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ÁREA DE CONCENTRAÇÃO CLÍNICA ODONTOLÓGICA  
INTEGRADA**

**PAOLA MARQUES DE MATTOS**

**REVISÕES SISTEMÁTICAS E META-ANÁLISES:  
ASPECTOS PERIODONTAIS EM DENTES TRACIONADOS  
ORTODONTICAMENTE E  
FATORES DE RISCO ASSOCIADOS A ESTABILIDADE DE  
MINI-IMPLANTES E MINI-PLACAS**

**Curitiba  
2021**

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**Tese apresentada ao Programa de Pós-Graduação em Odontologia da Pontifícia Universidade Católica do Paraná, como parte dos requisitos para obtenção do título de Doutor em Odontologia, Área de Concentração em Clínica Odontológica Integrada (Ênfase em Periodontia).**

**Orientador: Prof. Dr. Odilon Guariza Filho  
Coorientador: Prof. Dr. Cristiano Miranda de Araújo**

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## **TERMO DE APROVAÇÃO**

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DENTES TRACIONADOS ORTODONTICAMENTE E FATORES DE RISCO  
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## SUMÁRIO

1		
2		
3		
4		
5	RESUMO .....	3
6	INTRODUÇÃO GERAL.....	4
7	REFERÊNCIAS BIBLIOGRÁFICAS .....	6
8	ARTIGO 1 – VERSÃO EM INGLÊS (Submetido no periódico Clinical Oral	
9	Investigations - Qualis A1/IF 3.573) .....	10
10	Title Page .....	10
11	Abstract .....	12
12	Introduction.....	13
13	Material and Methods .....	14
14	Results .....	18
15	Discussion .....	39
16	Conclusion.....	41
17	References .....	41
18	Appendices.....	45
19	ARTIGO 2 - VERSÃO EM INGLÊS (Submetido no periódico Clinical Oral	
20	Investigations - Qualis A1/IF3.573) .....	60
21	Title Page.....	60
22	Abstract .....	62
23	Introduction.....	63
24	Material and Methods .....	64
25	Results .....	68
26	Discussion .....	81
27	Conclusion.....	84
28	References.....	85
29	Appendices.....	88
30	CONCLUSÕES GERAIS .....	98
31	Normas para publicação – Clinical Oral Investigations .....	99
32		
33		
34		
35		

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## 2 **RESUMO**

3 *Objetivo:* O objetivo desse trabalho foi responder através da realização de duas  
4 revisões sistemáticas as seguintes perguntas: “Como são os aspectos  
5 periodontais em dentes tracionados ortodonticamente?” e “Quais são os fatores  
6 de risco associados à estabilidade de mini-implantes e mini-placas?”. *Material e*  
7 *Métodos:* Estratégias de busca foram desenvolvidas para cada base de dados  
8 eletrônica: PubMed/Medline, LILACS, Scopus, Web of Science, Embase e  
9 Cochrane Library; e na literatura cinzenta: Google Scholar, Proquest e Open  
10 Grey. Meta-análises de efeitos aleatórios foram realizadas na primeira revisão  
11 sistemática, e meta-análises e meta-regressões de efeitos aleatórios foram  
12 realizadas para os desfechos de interesse na segunda revisão. *Resultados:* O  
13 total de 2.082 e 1.517 artigos foram encontrados, sendo 24 e 7 selecionados  
14 respectivamente para a realização da síntese qualitativa das duas revisões  
15 sistemáticas. Os dentes impactados apresentaram valores significativamente  
16 maiores nos índices gengival e profundidade de sondagem, comparados com os  
17 dentes contalaterais não tratados. Quando comparado o risco de a falha entre  
18 mini-implantes e mini-placas, é significativamente maior nos mini-implantes, e a  
19 instalação de dispositivos em mandíbula também apresentou de forma  
20 significativa maior risco de falha. *Conclusões:* As evidências encontradas na  
21 literatura indicam que dentes tracionados apresentaram piora nos parâmetros  
22 periodontais relacionados a índice gengival e profundidade de sondagem,  
23 contudo, a profundidade de sondagem deve ser ponderada quanto ao seu  
24 significado clínico, devido ao pequeno tamanho de efeito observado. A falha na  
25 estabilidade dos DATs está relacionada com o tipo de dispositivo e o local da  
26 instalação, com maior risco para utilização de mini-implantes isolados e quando  
27 posicionados em mandíbula. O tipo de movimento ortodôntico e higiene ao redor  
28 dos dispositivos podem agir como um fator de confusão não relatado pelos  
29 estudos incluídos, diminuindo a certeza de evidência deste desfecho.

30

31 *Palavras-chave:* dente impactado, tracionamento, dispositivos de ancoragem  
32 temporária, estabilidade.

33

# 1 INTRODUÇÃO GERAL

2 As revisões sistemáticas são essenciais para toda a comunidade científica,  
3 que de outra forma seria confrontada por um volume avassalador de pesquisas  
4 para basear suas decisões(1). Em conjunto com a metanálise, são os métodos  
5 atualmente mais adequados para sintetizar evidências quanto a eficácia e os  
6 efeitos de intervenções. Possibilita uma análise mais objetiva dos resultados,  
7 facilitando uma síntese conclusiva sobre determinada intervenção(2). Esse tipo  
8 de estudo busca reunir evidências que se enquadrem nos critérios de  
9 elegibilidade pré-estabelecidos e responder a uma pergunta de pesquisa  
10 específica. A sistematização visa apontar e minimizar o viés dos estudos  
11 existentes, utilizando métodos explícitos documentados com antecedência com  
12 um protocolo(3).

13 Impacção dentária é uma condição que pode variar na população em geral  
14 entre 0,8 e 3,6%(4,5), estima-se que na faixa etária de 15 a 19 anos, excluindo  
15 terceiros molares, 1,65% dos pacientes possuem algum dente impactado(6). A  
16 falta de um diagnóstico precoce em relação aos dentes impactados pode trazer  
17 sérios danos, como reabsorção dos dentes adjacentes, problemas estéticos, bem  
18 como alterações periodontais que podem levar a perda do dente (7,8). Alguns  
19 mecanismos ortodônticos podem ser utilizados para que ocorra a erupção  
20 espontânea, mas quando esta não ocorre mesmo após o ganho de espaço, pode  
21 ser optado pelo tracionamento ortodôntico(9).

22 O estado periodontal é um indicador de sucesso no tratamento de dentes  
23 impactados(10), contudo, algumas complicações podem ser observadas após o  
24 tratamento, como recessão gengival, doença periodontal, inflamação gengival e  
25 perda óssea alveolar e/ou de gengiva inserida(11). A estrutura anatômica do  
26 tecido mole que recobre o dente impactado é um dos principais fatores que  
27 determinam a chance de o método de exposição cirúrgico funcionar, pelo fato de  
28 que o tratamento ortodôntico-cirúrgico deverá estimular um padrão de erupção  
29 natural do dente impactado através da gengiva inserida(12).

30 Os dispositivos de ancoragem temporária (DATs) são amplamente  
31 utilizados na mecânica ortodôntica de forma a expandir o limite da movimentação  
32 dentária através da ancoragem esquelética(13-16). Os DATs são uma alternativa  
33 de tratamento útil em maloclusões complexas, principalmente com discrepâncias



1 verticais, como em casos de mordida aberta e extrusões dentárias pela perda do  
2 dente antagonista(17-22).

3 Estudos utilizando mini-placas para ancoragem esquelética têm mostrado  
4 a diminuição de efeitos dentários indesejáveis e grandes efeitos esqueléticos(23-  
5 26), com diminuição expressiva no tempo de tratamento utilizando em pacientes  
6 com maloclusões Classe III de Angle(26). Os mini-implantes também podem  
7 fornecer ancoragem esquelética para a movimentação ortodôntica(23,27),  
8 apresentando maior facilidade em sua inserção ou remoção, além de menor  
9 custo(23,28). Contudo, a estabilidade dos DATs depende do travamento  
10 mecânico que ocorre no tecido ósseo, diferente dos implantes dentários cuja  
11 estabilidade principal está diretamente relacionada ao processo de  
12 osseointegração. Esta estabilidade mecânica possibilita ao dispositivo suportar a  
13 movimentação dentária sem necessitar de períodos de cicatrização(13, 29, 30).  
14 Alguns fatores de risco podem estar associados a perda da estabilidade, como o  
15 tipo de dispositivo, diâmetro do parafuso e presença de inflamação no tecido  
16 mole ao redor do dispositivo(31).

17 Uma meta-análise avaliou os aspectos periodontais profundidade de  
18 sondagem e recessão gengival entre caninos impactados por palatina  
19 comparados com caninos contralaterais e não encontraram diferença estatística  
20 (32). Contudo, não foi encontrado até o presente momento nenhuma revisão  
21 sistemática que aborde os parâmetros periodontais envolvendo diferentes grupos  
22 de dentes tracionados. Sendo assim, justifica-se a realização de uma revisão  
23 sistemática sobre o assunto, uma vez que outros dentes além dos caninos,  
24 podem ser acometidos de impacção. Também não foram encontradas revisões  
25 sistemáticas que abordaram fatores de risco associados à estabilidade de mini-  
26 implantes comparados a mini-placas, apenas revisões envolvendo dados  
27 isolados em relação a estes dispositivos (27,31, 33-38), justificando a realização  
28 de uma revisão sistemática sobre o assunto. Desta forma, o objetivo desta  
29 primeira revisão sistemática foi responder a seguinte questão focada: “Como são  
30 os aspectos periodontais em dentes tracionados ortodonticamente?” e o objetivo  
31 do segundo estudo foi responder a seguinte questão focada: “Quais são os  
32 fatores de risco associados à estabilidade de mini-implantes e mini-placas?”

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1 **ARTIGO 1 – VERSÃO EM INGLÊS (submetido no periódico Clinical Oral**  
2 **Investigations – Qualis A1/IF 3.573)**

3

4 **Periodontal aspects in orthodontically tractioned teeth: systematic review and**  
5 **meta-analysis**

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1 **Abstract**

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3 *Objective:* This systematic review aims to answer the following question: “What are the  
4 periodontal aspects of orthodontically tractioned teeth?” *Material and methods:* Search  
5 strategies were developed for each of the following electronic databases:  
6 PubMed/Medline, LILACS, Scopus, Web of Science, Embase, and Cochrane Library.  
7 Moreover, a search of gray literature was conducted using Google Scholar, ProQuest,  
8 and Open Grey. Random effects meta-analyses were performed for the outcomes of  
9 interest. Risk of bias was assessed using the Cochrane Collaboration’s tool for  
10 assessing risk of bias and the Meta-Analysis of Statistics Assessment and Review  
11 Instrument. The certainty of the evidence was assessed using the GRADE approach.  
12 *Results:* A total of 2082 articles were found, 24 of which were selected for qualitative  
13 synthesis. Gingival index analysis showed a significant difference between impacted  
14 and contralateral teeth, with higher values of this index in impacted teeth [MD = 0.25;  
15 CI 95% = 0.10 – 0.40;  $I^2 = 0\%$ ]. Impacted teeth showed greater probing depth, with a  
16 statistically significant mean difference between groups [MD = 0.14; CI 95% = 0.07 –  
17 0.20;  $I^2 = 6\%$ ]. Most studies had a low risk of bias; however, the certainty of the  
18 evidence is still very low due to the design of existing studies. *Conclusions:* Literature  
19 evidence indicates that tractioned teeth showed worsening in the periodontal  
20 parameters of gingival index and probing depth. Notwithstanding, probing depth should  
21 be considered in terms of its clinical significance due to the small effect size observed.  
22 *Clinical relevance:* These results provide greater safety to the clinician, revealing  
23 important information for establishing the prognosis in these cases.

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25 *Keywords:* impacted tooth; ectopic eruption; unerupted tooth; traction.

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## 1 **Introduction**

2 Dental impaction is a condition that can affect from 0.8 to 3.6% of the  
3 general population [1, 2]. Estimates show that 1.65% of patients in the age group  
4 15-19 years have an impacted tooth, excluding third molars [3]. The most  
5 recurrent impacted teeth are, respectively, third molars (16.7%), upper canines  
6 (2.8%), lower premolars, and upper central incisors (both with 2.6%). This  
7 condition is more frequent in women [3-7]. The main causes of impactions  
8 correlate with primary factors, including the degree of root resorption of the  
9 deciduous tooth, trauma to the tooth germ, changes following eruption, reduced  
10 space in the dental arch, rotation of the impacted tooth, and premature closure of  
11 root apices. Secondary factors such as abnormal muscle pressure, vitamin D  
12 deficiency, endocrine disturbances, and fever are also among the causes of  
13 impaction [8].

14 Lack of an early diagnosis of impacted teeth can cause serious damage,  
15 including resorption of adjacent teeth, aesthetic problems, and periodontal  
16 changes that can lead to loss of the dental element [9, 10]. Dentists can apply  
17 orthodontic mechanisms for spontaneous eruption, but when this eruption does  
18 not occur even after space is gained, the professionals can choose to apply  
19 orthodontic traction [11]. The function of orthodontic treatment is to align the  
20 impacted tooth on the dental arch, reducing possible periodontal complications  
21 and maintaining the integrity of the supporting tissues [12]. Loss of support leads  
22 to the formation of a periodontal pocket, resulting in gingival recession [8].

23 Periodontal status is an indicator of success in the treatment of impacted  
24 teeth [13]. However, some complications may occur after treatment, such as  
25 gingival recession, periodontal disease, gingival inflammation, and bone loss in  
26 the alveolus and/or inserted gingiva[14]. The anatomical structure of the soft  
27 tissue overlying the impacted tooth is one of the main factors that determines  
28 whether the surgical exposure method will work, as the orthodontic-surgical  
29 treatment should stimulate a natural eruption pattern of the impacted tooth  
30 through the gum inserted [15].

31 A meta-analysis comparing periodontal aspects (probing depth and  
32 gingival recession) between palatal impacted canines and contralateral canines  
33 found no statistical difference [16]. However, to date, there is no systematic  
34 review addressing periodontal parameters involving different groups of tractioned

1 teeth, nor assessing whether there is heterogeneity between results according to  
2 the group of teeth included in the analysis. This justifies a systematic review on  
3 the subject since teeth other than canines may be affected by impaction. Thus,  
4 this systematic review aims to answer the following focused question: “What are  
5 the periodontal aspects of orthodontically tractioned teeth?”

6

## 7 **Material and methods**

8 This systematic review was performed according to the PRISMA  
9 (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) checklist  
10 [17].

### 11 *Eligibility criteria*

12 For the eligibility of studies to be included/excluded from this review, the  
13 acronym “PICOS” was used:

- 14 • Population (P) – Patients with impacted teeth
- 15 • Intervention (I) – Orthodontic traction
- 16 • Comparison (C) – Teeth with normal eruption (contralateral)
- 17 • Outcomes (O) – Periodontal aspect (gingival recession, probing  
18 depth, plaque index, gingival index, keratinized mucosa width)
- 19 • Study design (S) – Randomized, pseudorandomized, or  
20 nonrandomized clinical studies, cross-sectional observational  
21 studies, cohort or case-control studies

### 22 *Inclusion criteria*

23 The present study included studies in which the sample consisted of  
24 patients undergoing treatment for orthodontic-surgical traction of impacted teeth,  
25 regardless of the tooth group. There was no restriction on the type of  
26 malocclusion, gender, and age. There was also no restriction on the study  
27 language and publication time.

28 Studies that evaluated the following periodontal parameters were included:

- 29 a) Gingival recession: distance between the cemento-enamel junction (CEJ)  
30 and the gingival margin, with the gingival margin located apically to the

- 1 cementoenamel junction being positive, and the gingival margin located coronally  
2 to the cementoenamel junction being negative[18].
- 3 b) Probing depth: periodontal pockets are measured from the level of the free  
4 gingival margin to the bottom of the pocket[8].
- 5 c) Periodontal attachment level: measurement that involves the probing  
6 depth and the distance between the gingival margin and the cementoenamel  
7 junction. In cases of gingival recession, the clinical attachment level should be  
8 calculated as follows: clinical attachment level = periodontal probing depth +  
9 gingival recession[19].
- 10 d) Plaque index: tooth faces are classified with a score from 0 to 3 according  
11 to the method described by Silness and Loe [20].
- 12 e) Gingival index: tooth faces are classified in the same way as the score  
13 from 0 to 3 used to calculate the plaque index [20].
- 14 f) Gingival bleeding index: the presence or absence of bleeding is checked after  
15 periodontal probing using the method described by Carter and Barnes [21].
- 16 g) Keratinized mucosa width: measured from the distance between the  
17 gingival margin and the mucogingival junction[3].

18

19 Randomized and nonrandomized controlled clinical trials were included.  
20 Cohort, case-control, and cross-sectional studies were also included.

21

## 22 Exclusion criteria

23 The following exclusion criteria were applied:

- 24 • Studies in animals or including patients with associated syndromes;  
25 • Studies in which at least one of the variables has not been evaluated;  
26 • Reviews, letters, conference abstracts, expert opinions, case reports, and  
27 case series.

## 28 *Information sources and Search strategy*

29 Appropriate word combinations and truncations were selected and  
30 adapted for each database search.

31 Search strategies were developed specifically for each of the following  
32 electronic databases: PubMed/Medline, LILACS, Scopus, Web of Science,

1 Embase, and Cochrane. In addition, a search of gray literature was conducted  
2 using Google Scholar, ProQuest, and Open Grey (appendix 1).

3 Finally, a manual search of the references of the included studies was  
4 performed, and an expert on the subject was consulted to verify any possible  
5 publication on the subject. EndNote® software (EndNote® X7 Thomson Reuters,  
6 Philadelphia, PA) was used to manage and remove duplicate references.

### 7 *Selection process*

8 The selection of articles was carried out in two phases. In phase 1, two  
9 reviewers (P.M.M. and I.B.B.) independently reviewed the titles and abstracts of  
10 all references. All articles that did not meet the inclusion criteria were excluded.  
11 In phase 2, the same reviewers performed the complete reading of the selected  
12 articles, independently. In case of disagreement, and when this was not resolved  
13 through discussion between the first and second reviewers, a third author  
14 (C.M.A.) was involved for the final decision.

15 To blind the reading of references and guarantee independence and  
16 confidentiality in both phases, the Rayyan website (<http://rayyan.qcri.org>) was  
17 used. Reviewers were blinded in all evaluations, in which a member of the team  
18 (C.M.A.), who did not participate in the selection, acted as moderator.

### 19 *Data collection process*

20 Two reviewers (P.M.M. and I.B.B.) collected information from the included  
21 studies, and this information was discussed. The data collected consisted of:  
22 study characteristics (author, year of publication, country, study design),  
23 population characteristics (sample size, age), evaluation characteristics  
24 (composition of control and experimental groups, surgical technique, number of  
25 evaluators, parameters of interest, outcome assessment method, index used for  
26 assessment), characteristics of the results (results presented in relation to the  
27 outcome), and main conclusions.

28 In case of missing or incomplete data in the article, attempts were made  
29 to contact the authors to obtain pertinent unpublished information. Three attempts  
30 were made to contact the first author, the corresponding author, and the last  
31 author of the article, and the time interval between attempts was one week. In  
32 case of no response, the article was excluded with due justification.

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*Data items*

Mean, standard deviation, and sample size values for each group were extracted from the studies included in the synthesis, when available. For the variable probing depth, in the absence of the mean value, when more than one site was measured, the mean of the values between the measured sites was calculated. When standard deviation values were not reported, and there was no description of any measure of variability that would allow its calculation, the value from the study with the greatest variance within the analysis was then imputed. This produced a more conservative result, decreasing study weight and generating a broader confidence interval.

*Assessment of risk of bias*

The methodology of the selected observational studies was evaluated using the risk of bias tool Meta Analysis of Statistics Assessment and Review Instrument (MASTARI) [22]. Risk of bias was categorized as “high” when the study had “yes” scores lower than 49%; “moderate” when the study presented between 50% and 69% of “yes” scores; and “low” when the study presented more than 70% of “yes” scores for the risk of bias questions.

For interventional studies, the Cochrane Collaboration’s tool for assessing risk of bias was used [23]. This tool covers seven domains: random sequence generation, allocation concealment, blinding of participants and professionals, blinding of outcome evaluators, incomplete outcomes, selective outcome reporting, and other sources of bias. The judgment as to the possible risk of bias in each of these domains was made based on the information extracted from the study, and they were classified as “high risk” or “low risk” of bias. In case the study did not report enough details, risk of bias was judged to be “not clear” and the authors of the original study were contacted for more information. These judgments were performed by two independent reviewers (P.M.M. and I.B.B). Disagreements were first resolved by discussion; in case of lack of consensus, the third reviewer (C.M.A) was consulted to make a final decision.

1 *Effect measures*

2 As the evaluated outcomes are continuous, reported in the same  
3 measurement scale, the mean difference (MD) was calculated.

4 *Synthesis method*

5 A random effects meta-analysis method using the statistical softwares  
6 RStudio version 1.2.1335 (Rstudio Inc, Boston, USA) and Stata version 16.0  
7 (Stata Corp LLC, College Station, USA) was performed, with the studies weighted  
8 by the inverse variance method. Heterogeneity was calculated by the  
9 inconsistency index ( $I^2$ ), and variance by  $\text{Tau}^2$ , estimated by the DerSimonian-  
10 Laird method; 95% confidence intervals were generated (CI 95%) and the  
11 significance level was set at 5%.

12 When extreme effect sizes were found as a source of heterogeneity within  
13 the analysis, the Leave-one-out method was performed, recalculating the global  
14 effect estimate  $k - 1$  times, with the respective confidence intervals and  $I^2$  values.  
15 This was performed by omitting one study at a time, thus assessing whether the  
16 influence of any study has distorted the combined effect estimate [24].

17 *Reporting bias assessment*

18 The graphic evaluation of the existence of publication bias was performed  
19 using the funnel plot, in addition to the Egger test to assess the existence of  
20 asymmetry in the funnel.

21 *Certainty of evidence*

22 The certainty of the evidence was assessed using the Grading of  
23 Recommendations Assessment, Development, and Evaluation (GRADE) tool  
24 [25] in all domains of risk of bias, consistency, openness, accuracy, and  
25 publication bias. The certainty of evidence was judged as high, moderate, low, or  
26 very low.

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28 **Results**

29 *Study selection*

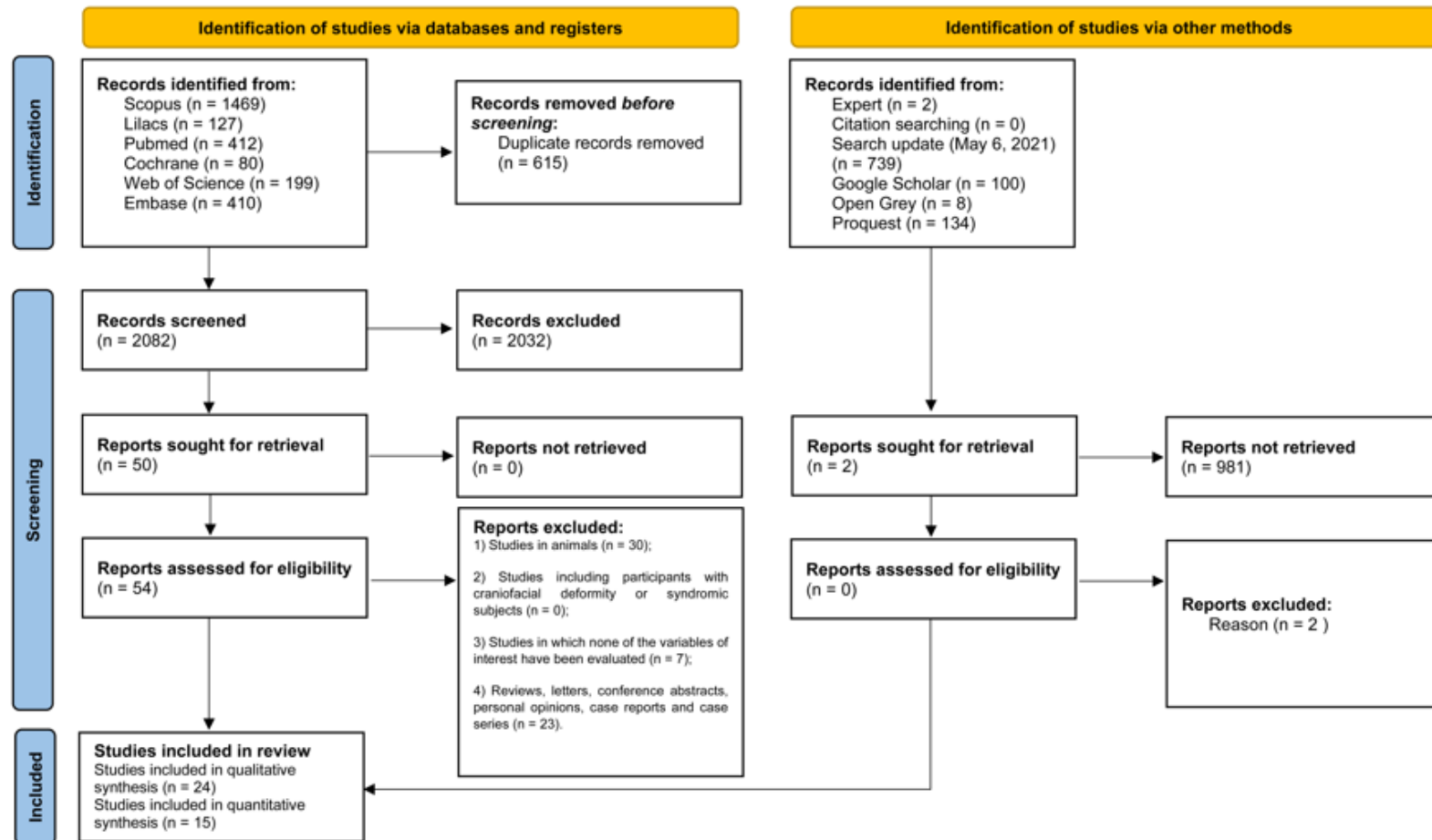
30 Through the elaborated research strategy, a database search was  
31 conducted, totaling 2697 articles. Excluding duplicate articles, 2082 articles were

1 selected for title and abstract reading. Of these articles, 54 were selected for full  
2 reading (phase 2), of which 30 were excluded (appendix 2), resulting in 24 articles  
3 for qualitative synthesis (Fig. 1).

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**Figure 1 - Flowchart of literature search and selection criteria**

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources



From: 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. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: <http://www.prisma-statement.org/>



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*Study characteristics*

Among the articles included, 23 studies were published in English and only 1 article was published in Portuguese, with the following countries as sources: Brazil, Belgium, Canada, Korea, Spain, Israel, Italy, Lithuania, United Kingdom, Sweden, and Turkey, with the year of publication ranging from 1978 to 2019.

Sample sizes ranged from 11 to 271 patients, with ages ranging from 11 to 52 years. The included studies that reported the gender of the samples showed a predominance of females.

As for study design, nineteen articles were classified as observational due to the absence of manipulation of the exposure factor, with 3 longitudinal prospective cohort and 16 cross-sectional studies. In addition to these, five clinical trials were included.

Twenty-one articles included assessed specific groups of dental elements treated orthodontically and submitted to traction; among these, eighteen studies evaluated upper canines and three articles evaluated upper incisors. Three articles evaluated groups of teeth, including maxillary incisors and canines, mandibular canines and premolars, canines and second premolars, and maxillary incisors and canines.

Regarding the type of surgical technique used in the articles included, twelve articles used the closed technique, six articles used the open technique, and six articles compared the closed and open techniques. All characterization data from the included studies are available in table 1.

**Table 1 – Characteristics of the included studies (n=24)**

Study, Author/Year (Country)	Title	Sample (gender, dental group)	Age (Median or Mean ± SD)	Surgical Technique	Results	Conclusions
Becker, A., et al., 2002 (Israel)	Closes eruption surgical technique for impacted maxillary incisors: A postorthodontic periodontal evaluation.	21 patients (6 M, 15 F / Upper Central Incisor)	17.5	Closed	PI and GI without statistical significance. There was a statistical difference between the means of PD between and LC and contralateral (p=0.002) and without statistical significance between LI and contralateral. Significantly higher PD was observed on the distobuccal and lingual surfaces when compared to the teeth alone.	It concludes a good long-term aesthetic result from the treatment of incisors impacted by traction in technique, even reporting statistical difference in some periodontal parameters.
Becker, A., et al., 1983 (Israel)	Periodontal status following the alignment of palatally impacted canine teeth	23 patients (9 M, 14 F / upper canine)	12.48±2.21	Closed	PI without statistical significance. There was statistical significance in GI and PD, greater in treated canine.	It is concluded that the parameter that clearly needs more attention is the loss of greater bone support in the treated region, assessed radiographically.

<p>Bollero, P., et al., 2017 (Italy)</p>	<p>Long-term periodontal status of palatally and buccally impacted canines after closed surgical -orthodontic approach</p>	<p>28 patients (14 canines impacted with palatine 6M 8 F / 14 canines impacted with vestibular - 7 M, 7 F)</p>	<p>13.5 ±1.4</p>	<p>Closed</p>	<p>Canines impacted by palatine with PD significantly higher in the mesiopalatine. No statistical significance in KMW, PI, GBI and GR. In canines impacted by vestibular there was a significant increase in KMW. No statistical difference for PD, PI, GBI and GR. The palatal impacted canines showed significantly higher PD in the mid-vestibular region and in all the palatal regions compared to the buccal impacted canines. No statistical difference for KMW, PI and GBI and GR.</p>	<p>It was concluded that after ortho-surgical treatment, there was no statistical periodontal difference after treatment in palatal impacted canines. Canines impacted by palatine showed greater probing depth in the lingual regions than those impacted by vestibular. Despite the statistical significance in some parameters, they did not show great clinical significance.</p>
<p>Caminiti, M.F., et al., 1998 (Canada)</p>	<p>Outcomes of the surgical exposure, bonding and eruption of 82 impacted maxillary canines</p>	<p>54 patients (82 canines, 60 impacted with palatine and 22 impacted with vestibular /23 M 31 F )</p>	<p>14 years</p>	<p>Open/Closed</p>	<p>Three canines with PD greater than 3mm. The cases presented with approximately 3mm of KMW, only two canines impacted by vestibular presented 1mm of KMW. They evaluated the prevalence of cases, without analyzing the data statistically.</p>	<p>No conclusions about periodontal parameters, no quantitative data collected</p>

Caprioglio, A., et al., 2013 (Italy)	Long-term periodontal response to orthodontic treatment of palatally impacted maxillary canines	33 patients (9 M, 24 F / upper canine impacted of palatine)	16.3±3.9	Closed	There was no clinical statistical difference for PD, only on the buccal aspect of the lateral incisor and the mesiopalatine aspect of the first premolar.	It was concluded that the use of a conservative surgical technique with light orthodontic force contributes to an adequate final periodontal state.
Cercadillo - Ibauguren, I., et al., 2011 (Spain)	Periodontal health and esthetic results in impacted teeth exposed by apically positioned flap technique	15 patients (5 M, 10 F / 12 UC, 2LC, 1UP)	16.8	Open	No statistical difference for PI, GI, GBI and KMW parameters. Significantly higher values for PD teeth in the palate (p=0.031) and lower values for GR (p=0.005).	It was concluded that it is possible to maintain periodontal health using the apically positioned flap technique to expose the impacted tooth.
Chaushu, S., et al., 2003 (Israel)	Periodontal status following surgical-orthodontic alignment of impacted central incisors with an open-eruption technique.	11 patients (4 M, 8F / upper central incisor)	22	Open	Statistical difference in the parameters PI, GI, PD (p=0.01) mesiobuccal (p=0.005), with higher values in tractioned incisors.	It was concluded that orthodontic alignment of LC impacted by open technique is accepted in orthodontic resolution. Negative aesthetic and periodontal effects on the treated tooth must be considered. Long-term stability and post-treatment periodontal health should be monitored.

<p>Chaushu, S., et al., 2009 (Israel)</p>	<p>Periodontal Status of Impacted Maxillary Incisors Uncovered by 2 Different Surgical Techniques</p>	<p>22 patients (open technique group 11 patients 4 M, 7F / closed technique group 11 patients 3 M, 8 F / upper central incisor)</p>	<p>21.5</p>	<p>Open/Closed</p>	<p>No statistical difference in the parameters of interest.</p>	<p>It was concluded that comparing the two surgical exposure techniques, the closed technique produces a superior result in terms of periodontal prognosis and final appearance.</p>
<p>Crescini, A., et al., 1994 (Italy)</p>	<p>Tunnel traction of infraosseous impacted maxillary canines. A three-year periodontal follow-up.</p>	<p>15 patients (upper canine, tractioned group - 7 impacted with vestibular and 8 impacted with palatine - and group of canines not tracted / 4 M, 11 F )</p>	<p>14.8±1.6</p>	<p>Open</p>	<p>T1: significantly higher KMW and PD also in 3 regions (MV, DV, DP) in the pulled canines. T2: PS significantly lower in canines pulled only in the MV region. No statistical difference for KMW. Comparing T1 and t2: There was a significant decrease in PD and KMW in both groups, more pronounced in the traction group (3 regions in the control group did not give statistical significance MV, DV, DP). Assessing the mean created by the decrease in the parameters of the two groups, there was a statistical difference in PD in the MV and DV regions in the KMW.</p>	<p>It was concluded that after the canine traction procedure - impacted both by buccal and palatal - using the repositioned flap and tunnel-type traction, no change in insertion levels, no GR and adequate amount of gingiva can be obtained and maintained in teeth treated for at least 3 years after treatment. Although they showed statistical differences in the PD and KMW parameters, they are clinically insignificant (&lt;1mm).</p>

Crescini, A., et al., 2007 (Italy)	Short- and long-term periodontal evaluation of impacted canines treated with a closed surgical-orthodontic approach	125 patients (31 M, 94F) 58 patients on follow-up (23 M, 35 f M / Upper canine)	16.9±5.9	Open	T1: PD with statistical difference considering the side of the tooth in the pulled canine and with higher values in the interproximal ones (p<0.0001). There was a statistical difference in the KMW, greater in the pulled canines (p=0.0028). T2: statistically significant difference in the group under traction in the PD, with higher values in the interproximal ones (p<0.0001). There was a statistical difference in theKMW, being higher in the traction group (p=0.0002).	It was concluded that the combined surgical-orthodontic technique (flap approach associated with direct orthodontic traction towards the center of the alveolar crest) favorably resulted in a correct alignment of the repositioned canine in the dental arch associated with an adequate amount of gingiva and probing depth physiological.
Crescini, A., et al., 2007 (Italy)	Orthodontic and periodontal outcomes of treated impacted maxillary canines.	168 patients (118 UC impacted with palatine and 50 UC impacted with vestibular / 40 M, 128 F)	17.2±6	Open	PD significantly higher in canines impacted by the palate than by the vestibular one (P=0.04). There was no statistical difference inKMW values.	It was concluded that the pretreatment radiographic characteristics assessed on panoramic radiographs are useful indicators for the duration of orthodontic traction, however, they are not valid predictors of the final periodontal status of impacted canines that have been orthodontically repositioned.

Crescini, A., et al., 2007 (Italy)	Pre-treatment radiographic features for the periodontal prognosis of treated impacted canines	168 patients (155 UC impacted with palatine and e 56 UP impacted with vestibular / 40 M, 128 F )	17.39±6.04	Open	PD significantly higher in interproximals (p<0.0001). KMW significantly higher in cases of impaction by the palate than by the vestibular (p=0.0149).	It was concluded that pretreatment radiographic characteristics aimed at defining the position of the canine on a panoramic X-ray are not valid predictors of the final periodontal status of impacted canines treated by the surgical-orthodontic approach.
Evren, A. D., et al., 2014 (Turkey)	Periodontal status of ectopic canines after orthodontic treatment	30 patients (Upper canine 15 impacted with palatine and 15 impacted with vestibular / 9 M, 21 F)	11.3 ±1.45	Closed/conventional orthodontics techniques	In canines impacted by the palate (treated by the closed technique), PD was significantly higher compared to untreated contralateral ones (p<0.01). in the vestibular impacted canines (treated with conventional orthodontic techniques), there was an increase in PI(p<0.01) ISG (p<0.01) and PD compared to the control group (p<0.05).	It was concluded that periodontal changes in palatal ectopic canines were in the form of increased probing depth. The buccal ectopic canines, on the other hand, pointed to an increase in the index of plaque and gingival bleeding and greater pocket depths.

Kohavi, D., et al., 1984 (Israel)	Periodontal status following the alignment of buccally ectopic maxillary canine teeth	29 patients (13 unilateral UC impacted with vestibular and 16 bilateral upper canine impacted with vestibular/ 12 M, 17 F)	CS unilaterais 12.72±1.6 / CS bilaterais 12.78±1.47	Closed	In unilateral cases, there was no statistical difference in PI, GI and PD compared to their contralateral ones. In bilateral cases, there was no statistical difference in PI. There was statistical difference in GI and PD, with higher values in the traction group compared to the control group (p<0.05).	It was concluded that the orthodontist is advised to be alert to the possibility, although apparently rare, of concluding the case and finding compromised periodontal support.
Landim, F. S., et al., 2010 (Brazil)	Avaliação clínico-radiográfica dos caninos após tratamento ortocirúrgico	17 patients ( ND, canines)	ND	ND	Prediction for females, left side and maxilla in relation to impacted canines. Four patients (23.5% of the sample) had GR associated with hypersensitivity.	It was concluded that orthodontic traction in the studied sample appears to be an effective, safe and reproducible procedure.
Lee, J. Y., et al., 2010 (Korea)	Labially impacted maxillary canines after the closed eruption technique and orthodontic traction: A split-mouth comparison of periodontal recession	54 patients (21 M, 33 F / canines impacted with vestibular)	12.85±3.5	Closed	There was a statistical difference in the variable KMW, smaller in the pulled canine (p=0.04). PD with statistical difference only in DP with higher value in the pulled canine (p=0.04).	It was concluded that the closed eruption technique exhibited slightly worse periodontal conditions in relation to the alveolar bone and gingiva in the pulled canine.



<p>Odenrick, L. and T. Modeer, 1978 (Sweden)</p>	<p>Peridontal status following surgical-orthodontic alignment of impacted teeth</p>	<p>22 patients (11 patients group open technique, 11 patients group closed technique/ ND / lincisors and upper canines)</p>	<p>13.6</p>	<p>Open/Closed</p>	<p>Attachment loss, evaluated by the PAL parameter, presented 1 case in the open technique group and 7 in the closed technique group. One patient out of 11 in the closed technique group and 7 out of 11 in the open technique group had GR. In the open technique group, 3 teeth presented on the buccal face and were positioned buccally, 3 on the lingual face of 5 that were positioned lingually. Of 3 cases positioned centrally, 1 presented GR. In the closed technique group, the only case that presented GR had a vestibular position.</p>	<p>It was concluded that the surgical flap technique in combination with orthodontic treatment creates several possible advantages. Most impacted teeth from the open technique group had loss of attachment. However, more studies are needed. to assess the effect of the surgical technique on the soft tissue reaction after the alignment of impacted teeth.</p>
<p>Quiryne, M., et al., 2000 (Belgium)</p>	<p>Periodontal Health of Orthodontically Extruded Impacted Teeth. A Split-Mouth, Long-Term Clinical Evaluation</p>	<p>38 patients (ND / 29 UC, 5 UI, 2 LC, 2 LP)</p>	<p>17-51</p>	<p>Open/Closed</p>	<p>There was no statistical significance in the parameters of interest comparing all teeth pulled with the control group of contralateral. Comparing only unilateral upper canines (n=26), there was a statistical difference in the KMW, which was lower in the traction group (p=0.006).</p>	<p>It can be concluded that the closed eruption technique with conservative periodontal surgery and careful orthodontics is a treatment with excellent long-term results. It should be recommended as the treatment of choice for impacted teeth, at least when its position and absence of ankylosis allow eruption to occur.</p>

Smailiene, D., et al., 2013 (Lithuania)	Posttreatment status of palatally impacted maxillary canines treated applying 2 different surgical-orthodontic methods.	43 patients (upper canines impacted with palatine, 22 group open technique with spontaneous eruption and 21 closed technique group / 8M, 35 F)	15,81±3.04	Open with spontaneous eruption/closed	PD with statistical difference in the traction group compared to the control in the MV region (p<0.05), but no difference between the techniques. No statistical difference between groups and contralateral groups regarding GR.	The post-treatment status of palatal impacted canines after surgical-orthodontic treatment did not differ significantly between the groups treated with 2 different surgical methods, and may be considered acceptable techniques for treatment.
Smailiene, D., et al., 2013 (Lithuania)	Palatally impacted maxillary canines: Choice of surgical-orthodontic treatment method does not influence post-treatment periodontal status. A controlled prospective study	43 patients (upper canines impacted with palatine, 22 group open technique with spontaneous eruption and 21 closed technique group / 8M, 35 F)	15,81±3.04	Open with spontaneous eruption/closed	Significant PD comparing the tractioned side with the contralateral in the MV region (P<0.05), but without statistical significance comparing the techniques. There was no statistical difference between groups and contralaterals in the parameters GR, KMW, GI and GBI.	After surgical-orthodontic treatment of canines impacted by the palate, by open surgery with spontaneous or closed eruption, there were no significant differences in periodontal status. Both treatments are acceptable even though the average time of exposure to the rash.

Caprioglio, A., et al., 2019 (Italy)	Effects of impaction severity of treated palatally displaced canines on periodontal outcomes: A retrospective study	271 patients (293 canines impacted eith palatine, ND)	13,8±1.2	Closed	There was no comparison to untreated canines. Significantly higher prevalence of PD less than 2mm (normal) compared to groups with PD greater than or equal to 2mm, or presence of GR. Low prevalence and non-significant SBI.	Little significant values of periodontal changes in the evaluated parameters. They should be limited to canines impacted by the palate, since the vestibular displacement can involve different results as well as treatment options and success rate.
Parkin, N. A., et al., 2013 (United Kingdom)	Periodontal health of palatally displaced canines treated with either na open or closed surgical technique: a randomized controlled trial	62 patients (upper canines, 33 open technique and 29 closed technique, ND)	ND	Open/Closed	No statistical difference in PAL and GR parameters between open and closed groups (P<0.05). Statistical difference in PAL parameters with greater attachment loss in treated canines (P>0.05) and RG, with greater prevalence in treated canines on MV and MP faces.	The exposure and alignment of palatal impacted canines had a small impact on periodontal health. This impact was not influenced by the type of technique and is so small and clinically irrelevant to influence tooth prognosis.
Zasciurinskiene, E., et al., 2008 (Lithuania)	Initial vertical and horizontal position of palatally impacted maxillary canine and effect on periodontal status following surgical-orthodontic treatment	32 patients (10 M, 22 F, upper canine impacted with palatine)	18,2±5.1	Closed	PD significantly higher on the MV face of treated canines (p<0.05). No statistical difference between groups in the RG parameter, prevalence of 18.75% over the sample.	Combined orthodontic-surgical treatment of impacted maxillary canines produces a clinically acceptable periodontal condition.

Crescini, A., et al., 2007 (Italy)	Combined surgical and orthodontic approach to reproduce the physiologic eruption pattern in impacted canines: report of 25 patients	25 patients (9 M, 16 F, upper canine / 13 impacted with vestibular e 12 with palatine)	15,2±2.1	Closed	Statistical difference in PD and KMW parameters, lower at follow-up than at the end of treatment (P<0.05). There was no RG in any of the samples observed	The tunnel-type technique can be considered safe and effective in the treatment of impacted canines. The application of this technique can result in optimal dental alignment and healthy periodontium.
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Legends: M, Male; F, Female; UI, Upper Incisor; CI, Central Incisor; LI, Lateral Incisor; UC, Upper Canine; LC, Lower Canine; UP, Upper Premolar; LP, Lower Premolar; GI, Gingival Index; PI, Plaque Index; GBI, Gingival Bleeding Index; KMW, Keratinized Mucosa Width; PAL, Periodontal Attachment Level; PD, Probing Depth; GR, Gingival Recession; DV, Dysto Vestibular; DP, Dysto Palatine; MV, Middle Vestibular; ND, Not Described

1 *Risk of bias*

2       Among the 19 observational studies included, 12 articles had low risk of  
3 bias, 5 articles had moderate risk of bias [26-30], and 2 articles had high risk of  
4 bias [31, 32]. Of the 5 interventional studies included, two articles presented more  
5 than 50% of the domains assessed as being at high risk or lacking information  
6 that would provide adequate judgment [8, 33] (appendix 3).

7 *Results of individual studies*

8       Probing depth and gingival recession were the most evaluated  
9 parameters, followed by plaque index, gingival index, and keratinized mucosa  
10 width.

11       When considering only the periodontal parameters of the upper incisors,  
12 [26, 34, 35], probing depth was significantly greater in the tractioned teeth, with  
13 no difference in relation to the gingival and plaque indices ( $p > 0.05$ ). Only one  
14 study showed higher values for gingival and plaque indices in central incisors  
15 under traction [34].

16       Similarly, when considering maxillary canines [8, 13, 18, 19, 27-29, 31, 33,  
17 36-43], pulled teeth showed greater probing depth [13, 27, 38-40, 42] in at least  
18 one face of the tooth. However, the literature diverged in relation to this outcome,  
19 with studies that did not find differences between these teeth and contralateral  
20 teeth [18], or with a difference in this variable only on the surfaces of teeth  
21 adjacent to the canine [8]. Regarding plaque, gingival bleeding, and gingival  
22 recession, statistical nonsignificance prevailed between the groups of treated and  
23 untreated canines. Only one study showed a statistical difference in the rates of  
24 plaque and gingival bleeding, which were higher in the treated group [38]. The  
25 literature also diverged for keratinized mucosa width, with studies showing lower  
26 values [13, 28, 29, 36, 38] or even larger values in treated canines [37], and  
27 studies that showed no difference between groups [13, 40].

28       Nonstatistical significance of the periodontal parameters plaque index and  
29 gingival index prevailed among the included studies that evaluated mixed groups  
30 of teeth [3, 30], and the parameters probing depth and gingival recession had  
31 higher values in the treated group [30].

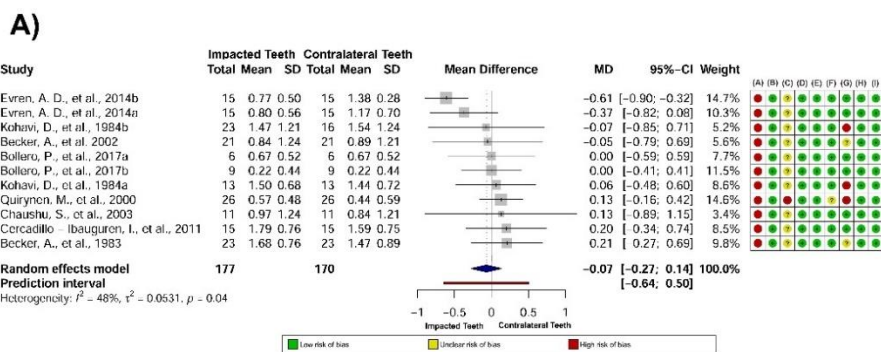
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1 **Synthesis of results**

2 Fifteen studies were included in the quantitative synthesis, making it  
 3 possible to evaluate the following outcomes: plaque index, gingival index,  
 4 keratinized tissue width, and periodontal probing depth.

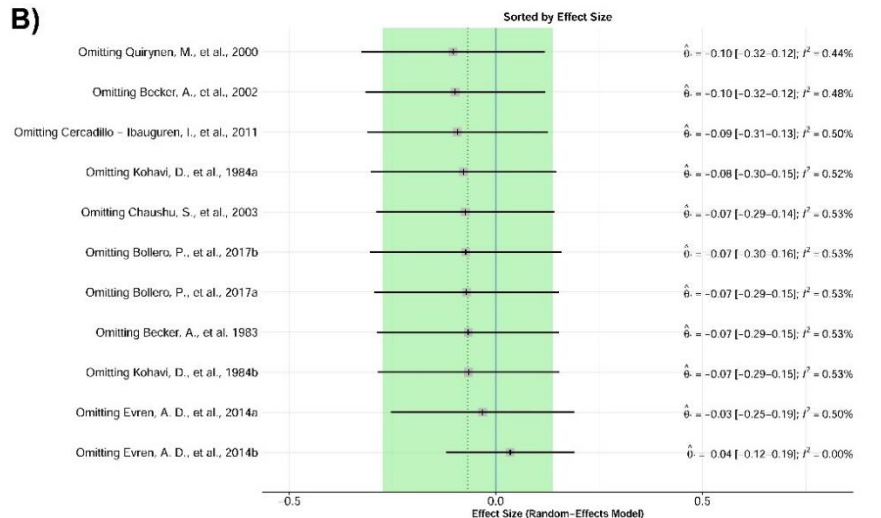
5 There was no relationship between dental impaction and plaque index [MD  
 6 = -0.07; PI 95% = -0.64 – 0.50; I<sup>2</sup> = 48%], with no difference for plaque index  
 7 between impacted and contralateral teeth (Figure 2a). Influence analysis showed  
 8 that the study by Evren et al. [38] was responsible for the observed heterogeneity  
 9 (I<sup>2</sup> = 48%). However, even with the removal of this study from the analysis, the  
 10 values remained without statistical significance (p > 0.05) (Figure 2b), denoting  
 11 robustness of the analysis.

12 **Figure 2** – Comparison of the plaque index between tractioned teeth and their  
 13 contralateral counterparts: a) Forest plot showing the risk of bias for each included study;  
 14 b) influence analysis.



**Risk of bias legends:**

(A) Was the study based on a random or pseudorandom sample?  
 (B) Were the criteria for inclusion in the sample clearly defined?  
 (C) Were confounding factors identified and strategies to deal with them stated?  
 (D) Were outcomes assessed using objective criteria?  
 (E) If comparisons are being made, was there sufficient description of the groups?  
 (F) Was the follow-up carried out over a sufficient time period?  
 (G) Were the outcomes of people who withdrew described and included in the analysis?  
 (H) Were the outcomes measured in a reliable way?  
 (I) Was an appropriate statistical analysis used?

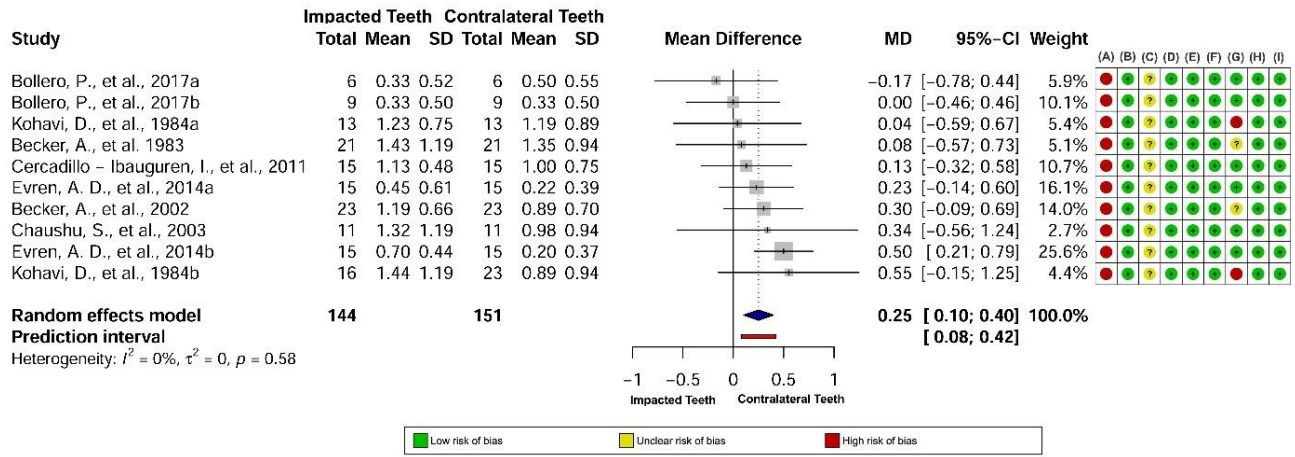


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The gingival index differed significantly between impacted and contralateral teeth [MD = 0.25; CI 95% = 0.10 – 0.40; I<sup>2</sup> = 0%]. Even including more than one group of teeth submitted to the traction procedure, there was no heterogeneity between the observed effect sizes, demonstrating similar values regardless of the type of tooth (p = 0.58; Tau<sup>2</sup> = 0.00). Thus, impacted teeth had higher gingival index scores than contralateral teeth, denoting a worse gingival condition (Figure 3). The analysis demonstrated robustness, with a narrow prediction interval [PI 95% = 0.08 – 0.42], even with the inclusion of studies that measured different groups of teeth. Therefore, this was not a confounding factor capable of altering the effect size.

**Figure 3** – Comparison of the gingival index between tractioned teeth and their contralateral counterparts, showing the risk of bias for each included study.



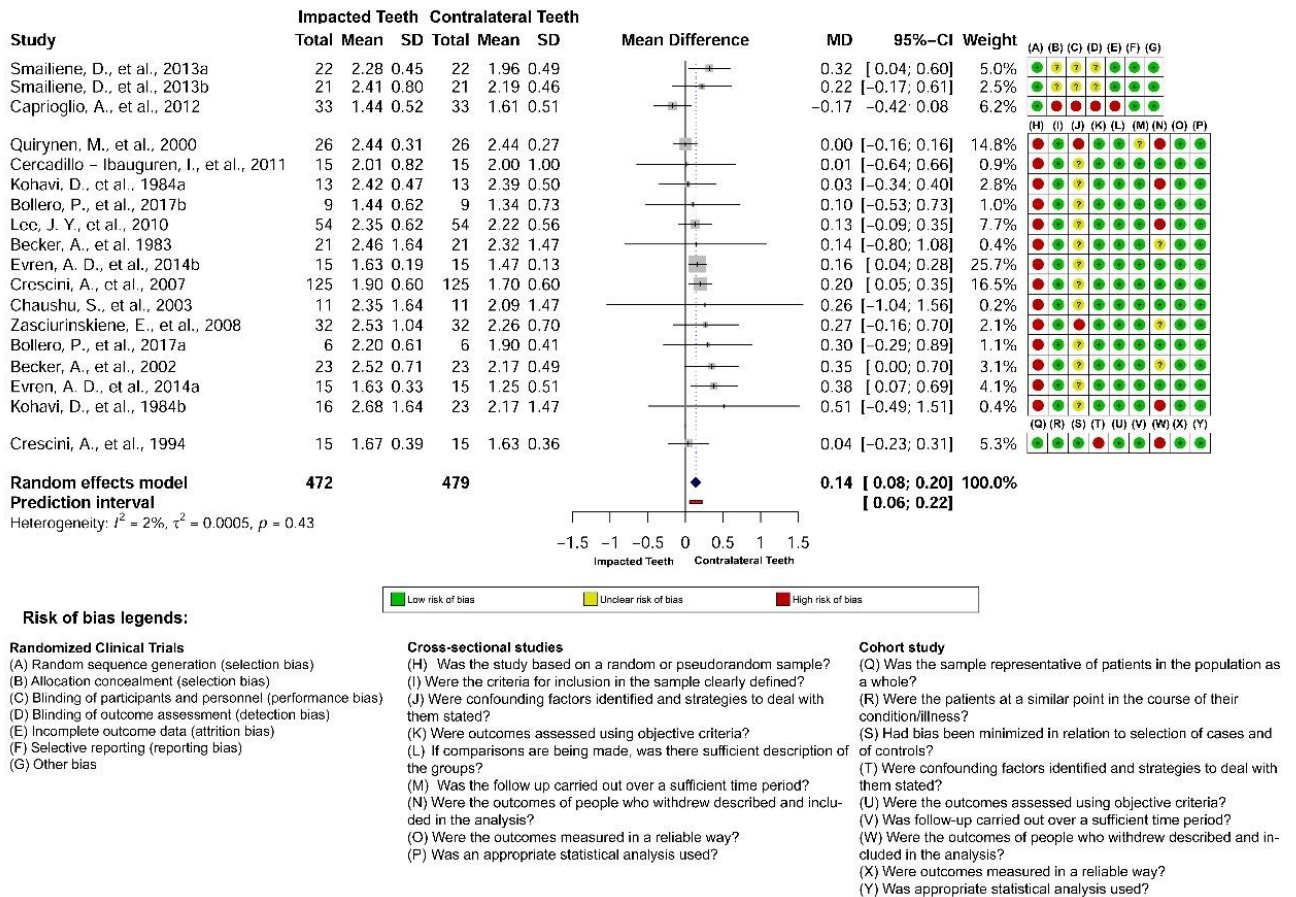
**Risk of bias legends:**

- (A) Was the study based on a random or pseudorandom sample?
- (B) Were the criteria for inclusion in the sample clearly defined?
- (C) Were confounding factors identified and strategies to deal with them stated?
- (D) Were outcomes assessed using objective criteria?
- (E) If comparisons are being made, was there sufficient description of the groups?
- (F) Was the follow up carried out over a sufficient time period?
- (G) Were the outcomes of people who withdrew described and included in the analysis?
- (H) Were the outcomes measured in a reliable way?
- (I) Was an appropriate statistical analysis used?

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In the same sense, when assessing periodontal probing depth, impacted teeth showed greater probing depth, with a statistically significant mean difference between groups [MD = 0.14; CI 95% = 0.08 – 0.20; I<sup>2</sup> = 2%]. Likewise, the variance observed between the effects was close to zero, with no significant

1 heterogeneity, regardless of the type of teeth included in the analysis ( $p = 0.38$ ;  
 2  $\text{Tau}^2 = 0.00$ ), and with a narrow prediction range (Figure 4).  
 3  
 4 **Figure 4** – Comparison of periodontal probing depth between tractioned teeth  
 5 and their contralateral counterparts, showing the risk of bias for each included  
 6 study.

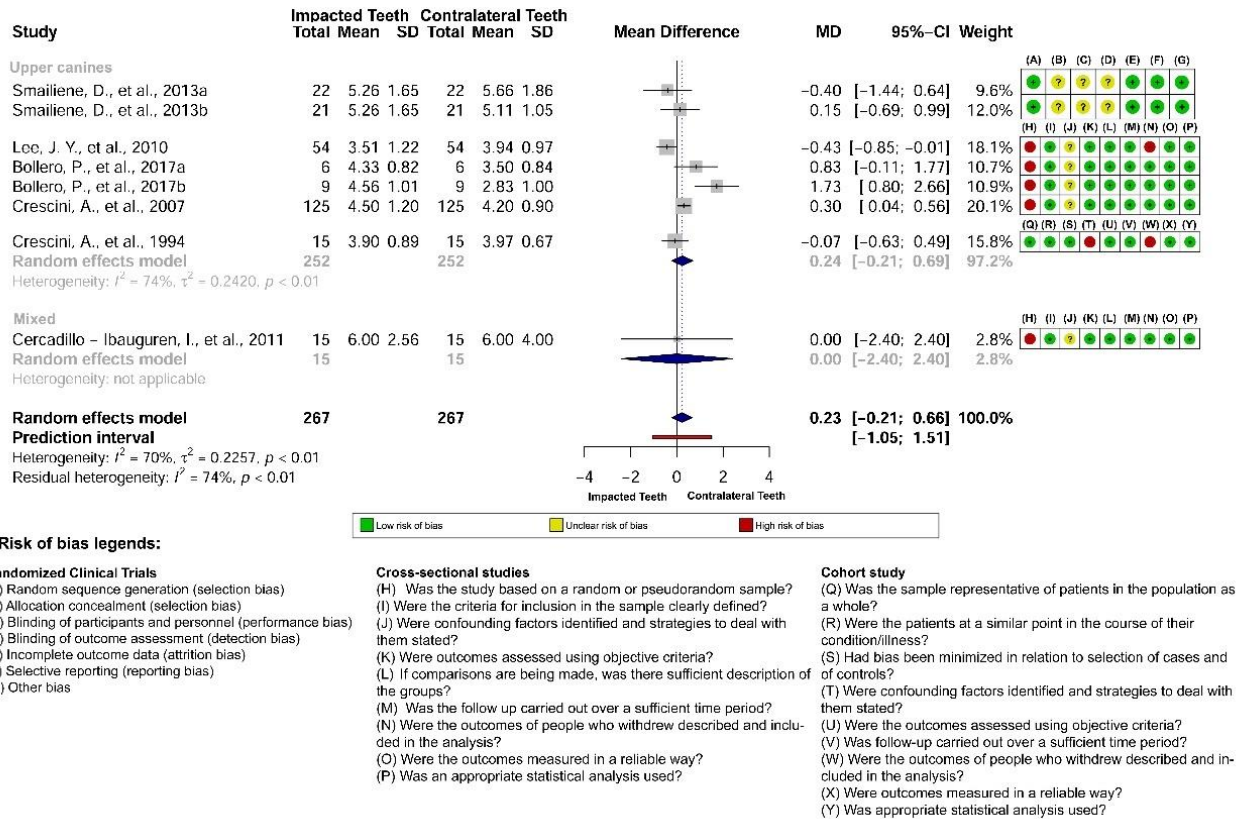


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 9 The evaluation of keratinized tissue width also showed no significant  
 10 difference when comparing the two groups [MD = 0.23; CI 95% = -0.21 – 0.66;  $I^2$   
 11 = 70%], with no difference between impacted teeth and their contralateral  
 12 counterparts (Figure 5). To explore heterogeneity, subgroup analysis was  
 13 performed; however, the type of teeth was not a predictive factor that explained  
 14 the heterogeneity between the observed effects.  
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**Figure 5 – Comparison of keratinized tissue width between tractioned teeth and their contralateral counterparts, showing the risk of bias for each included study.**



**Risk of bias legends:**

**Randomized Clinical Trials**

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

**Cross-sectional studies**

- (H) Was the study based on a random or pseudorandom sample?
- (I) Were the criteria for inclusion in the sample clearly defined?
- (J) Were confounding factors identified and strategies to deal with them stated?
- (K) Were outcomes assessed using objective criteria?
- (L) If comparisons are being made, was there sufficient description of the groups?
- (M) Was the follow up carried out over a sufficient time period?
- (N) Were the outcomes of people who withdrew described and included in the analysis?
- (O) Were the outcomes measured in a reliable way?
- (P) Was an appropriate statistical analysis used?

**Cohort study**

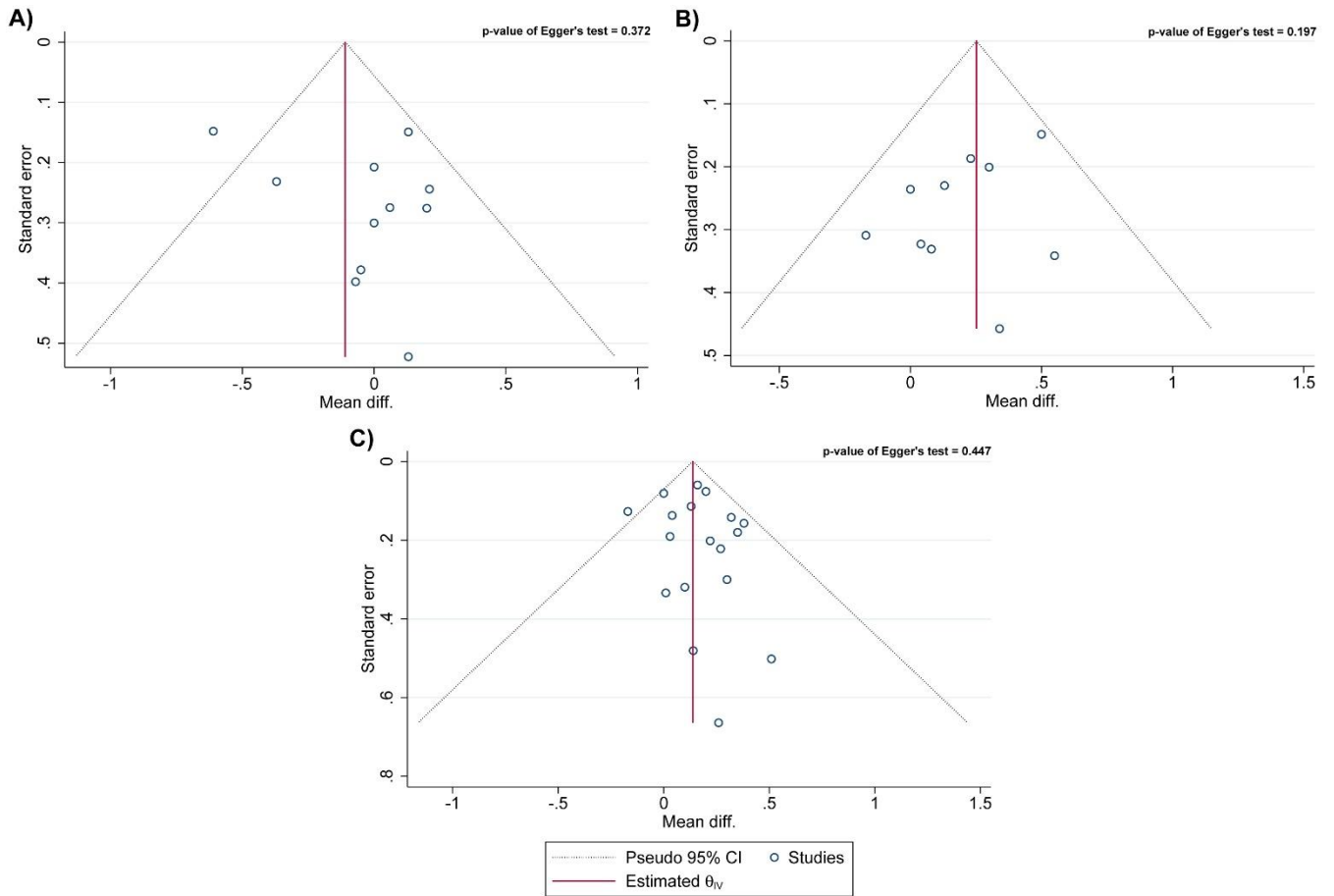
- (Q) Was the sample representative of patients in the population as a whole?
- (R) Were the patients at a similar point in the course of their condition/illness?
- (S) Had bias been minimized in relation to selection of cases and of controls?
- (T) Were confounding factors identified and strategies to deal with them stated?
- (U) Were the outcomes assessed using objective criteria?
- (V) Was follow-up carried out over a sufficient time period?
- (W) Were the outcomes of people who withdrew described and included in the analysis?
- (X) Were outcomes measured in a reliable way?
- (Y) Was appropriate statistical analysis used?

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**Reporting biases**

Funnel asymmetry, evaluated by the Egger test, showed no statistical significance ( $p > 0.05$ ), thus indicating the absence of publication bias (Fig. 6).

- 1 **Figura 6** - Funnel plot to assess the existence of publication bias for the following
- 2 outcomes: a) plaque index; b) gingival index; c) periodontal probing depth.



- 3
- 4 *Certainty of evidence*
- 5 As most of the included studies were cross-sectional, the certainty of
- 6 evidence was reduced for the outcomes: plaque index, gingival index, and
- 7 probing depth. Furthermore, the heterogeneity for the assessment of keratinized
- 8 tissue width persisted even after subgroup analysis, thus decreasing the certainty
- 9 of evidence to a very low level (appendix 4).
- 10

## 1 **Discussion**

2           The present study analyzed the available evidence on the periodontal aspects  
3 of orthodontically tractioned teeth in relation to their nontractioned contralateral  
4 counterparts. The current available literature and the eligibility criteria established  
5 for this systematic review enabled a quantitative analysis of data on the following  
6 periodontal parameters: plaque index, gingival index, keratinized mucosa width, and  
7 probing depth. The results indicate an association between orthodontic traction and  
8 worsening of periodontal parameters, measured through the significant increase in  
9 gingival index and periodontal probing depth, with no differences in relation to plaque  
10 index and keratinized mucosa width. Furthermore, the heterogeneity between the  
11 study effect sizes was very low for the analyses that demonstrated statistical  
12 significance, regardless of the group of teeth included in the analysis.

13           Dental plaque is considered a primary cause of periodontal disease, requiring  
14 mechanical cleaning of all sides of the tooth to maintain good oral health [44]. Bolero  
15 et al. [18] found no difference between impacted canines and their contralateral  
16 counterparts, regardless of the arch in which they were positioned. On the other  
17 hand, Evren et al. [38] observed an increase in plaque index and gingival index  
18 scores in lower canines under traction in relation to their contralateral counterparts;  
19 notwithstanding, the authors could not elucidate the reasons for this worsening in  
20 periodontal health. In the present systematic review, the mean of plaque index  
21 scores showed no statistical difference ( $p > 0.05$ ), with only one study [38] not  
22 touching the null line. However, the study showed no influence on the analysis to the  
23 point of changing the significance for this outcome.

24           Patients undergoing orthodontic treatment need periodontal evaluations at  
25 each visit due to possible periodontal implications during orthodontic  
26 therapy[45]. Based on data available in the current literature on this topic, tractioned  
27 teeth had higher gingival index scores and greater probing depth ( $p < 0.05$ ). Lee et  
28 al. [29] report that periodontal tissues may differ between canines impacted after  
29 orthodontic traction and canines with normal eruption. Factors involving the surgical  
30 procedure performed, such as the need for more extensive bone removal in closed  
31 flaps, may correlate with the increase in pocket depth and gingival level after

1 treatment [38]. In this review, both outcomes showed low heterogeneity between the  
2 effect sizes of the articles included in the analysis. This denotes that the type of tooth  
3 did not interfere with the observed effect, with a similar effect with worsening in these  
4 parameters, regardless of the type of impacted tooth. Despite demonstrating  
5 statistical significance, data regarding probing depth should be considered in relation  
6 to the clinical significance of these findings, as the difference between groups had a  
7 small effect size.

8 In clinical practice, factors such as the dimensions of soft and hard oral tissues  
9 are essential parameters that can influence periodontal diagnosis and treatment  
10 [46]. The results presented show divergent data on whether keratinized tissue width  
11 differs between impacted teeth and teeth with normal eruption after orthodontic-  
12 surgical traction. Lee et al. [29] found a significant decrease in keratinized tissue  
13 width in canines in relation to their nontractioned contralateral counterparts. In that  
14 study, the minimum width considered for the maintenance of periodontal health was  
15 2 mm, and the authors found values less than 2 mm for this parameter in treated  
16 teeth, which predisposes to recurrent inflammation and loss of periodontal support.  
17 Smailiene et al. [40] did not observe statistically different values between treated  
18 teeth and their nontractioned contralateral counterparts. On the other hand, Bollero  
19 et al. [18] observed a greater amount of keratinized tissue in tractioned canines in  
20 relation to contralateral teeth. The meta-analysis performed did not demonstrate  
21 statistical significance for this outcome ( $p > 0.05$ ); however, there was heterogeneity  
22 between the observed effects that persisted even after subgroup analysis. As the  
23 source causing the heterogeneity could not be identified, the certainty of evidence  
24 for this outcome is reduced.

25 The results of this systematic review and meta-analysis reveal important data  
26 on periodontal aspects in impacted teeth subjected to orthodontic treatment,  
27 revealing clinical parameters that can undergo significant changes after a tooth is  
28 exposed to this treatment. By demonstrating the current stage of knowledge on the  
29 subject, these findings help the orthodontist and/or the surgeon to stipulate the risks,  
30 know about the predictability of the techniques, and easily communicate with the  
31 patient. Some limitations should be pointed out, such as the study design. Most of

1 the included studies are cross-sectional observational studies, subject to different  
2 confounding factors due to the impossibility of randomization.

3  
4 **Conclusions**

5 Tracted teeth showed worsening in the periodontal parameters gingival  
6 index and probing depth. Notwithstanding, probing depth should be weighed as to  
7 its clinical significance due to the small effect size observed. Regardless of the group  
8 of teeth analyzed, the observed effect size remained similar.

9 **Other informations**

10 *Registration and protocol*

11 The protocol for this study was registered on the PROSPERO website  
12 (International Prospective Register of Systematic Reviews - Center for Reviews and  
13 Dissemination, University of York) under number CRD42020205104.

14

15 **Compliance with ethical standards**

16 **Conflict of interest** The authors declare that they have no conflict of interest.

17 **Funding** No external funding was provided in regard with this study. The authors  
18 received no other institutional funding beyond their employment.

19 **Ethical approval** This article does not contain any studies with human participants  
20 or animals performed by any of the authors.

21 **Informed consent** For this type of study, formal consent is not required.

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# 1 Appendices

## 2 Appendix 1- Search strategy used in electronic databases.

<b>COCHRANE</b>	("impacted tooth" OR "impacted teeth" OR "impacted" OR "unerupted tooth" OR "unerupted teeth" OR "ectopic Tooth eruption" OR "ectopic") AND ("traction" OR "tractioned" OR "orthodontic traction")
<b>LILACS</b>	("impacted tooth" OR "dente impactado" OR "diente impactado" OR "impacted teeth" OR "dentes impactados" OR "dientes impactados" OR "impacted" OR "impactado" OR "unerupted tooth" OR "dente não erupcionado" OR "diente sin erupción" OR "unerupted teeth" OR "dentes não erupcionados" OR "dientes sin erupción" OR "ectopic Tooth eruption" OR "erupção dentária ectópica" OR "erupción dental ectópica" OR "ectopic" OR "ectópica") AND ("traction" OR "tração" OR "tracción" OR "tractioned" OR "traccionado" OR "tracionado" OR "orthodontic traction" OR "tracionamento ortodôntico" OR "tracción ortodoncia")
<b>PUBMED</b>	"Tooth, Impacted"[mesh terms] OR "impacted"[All Fields] OR "tooth, unerupted"[MeSH Terms] OR "unerupted"[All Fields] OR "Tooth eruption, ectopic"[MeSH Terms] OR "ectopic tooth eruption"[All Fields] OR "ectopic"[All Fields] OR "traction"[All Fields] OR "tractioned"[All Fields] OR "orthodontic traction"[All Fields] #1 AND #2
<b>EMBASE</b>	('impacted tooth':ti,ab OR 'impacted teeth':ti,ab OR 'impacted':ti,ab OR 'unerupted tooth':ti,ab OR 'unerupted teeth':ti,ab OR 'ectopic tooth eruption':ti,ab OR 'ectopic':ti,ab) AND ('traction':ti,ab OR 'tractioned':ti,ab OR 'orthodontic traction':ti,ab)
<b>SCOPUS</b>	("impacted tooth" OR "impacted teeth" OR "impacted" OR "unerupted tooth" OR "unerupted teeth" OR "ectopic Tooth eruption" OR "ectopic") AND ("traction" OR "tractioned" OR "orthodontic traction")
<b>WEB OF SCIENCE</b>	<ol style="list-style-type: none"> <li>1. TS=("impacted tooth" OR "impacted teeth" OR "impacted" OR "unerupted tooth" OR "unerupted teeth" OR "ectopic Tooth eruption" OR "ectopic")</li> <li>2. TS=("traction" OR "tractioned" OR "orthodontic traction")</li> <li>3. #1 AND #2</li> </ol>
<b>GOOGLE SCHOLAR</b>	"impacted teeth" AND "traction"
<b>OPENGREY</b>	"impacted teeth"

<b>PROQUEST</b>	"impacted teeth" AND "traction"

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2

1 **Appendix 2 - Excluded articles and reasons for exclusion (n=30)**

Author, Year	Reason for exclusion
Albiol and Garcia. 2007 <sup>1</sup>	4
Azeem et al. 2018 <sup>2</sup>	3
Bado-Silveira and Recoing. 2005 <sup>3</sup>	4
Bariani et al. 2017 <sup>4</sup>	4
Bassigni and Knoche. 1975 <sup>5</sup>	4
Birn and Andersen. 1971 <sup>6</sup>	4
Carnero. 1976 <sup>7</sup>	4
Carnero 1977 <sup>8</sup>	4
Consolaro 2010. <sup>9</sup>	4
Cozzani et al. 2003 <sup>10</sup>	4
Dagg. 1973 <sup>11</sup>	4
Dijkiewicz et al. 2004 <sup>12</sup>	4
Diliberti. 2000 <sup>13</sup>	4
Ericson and Kurol. 1988 <sup>14</sup>	4
Fingeroth et al. 1979 <sup>15</sup>	4
Giancotti et al. 2009 <sup>16</sup>	4
Helmore. 1967 <sup>17</sup>	4
Hunt. 1977 <sup>18</sup>	4
Kurol. 2002 <sup>19</sup>	4
Mydlová et al. 2015 <sup>20</sup>	4
Migliorati et al. 2012 <sup>21</sup>	3
Sagnani and King. 2015 <sup>22</sup>	3
Schmidt and Kokich, 2007 <sup>23</sup>	3
Shino et al. 2012 <sup>24</sup>	4
Soroka-Letkiewicz et al. 2012 <sup>25</sup>	3
Spencer et al. 2010 <sup>26</sup>	3
Vaid et al, 2014 <sup>27</sup>	4
Vieira et al. 2013 <sup>28</sup>	4
Wang et al. 2008 <sup>29</sup>	3
Wang et al. 2012 <sup>30</sup>	4

2 1) Studies in animals; 2) Studies including participants with craniofacial deformity or  
3 syndromic subjects; 3) Studies in which none of the variables of interest have been  
4 evaluated; and 4) Reviews, letters, conference abstracts, personal opinions, case  
5 reports and case series.

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- 1 **Appendix 3** - Risk of bias of studies included in the qualitative and quantitative analyses assessed by: a) Cochrane  
 2 Collaboration's tool for assessing risk of bias; b) Meta-Analysis of Statistics Assessment and Review Instrument (MASTARI).  
 3  
 4 **3a** – Cochrane's tool to assessed risk of bias in randomized controlled trials (Higgins et al 2011)<sup>1</sup>

<b>Author, year</b>	<b>Questions</b>	<b>Suport for judgement</b>	<b>Risk of Bias</b>
Caminiti, M.F., et al., 1998 <sup>2</sup>	Random sequence generation (selection bias)	The sample was not randomized	HIGH RISK
	Allocation concealment (selection bias)	There was no randomization of the sample	HIGH RISK
	Blinding of participants and personnel (performance bias)	Not applicable	UNCLEAR RISK
	Blinding of outcome assessment (detection bias)	Not applicable	UNCLEAR RISK
	Incomplete outcome data (attrition bias)	Qualitative assessment, no statistical analysis was applied, no control group	LOW RISK

	Selective reporting (reporting bias)		LOW RISK
Caprioglio, A., et al., 2013 <sup>3</sup>	Random sequence generation (selection bias)	The sample was not randomized	HIGH RISK
	Allocation concealment (selection bias)	There was no randomization of the sample	HIGH RISK
	Blinding of participants and personnel (performance bias)	Not applicable	HIGH RISK
	Blinding of outcome assessment (detection bias)	Not applicable	HIGH RISK
	Incomplete outcome data (attrition bias)	No missing outcome data	LOW RISK
	Selective reporting (reporting bias)	The study include all expected outcomes	LOW RISK

Smailiene, D., et al., 2013 <sup>4</sup>	Random sequence generation (selection bias)	Simple randomization	LOW RISK
	Allocation concealment (selection bias)	Randomized allocation, but does not make clear the secrecy	UNCLEAR RISK
	Blinding of participants and personnel (performance bias)	Article does not report on blinding, only that the steps were not performed by the same operator	UNCLEAR RISK
	Blinding of outcome assessment (detection bias)	Article does not report on blinding, only that the evaluator is an expert and has been calibrated	UNCLEAR RISK
	Incomplete outcome data (attrition bias)	No missing outcome data	LOW RISK
	Selective reporting (reporting bias)	The study include all expected outcomes	LOW RISK
Smailiene, D., et al., 2013 <sup>5</sup>	Random sequence generation (selection bias)	Simple randomization	LOW RISK
	Allocation concealment (selection bias)	Randomized allocation, but does not make clear the secrecy	UNCLEAR RISK
	Blinding of participants and personnel (performance bias)	Article does not report on blinding, only that the steps were not performed by the same operator	UNCLEAR RISK
	Blinding of outcome assessment (detection bias)	Article does not report on blinding, only that the evaluator is an expert and has been calibrated	UNCLEAR RISK
	Incomplete outcome data (attrition bias)	No missing outcome data	LOW RISK
	Selective reporting (reporting bias)	The study include all expected outcomes	LOW RISK



Parkin et al., 2013 <sup>6</sup>	Blinding of participants and personnel (performance bias)	It was not possible to mask those administering the surgical treatment; Therefore, there was an unavoidable risk of treatment bias. For measurement purposes, a masked assessor would probably be able to guess which canine was previously impacted, owing to positional differences, but would not be able to tell which technique was used	LOW RISK
	Allocation concealment (selection bias)	Allocation concealment was done with consecutively numbered, sealed, opaque.	LOW RISK
	Random sequence generation (selection bias)	The randomization was undertaken using computer-generated random numbers to ensure that equal numbers were allocated to each intervention.	LOW RISK
	Blinding of outcome assessment (detection bias)	The examiners were masked as to the patient's group allocation for the clinical examinations. The patient details were removed from all study models and radiographs, which were labeled with only the participant's randomization number	LOW RISK
	Incomplete outcome data (attrition bias)	No missing outcome data.	LOW RISK
	Selective reporting (reporting bias)	All of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported.	LOW RISK

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1 **3b** - Risk of bias for the studies included in the qualitative and quantitative analysis, assessed by “Meta-Analysis of Statistics Assessment and Review Instrument”  
 2 (MAStARI) critical appraisal tools. Risk of bias was categorized as High when the study reaches up to 49% score “yes”, Moderate when the study reached 50%  
 3 to 69% score “yes”, and Low when the study reached more than 70% score “yes”.

4 **3.1** - Studies included in the qualitative analysis

5 **A** – *Cross-sectional. Descriptive Studies.*

Question	Answer															
	Becker, A., et al., 2002 <sup>7</sup>	Becker, A., et al., 1983 <sup>8</sup>	Bollero, P., et al., 2017 <sup>9</sup>	Caprioglio et al., 2019 <sup>10</sup>	Cercadillo - Ibauguren, I., et al., 2011 <sup>11</sup>	Chauhu, S., et al., 2003 <sup>12</sup>	Chauhu, S., et al., 2009 <sup>13</sup>	Crescini, A., et al., 2007 <sup>14</sup>	Crescini, A., et al., 2007 <sup>15</sup>	Evren, A. D., et al., 2014 <sup>16</sup>	Kohavi, D., et al., 1984 <sup>17</sup>	Landim, F. S., et al., 2010 <sup>18</sup>	Lee, J. Y., et al., 2010 <sup>19</sup>	Odenrick, L. and T. Modeer, 1978 <sup>20</sup>	Quiryren, M., et al., 2000 <sup>21</sup>	Zasciurinskie et al., 2008 <sup>22</sup>
1. Was the study based on a random or pseudorandom sample?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
2. Were the criteria for inclusion in the sample clearly defined?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	U	Y	Y
3. Were confounding factors identified and strategies to deal with them stated?	U	U	U	Y	U	U	U	U	U	U	U	U	U	U	N	N
4. Were outcomes assessed using objective criteria?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	U	Y	U	Y	Y
5. If comparisons are being made, was there sufficient description of the groups?	Y	Y	Y	Y	Y	Y	Y	NA	NA	Y	Y	N	Y	U	Y	Y
6. Was the follow up carried out over a sufficient time period?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	U	U	Y

7. Were the outcomes of people who withdrew described and included in the analysis?	U	U	Y	U	Y	Y	N	Y	Y	Y	N	Y	N	N	N	U
8. Were the outcomes measured in a reliable way?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	U	Y	U	Y	Y
9. Was an appropriate statistical analysis used?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	U	Y	Y
% yes/risk	66.6% Moderate	66.6% Moderate	77.7% Low	77.7% Low	77.7% Low	77.7% Low	66.6% Low	75% Low	75% Low	77.7% Low	66.6% Moderate	22.2% High	66.6% Moderate	0% High	55.5% Moderate	66.6% Low

1 Legend - \*Y=Yes, N=No, U=Unclear, NA=Not applicable

2

1 **B - Cohort Study/ case-controlled studies.**

2

Question	Crescini, A., et al., 1994 <sup>23</sup>	Crescini, A., et Al., 2007 <sup>24</sup>	Crescini, A., et Al., 2007 <sup>25</sup>
	1. Was the sample representative of patients in the population as a whole?	Y	Y
2. Were the patients at a similar point in the course of their condition/illness?	Y	Y	Y
3. Had bias been minimized in relation to selection of cases and of controls?	Y	Y	Y
4. Were confounding factors identified and strategies to deal with them stated?	N	N	N
5. Were the outcomes assessed using objective criteria?	Y	Y	Y
6. Was follow-up carried out over a sufficient time period?	Y	Y	Y
7. Were the outcomes of people who withdrew described and included in the analysis?	N	Y	Y
8. Were outcomes measured in a reliable way?	Y	Y	Y
9. Was appropriate statistical analysis used?	Y	Y	Y
% yes/risk	77.7% Low	88.8% Low	77.7% Low

3 Legend - Y=Yes, N=No, U=Unclear, NA=Not applicable.

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1 **Appendix 4 - Evaluation of the certainty of evidence by the GRADE tool, for the different periodontal parameters evaluated.**

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Anticipated absolute effects
			Periodontal aspects in impacted teeth
Plaque Index	347 (11 observational studies)	⊕⊕○○ LOW	MD <b>0.07 lower</b> (0.27 lower to 0.14 higher)
Gingival index	295 (10 observational studies)	⊕⊕○○ LOW	MD <b>0.25 higher</b> (0.1 higher to 0.4 higher)
Probing pocket depth	887 (17 observational studies)	⊕⊕○○ LOW	MD <b>0.14 higher</b> (0.07 higher to 0.2 higher)
Width of Keratinized tissue (mm)	534 (8 observational studies)	⊕○○○ VERY LOW <sup>a</sup>	MD <b>0.23 higher</b> (0.21 lower to 0.66 higher)

\*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; MD: Mean difference

**GRADE Working Group grades of evidence**

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

2 Explanations

3 a. Source of heterogeneity was not detected, persisting even after subgroup analysis

1 **ARTIGO 2 – VERSÃO EM INGLÊS (submetido no periódico Clinical Oral**  
2 **Investigations – Qualis A1/IF 3.573)**

3

4 **Risk factors associated with the stability of mini-implants and mini-plates:**  
5 **systematic review and metanalysis**

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16

1 **Abstract**

2

3 *Objective:* The objective of this systematic review is to answer the following question:  
4 "What are the risk factors associated with the stability of mini-implants and mini-  
5 plates?" *Material and methods:* Search strategies were developed for each electronic  
6 database (PubMed/Medline, LILACS, Scopus, Web of Science, Embase, and  
7 Cochrane Library) and gray literature (Google Scholar, Proquest, and Open Grey). The  
8 risk of bias was assessed using the Cochrane Collaboration tool for assessing the risk  
9 of bias and Meta-Analysis of Statistics Assessment and Review Instrument. The  
10 certainty of the evidence was assessed using the GRADE tool. Meta-analyses and  
11 meta-regressions of random effects were performed for the outcomes of interest.  
12 *Results:* A total of 1,517 articles were found, of which seven were selected for  
13 quantitative synthesis. When comparing the risk of failure between mini-implants and  
14 mini-plates, the risk values approached the threshold of statistical significance ( $p =$   
15  $0.07$ ) ( $RR = 1.83$ ;  $95\% CI = 0.96 - 3.50$ ;  $I^2 = 69\%$ ), showing significance after sensitivity  
16 analysis ( $p < 0.05$ ) and a greater risk for mini-implants. Mandible installation presented  
17 a higher risk of failure ( $RR = 1.85$ ;  $95\% CI = 1.17 - 2.91$ ). *Conclusions:* The evidence  
18 found indicates that failure in the stability is related to the type of device and that there  
19 is a greater risk by using isolated mini-implants, especially when positioned in the  
20 mandible. *Clinical relevance:* These findings, help the orthodontist and/or the surgeon  
21 to stipulate risks, learn about the predictability of techniques, and communicate with  
22 the patient in an easier way.

23

24 *Keywords:* temporary anchoring devices, mini-implant, mini-plate, stability, systematic  
25 review

1 **Introduction**

2 Temporary anchorage devices (TADs) are widely used in orthodontic  
3 mechanics to expand the limit of tooth movement through skeletal anchorage [1-  
4 4]. TADs are a helpful treatment alternative in complex malocclusions, especially  
5 those with vertical discrepancies, such as open bite and dental extrusions due to  
6 the loss of the antagonistic tooth [5-10].

7 The treatment for some severe discrepancies is usually surgical and  
8 sometimes invasive. Before orthodontists knew and used TADs, it was common  
9 to solve a case of dental extrusion with endodontic treatment and a fixed  
10 prosthesis. The use of these anchoring devices has shown a lower risk to the  
11 individual, as it is a more conservative treatment with satisfactory results [5-7].  
12 Skeletal anchorage with these devices is versatile and effective in treating all  
13 types of malocclusions when not associated with the need for extensive surgical  
14 interventions to achieve a harmonious skeletal relation [10, 11].

15 Studies using mini-plates for skeletal anchorage have decreased  
16 undesirable dental effects and significant skeletal effects [12-15]. There has been  
17 a substantial decrease in treatment time of patients with Angle Class III  
18 malocclusions [15]. The mini-implants may also provide skeletal anchorage for  
19 orthodontic movement [11, 12] by presenting an easier insertion or removal,  
20 besides a lower cost [12, 16]. However, the stability of TADs depends on the  
21 mechanical locking that occurs in bone tissue, unlike dental implants whose main  
22 stability is directly related to the osseointegration process. This mechanical  
23 stability allows the device to withstand tooth movement without requiring healing  
24 periods [1, 17, 18]. Some risk factors can be associated with loss of stability, such  
25 as the type of device, screw diameter and presence of inflammation in the soft  
26 tissue around the device[19].

27 There are no systematic reviews on risk factors associated with the  
28 stability of mini-implants compared to mini-plates; there are only studies reporting  
29 isolated data on these devices [11, 19-25], justifying the conduction of a  
30 systematic review on the subject. Thus, the objective of the present study is to  
31 answer the following focused question: "What are the risk factors associated with  
32 the stability of mini-implants and mini-plates?"

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**Material and Methods**

*Eligibility criteria*

To consider the eligibility of studies to be included/excluded in this review, the acronym "PICOS" was considered:

- Population (P) – Patients undergoing orthodontic treatment with TADs for skeletal anchorage;
- Intervention (I) – Mini-implants;
- Comparison (C) – Mini-plates;
- Outcomes (O) – Risk factors associated with the stability of TADs (type of device, place of installation, type of the soft tissue and width/diameter of the screw used, average age of the sample);
- Study design (S) – Randomized, pseudo-randomized, or non-randomized clinical studies, cross-sectional observational studies, cohort, or case control.

*Inclusion Criteria*

The studies included had necessarily evaluated patients with mini-implants, patients with mini-plates and the factors associated with failure in stability of the TADs in the same study were included, to allow inferences on risk association between both methods. Randomized, pseudo-randomized, non-randomized, prospective, or retrospective observational studies were included in controlled clinical trials. There was no restriction to the type of malocclusion, gender, and age. There was also no restriction to the language of the study and time of publication.

*Exclusion criteria*

The following exclusion criteria were considered:

- Studies on animals or those including patients with syndromes associated with dentofacial deformities;
- Studies that have not compared patients with mini-implants and patients with mini-plates;

- 1 • Studies in which none of the variables of interest have been evaluated;  
2 • Reviews, letters, conference summaries, expert opinions, reports, and  
3 case series.

#### 4 *Sources of information and search strategy*

5 Combinations of words and appropriate truncations were selected and  
6 adapted for each database search. Search strategies were developed specifically  
7 for each of the following electronic databases: PubMed/Medline, LILACS,  
8 Scopus, Web of Science, Cochrane Library, and Embase. In addition, the search  
9 for gray literature was carried out on Google Scholar, Proquest, and Open Gray  
10 (appendix 1). All searches were carried out on November 10, 2019 and updated  
11 on May 6, 2021.

12 Finally, a manual search of references of the studies included was carried  
13 out, and an expert on the subject was also consulted to verify any possible  
14 publications on the topic. The EndNote® software (EndNote® X7 Thomson  
15 Reuters, Philadelphia, PA) was used to manage and remove duplicate  
16 references.

#### 17 *Selection process*

18 The selection of articles was carried out in two phases. In phase 1, two  
19 reviewers (P.M.M. and I.B.B.) independently reviewed the titles and abstracts of  
20 all references. All studies that did not meet the inclusion criteria were excluded.  
21 In phase 2, the same reviewers performed a full reading of the selected articles  
22 independently. In case of disagreement, which was not resolved through  
23 discussion between the first and second reviewers, a third author (C.M.A.) was  
24 involved in the final decision.

25 To protect the reading of references and ensure independence and  
26 confidentiality in both phases, the Rayyan website (<http://rayyan.qcri.org>) was  
27 used, where the reviewers were blinded in all evaluations and a member of the  
28 team (C.M.A.), who did not participate in the selection, served as moderator.

#### 29 *Data collection process*

30 Two reviewers (P.M.M. and I.B.B.) collected information from the included  
31 studies, which was then discussed. The data collected consisted of study

1 characteristics (authors, year of publication, country, study design), population  
2 characteristics (sample size, age), evaluation characteristics (composition of the  
3 control and experimental groups, number of evaluators, parameters of interest,  
4 method of evaluation of outcomes, index used for assessment), characteristics  
5 of results (results presented concerning the effect), and main conclusions.

6 If any data were missing or incomplete in the article, attempts were made  
7 to contact the authors to obtain relevant unpublished information.

8 Three attempts were made to contact the first author, the corresponding  
9 author, and the last author of the article, and the time interval between attempts  
10 was one week. In case of non-response, the article was excluded with due  
11 justification.

## 12 *Data items*

13 The frequency of events of device loss was extracted from the studies  
14 included considering the type of device, the arch in which it was installed, and the  
15 characteristic of the gingival tissue where it was inserted. Possible confounding  
16 factors were also extracted concerning the estimation of effects, such as the  
17 mean age of participants and the diameter of the screw used in the study.

18

## 19 *Study risk of bias assessment*

20 The methodology of the selected observational studies was assessed  
21 using the Meta-Analysis of Statistics Assessment and Review Instrument  
22 (MASTARI) risk of bias tool for observational studies. The risk of bias was  
23 categorized as "high" when the study had a "yes" score lower than 50%;  
24 "Moderate" when the study presented between 50% to 69% of score "yes"; and  
25 "low" when the study showed more than 70% of score "yes" for questions of risk  
26 of bias.

27 For interventional studies, the "Cochrane Collaboration tool for assessing  
28 the risk of bias" was used. This tool covers seven domains: generation of random  
29 sequence, concealment of allocation, blinding of participants and professionals,  
30 blinding of outcome evaluators, incomplete outcomes, selective outcome  
31 reporting, and other sources of bias. The judgment regarding the possible risk of  
32 bias in each of these domains was made based on the information extracted from  
33 the study and classified as "high risk" or "low risk" of bias. If there were not

1 enough details reported in the study, the risk of bias was judged as "unclear," and  
2 the authors of the original study were contacted for further information. The  
3 judgments were made by two independent reviewers (P.M.M and I.B.B).  
4 Disagreements were first solved by discussions, and in case of non-consensus,  
5 the third reviewer (C.M.A) was consulted for the tiebreaker vote.

### 6 *Effect measures*

7 As the outcome chosen is binary, the relative risk was calculated to assess  
8 the association between the loss of the device related to the variables of interest.

### 9 *Synthesis methods*

10 A method of meta-analysis of random effects using the RStudio statistical  
11 software v. 1.2.1335 (Rstudio Inc, Boston, USA) was carried out. The studies  
12 were weighted by the Mantel-Haenszel method. The heterogeneity was  
13 calculated by the inconsistency index ( $I^2$ ) and the variance by  $\text{Tau}^2$ , estimated by  
14 the DerSimonian-Laird method. Possible confounding factors, where there was  
15 no direct comparison (pair by pair), were evaluated by meta-regression with  
16 random effect models to verify whether the variance in the effect estimates  
17 (failure prevalence) observed was explained by these covariables. For this, the  
18 failure frequency data were transformed by the Freeman-Tukey arcsine double  
19 method to follow an approximately normal distribution, and a bubble plot graph  
20 was generated for analysis.

21 A sensitivity analysis was performed to assess whether studies classified  
22 as high risk of bias affected the size of the summary effect. 95% confidence  
23 intervals were considered (95% CI), and the level of significance was 5%.

24

### 25 *Reporting bias assessment*

26 In case it was impossible to carry out evaluations using the funnel plot (n  
27 <10) to avoid publication bias, a broad search was carried out in several  
28 databases, including a database in a language other than English (LILACS), and  
29 also a search in the gray literature was performed.

1 *Certainty assessment*

2       The certainty of evidence was assessed using the GRADE tool [26] in all  
3 domains of risk of bias, consistency, accuracy, precision, and publication bias.  
4 Quality was judged as high, moderate, low, or very low.

5

6 **Results**

7 *Study selection*

8       The elaborated research strategy resulted in 1,707 articles after searching  
9 the databases. Excluding duplicate articles, 1,482 articles proceeded for reading  
10 the titles and abstracts (phase 1). Of these articles, 28 were read in full (phase  
11 2), of which 21 were excluded (appendix 2), resulting in seven articles for  
12 qualitative synthesis (Fig 1).

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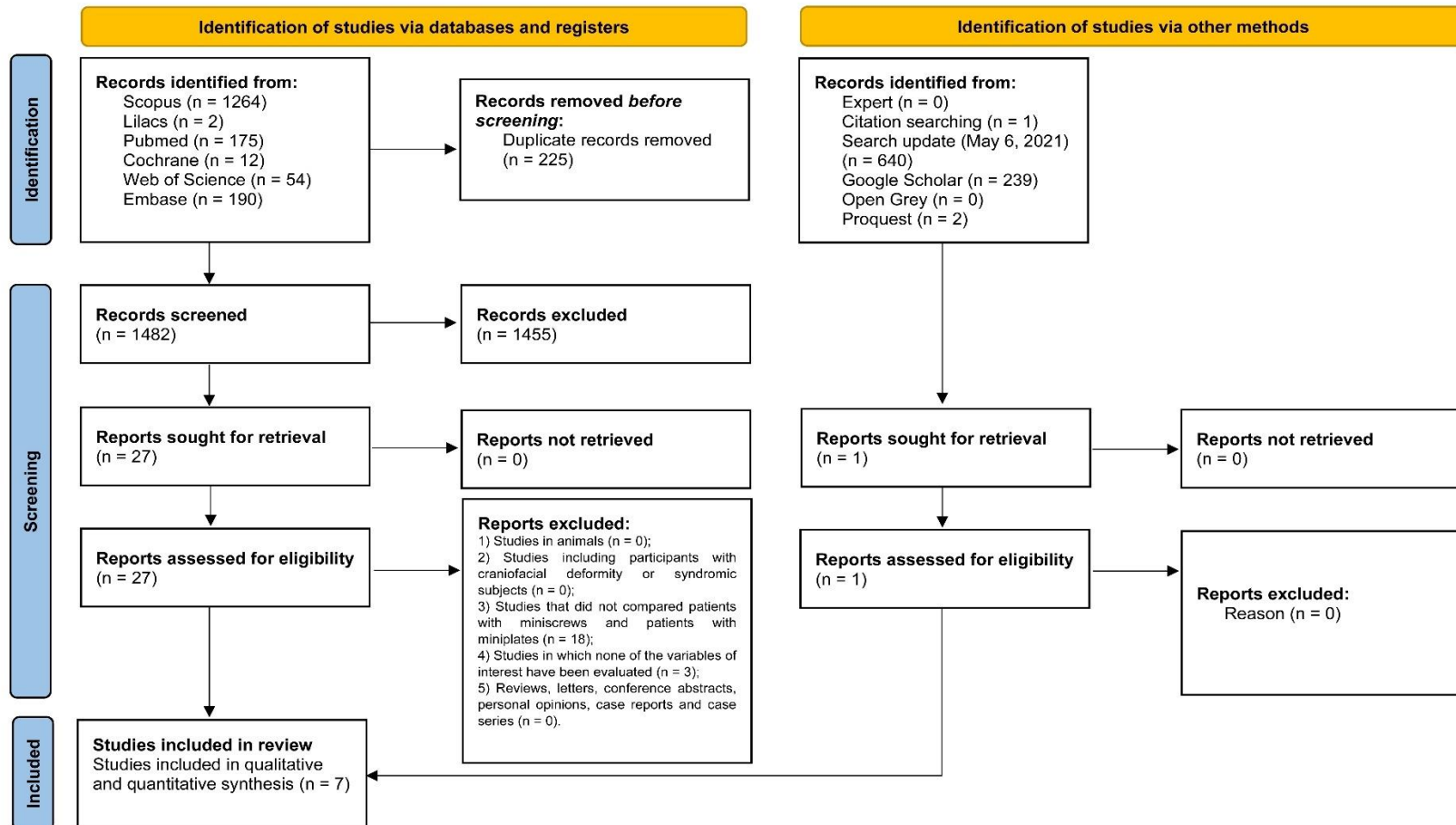
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**Figure 1 - Flowchart of literature search and selection criteria**

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources



From: 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. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: <http://www.prisma-statement.org/>

1 *Study characteristics*

2 All articles included were published in English in China, Japan, and  
3 Taiwan.

4 The sample sizes varied between 44 and 455 patients, with the average  
5 age ranging between 21.8 and 29.3 years. The included studies that reported the  
6 gender in samples showed a higher percentage of female patients (78%) than  
7 males (22%).

8 As for the study design, six articles were observational cross-sectional,  
9 and one was a randomized clinical trial. Four of the seven articles included  
10 directly evaluated the failure rate of the devices compared considering patients  
11 who used mini-plates and mini-implants of different sizes as a sample; these  
12 plates and implants were of titanium or stainless steel, pre-drilled, self-drilling, or  
13 palatal. The other three articles assessed success rates, indirectly assessing the  
14 factors that affect failure rates, factors associated with post-operative stability,  
15 pain or discomfort. These factors related to the implantation, type of device, and  
16 the proposed movement with the installation of devices. Other factors could also  
17 be related to the patient, such as age, gender, bone density, and the angle of the  
18 mandibular plane. Table 1 shows all characterization data of the studies.

1 **Table 1** - Characteristics of the studies included (n = 7)

Study, Author/Year (Country)	Sample (gender / device types)	Diameter and length of DATs	Age (Median or Mean $\pm$ SD)	Risk factors	Results	Conclusions
Chen, Y. J., et al., 2007 (Taiwan)	359 devices / 129 patients (25 M, 104 F / 86 miniplates, 201 mini-implants)	miniplates (2mm diameter screws, length 5-9mm) / mini-implants (2mm diameter, length 5-21mm)	24.5 $\pm$ 7.1	Gender, age, type of malocclusion, local treatment or total arch, installation site, proposed movement, method of applied force and healing time.	<p>There was no statistical difference in the factors gender, type of malocclusion, local treatment or full arch, buccal or lingual installation, length, load pattern and duration of the healing phase. Statistical difference for age (greater risk of failure in young patients), proposed movement (retraction or protraction), arch (mandible, region anterior to the 2nd premolars) and type of device (mini-implant - 66% - and micro-implants - 32.1% )</p> <p>After adjusting for potential confounding effects, only three factors (type of device, placement in the mandibular arch, and age) were considered statistically significant in predicting failure.</p>	Mini-implants installed in younger patients and in the mandibular arch have a higher risk of failure. The miniplate system has greater stability compared to mini-implants.

Chen, Y. J., et al., 2008 (Taiwan)	194 patients (42 M, 152 F /171 miniplates, 264 pre-drilled mini-implants and 57 self-drilling mini-implants)	miniplates (diameter 2mm pre-drilling screws, length 5-9mm) / pre- and self-drilling mini-implants (diameter 2mm, length 8-14mm)	25.1 +-8.7	Gender, age, type of malocclusion, facial divergence, proposed movement, method of applied force, device type, insertion site, bone density, soft tissue around device, degree of tissue inflammation, healing time, and operator.	There were no significant differences for the factors: sex, type of malocclusion, facial divergence, implantation site, location, method of force application, arch, type of soft tissue, type of examiner who installed and most cephalometric measurements that reflect the dentocraniofacial features. A significant failure rate was observed for the self-drilling mini-implant, used for uprighting teeth, inserted into bone with lower density, associated with local inflammation of the surrounding soft tissue, loaded within 3 weeks after insertion and installed in patients with greater mandibular retrusion.	Soft tissue inflammation around a TAD and early loading within 3 weeks of insertion were the most significant predictors of TAD failure.
Cheng, S. J., et al., 2004 (Taiwan)	44 patients (6 M, 38 F / 48 miniplates, 92 mini-implants)	miniplates (screws diameter 2 or 2.3mm length 5-15mm or 5-7mm / mini-implants diameter 2 or 2.3mm length 5-15mm or 5-7mm)	29+-8.9	Device type, mini-implant length, magnitude of orthodontic load, insertion site, and soft tissue around the device.	The cumulative success rate was 89% (125/140). There was no significant difference in the success rate between miniplates and independent mini-implants. The Cox proportional hazards regression model identified the anatomical location and character of the peri-implant soft tissue as 2 independent prognostic indicators. The estimated relative risk of implant failure in the posterior mandible was 1.101 (95% confidence interval, 0.942-1.301; p = 0.046). The risk of failure ratio for implants surrounded by non-keratinized mucosa was 1.117 (95% confidence interval, 0.899 to 1.405; p = 0.026).	The results confirmed the effectiveness of orthodontic mini-implants, but in certain situations the adjustment of the treatment plan or modifications in the implant placement technique can lead to better success rates.

<p>Yao, C. C., et al., 2015 (Taiwan)</p>	<p>220 patients (66 M, 154 F / 159 miniplates, 388 pre-drilled titanium mini- implants and 180 stainless steel self- drilling mini-implants)</p>	<p>ND</p>	<p>median 29.3</p>	<p>Gender, age, type of malocclusion, facial divergence, device type, insertion site, bone density, soft tissue around the device, soft tissue inflammation, and healing time.</p>	<p>The failure rate for miniplates was significantly lower than for mini-implants. The stability of pre-drilled titanium mini-implants and stainless steel self-drilling mini-implants were comparable to the first implantation. In the second implantation, the failure rate of stainless steel mini-implants increased. The following had a significant influence on mini-implant failure rates: age (35 years), type of mini-implant (self-drilling), implantation site (bone crest), late loading (after 30 days) and soft tissue characteristics around the mini-implants.</p>	<p>The stability of orthodontic mini-implants depends on the type of mini-implant, the patient's age, the implantation site and the healing time. Miniplates are a more viable anchorage system when mini-implants repeatedly fail.</p>
<p>Takaki, T., et al., 2010 (China)</p>	<p>455 patients (97 M, 358 F / 225 self- drilling mini-implants and 444 mini-plates)</p>	<p>Self-drilling mini-implants (diameter 1.4mm, length ND)</p>	<p>25.7 +-9.8</p>	<p>Soft tissue inflammation and granulation tissue formation.</p>	<p>Each type of device had a high success rate (about 90%). Failure rates were as follows: mini-screws, 6% and miniplates, 6%. The rate of inflammation in the soft tissue around the TADs was as follows: plaque, 7.6%; mini-screws, 1.3%. The frequencies of inflammation with the rate of granulation in the soft tissues around the TADs were: self-drilling mini-screws, 0%; plate, 0.9%.</p>	<p>Success rates were 94% for miniplates and mini-implants, 93%. The highest failure rate occurred in the palatal region of a young patient, the same with mini-implants in the alveolar region of the mandible. The rate of inflammation of the surrounding soft tissue was highest with the plate-type devices (acute inflammation), followed by mini-implants.</p>

Kuroda, S., et al., 2007 (Japan)	75 patients (12 M 63 F / 37 type A mini-implants, 79 type B mini-implants and 38 mini-plates)	Miniplates (2mm diameter, length 5mm) / type A mini-implants (diameter 2.0 or 2.3 mm, length 7 or 11 mm, screw head 3 mm) / type B mini-implants (diameter 1.3 mm, length 6, 7, 8, 10 and 12 mm, screw head 3 mm)	21.8+-8.2	Gender, age, mandibular plane angle, periodontitis control, temporomandibular disorder symptoms, applied load and device length.	The success rate for each type of device was over 80%. No statistical difference between device types. The analysis of 79 mini-implants with 1.3 mm in diameter did not show significant relationships between the success rate and the variables: age, sex, mandibular plane angle, anteroposterior mandibular base relationship, periodontitis control, dysfunction symptoms temporomandibular, load and length. Type B mini-implants had a higher success rate for intrusion and a lower success rate in the molar region than in the premolar when installed via the buccal.	Mini-implants installed without flaps have higher success rates than mini-implants installed in flap or mini-plate surgery.
Miyawaki, S., et al., 2003 (Japan)	51 patients (9 M, 42 F / 10 type A mini-implants, 101 type B mini-implants, 23 type C mini-implants and 17 mini-plates)	Miniplates (diameter 2mm, length 5mm) / type A (diameter 1.0 mm, length 6 mm) / type B (diameter 1.5 mm, length 11 mm) / type C (diameter 2.3 mm, length 14 mm)	21.8+-7	Gender, age, mandibular plane angle, soft tissue inflammation, device length, surgical technique, time of load application, site of installation, pain and swelling after 1 week, tooth crowding, periodontitis with controlled resorption and symptoms of dysfunction temporomandibular.	The 1-year success rate of smaller diameter mini-implants (type A) was significantly lower than that of type B, type C or miniplates (10% higher success rate than types B and C). An elevated angle of the mandibular plane and inflammation of the peri-implant tissue were risk factors for mobility. There was no significant association between the success rate and the following variables: length, surgical technique, applied load, implantation site, age, sex, dental crowding, anteroposterior relationship of the base of the mandible, controlled periodontitis and symptoms of temporomandibular disorders.	A diameter of 1.0 mm or less, inflammation of the peri-implant tissue, and a high angle of the mandibular plane (thin cortical bone) were associated with mobility due to failure of the mini-implant installed in the posterior alveolar alveolar bone. Mini-implants with a diameter greater than 1.0 mm are desirable in patients with a medium to low mandibular plane angle. Mini-implants with a diameter greater than 2.3 mm, or with miniplates is desirable in patients with a high mandibular plane angle (thin cortical bone).

M, Male; F, Female; SD, Standard Deviation; TAD, Temporary anchorage device; ND, Not described

1 *Risk of bias in studies*

2       Among the six observational studies included, five had a low risk of bias,  
3 and only one had a high risk of bias. The only randomized clinical trial included  
4 presented three of the six domains with a high risk (50%), and the other domains  
5 were considered of low risk (appendix 3).

6

7 *Results of individual studies*

8       Six articles included compared some variables between mini-plates and  
9 mini-implants that showed statistical significance ( $p < 0.05$ ).

10       Comparing the types of TADs, the failure rate of mini-implants was  
11 significantly higher than that of mini-plates regardless of length and diameter.  
12 Studies comparing more than one type of mini-implant diameter and devices with  
13 a smaller diameter showed a higher failure rate [11, 19]. Two studies compared  
14 self-drilling mini-implants and those for pre-drilled regions, and there was a  
15 statistical significance in relation to self-drilling devices with a high failure rate [27,  
16 28].

17       The literature is controversial regarding the influence of age as a risk  
18 factor. There are results with no differences according to age [11, 19, 27] and  
19 results presenting a higher risk for younger patients in relation to device failure  
20 [28, 29].

21       The type of the soft tissue around the device were factors that had a  
22 significant influence on failures. Devices associated with inflammation in non-  
23 keratinized tissue, compared to regions of keratinized tissue, also showed a  
24 higher failure rate [19, 27, 28, 30].

25       Regarding the location of installation and the function of the TAD, three  
26 articles reported the increase in failure rates of devices installed in the mandible  
27 [29, 30], specifically in the posterior region [11, 29]. There was a high failure rate  
28 in devices installed for the purpose of retraction [27, 29], protraction [29], or  
29 buccal teeth [27].

30       Two articles cited the moment of load application as a reason for the failure  
31 rate, presenting data in a controversial way. An article showed the relation of the  
32 application of an early loading within three weeks after installation [27]. Another

1 article, after 30 days of installation, reported that the late load affected the failure  
2 of the device [28].

### 3 4 *Results of syntheses*

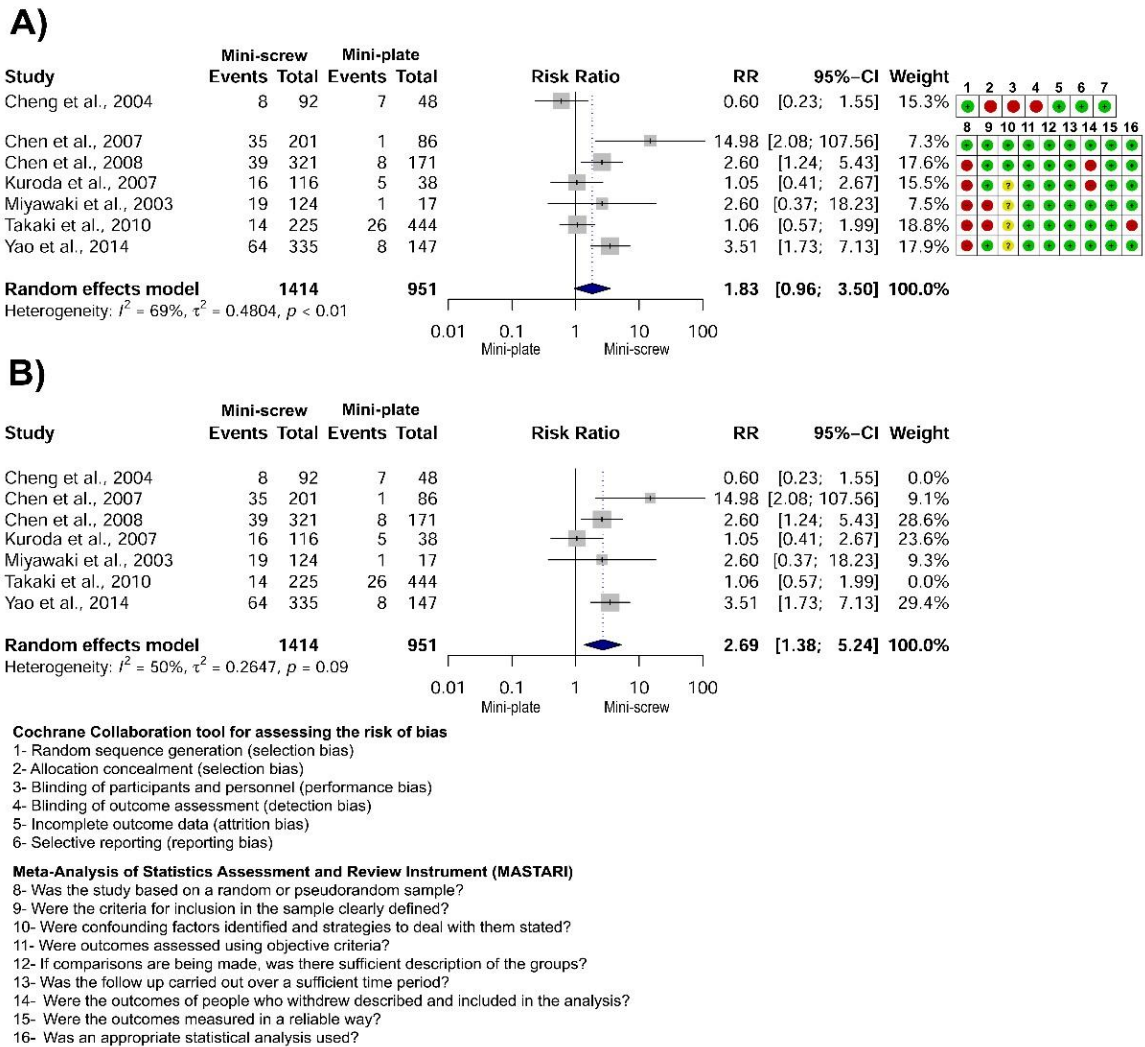
5 Seven articles underwent quantitative synthesis and random effect meta-  
6 analyses could be performed aiming the following outcomes: type of device, place  
7 of installation, and type of the soft tissue. Due to the lack of direct comparisons  
8 for the variables mean diameter of screw and mean age of the sample, underwent  
9 meta-regression of random effects.

10 When comparing the risk of failure between mini-implants and mini-plates,  
11 the risk values approached the threshold of statistical significance ( $p = 0.07$ ) ( $RR$   
12  $= 1.83$ ;  $95\% CI = 0.96 - 3.50$ ;  $I^2 = 69\%$ ) (Fig 2a). After conducting sensitivity  
13 analysis and excluding studies with a high risk of bias, there was a statistically  
14 significant difference, with a 2.69 times greater risk of mini-implants when  
15 installed individually compared to mini-plates [ $RR = 2.69$ ;  $95\% CI = 1.38 - 5.24$ ].  
16 There was a 19% decrease in the heterogeneity observed ( $I^2 = 50\%$ ;  $Tau^2 =$   
17  $0.264$ ;  $p = 0.09$ ) (Fig 2b).



1

2 **Figure 2** - Forest Plot graph to assess the association between the risk of failure when  
3 comparing mini-screws and mini-plates: a) analysis of all included studies, displaying risk  
4 of bias judgements for each study; b) sensitivity analysis, excluding studies with a high  
5 risk of bias.



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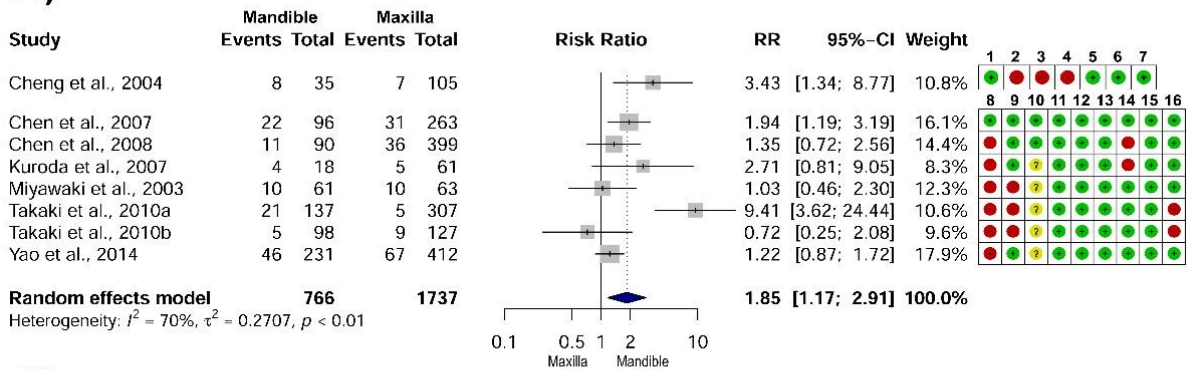
10 When assessing secondary outcomes, there was a greater risk of failure  
11 for anchoring devices when devices were installed in the mandibular arch,  
12 presenting a 1.85 times greater risk in this situation (RR = 1.85; 95% CI = 1.17 -  
13 2.91;  $I^2 = 70\%$ ) (Fig 3). With the exclusion of studies with a high risk of bias, the  
value of the relative risk showed a similar decrease as that of heterogeneity

1 between results [RR = 1.41; 95% CI = 1.11 - 1.79; I<sup>2</sup> = 0%]. However, it still had  
 2 a statistical significance.

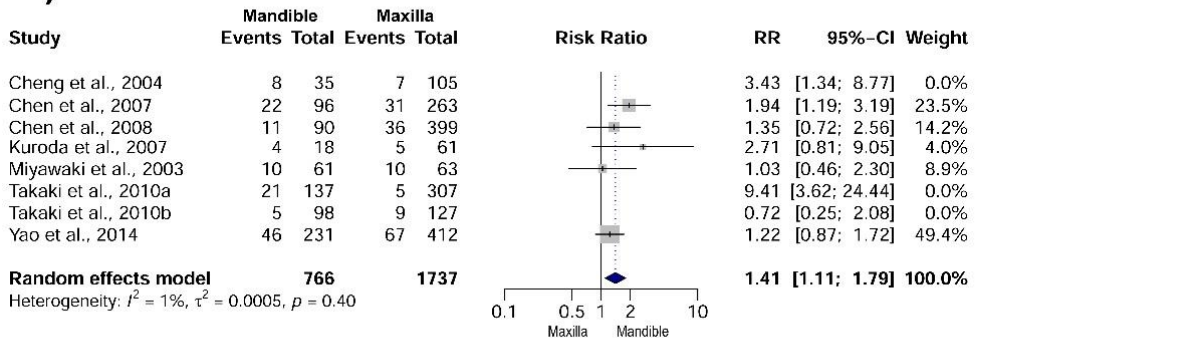
3 **Figure 3** - Forest Plot graph to assess the association between the risk of failure  
 4 according to the arch in which the anchoring device was installed: a) analysis with all  
 5 included studies, displaying risk of bias judgements for each study; b) sensitivity analysis  
 6 excluding studies with a high risk of bias.

7

**A)**



**B)**



**Cochrane Collaboration tool for assessing the risk of bias**

- 1- Random sequence generation (selection bias)
- 2- Allocation concealment (selection bias)
- 3- Blinding of participants and personnel (performance bias)
- 4- Blinding of outcome assessment (detection bias)
- 5- Incomplete outcome data (attrition bias)
- 6- Selective reporting (reporting bias)

**Meta-Analysis of Statistics Assessment and Review Instrument (MASTARI)**

- 8- Was the study based on a random or pseudorandom sample?
- 9- Were the criteria for inclusion in the sample clearly defined?
- 10- Were confounding factors identified and strategies to deal with them stated?
- 11- Were outcomes assessed using objective criteria?
- 12- If comparisons are being made, was there sufficient description of the groups?
- 13- Was the follow up carried out over a sufficient time period?
- 14- Were the outcomes of people who withdrew described and included in the analysis?
- 15- Were the outcomes measured in a reliable way?
- 16- Was an appropriate statistical analysis used?

8

9 There was no statistically significant difference when considering the type  
 10 of soft tissue in which the device was inserted even after performing the sensitivity  
 11 analysis (Fig 4). There was a 12% decrease in heterogeneity, with a substantial  
 12 level of variance between the effects of the studies included (Tau<sup>2</sup> = 0.237; p =

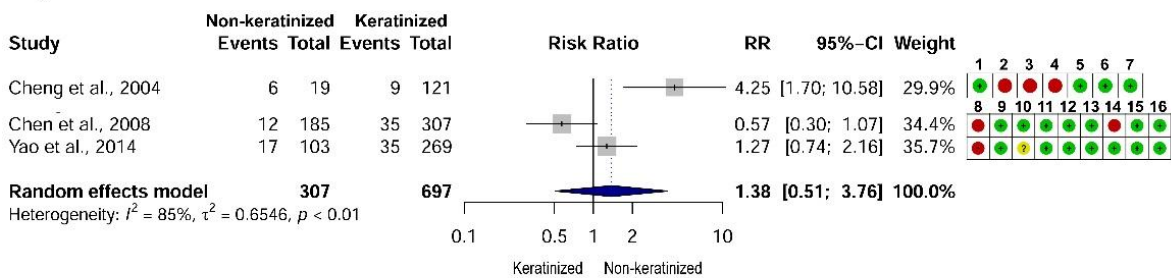
1 0.06). However, even with different directions of effects, both studies approached  
 2 the null line, showing no significance.

3

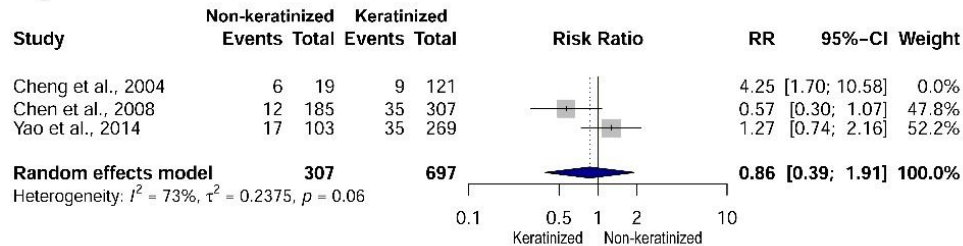
4 **Figure 4** - Forest Plot graph to assess the association between the risk of failure  
 5 according to the type of the soft tissue where the device was inserted: a) analysis with  
 6 all included studies, displaying risk of bias judgements for each study; b) sensitivity  
 7 analysis excluding studies with a high risk of bias.

8

**A)**



**B)**



**Cochrane Collaboration tool for assessing the risk of bias**

- 1- Random sequence generation (selection bias)
- 2- Allocation concealment (selection bias)
- 3- Blinding of participants and personnel (performance bias)
- 4- Blinding of outcome assessment (detection bias)
- 5- Incomplete outcome data (attrition bias)
- 6- Selective reporting (reporting bias)

**Meta-Analysis of Statistics Assessment and Review Instrument (MASTAR)**

- 8- Was the study based on a random or pseudorandom sample?
- 9- Were the criteria for inclusion in the sample clearly defined?
- 10- Were confounding factors identified and strategies to deal with them stated?
- 11- Were outcomes assessed using objective criteria?
- 12- If comparisons are being made, was there sufficient description of the groups?
- 13- Was the follow up carried out over a sufficient time period?
- 14- Were the outcomes of people who withdrew described and included in the analysis?
- 15- Were the outcomes measured in a reliable way?
- 16- Was an appropriate statistical analysis used?

9

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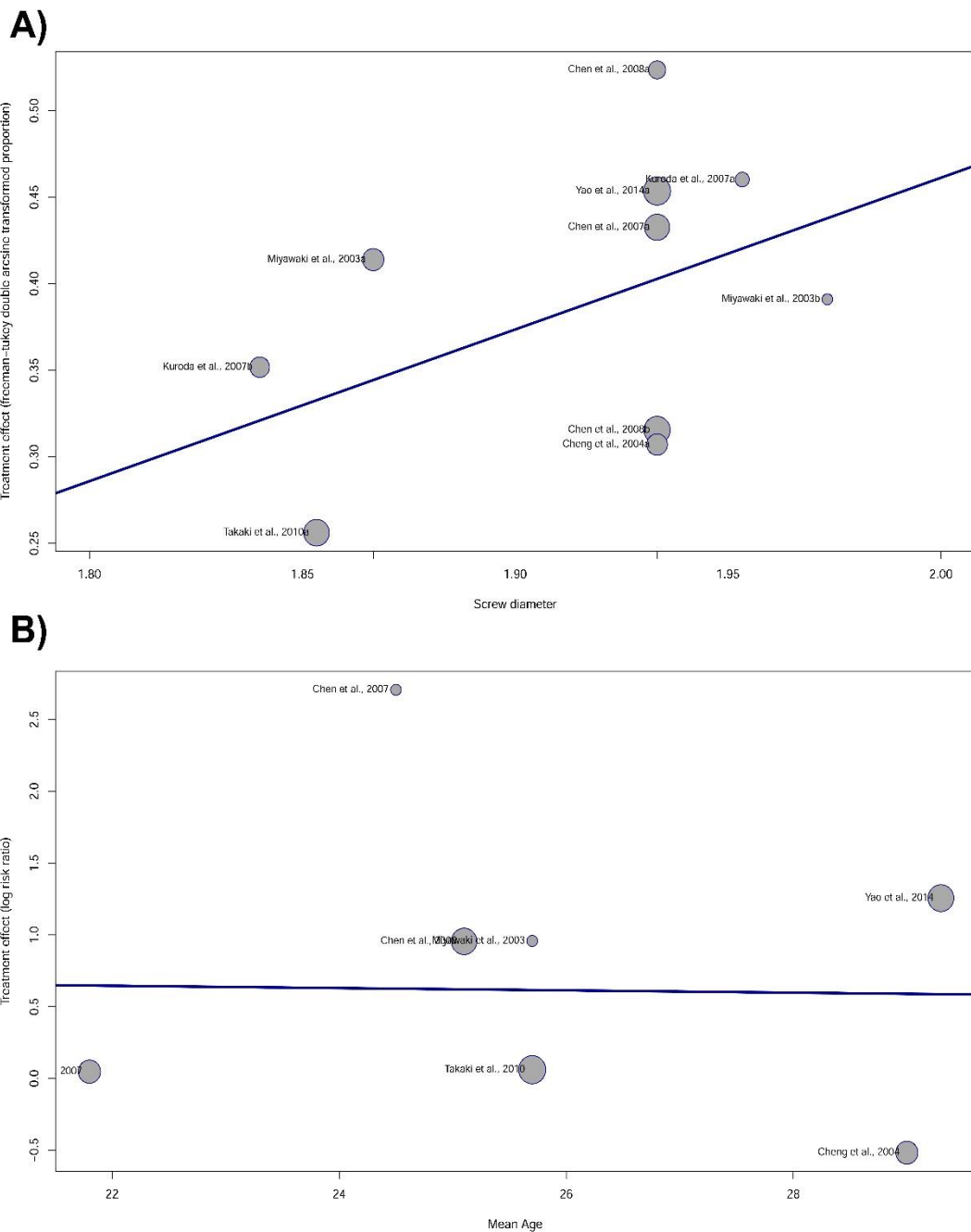
11 When considering confounding factors, the mean diameter of the screw  
 12 used in the study partially explained the regression model ( $R^2 = 21.24\%$ ).  
 13 However, the p-value was not significant for this model ( $p = 0.176$ ). In the same  
 14 meta, the covariable average age did not explain the variation between the sizes

1 of effects observed in the meta-analysis ( $p = 0.95$ ;  $R^2 = 0\%$ ); thus, there is no  
2 linear relation between these covariables and the observed effect size (Fig 5).

3

4 **Figure 5** - Bubble-plot graph for meta-regression: a) Prevalence of failures in mini-  
5 implants in relation to the diameter; b) Log of the relative risk of comparison of failures  
6 between mini-implants and mini-plates, which was regressed in relation to the average  
7 age of the sample.

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*Reporting biases*

Due to the number of studies included in the analysis, it was not possible to assess the presence of publication bias using the funnel plot. However, the inclusion of a Latin American database (LILACS) with a language other than English, the broad search strategy, and the search in gray literature, decrease the probability of occurrence of this bias.

*Certainty of evidence*

The certainty of evidence was very low for all comparisons. The domains related to risk of bias, imprecision, and inconsistency were responsible for the loss of score of the assessed certainty (appendix 4).

**Discussion**

This systematic review and meta-analysis analyzed the available evidence on risk factors related to the stability of mini-implants and mini-plates, as well as the type of device with a greater or a lesser risk of failure. Based on the current available literature and the eligibility criteria established for this systematic review, it was only possible to quantitatively analyze data regarding the type of device, the arch in which it was installed, and the type of the soft tissue where the device was inserted. In addition, the literature reported that the covariables screw diameter and mean age were possible confounding factors; as they were not directly compared in the studies, they were then meta-regressed. The results indicate that the installation of TADs in the lower arch (mandible) presents a significant risk of failure in relation to stability. There was a greater risk of failure when using isolated mini-screws. The demonstration of the tendency of the screw diameter affected the failure of the device but presenting a statistically non-significant result.

The mandibular bone has a higher density and cortical thickness than the maxilla, which may enable a greater stability of TADs through mechanical retention. According to Chen et al. [29], surgical factors such as overheating of perforation (when there is a harder bone in the jaw) or the amount of gingiva inserted (smaller in the jaw) may contribute to the high failure rate of the devices

1 installed. Accordingly, Cheng et al. [30] also report that posterior implants in the  
2 mandible region are more susceptible to infection because, in addition to the low  
3 amount of attached gingiva, there is a greater influence of food and difficulty in  
4 cleaning. The authors highlight overheating, especially in the use of self-drilling  
5 mini-implants, which contributes to the loss of stability and failure of devices. In  
6 the same sense, the data in the present review point to a greater risk of loss of  
7 devices when they are inserted in the lower arch, with a risk of failure 1.85 times  
8 greater when compared to insertion in the maxilla. However, the data are not  
9 statistically significant when considering the type of tissue to be inserted. The  
10 meta-analysis shows a difference in the direction of the effects observed between  
11 the studies included, requiring further studies to increase the certainty of evidence  
12 of this outcome in relation to non-significance.

13         Regarding the types of devices compared in this article and based on the  
14 results of the articles included that showed statistically significant results, the use  
15 of mini-implants associated with mini-plate shows a tendency towards a low  
16 failure rate, approaching the significance threshold ( $p = 0.07$ ). However, after  
17 excluding studies with a high risk of bias, there was a 2.69 times greater risk of  
18 failure of mini-implants compared to mini-plates. The use of mini-implants alone  
19 has some advantages, such as lower cost, versatility, and simple surgical  
20 installation compared to the association with mini-plates, which requires different  
21 surgical times for installation and removal [31]. Chen et al. [29] found an  
22 association between the type of movement performed with the device and the  
23 failure rates, which proved to be higher in regions where the device was installed  
24 for dental movements associated with retraction and protraction than for intrusion  
25 movements. The authors regarded it as a possible justification for failure rates to  
26 be lower in mini-plates because they were used for intrusion to a greater extent.  
27 In the same sense, the data in the present review point to a statistical significance  
28 as for the type of device installed. However, the type of orthodontic movement  
29 may act as a confounding factor not reported by the studies included, reducing  
30 the certainty of evidence of this outcome.

31         The stability of TADs occurs when there is mechanical retention of TADs  
32 to the bone tissue through bone-metal contact. Mini-implants are manufactured  
33 in different lengths and diameters, and studies such as that of Miyasaki et al. [19]

1 evaluated whether different lengths and diameters of mini-implants - that is,  
2 different areas of the bone-metal contact – affect the failure rates in terms of  
3 stability. The authors found a significant difference in stability in relation to the  
4 mini-implant diameter. They considered that a length from 5 mm is acceptable,  
5 since the highest success rate of the study occurred with the mini-plates (96.4%)  
6 and the length of the two screws installed was 5 mm. Regarding the diameter,  
7 the failure rate was higher in mini-implants with smaller diameters (100% for 1-  
8 mm diameter, 16.1% for 1.5-mm diameter, 15% for 2.3-mm diameter). In addition,  
9 they concluded that in regions with the thinnest cortical bone, the mini-implant  
10 with a larger diameter - in the study, 2.3 mm - are more suitable, and in regions  
11 with anatomical limitation and thicker cortical bone the thinnest mini-implant (1.5  
12 mm) must be used. The study of Kuroda et al. [11] used implants with a diameter  
13 of 1.3 mm in the sample and had a failure rate of 11.4%, concluding that mini-  
14 implants are as stable as mini-plates or mini-implants with a larger diameter, not  
15 substantially proving the diameter influence on stability. These data are in line  
16 with the findings of the present study, where there was no statistical significance  
17 when the screw diameter was measured in relation to the prevalence of failures.  
18 On the other hand, the diameter explained 21.24% of the regression model, thus  
19 denoting a trend. As the p-value is a probability that depends on the standard  
20 error, a greater number of future studies should be included in the analysis to  
21 guarantee a greater reliability in the meta-regression estimate.

22         Regarding age as a possible risk factor, Chen et al. [29] observed a higher  
23 failure rate in younger patients (<30 years), and considered that in older patients  
24 the cortical bone has a greater density and thickness, contributing to the  
25 mechanical retention and, consequently, to the stability of TADs. Likewise, Yao  
26 et al. [28] also observed that density and bone maturation affected the stability of  
27 devices. These factors may compromise the stability of anchoring devices,  
28 increasing the risk of failure in patients under 35 years old. On the other hand,  
29 other studies [11, 20, 31] did not find statistical significances in relation to age as  
30 a risk factor in relation to stability, which is consistent with the results of the  
31 present study. The meta-regression carried out considered the average age of  
32 the sample of the studies included. However, all studies had an average below  
33 35 years old; therefore, to confirm this finding, it is necessary that further studies

1 with an average age above 35 years old be performed and included in the  
2 regression analysis.

3 The results of this systematic review and meta-analysis reveal important  
4 data on risk factors related to the lack of stability and that may affect the loss of  
5 mini-implants and mini-plates. These findings, as they show the current stage of  
6 knowledge on the subject, help the orthodontist and/or the surgeon to stipulate  
7 risks, learn about the predictability of techniques, and communicate with the  
8 patient in an easier way. However, some limitations should be pointed out, such  
9 as the number of studies included and the study design – six studies included out  
10 of seven are observational. Confounding factors, such as the type of orthodontic  
11 movement performed, the complexity of cases, and the level of hygiene around  
12 the devices, in the absence of a process of randomization and control of these  
13 variables, may act by altering the observed effect and reducing the certainty of  
14 evidence. The inability to analyze quantitatively directly through the meta-  
15 analysis variables that may also influence the failure in relation to the stability of  
16 devices (such as screw diameter and average age) is also a limitation of this  
17 review. Thus, the present study emphasizes the need for further prospective,  
18 multicenter, randomized clinical studies that are well conducted methodologically  
19 in order to make the analysis more robust, with a greater control of possible  
20 confounding factors.

## 21 22 **Conclusion**

23 The evidence found in the literature indicates that failures in the stability of  
24 TADs is related to the type of device, with a greater risk for the use of isolated  
25 mini-implants, especially when positioned in the mandible. It is not possible to  
26 state that age affects the stability of these devices. There is a tendency for screw  
27 diameter in explaining the variance observed in the results. However, the number  
28 of available studies is not sufficient to confirm this finding. The type of orthodontic  
29 movement and hygiene around the devices may act as a confounding factor not  
30 reported by the studies included, reducing the certainty of evidence of this  
31 outcome.

32  
33



1 **Other information**

2 *Protocol and registration*

3 This systematic review was carried out in accordance with the PRISMA  
4 (Preferred Reporting Items for Systematic Reviews and Meta-Analysis Checklist)  
5 [32] and the protocol was registered at the PROSPERO website (International  
6 prospective register of systematic review - Center for Reviews and Dissemination  
7 University of York) - CRD42020222035.

8

9 **Compliance with ethical standards**

10 **Conflict of interest** The authors declare that they have no conflict of interest.

11 **Funding** No external funding was provided in regard with this study. The authors  
12 received no other institutional funding beyond their employment.

13 **Ethical approval** This article does not contain any studies with human  
14 participants or animals performed by any of the authors.

15 **Informed consent** For this type of study, formal consent is not required.

16

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1 **Appendices**

2 **Appendix 1 - Search strategy used in electronic databases**

<b>COCHRANE</b>	<p>(“miniplates” OR “miniplate” OR “mini-plate” OR “mini-plates”)  AND (“bone screw” OR “bone screws” OR “mini-implant” OR  “mini-implants” OR “mini implant” OR “mini implants” OR  “miniscrews” OR “miniscrew” OR “mini-screw” OR “mini-  screws”) AND (“risk factors” OR “risk factors” OR “stability”  OR “risk factor” OR “risk”)</p>
<b>LILACS</b>	<p>("miniplates" OR "miniplacas" OR "miniplate" OR "miniplaca"  OR "mini-plate" OR "mini-placa" OR "mini-plates" OR "mini-  placas") AND ("bone screw" OR "parafuso óseo" OR "tornillo  de hueso" OR "bone screws" OR "tornillo de huesos" OR  "parafusos óseos" OR "mini-implant" OR "mini-implante" OR  "mini-implants" OR "mini-implantes" OR "mini implant" OR  "mini implante" OR "mini implants" OR "mini implantes" OR  "miniscrews" OR "miniparafusos" OR "miniscrew" OR  "miniparafusos" OR "mini-screw" OR "mini-screws") AND  ("risk factors" OR "risk factors" OR "stability" OR "risk factor"  OR "risk" OR "factores de risco" OR "factores de riesgo" OR  "factor de riesgo" OR "estabilidad" OR "estabilidade" OR  "risco" OR "riesgo")</p>
<b>PUBMED</b>	<p>(“miniplates”[All Fields] OR “miniplate”[All Fields] OR “mini-  plate”[All Fields] OR “mini-plates”[All Fields])  (“bone screw”[MeSH] OR “bone screws”[All Fields] OR “mini-  implant”[All Fields] OR “mini-implants”[All Fields] OR “mini  implant”[All Fields] OR “mini implants”[All Fields] OR  “miniscrews”[All Fields] OR “miniscrew”[All Fields] OR “mini-  screw”[All Fields] OR “mini-screws”[All Fields])  (“Risk factors”[MeSH Terms] OR “risk factors”[All Fields] OR  “stability”[All Fields] OR “risk factor”[All Fields] OR “risk”[All  Fields])  #1 AND #2 AND #3</p>

<b>SCOPUS</b>	(“miniplates” OR “miniplate” OR “mini-plate” OR “mini-plates”) AND (“bone screw” OR “bone screws” OR “mini-implant” OR “mini-implants” OR “mini implant” OR “mini implants” OR “miniscrews” OR “miniscrew” OR “mini-screw” OR “mini-screws”) AND (“Risk factors” OR “risk factors” OR “stability” OR “risk factor” OR “risk”)
<b>EMBASE</b>	('miniplates' OR 'miniplate'/exp OR 'miniplate' OR 'mini-plate' OR 'mini-plates') AND ('bone screw'/exp OR 'bone screw' OR 'bone screws'/exp OR 'bone screws' OR 'mini-implant' OR 'mini-implants' OR 'mini implant'/exp OR 'mini implant' OR 'mini implants' OR 'miniscrews' OR 'miniscrew'/exp OR 'miniscrew' OR 'mini-screw' OR 'mini-screws') AND ('risk factors'/exp OR 'risk factors' OR 'stability'/exp OR 'stability' OR 'risk factor'/exp OR 'risk factor' OR 'risk'/exp OR 'risk')
<b>WEB OF SCIENCE</b>	TS=(“miniplates” OR “miniplate” OR “mini-plate” OR “mini-plates”) TS=(“bone screw” OR “bone screws” OR “mini-implant” OR “mini-implants” OR “mini implant” OR “mini implants” OR “miniscrews” OR “miniscrew” OR “mini-screw” OR “mini-screws”) TS=(“Risk factors” OR “risk factors” OR “stability” OR “risk factor” OR “risk”) #1 AND #2 AND #3
<b>GOOGLE SCHOLAR</b>	“miniscrew” AND “mini-plate”
<b>OPENGREY</b>	“miniscrew” AND “mini-plate”
<b>PROQUEST</b>	“miniscrew” AND “mini-plate”

1 **Appendix 2 - Excluded articles and reasons for exclusion (n = 21).**

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Author, Year	Reason for exclusion
Barros et al. 2011 <sup>1</sup>	3
Baxmann et al. 2010 <sup>2</sup>	3
Chang et al. 2015 <sup>3</sup>	3
Choi et al. 2005 <sup>4</sup>	3
Dobranszki et al. 2014 <sup>5</sup>	3
Findik et al. 2017 <sup>6</sup>	3
Hibi et al. 2010 <sup>7</sup>	3
Janson et al. 2013 <sup>8</sup>	3
Jing et al. 2016 <sup>9</sup>	3
Kim et al. 2016 <sup>10</sup>	3
Kuroda et al. 2007 <sup>11</sup>	3
Lai and Chen. 2014 <sup>12</sup>	4
Lam et al. 2018 <sup>13</sup>	3
Lee et al. 2008 <sup>14</sup>	3
Leung et al. 2008 <sup>15</sup>	3
Lin et al. 2015 <sup>16</sup>	3
Lu et al. 2011 <sup>17</sup>	4
Madalone et al. 2010 <sup>18</sup>	4
Rodrigues et al. 2014 <sup>19</sup>	3
Topouzelis and Tsaousoglou. 2012 <sup>20</sup>	3
Tsai et al. 2016 <sup>21</sup>	3

3 1) Studies in animals; 2) Studies including participants with craniofacial deformity  
 4 or syndromic subjects; 3) Studies that did not compared patients with miniscrews  
 5 and patients with miniplates; 4) Studies in which none of the variables of interest  
 6 have been evaluated; and 5) Reviews, letters, conference abstracts, personal  
 7 opinions, case reports and case series.

8

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1 **Appendix 3** – Risk of bias of the studies included in the qualitative and quantitative analysis assessed by: a) "Meta-Analysis of  
 2 Statistics Assessment and Review Instrument" (MAStARI) critical appraisal tools. Risk of bias was categorized as High when the  
 3 study reached up to 49% score "yes," Moderate when the study reached 50% to 69% of score "yes," and Low when the study reached  
 4 more than 70% score "yes."; b) Cochrane's tool to assess risk of bias in randomized controlled trials (Higgins et al 2011)<sup>1</sup>

5 **3.1** - Studies included in the qualitative analysis

6 **A** – *Cross-sectional. Descriptive Studies.*

Question	Chen, Y. J., et al., 2007 <sup>1</sup>	Chen, Y. J., et al. 2008 <sup>2</sup>	Kuroda , S., et al., 2007 <sup>3</sup>	Miyaw aki, S., et al., 2003 <sup>4</sup>	Takaki, T., et al., 2010 <sup>5</sup>	Yao, C. C., et al., 2015 <sup>6</sup>
	1. Was the study based on a random or pseudorandom sample?	Y	N	N	N	
2. Were the criteria for inclusion in the sample clearly defined?	Y	Y	Y	N	N	Y
3. Were confounding factors identified and strategies to deal with them stated?	Y	Y	U	U	U	U
4. Were outcomes assessed using objective criteria?	Y	Y	Y	Y	Y	Y
5. If comparisons are being made, was there sufficient description of the groups?	Y	Y	Y	Y	NA	Y
6. Was the follow up carried out over a sufficient time period?	Y	Y	Y	Y	Y	Y



7. Were the outcomes of people who withdrew described and included in the analysis?	Y	N	N	Y	Y	Y
8. Were the outcomes measured in a reliable way?	Y	Y	Y	Y	Y	Y
9. Was an appropriate statistical analysis used?	Y	Y	Y	Y	N	Y
% yes/risk	100% Low	87.5% Low	85.7% Low	85.7% Low	% High	87.5% Low

Legend - \*Y=Yes, N=No, U=Unclear, NA=Not applicable

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- 1
- 2 **b** – Cochrane’s tool to assessed risk of bias in randomized controlled trials (Higgins et al 2011)<sup>1</sup>

<b>Author, year</b>	<b>Questions</b>	<b>Support for judgement</b>	<b>Risk of Bias</b>
Cheng, S. J., et al., 2004 <sup>2</sup>	Random sequence generation (selection bias)	Simple randomization	LOW RISK
	Allocation concealment (selection bias)	Randomized allocation, but does not make clear the secrecy	HIGH RISK
	Blinding of participants and personnel (performance bias)	The authors did not report on how the allocation was carried out and whether there was confidentiality	HIGH RISK
	Blinding of outcome assessment (detection bias)	The authors did not report on how the allocation was carried out and whether there was confidentiality	HIGH RISK
	Incomplete outcome data (attrition bias)	No missing outcome data	LOW RISK
	Selective reporting (reporting bias)	The study included all expected outcomes	

			LOW RISK
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5 Orthodontic Anchorage. Int J Oral Maxillofac Implants 19(1): 100-106.  
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2 **Appendix 4** - Assessment of the Certainty of evidence by the GRADE tool for the different comparisons: a) risk of failure according to the type of  
 3 device; b) risk of failure according to the arch in which the anchoring device was installed; c) risk of failure according to the type of the soft tissue.

A)

Participants (studies) Follow up	Certainty assessment					Overall certainty of evidence	Study event rates (%)		Summary of findings		
	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias		With Mini-plate	With Mini-screw	Relative effect (95% CI)	Anticipated absolute effects Risk with Mini-plate	Risk difference with Mini-screw
<b>Failure</b> 2365 (7 observational studies)	serious <sup>a</sup>	serious <sup>b</sup>	not serious	not serious	none	⊕○○○ VERY LOW	56/951 (5.9%)	195/1414 (13.8%)	<b>RR 1.83</b> (0.96 to 3.50)	59 per 1.000	<b>49 more per 1.000</b> (from 2 fewer to 147 more)

4

5 B)

6

Participants (studies) Follow up	Certainty assessment					Overall certainty of evidence	Study event rates (%)		Relative effect (95% CI)	Anticipated absolute effects	
	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias		With Mandible	With Maxilla		Risk with Mandible	Risk difference with Maxilla
<b>Failure</b> 2503 (8 observational studies)	not serious	serious <sup>b</sup>	not serious	not serious	none	⊕○○○ VERY LOW	170/1737 (9.8%)	127/766 (16.6%)	<b>RR 1.85</b> (1.17 to 2.91)	98 per 1.000	<b>83 more per 1.000</b> (from 17 more to 187 more)

7 **CI:** Confidence interval; **RR:** Risk ratio

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c)

Participants (studies) Follow up	Certainty assessment					Overall certainty of evidence	Study event rates (%)		Summary of findings		
	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias		With non-keratinized	With Keratinized	Relative effect (95% CI)	Risk with non-keratinized	Risk difference with Keratinized
<b>Failure</b> 1004 (3 observational studies)	not serious	very serious <sup>c</sup>	not serious	very serious <sup>d</sup>	none	⊕○○○ VERY LOW	79/697 (11.3%)	35/307 (11.4%)	<b>RR 1.38</b> (0.51 to 3.76)	113 per 1.000	<b>43 more per 1.000</b> (from 56 fewer to 313 more)

5 **CI:** Confidence interval; **RR:** Risk ratio

6

7 **Explanations**

- 8 a. A study with a high risk of bias, altered the final effect estimate, verified by sensitivity analysis  
 9 b. Presence of substantial heterogeneity  
 10 c. Presence of substantial heterogeneity and different direction of effect  
 11 d. Wide confidence interval

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## **CONCLUSÕES GERAIS**

As evidências encontradas na atual literatura indicam que dentes tracionados ortodonticamente apresentaram piora nos parâmetros periodontais índice gengival e profundidade de sondagem, contudo, a profundidade de sondagem deve ser ponderada quanto ao seu significado clínico, devido ao pequeno tamanho de efeito observado. A falha na estabilidade dos DATs está relacionada com o tipo de dispositivo e o local da instalação, com maior risco para utilização de mini-implantes isolados e quando posicionados em mandíbula. O tipo de movimento ortodôntico e higiene ao redor dos dispositivos podem agir como fatores de confusão não descritos pelos estudos incluídos, diminuindo a certeza de evidência deste desfecho.

A falha na estabilidade dos DATs está relacionada com os fatores de risco tipo de dispositivo e local da instalação, sendo maior quando utilizados os mini-implantes isolados e posicionados em mandíbula. Não é possível afirmar que a idade pode afetar a estabilidade destes dispositivos. Houve tendência de que o diâmetro do parafuso explique a variância observada nos resultados, porém, o número de estudos disponíveis não é suficiente para afirmar esse achado. O tipo de movimento ortodôntico e higiene ao redor dos dispositivos podem agir como fatores de confusão não relatados pelos estudos incluídos, diminuindo a certeza de evidência deste desfecho.

1 **Normas para publicação – Clinical Oral Investigations**

2 Instructions for authors

3 Types of papers

4 Papers may be submitted for the following sections:

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6 Original articles

7 Invited reviews

8 Short communications – with up to 2000 words and up to two figures and/or tables

9 Discussion paper

10 Letters to the editor

11 It is the general policy of this journal not to accept case reports and pilot studies.

12 Editorial Procedure

13 If you have any questions please contact:

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15 University Hospital of Saarland

16 Department of Parodontology and Conservative Dentistry

17 Building 73

18 66421 Homburg/Saar

19 Germany

20 Email: [eic.hannig@uks.eu](mailto:eic.hannig@uks.eu)

21

22 Manuscript Submission

23 Submission of a manuscript implies: that the work described has not been  
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25 that its publication has been approved by all co-authors, if any, as well as by the  
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15 mainly geared towards first-time authors. At this point, more than 50 pages offer  
16 advice to authors on how to write and publish a journal article.

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21 The title page should include:

22 The name(s) of the author(s)

23 A concise and informative title

24 The affiliation(s) and address(es) of the author(s)

25 The e-mail address, telephone and fax numbers of the corresponding author

26

#### 27 Abstract

28 Please provide a structured abstract of 150 to 250 words which should be divided  
29 into the following sections:

30 Objectives (stating the main purposes and research question)

31 Materials and Methods

32 Results

33 Conclusions



1 Clinical Relevance

2 These headings must appear in the abstract.

3

4 Keywords

5 Please provide 4 to 6 keywords which can be used for indexing purposes.

6

7 Text

8 Text Formatting

9 Manuscripts should be submitted in Word.

10

11 Use a normal, plain font (e.g., 10-point Times Roman) for text.

12 Use italics for emphasis.

13 Use the automatic page numbering function to number the pages.

14 Do not use field functions.

15 Use tab stops or other commands for indents, not the space bar.

16 Use the table function, not spreadsheets, to make tables.

17 Use the equation editor or MathType for equations.

18 Save your file in docx format (Word 2007 or higher) or doc format (older Word  
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21 recommend using Springer Nature's LaTeX template.

22

23 Headings

24 Please use no more than three levels of displayed headings.

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26 Abbreviations

27 Abbreviations should be defined at first mention and used consistently thereafter.

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29 Footnotes

30 Footnotes can be used to give additional information, which may include the  
31 citation of a reference included in the reference list. They should not consist solely  
32 of a reference citation, and they should never include the bibliographic details of  
33 a reference. They should also not contain any figures or tables.

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Always use footnotes instead of endnotes.

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Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

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1 Ideally, the names of all authors should be provided, but the usage of “et al” in  
2 long author lists will also be accepted:

3

4 Smith J, Jones M Jr, Houghton L et al (1999) Future of health insurance. *N Engl*  
5 *J Med* 965:325–329

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7 Article by DOI

8 Slifka MK, Whitton JL (2000) Clinical implications of dysregulated cytokine  
9 production. *J Mol Med*. <https://doi.org/10.1007/s001090000086>

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11 Book

12 South J, Blass B (2001) *The future of modern genomics*. Blackwell, London

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14 Book chapter

15 Brown B, Aaron M (2001) The politics of nature. In: Smith J (ed) *The rise of*  
16 *modern genomics*, 3rd edn. Wiley, New York, pp 230-257

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18 Online document

19 Cartwright J (2007) Big stars have weather too. IOP Publishing PhysicsWeb.  
20 <http://physicsweb.org/articles/news/11/6/16/1>. Accessed 26 June 2007

21

22 Dissertation

23 Trent JW (1975) *Experimental acute renal failure*. Dissertation, University of  
24 California

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27 List of Title Word Abbreviations, see

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29 ISSN.org LTWA

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2 sn-basic.bst which is included in the Springer Nature Article Template.

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8 the table.

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10 of a reference at the end of the table caption.

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12 asterisks for significance values and other statistical data) and included beneath  
13 the table body

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17 Supply all figures electronically.

18 Indicate what graphics program was used to create the artwork.

19 For vector graphics, the preferred format is EPS; for halftones, please use TIFF  
20 format. MSOffice files are also acceptable.

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23

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25 Definition: Black and white graphic with no shading.

26 Do not use faint lines and/or lettering and check that all lines and lettering within  
27 the figures are legible at final size.

28 All lines should be at least 0.1 mm (0.3 pt) wide.

29 Scanned line drawings and line drawings in bitmap format should have a  
30 minimum resolution of 1200 dpi.

31 Vector graphics containing fonts must have the fonts embedded in the files.

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#### 33 Halftone Art

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Definition: Photographs, drawings, or paintings with fine shading, etc.  
If any magnification is used in the photographs, indicate this by using scale bars within the figures themselves.  
Halftones should have a minimum resolution of 300 dpi.

Combination Art

Definition: a combination of halftone and line art, e.g., halftones containing line drawing, extensive lettering, color diagrams, etc.  
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If the figures will be printed in black and white, do not refer to color in the captions.  
Color illustrations should be submitted as RGB (8 bits per channel).

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To add lettering, it is best to use Helvetica or Arial (sans serif fonts).  
Keep lettering consistently sized throughout your final-sized artwork, usually about 2–3 mm (8–12 pt).  
Variance of type size within an illustration should be minimal, e.g., do not use 8-pt type on an axis and 20-pt type for the axis label.  
Avoid effects such as shading, outline letters, etc.  
Do not include titles or captions within your illustrations.

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3 continue the consecutive numbering of the main text. Do not number the  
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5 Information (SI)] should, however, be numbered separately.

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10 Figure captions begin with the term Fig. in bold type, followed by the figure  
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12 No punctuation is to be included after the number, nor is any punctuation to be  
13 placed at the end of the caption.

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15 circles, etc., as coordinate points in graphs.

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26 on this subject. Authors should check with their institution to make sure they are  
27 complying with the specific requirements of their institution and seek ethics  
28 approval where needed. Authors should be aware to secure informed consent  
29 from the individual (or parent or guardian if the participant is a minor or incapable)  
30 See also section on Informed Consent.

31

#### 32 Cell lines

1 If human cells are used, authors must declare in the manuscript: what cell lines  
2 were used by describing the source of the cell line, including when and from  
3 where it was obtained, whether the cell line has recently been authenticated and  
4 by what method. If cells were bought from a life science company the following  
5 need to be given in the manuscript: name of company (that provided the cells),  
6 cell type, number of cell line, and batch of cells.

7

8 It is recommended that authors check the NCBI database for misidentification  
9 and contamination of human cell lines. This step will alert authors to possible  
10 problems with the cell line and may save considerable time and effort.

11

12 Further information is available from the International Cell Line Authentication  
13 Committee (ICLAC).

14

15 Authors should include a statement that confirms that an institutional or  
16 independent ethics committee (including the name of the ethics committee)  
17 approved the study and that informed consent was obtained from the donor or  
18 next of kin.

19

#### 20 Research Resource Identifiers (RRID)

21 Research Resource Identifiers (RRID) are persistent unique identifiers  
22 (effectively similar to a DOI) for research resources. This journal encourages  
23 authors to adopt RRIDs when reporting key biological resources (antibodies, cell  
24 lines, model organisms and tools) in their manuscripts.

25

26 RRIDs are provided by the Resource Identification Portal. Many commonly used  
27 research resources already have designated RRIDs. The portal also provides  
28 authors links so that they can quickly register a new resource and obtain an RRID.

29

#### 30 Clinical Trial Registration

31 The World Health Organization (WHO) definition of a clinical trial is "any research  
32 study that prospectively assigns human participants or groups of humans to one  
33 or more health-related interventions to evaluate the effects on health outcomes".

1 The WHO defines health interventions as “A health intervention is an act  
2 performed for, with or on behalf of a person or population whose purpose is to  
3 assess, improve, maintain, promote or modify health, functioning or health  
4 conditions” and a health-related outcome is generally defined as a change in the  
5 health of a person or population as a result of an intervention.

6  
7 To ensure the integrity of the reporting of patient-centered trials, authors must  
8 register prospective clinical trials (phase II to IV trials) in suitable publicly available  
9 repositories. For example [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or any of the primary registries  
10 that participate in the WHO International Clinical Trials Registry Platform.

11  
12 The trial registration number (TRN) and date of registration should be included  
13 as the last line of the manuscript abstract.

14  
15 For clinical trials that have not been registered prospectively, authors are  
16 encouraged to register retrospectively to ensure the complete publication of all  
17 results. The trial registration number (TRN), date of registration and the words  
18 'retrospectively registered' should be included as the last line of the manuscript  
19 abstract.

20  
21 Standards of reporting  
22 Springer Nature advocates complete and transparent reporting of biomedical and  
23 biological research and research with biological applications. Authors are  
24 recommended to adhere to the minimum reporting guidelines hosted by the  
25 EQUATOR Network when preparing their manuscript.

26  
27 Exact requirements may vary depending on the journal; please refer to the  
28 journal's Instructions for Authors.

29  
30 Checklists are available for a number of study designs, including:

31  
32 Randomised trials (CONSORT) and Study protocols (SPIRIT)

33

- 1 Observational studies (STROBE)
- 2 Systematic reviews and meta-analyses (PRISMA) and protocols (Prisma-P)
- 3 Diagnostic/prognostic studies (STARD) and (TRIPOD)
- 4 Case reports (CARE)
- 5 Clinical practice guidelines (AGREE) and (RIGHT)
- 6 Qualitative research (SRQR) and (COREQ)
- 7 Animal pre-clinical studies (ARRIVE)
- 8 Quality improvement studies (SQUIRE)
- 9 Economic evaluations (CHEERS)
- 10
- 11 Summary of requirements
- 12 The above should be summarized in a statement and placed in a 'Declarations'
- 13 section before the reference list under a heading of 'Ethics approval'.
- 14
- 15 Examples of statements to be used when ethics approval has been obtained:
- 16
- 17 • All procedures performed in studies involving human participants were in
- 18 accordance with the ethical standards of the institutional and/or national research
- 19 committee and with the 1964 Helsinki Declaration and its later amendments or
- 20 comparable ethical standards. The study was approved by the Bioethics
- 21 Committee of the Medical University of A (No. ...).
- 22
- 23 • This study was performed in line with the principles of the Declaration of
- 24 Helsinki. Approval was granted by the Ethics Committee of University B
- 25 (Date.../No. ...).
- 26
- 27 • Approval was obtained from the ethics committee of University C. The
- 28 procedures used in this study adhere to the tenets of the Declaration of Helsinki.
- 29
- 30 • The questionnaire and methodology for this study was approved by the Human
- 31 Research Ethics committee of the University of D (Ethics approval number: ...).
- 32
- 33 Examples of statements to be used for a retrospective study:



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- Ethical approval was waived by the local Ethics Committee of University A in view of the retrospective nature of the study and all the procedures being performed were part of the routine care.

- This research study was conducted retrospectively from data obtained for clinical purposes. We consulted extensively with the IRB of XYZ who determined that our study did not need ethical approval. An IRB official waiver of ethical approval was granted from the IRB of XYZ.

- This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The Human Investigation Committee (IRB) of University B approved this study.

Examples of statements to be used when no ethical approval is required/exemption granted:

- This is an observational study. The XYZ Research Ethics Committee has confirmed that no ethical approval is required.

- The data reproduced from Article X utilized human tissue that was procured via our Biobank AB, which provides de-identified samples. This study was reviewed and deemed exempt by our XYZ Institutional Review Board. The BioBank protocols are in accordance with the ethical standards of our institution and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Authors are responsible for correctness of the statements provided in the manuscript. See also Authorship Principles. The Editor-in-Chief reserves the right to reject submissions that do not meet the guidelines described in this section.

1 Informed consent

2 All individuals have individual rights that are not to be infringed. Individual  
3 participants in studies have, for example, the right to decide what happens to the  
4 (identifiable) personal data gathered, to what they have said during a study or an  
5 interview, as well as to any photograph that was taken. This is especially true  
6 concerning images of vulnerable people (e.g. minors, patients, refugees, etc) or  
7 the use of images in sensitive contexts. In many instances authors will need to  
8 secure written consent before including images.

9

10 Identifying details (names, dates of birth, identity numbers, biometrical  
11 characteristics (such as facial features, fingerprint, writing style, voice pattern,  
12 DNA or other distinguishing characteristic) and other information) of the  
13 participants that were studied should not be published in written descriptions,  
14 photographs, and genetic profiles unless the information is essential for scholarly  
15 purposes and the participant (or parent/guardian if the participant is a minor or  
16 incapable or legal representative) gave written informed consent for publication.  
17 Complete anonymity is difficult to achieve in some cases. Detailed descriptions  
18 of individual participants, whether of their whole bodies or of body sections, may  
19 lead to disclosure of their identity. Under certain circumstances consent is not  
20 required as long as information is anonymized and the submission does not  
21 include images that may identify the person.

22

23 Informed consent for publication should be obtained if there is any doubt. For  
24 example, masking the eye region in photographs of participants is inadequate  
25 protection of anonymity. If identifying characteristics are altered to protect  
26 anonymity, such as in genetic profiles, authors should provide assurance that  
27 alterations do not distort meaning.

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29 Exceptions where it is not necessary to obtain consent:

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31 • Images such as x rays, laparoscopic images, ultrasound images, brain scans,  
32 pathology slides unless there is a concern about identifying information in which  
33 case, authors should ensure that consent is obtained.

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- Reuse of images: If images are being reused from prior publications, the Publisher will assume that the prior publication obtained the relevant information regarding consent. Authors should provide the appropriate attribution for republished images.

Consent and already available data and/or biologic material

Regardless of whether material is collected from living or dead patients, they (family or guardian if the deceased has not made a pre-mortem decision) must have given prior written consent. The aspect of confidentiality as well as any wishes from the deceased should be respected.

Data protection, confidentiality and privacy

When biological material is donated for or data is generated as part of a research project authors should ensure, as part of the informed consent procedure, that the participants are made aware what kind of (personal) data will be processed, how it will be used and for what purpose. In case of data acquired via a biobank/biorepository, it is possible they apply a broad consent which allows research participants to consent to a broad range of uses of their data and samples which is regarded by research ethics committees as specific enough to be considered “informed”. However, authors should always check the specific biobank/biorepository policies or any other type of data provider policies (in case of non-bio research) to be sure that this is the case.

Consent to Participate

For all research involving human subjects, freely-given, informed consent to participate in the study must be obtained from participants (or their parent or legal guardian in the case of children under 16) and a statement to this effect should appear in the manuscript. In the case of articles describing human transplantation studies, authors must include a statement declaring that no organs/tissues were obtained from prisoners and must also name the

1 institution(s)/clinic(s)/department(s) via which organs/tissues were obtained. For  
2 manuscripts reporting studies involving vulnerable groups where there is the  
3 potential for coercion or where consent may not have been fully informed, extra  
4 care will be taken by the editor and may be referred to the Springer Nature  
5 Research Integrity Group.

6

### 7 Consent to Publish

8 Individuals may consent to participate in a study, but object to having their data  
9 published in a journal article. Authors should make sure to also seek consent  
10 from individuals to publish their data prior to submitting their paper to a journal.  
11 This is in particular applicable to case studies. A consent to publish form can be  
12 found here. (Download docx, 36 kB)

13

### 14 Summary of requirements

15 The above should be summarized in a statement and placed in a 'Declarations'  
16 section before the reference list under a heading of 'Consent to participate' and/or  
17 'Consent to publish'. Other declarations include Funding, Conflicts of  
18 interest/competing interests, Ethics approval, Consent, Data and/or Code  
19 availability and Authors' contribution statements.

20

21 Please see the various examples of wording below and revise/customize the  
22 sample statements according to your own needs.

23 Sample statements for "Consent to participate":

24 Informed consent was obtained from all individual participants included in the  
25 study.

26 Informed consent was obtained from legal guardians.

27 Written informed consent was obtained from the parents.

28 Verbal informed consent was obtained prior to the interview.

29 Sample statements for "Consent to publish":

30 The authors affirm that human research participants provided informed consent  
31 for publication of the images in Figure(s) 1a, 1b and 1c.

32 The participant has consented to the submission of the case report to the journal.

1 Patients signed informed consent regarding publishing their data and  
2 photographs.

3 Sample statements if identifying information about participants is available in the  
4 article:

5 Additional informed consent was obtained from all individual participants for  
6 whom identifying information is included in this article.

7 Authors are responsible for correctness of the statements provided in the  
8 manuscript. See also Authorship Principles. The Editor-in-Chief reserves the right  
9 to reject submissions that do not meet the guidelines described in this section.

10 Images will be removed from publication if authors have not obtained informed  
11 consent or the paper may be removed and replaced with a notice explaining the  
12 reason for removal.

13

#### 14 Research Data Policy

15 This journal operates a type 1 research data policy. The journal encourages  
16 authors, where possible and applicable, to deposit data that support the findings  
17 of their research in a public repository. Authors and editors who do not have a  
18 preferred repository should consult Springer Nature's list of repositories and  
19 research data policy.

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#### 21 List of Repositories

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#### 23 Research Data Policy

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25 General repositories - for all types of research data - such as figshare and Dryad  
26 may also be used.

27

28 Datasets that are assigned digital object identifiers (DOIs) by a data repository  
29 may be cited in the reference list. Data citations should include the minimum  
30 information recommended by DataCite: authors, title, publisher (repository  
31 name), identifier.

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#### 33 DataCite

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