

INPLASY2025100009  
doi: 10.37766/inplasy2025.10.0009  
Received: 3 October 2025  
Published: 4 October 2025

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**ADMINISTRATIVE INFORMATION**

**Support** - King Khalid University.

**Review Stage at time of this submission** - Completed but not published.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY2025100009

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 4 October 2025 and was last updated on 4 October 2025.

**INTRODUCTION**

**Review question / Objective** To assess the clinical effectiveness of bioactive and antimicrobial denture liners on tissue healing, microbial load, and patient-reported outcomes in diabetic denture-wearers.

**Rationale** Diabetic denture-wearers are at higher risk of denture stomatitis and Candida colonization, and innovative liners may improve tissue healing and reduce microbial load.

**Condition being studied** Denture stomatitis and Candida albicans colonization in adult patients with diabetes mellitus.

**METHODS**

**Search strategy** Systematic searches were performed in PubMed, Scopus, Web of Science, and Cochrane Library for English-language studies from January 2015 to September 2025.

**Participant or population** Adults with type II diabetes who are complete denture wearers, including those with and without active denture stomatitis.

**Intervention** Bioactive or antimicrobial denture liners, including drug-eluting tissue conditioners and alternative flexible polymeric denture base materials.

**Comparator** Conventional soft liners without additives, standard topical antifungal therapy, or traditional acrylic denture base material.

**Study designs to be included** Randomized controlled trials (RCTs) and comparative observational studies.

**Eligibility criteria** English-language studies published from 2015 onwards, involving diabetic adults, and directly comparing antimicrobial liners against conventional liners.

**Information sources** Electronic databases like PubMed, Scopus, Web of Science, Cochrane Library.

**Main outcome(s)** Denture stomatitis healing and Candida load.

**Additional outcome(s)** Patient-reported outcomes and safety.

**Data management** Two reviewers independently screened studies, extracted data, and assessed the risk of bias; data were synthesized narratively and via meta-analysis where appropriate.

**Quality assessment / Risk of bias analysis** Risk of bias was assessed using RoB 2 for RCTs and the Newcastle-Ottawa Scale for observational studies.

**Strategy of data synthesis** A random-effects meta-analysis was performed for microbial outcomes where possible, and a narrative synthesis was used for all other outcomes due to lack of quantitative data.

**Subgroup analysis** No subgroup analyses were performed due to the limited number of included studies.

**Sensitivity analysis** Not feasible given small number of studies.

**Language restriction** Included only English-language publications.

**Country(ies) involved** Saudi Arabia, United States of America, India.

**Other relevant information** The authors declared no conflict of interest.

**Keywords** Denture stomatitis; Candida albicans; bioactive denture liner; antimicrobial denture liner; diabetes mellitus.

**Dissemination plans** The findings are presented in this systematic review will be soon published in a peer reviewed journal.

#### **Contributions of each author**

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