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Bar fracture of implant-retained overdenture: Protocol of a systematic review and meta-analysis

J. STANEK[1], A. RIAD[2,3], S. SLEZAKOVA[2], B. AZAR[1], J. KLUGAROVA[2], A. POKORNA[2,4], M. KLUGAR[2]

[1] Department of Prosthetic Dentistry, Faculty of Medicine and Dentistry, Palacky University, Olomouc, Czech Republic
[2] Czech National Centre for Evidence-Based Healthcare and Knowledge Translation (CEHBC-KT), Institute of Biostatistics and Analyses, Faculty of Medicine, Masaryk University, Brno, Czech Republic
[3] Department of Public Health, Faculty of Medicine, Masaryk University, Brno, Czech Republic
[4] Department of Nursing, Faculty of Medicine, Masaryk University, Brno, Czech Republic

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ABSTRACT

Aim The fractured bar is a common prosthetic complication that deteriorates the patient's experience and prosthesis functionality; therefore, we aim to determine risk factors, prevalence, and incidence of bar fracture.
Methods We will conduct a systematic review using the guidelines of Cochrane's Handbook and Joanna Briggs Institute's (JBI) Manual and will adhere to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). A three-step search strategy will be conducted to retrieve interventional and observational studies from biomedical bibliographic databases as well as grey literature. Two authors will assess the retrieved studies according to the predefined eligibility criteria. Data collection will be conducted using Extraction Forms. Risk of bias of included interventional studies will be assessed using the Risk of Bias 2 tool, while observational studies will be evaluated by ROBINS-E. Studies findings will be qualitatively and quantitively synthesized using JBI SUMARI.
Results The results of this systematic review will be presented to clinicians and researchers in speciality conferences and a peer-reviewed journal.
Conclusion This review is the first to identify the clinical and biological risk factors of bar fracture and to evaluate its prevalence and incidence rates; aiming to provide evidence-based recommendations for treatment planning and maintenance of implant-retained overdenture using bar-clip attachment system.

KEYWORDS Systematic review; Meta-analysis; Overdenture; Dental implants; Complications.

INTRODUCTION

Edentulism, tooth loss, is a disability that imposes a higher risk of early mortality; therefore, prosthetic rehabilitation aims to reduce morbidity and to improve quality of life (1). Compared to conventional complete dentures, implant-retained overdentures (IOD) is an effective method of prosthetic rehabilitation with predictable outcomes for edentulous patients (2). IOD leads to higher levels of patient satisfaction and quality of life, improved masticatory efficiency, and implant and prosthesis survival rates (3–5). Different attachment systems are used to enhance the retention and stability of IOD; however, they may differ in implant survival rate, biological and mechanical complications, and patient satisfaction (6). Maintenance requirements are higher for solitary attachment systems (ball or magnet attachment) more than splinted attachment systems (bar and clip attachment) (7). Bar-clip attachment is a retentive system that resists vertical and oblique forces better than ball and magnet attachments; therefore, bar-clip is a commonly used attachment system (6,8).
The implant survival rate is strongly dependent on biological factors like bone quality and quantity; however, it is not systematically concluded whether it is associated with attachment system or not (9–11). Regarding the biological complications, marginal bone loss was not found different between attachment systems in prospective longitudinal studies, but ball attachment showed more marginal bone loss than bar-clip attached implants in retrospective studies (10–13). Peri-implant tissue can be maintained healthy regardless of attachment system; however, the bar-clip attachment imposes a greater risk of mucosal hyperplasia (10,14,15). Mechanical complications and patient satisfaction are not significantly different between attachment systems; however, implant loss was frequently predicted to occur during the first year of service (6,16,17). Metal reinforcement of IOD framework can decrease mechanical complications (11).
The fractured bar is a common phenomenon that re-

quires remaking of the bar and/or the whole prosthesis; therefore, it is a time-consuming and resource-intensive mechanical complication. Incidence of bar fracture is not systematically synthesized; however, it may follow the same pattern of implant loss in emergence during the first year of service. Bar fracture leaves the patient without prosthesis for a long period of time compromising the patient's functionality, aesthetics, and quality of life. To the best of our knowledge, this review is the first to identify the clinical and biological risk factors of bar fracture and to evaluate its prevalence and incidence rates; aiming to provide the clinical practice with the best available recommendations for treatment planning and maintenance of implant-retained overdenture using bar-clip attachment system.

Aims of the work

This systematic review aims to identify the risk factors of bar fracture in implant-retained overdentures. This review is trying to answer the following questions:

1. What are the independent variables correlated with bar fracture?
2. What are the prevalence and incidence rates of bar fracture?
3. What are the maintenance practices for bar fracture?

MATERIALS AND METHODS

Eligibility criteria

This systematic review will be developed according to published guidelines and reported according to the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) and methodology developed by JBI and Cochrane (18–20).

Eligibility of papers for inclusion in the review will be assessed, inclusion and exclusion criteria applied to each of the following domains: study designs, types of participants, types of interventions, comparisons, and outcomes. Inclusion and exclusion criteria within each of these domains are described below.

Study designs

In accordance with the objective of providing an overview of the current evidence on bar fracture of implant-retained overdenture, the following types of observational and interventional clinical studies will be included: experimental, quasi-experimental, and observational analytical studies. If all studies in different level of evidence are identified, they will be appraised, extracted, and pooled accordingly (by subgroup analyses). *In vitro* studies, observational descriptive studies, literature reviews, editorials, and book chapters will be excluded. No language or time barriers will be applied.

Types of participants

The studies of adult patients who lost all of their teeth (complete edentulism) in one or both jaws due to periodontal disease, traumatic injury, or destruction of the dentition by dental caries will be included in this review. Children (under 18) with congenital anomalies, partially edentulous patients, and oncology patients receiving reconstructive surgery prior to implant treatment will be excluded.

Types of interventions

The intervention of interest is implant-retained overdenture attached with the bar-clip system. The studies with a post-treatment follow-up period of at least six months, with all follow-up intervals, and with regular or emergency follow-up visits will be included in this review.

Comparison conditions

Given the broad perspective of the intervention of interest, all types of implants, bars and overdenture will be included.

a) Characteristics of implant: number, length, diameter, location, and material of implants, and time of loading.
b) Characteristics of bar: number, length, cross-section and material of bars, number of clips, and the existence of extension (cantilever).
c) Characteristics of overdenture: reinforcement of overdenture.

Types of outcome measures

The primary outcome is bar fracture that may occur once per lifetime or recurrently. As a dichotomous outcome, fracture of the bar can be assessed by the operator during follow-up visits or reported by the patient seeking an emergency visit. Risk factors of bar fracture will be determined according to the correlation between the bar fracture and prosthetic characteristics.

The secondary outcomes are prevalence and incidence of bar fracture, and maintenance practices used to resolve bar fracture consequences, e.g. replacement and repair.

Information sources

An initial limited search of MEDLINE and EMBASE will be undertaken, followed by the analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be conducted across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies.

Studies published in all possible languages, if they have a title and an abstract in English, will be considered for inclusion in this review.

Studies published without any time restriction will also be considered for inclusion in this review. The databases to be searched include; Ovid Medline(R), EMBASE, Co-

chrane Library, Web of Science Core Collection, Scopus, ProQuest Central, ProQuest Dissertations & Theses Global, Bibliographia Medica Čechoslovaca, Dentistry and Oral Sciences Source.
The search for unpublished studies will include; Open Grey, Current Controlled Trials (ISRCTN registry), MedNar, and ClinicalTrials.gov.

Search strategy

In accordance with the methods detailed in Cochrane Guidelines for systematic reviews, the search strategy will be conducted as follows (21).

- Abstract, title, keywords of the identified database will be searched.
- Both observational and interventional clinical trials will be retrieved. No study design, date, or language restrictions will be applied.
- Reference lists of identified publications will be manually searched to identify any additional publications.
- These searches will be re-run just before final analyses and further studies retrieved for inclusion.
- The search strategy of Ovid Medline(R) is presented in Table 1.

STUDY RECORDS

Data management

Literature search results will be uploaded to reference management software (EndNote X9), and duplicate citations will be removed electronically, and completeness of the deduplication will be checked manually.

Selection process

After duplicates removal, JS and AR will develop and test screening questions and forms for level 1 and 2 assessments based on the inclusion and exclusion criteria. Both reviewers will classify the entries independently according to the eligibility criteria.
Disagreements will be resolved by discussion between the two reviewers or (when unable to be resolved) third author MK adjudication. Reasons for studies exclusion will be documented. Review authors will not be blind to the journal titles, nor authorship information of the studies.

- Screening Level 1: Titles and/or abstracts of retrieved entries will be checked against general exclusion criteria of studies designs (*in vitro* studies, case reports, literature reviews, editorials, and book chapters), types of participants (children, partially edentulous, and oncology patients), types of interventions (follow-up period less than six months) and outcome measures (studies without bar fracture). Each entry will be classified as one of the following options; a) eligible for inclusion, b) eligible for exclusion, c) unclear.
- Screening Level 2: The full text of eligible-for-inclusion and unclear entries will be retrieved for extensive review. If necessary, reviewers will seek additional information from study authors to resolve any concerns about eligibility.

Data collection process

The Cochrane template of RCTs Data Extraction Forms (EF) will be used (22). To optimize the parameters of EF, piloting of data extraction will be performed by two reviewers independently on ten pilot articles which will be randomly chosen from the full list of included entries.

Data Items

In addition to the standard parameters of Cochrane EF, the following variables will be recorded.
Follow-up characteristics:

- Length of follow-up visits.
- Intervals between follow-up visits.
- Reason for follow-up visits.

Implant characteristics:

- Number of implants.
- Length of implants.
- Diameter of implants.
- Location of implants.
- Material of implants.
- Time of loading.

Bar characteristics:

- Number of bars.
- Length of bars.
- Cross-section of bars.
- Material of bars.
- Existence of cantilever.

Overdenture characteristics:

- Material of overdenture.
- Reinforcement of overdenture.

When multiple reports of the same study are identified like related journal articles and conference presentations which are then published, data from each report will be extracted separately and then combined across multiple EFs.

Outcomes and prioritization

- The primary outcomes will be risk factors of bar fracture which will be calculated by regression analysis between the dichotomous dependent variable (bar fracture) and the independent variables (prosthetic characteristics of implant, bar, and overdenture).
- The secondary outcomes will be the prevalence and incidence of bar fracture, and maintenance practices used to resolve bar fracture.
- The estimate of effect which will be used is the risk ratio (RR) and corresponding 95% confidence intervals (CI).

Risk of bias

The critical appraisal of individual studies will be guided

No.	Keyword	Results
1	exp Denture, Overlay/	3812
2	overdenture?.mp.	2693
3	over-denture?.mp.	50
4	over denture?.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	50
5	Overlay Denture?.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	85
6	Hybrid Prosthes*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	169
7	(denture? and implant?).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	8586
8	1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7	10340
9	bar?.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	92119
10	bar-retained.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	111
11	bars-retained.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	0
12	9 OR 10 OR 11	92119
13	fracture?.af.	266690
14	complication?.af.	2912638
15	maintenance?.af.	271777
16	outcome?.af.	2167322
17	evaluation?.af.	1565172
18	survival?.af.	1103543
19	follow-up?.af.	1195012
20	follow up?.af.	1195012
21	management?.af.	1250114
22	remade?.af.	141
23	condition?.af.	1593735
24	"fail*".af.	1133401
25	"repair*".af.	318996
26	"stabilit*".af.	366968
27	(success or successes).af.	244089
28	lost.af.	142490
29	"loose*".af.	43986
30	remove?.af.	251220
31	problem?.af.	912900
32	broke?.af.	21785
33	break?.af.	71388
34	13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33	10325701
35	8 AND 12 AND 34	580

TABLE 1 Ovid Medline® Search Strategy - The search was conducted on May 18th, 2020 at 13:00 am (CET).

by an experienced methodologist, MK. To facilitate this process, the revised version of Risk of Bias Assessment Tool (RoB 2) will be used for interventional studies (23). This tool uses signalling questions to appraise the following methodological domains critically.

- Domain 1: Risk of bias arising from the randomization process.
- Domain 2: Risk of bias due to deviations from the intended interventions.
- Domain 3: Risk of bias due to missing outcome data.
- Domain 4: Risk of bias in the measurement of the outcome.
- Domain 5: Risk of bias in the selection of the reported result.
- The overall risk of bias.

For observational studies, the Risk of Bias in Non-randomized Studies - of Exposures (ROBINS-E) will be used (21). This tool uses signalling questions to appraise the following methodological domains critically.

- Domain 1: Confounders.
- Domain 2: Measurement of the accuracy of exposure and outcome.
- Domain 3: Co-exposures.
- Domain 4: Risk of bias assessment.

After receiving proper training and calibration of their skills, JS and AR will assess each included study according to each risk of bias domain independently. Disagreements will be resolved through discussion between the two reviewers or, when unable to be resolved, MK will be consulted.

Data synthesis

- Quantitative data will, where possible, be pooled in statistical meta-analyses using JBI-SUMARI. All results will be subject to double-data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. If we retrieve only homogeneous RCTs, we will then perform fixed-effects meta-analyses to synthesize the data by pooling the results of included studies. If we do not retrieve homogeneous RCTs, or have to include other study designs, we will perform random-effects meta-analyses. We will pool studies with similar designs. For example, the data from RCT will not be pooled with data from quasi-randomized trials or non-randomized trials. Where statistical pooling is not possible, the findings will be presented in narrative form, including tables and figures to aid in data presentation where appropriate.
- Subgroup analysis will be used for different age, gender, and bar fracture. Another subgroup analysis will be used for different types of study (RCT, quasi RCT).
- Narrative synthesis using "summary of findings" (SOF) tables will explore the findings within and between each included study as they pertain to the risk factors of bar fracture of implant-retained overdenture, prevalence, and incidence of the bar fracture.
- For heterogeneity assessment, an inspection of a graphical display of the estimated treatment effects from the trials along with their 95% CI and by Cochran's test for heterogeneity will be undertaken before each meta-analysis as described in the Cochrane Handbook for Systematic Reviews of interventions (21). The heterogeneity will be quantified using the I2 statistic, using guidance for interpretation from the Cochrane Handbook for Systematic Reviews of Interventions (21).

  0% to 40%: might not be important;
  30% to 60%: may represent moderate heterogeneity;
  50% to 90%: may represent substantial heterogeneity;
  75% to 100%: considerable heterogeneity.
- An overall assessment of the robustness of the evidence will be ascertained using weightings from the quality appraisals; the strength of evidence for each main outcome variable will be synthesized and presented as key recommendations for policy and practice and to inform future inquiry.

Meta-bias(es)

To evaluate reporting bias, the revised version of Risk of Bias Assessment Tool (RoB 2) and the Risk of Bias in Non-randomized Studies - of Exposures (ROBINS-E) will be thoroughly used.

An important part of these tools mechanism is to document all the available sources that are used to complete the assessment including journal article(s), trial protocol, statistical analysis plan (SAP), non-commercial trial registry record (e.g. ClinicalTrials.gov record), company-owned trial registry record (e.g. GSK Clinical Study Register record), grey literature (e.g. unpublished thesis), conference abstract(s) about the trial, regulatory document (e.g. Clinical Study Report, Drug Approval Package), research ethics application, grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research). The second and fifth domains of RoB 2 and the fourth domain of ROBINS-E will enable us to detect if there is any selective reporting bias, especially in case of deviation from the protocol and departures from intended exposures.

Confidence in cumulative evidence

the certainty of the evidence for all outcomes will be evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group methodology. SOF table for this review outcomes will be created using GRADEpro GDT SW.

Ethics and dissemination

No primary data collection will be undertaken; therefore, no formal ethical assessment is required.

We plan to present the findings of this systematic review for peer-review in a speciality journal. We also intend to present our results to clinicians and researchers

at relevant conferences.

Conflict of Interest

The authors declare that there is no conflict of interest.

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