TITLE: Permanent Soft Liner Denture Materials: Clinical Evidence and Cost-Effectiveness

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RESEARCH QUESTIONS

1. What is the clinical effectiveness of soft liner denture materials?
2. What is the cost-effectiveness of soft liner denture materials?

KEY MESSAGE

Evidence suggests that soft liner denture materials result in improved masticatory performance and patient satisfaction; no cost-effectiveness information was identified.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2011, Issue 11), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and abbreviated list of major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between Jan 1, 2001 and Nov 16, 2011. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are
presented first. These are followed by randomized controlled trials, non-randomized studies, and economic evaluations.

Three randomized controlled trials and two non-randomized studies were identified regarding the clinical effectiveness of soft liner denture materials. No literature regarding the cost effectiveness of soft liner denture materials was identified. Additional references of potential interest are provided in the appendix.

OVERALL SUMMARY OF FINDINGS

One randomized controlled trial\(^1\) (RCT) evaluated the clinical performance of four denture soft liners and found that the performance of the liners was good after six months of use and that performance was only slightly impaired over a one-year observation. Two RCTs\(^2,3\) compared silicone-based resilient denture liners with heat-activated acrylic resin denture liners and found that silicone-based denture liners resulted in higher masticatory performance and higher patient preference. Similarly, a non-randomized study\(^5\) found that soft liner dentures may have a positive impact on the perceived oral health of edentulous patients.

In terms of the clinical benefit of soft liner dentures for patients with submerged implants, a non-randomized study\(^4\) found that the use of soft liners decreased the levels of stress and strain in peri-implant bone.
REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses
No literature identified.

Randomized Controlled Trials


OBJECTIVE: The aim of the present study was to evaluate the clinical performance of four denture soft liners up to 12 months. MATERIALS AND METHODS: Thirty-three edentulous patients who experienced difficulties when using hard denture bases because of changes in denture-supporting tissues were accepted for the study and randomly received Molloplast B, GC Reline Soft, Silagum Comfort, or Mollosil Plus relines. Performance of the materials was evaluated using nine criteria at 3, 6, and 12 months: physical integrity, surface detail, adhesion, color, odor, plaque accumulation, resilience, hygiene, and mucosal condition. A four-point categorized scale (1=poor, 2=fair, 3=good, 4=excellent) was used. Unscheduled maintenance events and the presence of fungal colonization were also recorded. RESULTS: The percentage of patients available at 3, 6, and 12 months were 91%, 91%, and 66%. Main reasons for dropouts and discontinuation were fractured dentures and patient dissatisfaction. At 6 months, 96% of the performance scores were good or excellent and the largest changes were observed for physical integrity, surface detail, color, and fungal colonization. Fungal colonization was the most commonly observed problem and was the only reason of failure at 12 months. CONCLUSIONS: The clinical performance of all soft liners was slightly impaired over the 12-month observation. Except for cases showing extensive fungal colonization, the observed changes in clinical performance did not necessitate remaking of the dentures. Mollosil Plus showed a performance comparable to that of Molloplast B, and the other materials had slightly lower performance especially in terms of fungal colonization.


PURPOSE: The purpose of this study was to investigate whether application of permanent silicone-based resilient denture liner (SR) to mandibular complete dentures significantly improves patients’ masticatory ability compared to conventional heat-activated acrylic resin (AR). MATERIALS AND METHODS: Twenty-eight edentulous patients were randomly placed into 1 of 2 crossover groups (AR-SR/SR-AR) by using a random permuted block within strata method. The AR-SR group received AR denture treatments followed by SR denture treatments. The SR-AR group received
treatments in the reverse sequence. The outcomes were classified by masticatory performance, mandibular movement, electromyographic activity, and maximum occlusal force. RESULTS: No significant differences were observed in any of the baseline characteristic measurements between groups. **SR denture wearers exhibited significantly higher masticatory performance than AR denture wearers.** SR denture wearers exhibited a longer early-stage occluding period than AR denture wearers. There were no differences in electromyographic activity between the AR and SR groups. There were no significant differences in maximum occlusal force between the AR and SR groups. CONCLUSION: This study showed that the application of SR to mandibular complete dentures resulted in significant improvements to the patients’ masticatory ability compared to AR.


**PURPOSE:** The purpose of this study was to measure patients' satisfaction and their preference between mandibular dentures with permanent silicone-based resilient denture liner (SR) and conventional heat-activated acrylic resin (AR), both opposed by acrylic resin-based maxillary complete dentures. **MATERIALS AND METHODS:** Twenty-eight edentulous patients who had fulfilled selection criteria and provided informed consent were enrolled in this trial. Subjects were allocated randomly to either arm of cross-over groups (AR-SR/SR-AR), stratified by gender, using a random permuted block within the strata method. The AR-SR group received AR denture treatment followed by SR denture treatment. The SR-AR group received treatment in the reverse sequence. The primary outcome was patient satisfaction measured on 100-mm VAS, analyzed by two-way ANOVA and the Bonferroni multiple comparison as a post hoc test. The secondary outcome was patients' preference, evaluated by chi-square goodness-of-fit test. An intention-to-treat analysis was performed. RESULTS: Twenty-five subjects were enrolled in the analysis. There were no significant differences between AR and SR dentures 1, 2, and 3 months after the completion of control. Eighteen of 25 patients preferred SR dentures. CONCLUSION: Although there were no significant differences in patient satisfaction ratings between the two types of dentures, a significant majority of patients preferred those with a resilient denture liner.

### Non-Randomized Studies


**Abstract** The aim of this study was to evaluate the stress distribution in the bone adjacent to submerged implants during masticatory function in conventional complete dentures with different soft liners through finite element analysis. Three-dimensional models of a severely resorbed mandible with two and four submerged implants in the anterior region were created and divided into the following situations: (1) conventional complete dentures (control group); and conventional complete dentures with...
different soft liner materials: (2) Coe-comfort(R), (3) Softliner(R) and (4) Molteno Hard(R). The models were exported to mechanical simulation software and two simulations were done with the load in the inferior right canine (35N) and the inferior right first molar (50N). The data were qualitatively evaluated using the maximum principal stress and microstrain values given by the software. **The use of soft liners provides decreased levels of stress and microstrains in peri-implant bone when the load was applied to canine teeth. Considering all the values obtained in this study, the use of softer materials is the most suitable for use during the period of osseointegration.**


**PubMed: PM21696442**

Background: Knowledge of benefits caused by a treatment on quality of life is very relevant. Despite the wide use and acceptance of soft denture liners, it is necessary to evaluate the patient's response about the use of these materials with regard to improvement in oral health related quality of life (OHRQoL). **Objectives: The aim of this study was to evaluate the influence of denture relining in the OHRQoL of edentulous patients.** Materials and methods: Thirty-two complete denture wearers had their lower dentures relined with a silicone-based material (Mucopren soft, Kettenbach, Germany) according to chairside procedures. OHRQoL was assessed before and after 3 months of relining by means of OHIP-EDENT, and the median scores were compared by Wilcoxon test (p <= 0.05). Results: After 3 months of relining, participants reported significant improvement of their OHRQoL (p <= 0.01). **Conclusion: Denture relining with a soft liner may have a positive impact on the perceived oral health of edentulous patients.**

**Economic Evaluations**
No literature identified.

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APPENDIX – FURTHER INFORMATION:

Review Articles


This article presents a contemporary overview of soft or compliant denture lining materials. It does not focus on denture bases, which are intrinsically flexible, and suggests some clinical options which readers might wish to consider. CLINICAL RELEVANCE: The aim of this article is to update clinicians on the types of compliant linings currently available and to advise on how some might be used.


The article provides a background for understanding the properties of soft liner materials, describing associated problems, and discussing clinical applications of soft liners in dental practice. Although not a panacea, soft liner materials provide the practitioner with a variable tool in providing excellent clinical care for patients.

Additional References