was lower than that of the oral mucosa. This is attributed to their weaker resistance to the force applied during mastication, which results in a weaker crushing force on food. In an impact test, in which objects are impacted under the same conditions, the impact of the SDR material was reported to be 15% smaller than that of the hard material[72]; therefore, the impact of occlusal forces on the mucosa under the denture is mitigated using an SDR material.

The thickness of SDR materials significantly affect the stress-breaking effect and transmission efficiency of the occlusal force[73]. The thickness of SDR materials can also affect mastication methods differently (e.g., excessive occlusal force load), causing significant changes in the outcomes. The effect of relining with SDR material on the maxilla remains unknown because the literature that served as evidence was specific to edentulous patients with maxillae and mandibles, and all interventions involved SDR for mandibular complete dentures. Although MA can be improved by alleviating denture-related pain, the SDR material should be carefully selected before the procedure.

A systematic review by Palla *et al.*[49] focused on masticatory performance and muscle activity and confirmed that SDR improved the masticatory performance of denture wearers, compared with conventional denture base materials. Long-term use of silicone-based SDR materials significantly improved masticatory parameters, and this systematic review provided the same conclusions as CQ3. Therefore, patients wearing complete dentures relined with SDR material showed significantly improved masticatory parameters. The fact that dentures fitted with soft-line materials improve masticatory parameters is highly valid; however, the systematic review by Palla *et al.*[49] exhibited some limitations, such as the lack of a bias risk assessment and comparison with controls. In this respect, the validity of our systematic review covering these issues was high.

4.5. Functional duration

For the longevity of the denture base, the silicone-based SDR material adheres to the base resin through an adhesive but peels from the adhesive surface after long-term use[11,14,16]. Acrylic-based SDR materials are chemically bonded to resin[11,14,16]. They do not delaminate but lose elasticity because of the elution of plasticizers, and the surface becomes rough, resulting in severe surface contami-

nation. From the selected literature, the relining and refabrication of dentures increased in the first two years after using both SDR and HDR materials; however, the decrease in survival rate was more pronounced for SDR materials. Reasons for relining or refabricating dentures include problems with denture fitness for HDR materials and material deterioration for SDR materials.

Case reports on the annual observation of denture function after relining with SDR materials indicate that dentures with SDR materials could be used for approximately one to six years, although the SDR materials deteriorated in patients who had difficulty wearing dentures with hard bases owing to pain and functional impairment[35,60,74,75].

Kreve *et al.*[63] and Muddugangadhar *et al.*[16] reviewed the material science aspects of adhesives and mechanical properties of denture relining materials. Kreve *et al.*[63] reported that poor adhesion reduces the longevity of the relining procedure and promotes microbial colonization, which is relevant to CQ4 and CQ6 in this systematic review and is an important piece of evidence for understanding these CQs. The use of solvents in silicone-based SDR materials improves their adhesion to PMMA bases. Adhesion to polyamide denture bases requires surface treatment with acetic acid or tribochemical silica. For PMMA surfaces, better adhesion was observed when the chemistries of the liner and denture base were the same. Based on a systematic review by Muddugangadhar *et al.*[16] on the adhesion of commercially available SDR materials to base resins, the following adhesive treatments were used: laser pretreatment, oxygen plasma treatment, acid etching, silica coating, primer or monomer application, acetone or methacrylic acid isobutyl methacrylate, and immersion of the denture base in acetone or isobutyl methacrylate.

Thus, chemical bonding between SDR materials and denture base resin is highly relevant for prolonging the functional duration of dentures with SDR. Therefore, the adhesion problem should be resolved during material development. This evidence may change in the future.

4.6. Residual ridge resorption (RRR)

No studies have been conducted on the RRR measured using bone specimens or CT. The RRR was evaluated using orthopantomography[53,54], changes in blood flow[55], and subjective evaluation of patient denture fitness[53], which acknowledged the limitations of the study design. Although blood flow change is speculated to be directly related to RRR, additional osteoplastic bone resorption has been reported owing to interference with the vascular supply following denture insertion[55]. Another study using an animal model suggested that improved blood flow related to mechanical stress could decrease alveolar ridge resorption[76]. Therefore, changes in blood flow were used as the outcomes. In addition, denture fitness, according to each patient's subjective assessment, was used as an outcome because gradual alveolar ridge resorption can disrupt denture fitness. In contrast, the tendency of SDR to reduce RRR more than HDR was observed in a report by elCharkawi *et al.*[59]. Although Woelfel *et al.* reported an abnormal RRR in patients with complete dentures with home liners[77], this study was not conducted under the control of a dentist, suggesting that an abnormal RRR may not occur in well-conditioned complete dentures.

4.7. Microbial contamination

Microbial contamination of denture relines is affected by the following factors: denture material and surface properties[78–81], properties of relining materials[14,17,20], adhesion of relining materials to the denture base[14], denture cleaning conditions[82], and subject-dependent factors[83]. The surface of the SDR material deteriorates over time, and the silicone-based SDR material delaminates from the adhesive bond with the denture base resin. Furthermore, highly resilient materials are less likely to adhere, while less resilient materials are more likely to adhere because of the differences in their molecular densities[79–81]. Thus, we predicted that acrylic-based SDR would be more susceptible to long-term contamination than silicone-based SDR.

Chaves *et al.*[62] provided evidence that heat-polymerized resins have lower cytotoxic effects than auto-polymerized denture base acrylic resins and light- or dual-polymerized resins. Cytotoxicity has an antimicrobial effect[17,84]; the evidence was obtained from studies with shorter periods of less than three weeks for these CQs and considered the fact that acrylic-based SDRs may be less susceptible to microbial contamination than HDRs because of the cytotoxic effects of monomer leaching. However, a systematic review of *in vitro* studies using animal or human cells by Chaves *et al.*[62] indicated that a definitive conclusion regarding the cytotoxicity of denture bases and HDR materials could not be drawn because of the number of variables. Laser pretreatment of the denture base surface, oxygen plasma treatment, acid etching, silica coating, primer or monomer application, and immersion of the denture base in acetone or isobutyl methacrylate have been reported to be effective in preventing microbial contamination[16,63].

Although long-term use was only investigated in an observational study, the microbial contamination of SDR materials was more significant than that of HDR materials or acrylic resin dentures. A direct proportional relationship was identified between the duration of use and the total number of microbes, with silicone-based SDR materials being more microbially contaminated than acrylic-based SDR materials. Detachment of the silicone-based SDR materials from the denture base may have caused microbial growth. The study was conducted after teaching mechanical and chemical denture cleaning methods. However, it did not state whether denture cleaning was performed adequately during the study period. The adopted literature was used for a maximum of two years, which indicates that the long-term prognosis may differ. The selected literature for evidence was published before 2013, and the trends observed in the evidence are expected to improve because of the evolution of materials. However, caution should be exercised regarding the possibility of microbial contamination during long-term use of SDR materials.

4.8. Evaluation of the risk of bias and limitations of this systematic review

The risk of bias was high for most CQs for various reasons. First, single-blind or double-blind studies were rarely established when conducting clinical studies because both the patient and dentist were aware of whether the patient had SDR or HDR in each instance. In CQ6, some literature sources indicated that multiple denture relining materials per single denture base (SDR or HDR materials/acrylic resin dentures) were applied to a circular hollowed-out area of the internal surface. After a certain period, these materials were extracted and filled with another material. For the other CQs, SDR or

HDR/acrylic resin dentures were applied as one material per internal denture surface. Outcomes may differ between *in vitro* and *in vivo* studies depending on patients' oral hygiene and systemic conditions.

Second, most of the selected studies were judged to have a high risk of bias for the following reasons: no statistical analysis, lack of statistical analysis associated with case attrition, and no report of COI. Most of the selected studies were published before 2007; therefore, the number of RCTs specific to clinical dentistry was limited. In addition, problems with the sample size, difficulties in standardizing treatment, and ethical constraints limit this study. Therefore, studies on denture relines with SDR materials have resulted in a low level of evidence owing to the above limitations.

A limitation of this review is that the SDR was performed an indirect method. Denture relining can be performed by direct (immediate) or indirect (mediated) methods. Direct relining is a simple method that does not require patients to leave without wearing dentures. Indirect relining is superior to direct relining because of its longevity, materials used, detailed reproducibility, adequate flow, and low porosity[85]. When applying SDR materials, a translation thickness of 1–2 mm is required for the cushioning effect to be fully realized[86]. Obtaining an appropriate thickness is difficult when direct relining is used, and direct relining can result in a higher occlusal height or positional deviation from the target occlusion. Furthermore, the relining materials used in the direct method are autopolymerized resins; therefore, they are inferior to heat-polymerized materials in terms of longevity. Most studies with SDR materials in the selected literature were performed using an indirect method; therefore, the possibility that the results may be different from those involving direct SDR should be considered.

Although we collected evidence that could be aggregated and compiled into a systematic review, we expect new clinical studies to support these data in the future as *in vivo* studies provide new findings and data. Both hard and soft reline materials present a variety of characteristics depending on the techniques and specific materials used, and the results regarding the longevity of denture function and microbial contamination may differ significantly depending on these factors in this systematic review. Future studies should examine the use of these techniques, materials, adhesives, and physical properties in detail.

5. Conclusions

Denture relines with SDR materials provide beneficial outcomes for patients with complete dentures. However, caution must be exercised because they may shorten the functional duration and cause microbial contamination during long-term use.

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Conflict of interest statement

The authors declare no conflicts of interest.

References

- [1] Zarb GA, Hobkirk J, Eckert S, Jacob R. Prosthodontic treatment for edentulous patients: complete dentures and implant-supported prostheses. 13th edition. St. Louis, MO, USA: Mosby; 2012.
- [2] Atwood DA, Coy WA. Clinical, cephalometric, and densitometric study of reduction of residual ridges. J Prosthet Dent. 1971;26:280–95. [https://doi.org/10.1016/0022-3913\(71\)90070-9](https://doi.org/10.1016/0022-3913(71)90070-9), PMID:5284182
- [3] Shigli K. Aftercare of the complete denture patient. J Prosthodont. 2009;18:688–93. <https://doi.org/10.1111/j.1532-849X.2009.00500.x>, PMID:19682212
- [4] Crum RJ, Loiselle RJ, Rooney GE Jr. Clinical use of a resilient mandibular denture. J Am Dent Assoc. 1971;83:1093–6. <https://doi.org/10.14219/jada.archive.1971.0419>, PMID:5286142
- [5] Wendt DC. The degenerative denture ridge—care and treatment. J Prosthet Dent. 1974;32:477–92. [https://doi.org/10.1016/0022-3913\(74\)90002-X](https://doi.org/10.1016/0022-3913(74)90002-X), PMID:4613820
- [6] Heartwell CM, Rahn AO. Syllabus of complete dentures. 4th ed. Philadelphia, PA, USA: Lea & Febiger; 1986.
- [7] Kawano F, Dootz ER, Koran A III, Craig RG. Comparison of bond strength of six soft denture liners to denture base resin. J Prosthet Dent. 1992;68:368–71. [https://doi.org/10.1016/0022-3913\(92\)90347-D](https://doi.org/10.1016/0022-3913(92)90347-D), PMID:1501192
- [8] Pinto JRR, Mesquita MF, Henriques GEP, de Arruda Nóbilo MA. Effect of thermocycling on bond strength and elasticity of 4 long-term soft denture liners. J Prosthet Dent. 2002;88:516–21. <https://doi.org/10.1067/mpr.2002.128953>, PMID:12474002
- [9] Mutluay MM, Ruyter IE. Evaluation of bond strength of soft relining materials to denture base polymers. Dent Mater. 2007;23:1373–81. <https://doi.org/10.1016/j.dental.2006.11.014>, PMID:17222898
- [10] Wright PS. A three year longitudinal study of denture soft lining materials in clinical use. Clin Mater. 1986;1:281–9. [https://doi.org/10.1016/S0267-6605\(86\)80019-1](https://doi.org/10.1016/S0267-6605(86)80019-1)
- [11] Braden M, Wright PS, Parker S. Soft lining materials—a review. Eur J Prosthodont Restor Dent. 1995;3:163–74. PMID:8601159

- [12] Baysan A, Parker S, Wright PS. Adhesion and tear energy of a long-term soft lining material activated by rapid microwave energy. *J Prosthet Dent.* 1998;79:182–7. [https://doi.org/10.1016/S0022-3913\(98\)70214-8](https://doi.org/10.1016/S0022-3913(98)70214-8), PMID:9513105
- [13] Kuboki T, Ichikawa T, Baba K, Fujisawa M, Sato H, Aita H, et al. A multi-centered epidemiological study evaluating the validity of the treatment difficulty indices developed by the J Prosthodont Society. *Annals of Japan Prosthodontic Society.* 2019;11:355–75. <https://doi.org/10.2186/ajps.11.355>
- [14] Mutluay MM, Oğuz S, Ørstavik D, Fløystrand F, Doğan A, Söderling E, et al. Experiments on *in vivo* biofilm formation and *in vitro* adhesion of *Candida* species on polysiloxane liners. *Gerodontology.* 2010;27:283–91. <https://doi.org/10.1111/j.1741-2358.2009.00329.x>, PMID:19804557
- [15] Hussein FA. Advances in soft denture liners: an update. *J Contemp Dent Pract.* 2015;16:314–8. <https://doi.org/10.5005/jp-journals-10024-1682>, PMID:26067736
- [16] Muddugangadhar BC, Mawani DP, Das A, Mukhopadhyay A. Bond strength of soft liners to denture base resins and the influence of different surface treatments and thermocycling: A systematic review. *J Prosthet Dent.* 2020;123:800–806.e6. <https://doi.org/10.1016/j.prosdent.2019.06.013>, PMID:31703921
- [17] Jabłońska-Stencel E, Pakielna W, Mertas A, Bobela E, Kasperski J, Chladek G. Effect of silver-emitting filler on antimicrobial and mechanical properties of soft denture lining material. *Materials (Basel).* 2018;11:318. <https://doi.org/10.3390/ma11020318>, PMID:29470441
- [18] Doğan OM, Keskin S, Doğan A, Ataman H, Usanmaz A. Structure-property relation of a soft liner material used in denture applications. *Dent Mater J.* 2007;26:329–34. <https://doi.org/10.4012/dmj.26.329>, PMID:17694740
- [19] Demir H, Dogan A, Dogan OM, Keskin S, Bolayir G, Soygun K. Peel bond strength of two silicone soft liners to a heat-cured denture base resin. *J Adhes Dent.* 2011;13:579–84. <https://doi.org/10.3290/jjad.a21851>, PMID:21734974
- [20] Pereira-Cenci T, da Silva WJ, Cenci MS, Cury AA. Temporal changes of denture plaque microbiologic composition evaluated in situ. *Int J Prosthodont.* 2010;23:239–42. PMID:20552089
- [21] Murata H. Fundamental knowledge and evidence regarding soft denture lining. *Annals of Japan Prosthodontic Society.* 2018;10:57–62. <https://doi.org/10.2186/ajps.10.57>
- [22] Society JP. Appraisal for the lining of mandibular complete dentures with soft lining materials. https://hotetsu.com/files/files_206.pdf [accessed 30 September 2023].
- [23] Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *Syst Rev.* 2021;10:89. <https://doi.org/10.1186/s13643-021-01626-4>, PMID:33781348
- [24] Minds Manual for Guideline Development. 2017. https://minds.jcqhcr.or.jp/docs/minds/guideline/pdf/manual_0_2017.pdf; 2017 [accessed 30 September 2023].
- [25] Yoko H, Ishii T, Sato Y, Nishio K, Nishiyama Y, Yoshioka F, et al. A study on the efficacy of relining and rebasing in patients with removable dentures. https://www.crd.york.ac.uk/prospetro/display_record.php?RecordID=282206; 2021 [accessed 30 September 2023].
- [26] Minakuchi H, Fujisawa M, Abe Y, Iida T, Oki K, Okura K, et al. Managements of sleep bruxism in adult: A systematic review. *Jpn Dent Sci Rev.* 2022;58:124–36. <https://doi.org/10.1016/j.jdsr.2022.02.004>, PMID:35356038
- [27] Miller SA, Forrest JL. Enhancing your practice through evidence-based decision making: PICO, learning how to ask good questions. *J Evid Based Dent Pract.* 2001;1:136–41. [https://doi.org/10.1016/S1532-3382\(01\)70024-3](https://doi.org/10.1016/S1532-3382(01)70024-3)
- [28] Higgins JPT, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al.; Cochrane Bias Methods Group; Cochrane Statistical Methods Group. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ.* 2011;343:d5928. <https://doi.org/10.1136/bmj.d5928>, PMID:22008217
- [29] Guyatt GH, Oxman AD, Kunz R, Brozek J, Alonso-Coello P, Rind D, et al. GRADE guidelines 6. Rating the quality of evidence—imprecision. *J Clin Epidemiol.* 2011;64:1283–93. <https://doi.org/10.1016/j.jclinepi.2011.01.012>, PMID:21839614
- [30] Guyatt GH, Oxman AD, Montori V, Vist G, Kunz R, Brozek J, et al. GRADE guidelines: 5. Rating the quality of evidence—publication bias. *J Clin Epidemiol.* 2011;64:1277–82. <https://doi.org/10.1016/j.jclinepi.2011.01.011>, PMID:21802904
- [31] Guyatt GH, Oxman AD, Kunz R, Woodcock J, Brozek J, Helfand M, et al.; GRADE Working Group. GRADE guidelines: 7. Rating the quality of evidence—inconsistency. *J Clin Epidemiol.* 2011;64:1294–302. <https://doi.org/10.1016/j.jclinepi.2011.03.017>, PMID:21803546
- [32] Guyatt GH, Oxman AD, Kunz R, Woodcock J, Brozek J, Helfand M, et al.; GRADE Working Group. GRADE guidelines: 8. Rating the quality of evidence—indirectness. *J Clin Epidemiol.* 2011;64:1303–10. <https://doi.org/10.1016/j.jclinepi.2011.04.014>, PMID:21802903
- [33] Mäkilä E, Honka O. Clinical study of a heat-cured silicone soft lining material. *J Oral Rehabil.* 1979;6:199–204. <https://doi.org/10.1111/j.1365-2842.1979.tb01281.x>, PMID:374698
- [34] Schmidt WF Jr, Smith DE. A six-year retrospective study of Molloplast-B-lined dentures. Part I: patient response. *J Prosthet Dent.* 1983;50:308–13. [https://doi.org/10.1016/S0022-3913\(83\)80082-1](https://doi.org/10.1016/S0022-3913(83)80082-1), PMID:6578339
- [35] Hosoi N, Hamada T, Hayakawa I, Murata H, Taguchi N, Morisawa M, et al. Effect of the application of soft lining materials under denture bases. *Journal of the Japanese Association for Dental Science: JDS.* 2003;22:51–61.
- [36] Kimoto S. Investigation of complete denture with a permanent soft lining material by randomized controlled clinical trial. *Nippon Hotetsu Shika Gakkai Zasshi.* 2003;47:554–63. <https://doi.org/10.2186/jjps.47.554>
- [37] Murata H, Taguchi N, Hamada T, Kawamura M, McCabe JF. Dynamic viscoelasticity of soft liners and masticatory function. *J Dent Res.* 2002;81:123–8. <https://doi.org/10.1177/0810123>, PMID:11827257
- [38] Kimoto S, Kimoto K, Gunji A, Kawai Y, Murakami H, Tanaka K, et al. Effects of resilient denture liner in mandibular complete denture on the satisfaction ratings of patients at the first appointment following denture delivery. *Nippon Hotetsu Shika Gakkai Zasshi.* 2008;52:160–6. <https://doi.org/10.2186/jjps.52.160>, PMID:18467785
- [39] Kimoto S, Kimoto K, Murakami H, Atsuko G, Ogawa A, Kawai Y. Effect of an acrylic resin-based resilient liner applied to mandibular complete dentures on satisfaction ratings among edentulous patients. *Int J Prosthodont.* 2014;27:561–6. <https://doi.org/10.11607/jip.3935>, PMID:25390871
- [40] Kimoto S, Kimoto K, Gunji A, Kawai Y, Murakami H, Tanaka K, et al. Clinical effects of acrylic resilient denture liners applied to mandibular complete dentures on the alveolar ridge. *J Oral Rehabil.* 2007;34:862–9. <https://doi.org/10.1111/j.1365-2842.2007.01728.x>, PMID:17919254
- [41] Furokawa S, Kimoto S, Furuse N, Furuya Y, Ogawa T, Nakashima Y, et al. The effects of silicone-based resilient denture liners on pain: A randomized controlled trial. *J Prosthodont Res.* 2020;64:417–23. <https://doi.org/10.1016/j.jpor.2019.11.006>, PMID:32061571
- [42] Krunić N, Kostić M, Petrović M, Igić M. Oral health-related quality of life of edentulous patients after complete dentures relining. *Vojnosanit Pregl.* 2015;72:307–11. <https://doi.org/10.2298/VSP1504307K>, PMID:26040175
- [43] Pisani MX, Malheiros-Segundo AL, Balbino KL, Souza RF, Paranhos HFO, Lovato da Silva CH. Oral health related quality of life of edentulous patients after denture relining with a silicone-based soft liner. *Gerodontology.* 2012;29:e474–80. <https://doi.org/10.1111/j.1741-2358.2011.00503.x>, PMID:21696442
- [44] Kimoto S, So K, Yamamoto S, Ohno Y, Shinomiya M, Ogura K, et al. Randomized controlled clinical trial for verifying the effect of silicone-based resilient denture liner on the masticatory function of complete denture wearers. *Int J Prosthodont.* 2006;19:593–600. PMID:17165299
- [45] Shinomiya M. In-vivo and in-vitro studies for analysis of mastication in complete denture wearers with resilient denture liners. *Int J Oral Med Sci.* 2007;5:107–16. <https://doi.org/10.5466/ijoms.5.107>
- [46] Tata S, Nandeeshwar DB. A clinical study to evaluate and compare the masticatory performance in complete denture wearers with and without soft liners. *J Contemp Dent Pract.* 2012;13:787–92. <https://doi.org/10.5005/jp-journals-10024-1230>, PMID:23404004
- [47] Kimoto S, Kimoto K, Gunji A, Shinomiya M, Sawada T, Saita M, et al. Randomized controlled trial investigating the effect of an acrylic-based resilient liner on perceived chewing ability in edentulous patients wearing mandibular complete dentures. *Int J Prosthodont.* 2010;23:110–6. PMID:20305847
- [48] Kar S, Tripathi A, Fatima T. A comparative study of masticatory performance in complete denture patients before and after application of soft liner. *Med J Armed Forces India.* 2019;75:437–43. <https://doi.org/10.1016/j.mjafi.2018.03.013>, PMID:31719739
- [49] Palla ES, Karaoglanli E, Naka O, Anastassiadou V. Soft denture liners' effect on the masticatory function in patients wearing complete dentures: A systematic review. *J Dent.* 2015;43:1403–10. <https://doi.org/10.1016/j.jdent.2015.09.005>, PMID:26404406
- [50] Pisani MX, Segundo ALM, Leite VMF, de Souza RF, da Silva MAMR, da Silva CHL. Electromyography of masticatory muscles after denture relining with soft and hard denture liners. *J Oral Sci.* 2013;55:217–24. <https://doi.org/10.2334/josnusd.55.217>, PMID:24042588

- [51] Kimoto S, Yamamoto S, Shinomiya M, Kawai Y. Randomized controlled trial to investigate how acrylic-based resilient liner affects on masticatory ability of complete denture wearers. *J Oral Rehabil*. 2010;37:553–9. <https://doi.org/10.1111/j.1365-2842.2010.02070.x>, PMID:20202095
- [52] Kimoto S, Kimoto K, Murakami H, Gunji A, Ito N, Kawai Y. Survival analysis of mandibular complete dentures with acrylic-based resilient liners. *Gerodontology*. 2013;30:187–93. <https://doi.org/10.1111/j.1741-2358.2012.00658.x>, PMID:22607455
- [53] Badawy MS, el-Sherbiny N. Effect of using soft liner on bone density around the abutments supporting complete lower overdenture. *Egypt Dent J*. 1992;38:105–12. PMID:1343994
- [54] Jain V, Babu BD, Pruthi G, Mangtani N, Pillai R. Effect of denture soft liner on mandibular ridge resorption in complete denture wearers after 6 and 12 months of denture insertion: A prospective randomized clinical study. *J Indian Prosthodont Soc*. 2017;17:233–8. https://doi.org/10.4103/jips.jips_113_17, PMID:28936036
- [55] Kocabalkan E, Turgut M. Variation in blood flow of supporting tissue during use of mandibular complete dentures with hard acrylic resin base and soft relining: a preliminary study. *Int J Prosthodont*. 2005;18:210–3. PMID:15945307
- [56] Bal BT, Yavuzylmaz H, Yücel M. A pilot study to evaluate the adhesion of oral microorganisms to temporary soft lining materials. *J Oral Sci*. 2008;50:1–8. <https://doi.org/10.2334/josn.50.1>, PMID:18403876
- [57] Valentini F, Luz MS, Boscato N, Pereira-Cenci T. Biofilm formation on denture liners in a randomised controlled in situ trial. *J Dent*. 2013;41:420–7. <https://doi.org/10.1016/j.jdent.2013.02.012>, PMID:23454226
- [58] Mäkilä E, Hopsu-Havu VK. Mycotic growth and soft denture lining materials. *Acta Odontol Scand*. 1977;35:197–205. <https://doi.org/10.3109/00016357709004655>, PMID:331850
- [59] Mutluay MM, Oguz S, Fløystrand F, Saxegaard E, Dogan A, Bek B, et al. A prospective study on the clinical performance of polysiloxane soft liners: one-year results. *Dent Mater J*. 2008;27:440–7. <https://doi.org/10.4012/dmj.27.440>, PMID:18717174
- [60] ElCharkawi HG, ElMahdy AS. The effect of resilient layer and occlusal reactive complete dentures on the residual alveolar ridge. *J Prosthet Dent*. 1988;59:598–602. [https://doi.org/10.1016/0022-3913\(88\)90078-9](https://doi.org/10.1016/0022-3913(88)90078-9), PMID:3290456
- [61] Murata H, Taguchi N, Hamada T, McCabe JF. Dynamic viscoelastic properties and the age changes of long-term soft denture liners. *Biomaterials*. 2000;21:1421–7. [https://doi.org/10.1016/S0142-9612\(00\)00010-7](https://doi.org/10.1016/S0142-9612(00)00010-7), PMID:10872771
- [62] de Andrade Lima Chaves C, Machado AL, Vergani CE, de Souza RF, Giampaolo ET. Cytotoxicity of denture base and hard chairside relining materials: A systematic review. *J Prosthet Dent*. 2012;107:114–27. [https://doi.org/10.1016/S0022-3913\(12\)60037-7](https://doi.org/10.1016/S0022-3913(12)60037-7), PMID:22304746
- [63] Kreve S, Dos Reis AC. Denture liners: a systematic review relative to adhesion and mechanical properties. *ScientificWorldJournal*. 2019;2019:1–11. <https://doi.org/10.1155/2019/6913080>, PMID:30940994
- [64] Mack PJ. Denture soft lining materials: clinical indications. *Aust Dent J*. 1989;34:454–8. <https://doi.org/10.1111/j.1834-7819.1989.tb00704.x>, PMID:2684116
- [65] Qudah S, Harrison A, Huggett R. Soft lining materials in prosthetic dentistry: a review. *Int J Prosthodont*. 1990;3:477–83. PMID:2088386
- [66] Jagger DC, Harrison A. Complete dentures—the soft option. An update for general dental practice. *Br Dent J*. 1997;182:313–7. <https://doi.org/10.1038/sj.bdj.4809374>, PMID:9154711
- [67] Chladek G, Żmudziński J, Kasperski J. Long-term soft denture lining materials. *Materials (Basel)*. 2014;7:5816–42. <https://doi.org/10.3390/ma7085816>, PMID:28788163
- [68] Yamaga E, Sato Y, Minakuchi S. A structural equation model relating oral condition, denture quality, chewing ability, satisfaction, and oral health-related quality of life in complete denture wearers. *J Dent*. 2013;41:710–7. <https://doi.org/10.1016/j.jdent.2013.05.015>, PMID:23747823
- [69] Oweis Y, Erefej N, Al-Asmar A, Nedal A. Factors affecting patient satisfaction with complete dentures. *Int J Dent*. 2022;2022:1–7. <https://doi.org/10.1155/2022/9565320>, PMID:35432542
- [70] Inoue K, Arikawa H, Fujii K, Shinohara N, Kawahata N. Viscoelastic properties of oral soft tissue. 1. A method of determining elastic modulus of oral soft tissue. *Dent Mater J*. 1985;4:47–53,121. <https://doi.org/10.4012/dmj.4.47>, PMID:3879991
- [71] Sawamura Kubo C, Reskalla Amaral F, Alves de Campos E, Cinthia Sawamura Kubo¹, Fabrício Reskalla Amaral; Edson Alves de Campos. Relining of removable dentures: a literature review. *RSBO*. 2015;11:192–8. <https://doi.org/10.21726/rsbo.v11i2.843>
- [72] Yamamoto S, Kimoto S, Saeki H, So K, Shinomiya M, Kobayashi K. In vitro study on changes in the stress behavior under simulated mucosa exposed to denture bases with different resilient denture liners. *Annals of Japan Prosthodontic Society*. 2009;1:277–83. <https://doi.org/10.2186/ajps.1.277>
- [73] Kawano F, Nagao K, Noda M, Matsumoto N, Kon M, Asaoka K. Shock-absorbing behavior of soft denture liner Part 1. Plate specimens. *Nihon Hotetsu Shika Gakkai Zasshi*. 1993;37:1172–9. <https://doi.org/10.2186/jjps.37.1172>
- [74] Schmidt WF Jr, Smith DE. A six-year retrospective study of Molloplast-B-lined dentures. Part II: liner serviceability. *J Prosthet Dent*. 1983;50:459–65. [https://doi.org/10.1016/0022-3913\(83\)90563-2](https://doi.org/10.1016/0022-3913(83)90563-2), PMID:6579284
- [75] Soni A. Management of severe undercuts in fabrication of complete dentures. *N Y State Dent J*. 1994;60:36–9. PMID:7936493
- [76] Maruo Y, Nishigawa G, Irie M, Oka M, Hara T, Suzuki K, et al. Stress distribution prevents ischaemia and bone resorption in residual ridge. *Arch Oral Biol*. 2010;55:873–8. <https://doi.org/10.1016/j.archoralbio.2010.07.022>, PMID:20801425
- [77] Woelfel JB, Berg T Jr, Mann AW, Kreider JA. Documented reports of bone loss caused by use of a denture reliner. *J Am Dent Assoc*. 1965;71:23–34. <https://doi.org/10.14219/jada.archive.1965.0132>, PMID:14309679
- [78] de Luna Malheiros-Segundo A, Pisani MX, Paranhos HdFO, de Souza RF. Effect of a denture cleanser on hardness, roughness and tensile bond strength of denture liners. *Braz J Oral Sci*. 2008;7:1596–601.
- [79] Guégan C, Garderes J, Le Pennec G, Gaillard F, Fay F, Linossier I, et al. Alteration of bacterial adhesion induced by the substrate stiffness. *Colloids Surf B Biointerfaces*. 2014;114:193–200. <https://doi.org/10.1016/j.colsurfb.2013.10.010>, PMID:24189194
- [80] Song F, Koo H, Ren D. Effects of material properties on bacterial adhesion and biofilm formation. *J Dent Res*. 2015;94:1027–34. <https://doi.org/10.1177/0022034515587690>, PMID:26001706
- [81] Wang J, Li P, Wang N, Wang J, Xing D. Antibacterial features of material surface: strong enough to serve as antibiotics? *J Mater Chem B*. 2023;11:280–302. <https://doi.org/10.1039/D2TB02139K>, PMID:36533438
- [82] Mylonas P, Milward P, McAndrew R. Denture cleanliness and hygiene: an overview. *Br Dent J*. 2022;233:20–6. <https://doi.org/10.1038/s41415-022-4397-1>, PMID:35804119
- [83] Okita N, Ørstavik D, Ørstavik J, Østby K. In vivo and in vitro studies on soft denture materials: microbial adhesion and tests for antibacterial activity. *Dent Mater*. 1991;7:155–60. [https://doi.org/10.1016/0109-5641\(91\)90035-W](https://doi.org/10.1016/0109-5641(91)90035-W), PMID:1813337
- [84] Makvandi P, Jamaledin R, Jabbari M, Nikfarjam N, Borzacchiello A. Antibacterial quaternary ammonium compounds in dental materials: A systematic review. *Dent Mater*. 2018;34:851–67. <https://doi.org/10.1016/j.dental.2018.03.014>, PMID:29678327
- [85] Complete Denture Technique. 6th ed. Japan: Medical and Dental Publishing; 2011.
- [86] Newsome PRH, Baskin RM, Bergman B, Glantz PO. The softness and initial flow of temporary soft lining materials. *Acta Odontol Scand*. 1988;46:9–17. <https://doi.org/10.3109/00016358809004741>, PMID:3164166



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