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Al Dossari, L; Chauhan, E; Kanwalpreet, K; Saini, R; Shetty S;
Heboyan, A.

Corresponding author:
Lujain Ibrahim N Aldosari

lualdossari@kku.edu.sa

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: INPLASY202590053

Author Affiliation:
King Khalid University.

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 September 2025 and was last updated on 14 September 2025.

INTRODUCTION

Review question / Objective To systematically compare the efficacy, safety, and patient-centered outcomes of occlusal splints versus botulinum toxin type A in the management of sleep bruxism in adults.

Rationale There is a lack of definitive synthesis comparing these two common treatments despite their increasing clinical use.

Condition being studied Sleep bruxism (SB) in adults, including associated myofascial pain, reduced function and tooth wear risk.

METHODS

Search strategy Comprehensive search across PubMed, Embase, Scopus, Web of Science, ScienceDirect, and Google Scholar from 1998 to 2025.

Participant or population Adults (≥18 years) diagnosed with sleep bruxism via clinical or instrumental methods.

Intervention Botulinum toxin type A (BTX-A) injections into masticatory muscles.

Comparator Occlusal splints (OS), including hard or soft appliances worn during sleep.

Study designs to be included Randomised controlled trials, controlled clinical trials, prospective or retrospective cohort studies, and comparative case studies.

Eligibility criteria English-language studies from 1998–2025 directly comparing OS and BTX-A in adults with Sleep Bruxism.

Information sources Electronic databases like PubMed, Embase, Scopus, Web of Science, ScienceDirect, and Google Scholar.

Main outcome(s) Pain reduction, bruxism frequency/intensity, functional outcomes, adverse effects.

Email: dr_ravi_saini@yahoo.com
 Author 6 - Artak Heboyan - Supervision, Administration, Funding acquisition.
 Email: heboyan.artak@gmail.com

Additional outcome(s) Patient satisfaction, quality of life, tooth wear progression.

Data management Data extracted using a standardized Excel form by two independent reviewers; discrepancies resolved via consensus.

Quality assessment / Risk of bias analysis Cochrane RoB 2 for RCTs and modified Newcastle-Ottawa Scale for observational studies.

Strategy of data synthesis Meta-analysis using random-effects model for primary pain outcomes.

Subgroup analysis Analysis based on treatment timing effects, with BTX-A showing faster short-term relief than Occlusal splints.

Sensitivity analysis Conducted by excluding outliers (e.g., Yurttutan et al.) to assess robustness of pain outcome results.

Language restriction Included only English-language publications.

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

Other relevant information PRISMA 2020 guidelines followed.

Keywords Sleep bruxism, occlusal splint, botulinum toxin, BTX-A, pain, masticatory muscles, systematic review, meta-analysis.

Dissemination plans Data will be published in peer-reviewed journals and conference presentation to be done.

Contributions of each author

Author 1 - Lujain Ibrahim Al Dossari - Conceptualization, Methodology.

Email: lualdossari@kku.edu.sa

Author 2 - Eva Chauhan - Data Curation, Formal analysis.

Email: evachauhan015@gmail.com

Author 3 - Kanwalpreet Kaur - Validation and formal analysis.

Email: drkanwalpreet@yahoo.co.in

Author 4 - Ravinder Saini - Resources, Original draft preparation.

Email: rsaini@kku.edu.sa

Author 5 - Shashit Shetty - Reviewing and Editing, Publication.