

Systematic Review Article

Stainless steel or titanium mini-implants? A systematic review

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ABSTRACT

Objectives: To investigate whether there was a difference in success rates when stainless steel (SS) was compared to titanium mini-implants (MIs) in orthodontic patients.

Materials and Methods: PubMed, Cochrane, Scopus, Web of Science, Lilacs, Google Scholar, Clinical Trials, and OpenGray were searched without restrictions. A manual search was also performed in the references of the included articles. Studies comparing the success rate between SS and titanium MIs were included. Risk of bias (RoB) was assessed using the ROBINS-I (Risk of Bias in Non-randomized Studies-of Interventions) Tool or RoB 2.0 according to the study design. The level of evidence was assessed through GRADE (Grading of Recommendation, Assessment, Development, and Evaluation).

Results: Six studies met the eligibility criteria. One study was a randomized clinical trial that evaluated extraalveolar MIs, and nonrandomized trials examined interradiolar MIs. The RCT presented a low RoB, two nonrandomized trials presented a moderate risk, and three presented a high risk. The quality of the evidence was high for the randomized clinical trial and moderate for the nonrandomized trials. Most studies found no difference between materials, with good success rates for both (SS, 74.6%–100%; titanium: 80.9%–100%) and only one study, with a high RoB, showed a higher success rate with titanium MIs (90%) when compared with SS (50%). A quantitative analysis was not because of the great heterogeneity among the studies.

Conclusions: Although limited, the current evidence seems to show that the material used is not a major factor in the success rate of MIs. Because it has a lower cost than titanium and presents similar clinical efficiency, SS is a great material for orthodontic MIs. (*Angle Orthod.* 2020;90:587–597.)

KEY WORDS: Mini-implant; Stainless steel; Titanium; Success rate; TADs; Review

INTRODUCTION

The development of temporary anchorage devices (TADs) extended the possibility for orthodontic movement. Compared with traditional means of anchorage, TADs provided simpler orthodontic mechanics, greater patient comfort, reduction of treatment time, no

dependence on patient collaboration, and minor anchorage loss.^{1,2}

The most commonly used TADs are miniplates and mini-implants (MIs). MIs are small enough to be placed in different sites, allowing them to be used routinely in daily orthodontic practice. They have a lower cost than miniplates and require simple handling techniques, which allow them to be installed and removed easily. With the advent of extraalveolar MIs, MIs can be also used in cases that require higher forces and large amounts of movement.^{3,4}

MIs are used for various situations from mass retraction and occlusal plane correction to simpler movements such as tooth intrusion or uprighting.^{5–7} Most available MIs are made of titanium, but SS MIs are also commonly found. Despite the distinct characteristics between these two materials, both fulfill the biomechanical prerequisites of devices used for orthodontic anchorage.^{8–10}

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MIs must remain stable from their installation to the end of the mechanics employed, and factors such as location, surgeon's ability, and patient hygiene can influence their success.^{3,11,12} Although some meta-analyses have evaluated risk factors for MI failure,^{12,13} none investigated how different materials used to manufacture MIs affected their success rate. Recently published studies did not reach consensus about this issue.^{14,15} This systematic review aimed to investigate whether there was a difference in the success rates when SS was compared with titanium MIs in orthodontic patients.

MATERIALS AND METHODS

This work was registered at the PROSPERO database (<http://www.crd.york.ac.uk/PROSPERO>) under registration code CRD42019129534 and performed according to PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) guidelines.¹⁶

Eligibility Criteria

The following selection criteria were adopted:

1. Study design: randomized clinical trials (RCTs) or nonrandomized trials (CCT), prospective or retrospective;
2. Population: patients with fixed appliances needing TADs;
3. Intervention: patients in whom stainless steel (SS) MIs were used;
4. Comparison: patients in whom titanium MIs were used;
5. Outcome: success rate of MIs; and
6. Exclusion criteria: Patients with any bone disease or craniofacial syndrome; studies that used other types of TADs; opinion articles, animal or laboratorial studies, case reports, case-series, and literature reviews.

Information Sources

The following databases were searched: PubMed, Scopus, Web of Science, Cochrane, LILACS, Open-Gray, and Google Scholar. A hand search was conducted by reading the references of the included articles for eventual additional relevant studies. The search was extended to the database clinicaltrials.gov. No restriction on language or date of publication was applied. The search was continued until July 2019.

Search Strategy and Study Selection

The databases were searched independently by two reviewers (P.M. and D.G.E.). Disagreements were

settled through discussion and consensus and, when necessary, a third author's opinion (D.N.) was consulted. The search strategy was developed through a combination between MeSH, entry terms, and keywords related to the PICO (Population, Intervention, Comparison, Outcome) strategy using Boolean operators. The full search strategy for each database is illustrated in Table 1.

The citations were saved in a reference manager (EndNote, x9 version; Clarivate Analytics, Philadelphia, Pa) and, at first, titles and abstract were analyzed according to the eligibility criteria. The selected articles were evaluated by full text, and a final selection was determined.

Risk of Bias Assessment

For the CCTs, the risk of bias (RoB) was performed following the ROBINS-I (Risk of Bias in Non-randomized Studies-of Interventions) tool.¹⁷ The checklist included the following three main domains of bias: preintervention, intervention, and postintervention. The RoB was judged for each domain and for overall evaluation as low, moderate, serious, critical, or no information (Table 2).

For the RCTs, the Cochrane RoB 2.0 tool¹⁸ was used. This tool assessed the following five main bias domains: bias arising from the randomization process, bias as a result of deviations from the intended interventions, bias as a result of missing outcome data, bias in the measurement of the outcome, and bias in the selection of the reported results. The RoB was judged for each domain and for overall evaluation as low, some concerns, or high. Each analysis of RoB was made by two researchers (P.M. and D.G.E.) and, in the case of disagreement, a third reviewer (D.N.) was consulted.

Evaluation of Quality of Evidence

The included studies were given a quality grade related to the MI success rate in accordance with the grading of recommendation, assessment, development, and evaluation (GRADEpro Guideline Development Tool, gradepr.org).¹⁹ This tool considered five aspects for rating the quality of evidence as high, moderate, low, or very low.

Data Extraction

Two reviewers collected the data independently (P.M. and D.G.E.), recording the following items: author, year and location, type of study, participants, type of MI and their characteristics, loading force, and healing time, MI location, follow-up period, purpose of installation, statistical analysis, outcome

Table 1. Continued

Database	Keywords	Results
Web of Science	(("Orthodontic anchorage procedures") OR TÓPICO: ("Anchorage Procedure, Orthodontic") OR TÓPICO: ("Anchorage Procedures, Orthodontic") OR TÓPICO: ("Orthodontic Anchorage Procedure") OR TÓPICO: ("Procedure, Orthodontic Anchorage") OR TÓPICO: ("Procedures, Orthodontic Anchorage") OR TÓPICO: ("Orthodontic Anchorage Techniques") OR TÓPICO: ("Anchorage Technique, Orthodontic") OR TÓPICO: ("Anchorage Techniques, Orthodontic") OR TÓPICO: ("Orthodontic Anchorage Technique") OR TÓPICO: ("Technique, Orthodontic Anchorage") OR TÓPICO: ("Techniques, Orthodontic Anchorage") OR (Miniimplant*) OR TÓPICO: ("Mini implant*") OR TÓPICO: (Mini-implant*) OR TÓPICO: ("Orthodontic mini-implant") OR TÓPICO: (Miniscrew*) OR TÓPICO: ("Orthodontic miniscrew") OR TÓPICO: (Microscrew*) OR TÓPICO: ("Orthodontic microscrew") OR TÓPICO: ("orthodontic bone screws") OR TÓPICO: (Micro-implant*) OR TÓPICO: (Microimplant*) OR TÓPICO: ("Skeletal Anchorage bone screw*") OR TÓPICO: (TAD*) OR TÓPICO: ("Intraosseous screw*") OR TÓPICO: ("Interradicular screw*") OR TÓPICO: ("Temporary anchorage devices") AND (((Titanium) OR TÓPICO: ("Titanium alloy") OR TÓPICO: (Ti6Al4V) OR TÓPICO: ("Ti-6Al-4V alloy") OR TÓPICO: ("Ti-6Al-V4 alloy") OR TÓPICO: ("titanium 6-aluminum-4-vanadium") OR TÓPICO: (Tivanium) OR TÓPICO: ("Tytanium R") OR TÓPICO: ("Protasul-64WF alloy") OR TÓPICO: (TiA) OR TÓPICO: (Ti-alloy)) AND (("Stainless steel") OR TÓPICO: ("Stainless Steels") OR TÓPICO: ("Steel, Stainless") OR TÓPICO: ("Steels, Stainless") OR TÓPICO: (SS) OR TÓPICO: (Steel) OR TÓPICO: (Steels) OR TÓPICO: ("Stainless 316L")) OR (("Survival rate") OR TÓPICO: ("Rate, Survival") OR TÓPICO: ("Rates, Survival") OR TÓPICO: ("Survival Rates") OR TÓPICO: ("Mean Survival Time") OR TÓPICO: ("Mean Survival Times") OR TÓPICO: ("Survival Time, Mean") OR TÓPICO: ("Survival Times, Mean") OR TÓPICO: ("Time, Mean Survival") OR TÓPICO: ("Times, Mean Survival") OR TÓPICO: ("Cumulative Survival Rate") OR TÓPICO: ("Cumulative Survival Rates") OR TÓPICO: ("Rate, Cumulative Survival") OR TÓPICO: ("Rates, Cumulative Survival") OR TÓPICO: ("Survival Rate, Cumulative"))))	217
Cochrane	#1 ("Orthodontic anchorage procedures"):ti,ab,kw OR ("Anchorage Procedure, Orthodontic"):ti,ab,kw OR ("Anchorage Procedures, Orthodontic"):ti,ab,kw OR ("Orthodontic Anchorage Procedure"):ti,ab,kw OR ("Procedure, Orthodontic Anchorage"):ti,ab,kw (Word variations have been searched) #2 ("Procedures, Orthodontic Anchorage"):ti,ab,kw OR ("Orthodontic Anchorage Techniques"):ti,ab,kw OR ("Anchorage Technique, Orthodontic"):ti,ab,kw OR ("Anchorage Techniques, Orthodontic"):ti,ab,kw OR ("Orthodontic Anchorage Technique"):ti,ab,kw (Word variations have been searched) #3 ("Technique, Orthodontic Anchorage"):ti,ab,kw OR ("Techniques, Orthodontic Anchorage"):ti,ab,kw OR (Miniimplant\$):ti,ab,kw OR ("Mini implant\$"):ti,ab,kw OR (Mini-implant\$):ti,ab,kw (Word variations have been searched) #4 ("Orthodontic mini-implant"):ti,ab,kw OR (Miniscrew\$):ti,ab,kw OR ("Orthodontic miniscrew"):ti,ab,kw OR (Microscrew\$):ti,ab,kw OR ("Orthodontic microscrew"):ti,ab,kw (Word variations have been searched) #5 ("orthodontic bone screws"):ti,ab,kw OR (Micro-implant\$):ti,ab,kw OR (Microimplant\$):ti,ab,kw OR ("Skeletal Anchorage bone screw\$"):ti,ab,kw OR (TAD\$):ti,ab,kw (Word variations have been searched) #6 ("Intraosseous screw\$"):ti,ab,kw OR ("Interradicular screw\$"):ti,ab,kw OR ("Temporary anchorage devices"):ti,ab,kw (Word variations have been searched) #7 #1 or #2 or #3 or #4 or #5 or #6 #8 (Titanium):ti,ab,kw OR ("Titanium alloy"):ti,ab,kw OR (Ti6Al4V):ti,ab,kw OR ("Ti-6Al-4V alloy"):ti,ab,kw OR ("Ti-6Al-V4 alloy"):ti,ab,kw (Word variations have been searched) #9 ("titanium 6-aluminum-4-vanadium"):ti,ab,kw OR (Tivanium):ti,ab,kw OR ("Tytanium R"):ti,ab,kw OR ("Protasul-64WF alloy"):ti,ab,kw OR (TiA):ti,ab,kw (Word variations have been searched) #10 (Ti-alloy):ti,ab,kw (Word variations have been searched) #11 #8 or #9 or #10 #12 ("Stainless steel"):ti,ab,kw OR ("Stainless Steels"):ti,ab,kw OR ("Steel, Stainless"):ti,ab,kw OR ("Steels, Stainless"):ti,ab,kw OR (SS):ti,ab,kw (Word variations have been searched) #13 (Steel):ti,ab,kw OR (Steels):ti,ab,kw OR ("Stainless 316L"):ti,ab,kw (Word variations have been searched) #14 #12 or #13 #15 ("survival rate"):ti,ab,kw OR ("Rate, Survival"):ti,ab,kw OR ("Rates, Survival"):ti,ab,kw OR ("Survival Rates"):ti,ab,kw OR ("Mean Survival Time"):ti,ab,kw (Word variations have been searched) #16 ("Mean Survival Times"):ti,ab,kw OR ("Survival Time, Mean"):ti,ab,kw OR ("Survival Times, Mean"):ti,ab,kw OR ("Time, Mean Survival"):ti,ab,kw OR ("Times, Mean Survival"):ti,ab,kw (Word variations have been searched) #17 ("cumulative survival rate"):ti,ab,kw OR ("Cumulative Survival Rates"):ti,ab,kw OR ("Rate, Cumulative Survival"):ti,ab,kw OR ("Rates, Cumulative Survival"):ti,ab,kw OR ("Survival Rate, Cumulative"):ti,ab,kw (Word variations have been searched) #18 ("Survival Rates, Cumulative"):ti,ab,kw (Word variations have been searched) #19 #15 or #16 #17 or #18 #20 #11 and #14 #21 #20 or #19 #22 #7 and #21	20

Table 1. Continued

Database	Keywords	Results
LILACS	(tw:((Orthodontic anchorage procedures) OR (Anchorage Procedure, Orthodontic) OR (Anchorage Procedures, Orthodontic) OR (Orthodontic Anchorage Procedure) OR (Procedure, Orthodontic Anchorage) OR (Procedures, Orthodontic Anchorage) OR (Orthodontic Anchorage Techniques) OR (Anchorage Technique, Orthodontic) OR (Anchorage Techniques, Orthodontic) OR (Orthodontic Anchorage Technique) OR (Technique, Orthodontic Anchorage) OR (Techniques, Orthodontic Anchorage) OR (Miniimplant\$) OR (Mini implant\$) OR (Mini-implant\$) OR (Orthodontic mini-implant) OR (Miniscrew\$) OR (Orthodontic miniscrew) OR (Microscrew\$) OR (orthodontic Microscrew) OR (orthodontic bone screws) OR (Micro-implant\$) OR (Microimplant\$) OR (Skeletal Anchorage bone screw\$) OR (TAD\$) OR (Intraosseous screw\$) OR (Interradicular screw\$) OR (Temporary anchorage devices\$))) AND (tw:((tw:((Titanium) OR (Titanium alloy) OR (Ti6Al4V) OR (Ti-6Al-4V alloy) OR (Ti-6Al-V4 alloy) OR (titanium 6-aluminum-4-vanadium) OR (Tivanium) OR (Tytanium R) OR (Protasul-64WF alloy) OR (TiA) OR (Ti-alloy))) AND (tw:((Stainless steel) OR (Stainless Steels) OR (Steel, Stainless) OR (Steels, Stainless) OR (SS) OR (Steel) OR (Steels) OR (Stainless 316L)))))) OR (tw:((Survival rate) OR (Rate, Survival) OR (Rates, Survival) OR (Survival Rates) OR (Mean Survival Time) OR (Mean Survival Times) OR (Survival Time, Mean) OR (Survival Times, Mean) OR (Time, Mean Survival) OR (Times, Mean Survival) OR (Cumulative Survival Rate) OR (Cumulative Survival Rates) OR (Rate, Cumulative Survival) OR (Rates, Cumulative Survival) OR (Survival Rate, Cumulative) OR (Survival Rates, Cumulative))))))	52
Google Scholar	Humans+(Orthodontic anchorage procedures OR mini implant OR miniscrew)+(Titanium AND Stainless steel OR Survival rate)	540
OpenGray	Orthodontic anchorage procedures AND Stainless Steel AND Titanium	0
Clinical trials	(Mini implant OR Miniscrew OR Micro implant) AND (Steel AND Titanium OR Survival Rate)	12

assessment, and outcomes. The quantitative data analysis was evaluated through risk ratio (RR). A meta-analysis was not performed because of the large methodological heterogeneity among the studies examined, principally because of the different sizes and location of MIs, as well as the amount of force used.

RESULTS

Study Selection

The electronic search revealed a total of 1680 articles: 327 from PubMed, 512 from SCOPUS, 217

from Web of Science, 20 from Cochrane, 52 from LILACS, 540 from Google Scholar, 12 from Clinical Trials, and 0 from OpenGray. After removing duplicates, 1261 studies remained. One article was added for screening after a hand search of the references in the included articles. After reading the titles and abstracts, 20 articles were evaluated by full text, and 14 were excluded. The reasons for exclusion were as follows: in vitro studies (n = 7), evaluation of only one type of MI (n = 3), animal studies (n = 2), and study not related to the research objective (n = 1; Table 3). As a result, six articles were included (Figure 1).

Table 2. Bias and Domains Considered in Risk of Bias Evaluation According to the ROBINS-I (Risk of Bias in Non-randomized Studies-of Interventions) Tool

Domain Bias	Description
Preintervention	
Bias as a result of confounding	Baseline confounding: large discrepancy in the number of participants or mini-implants per group Mini-implant characteristics confounding: differences in mini-implants characteristics and his location
Bias in selection of participants into the study	Absence of clear eligibility criteria Exclusion of some elegeible participants or difference between the follow-up period
Intervention	
Bias in classification of interventions	When the intervention status (applied force, healing time, purpose of installation, follow-up period) was not described correctly
Postintervention	
Bias as a result of deviations from intended interventions	In the occurrence of systemic differences between the intervention group (stainless steel mini-implants) and the comparation group (titanium mini-implants)
Bias as a result of missing data	In the event of loss of follow-up, incomplete data collection and exclusion of participants in the analysis
Bias in measurement of the outcomes	When success rates or other parameters of interest were measured with error
Bias in selection of the reported results	Selective reporting of results when the effects of all measurements of results were not fully reported

Table 3. List of Excluded Studies With Reason

Reference	Reason for Exclusion
Antoszewska et al. (2009)	No use of both types of mini-implants
Bourguigui et al. (2014)	No use of both types of mini-implants
Brown et al. (2014)	Animal study
Carano et al. (2005)	In vitro study
Chen et al. (2018)	In vitro study
Gritsch et al. (2013)	Animal study
Khan et al. (2016)	No use of both types of mini-implants
Kliauga et al. (2010)	In vitro study
Natarajan et al. (2017)	Studies not related with the research objective
Pan et al. (2012)	In vitro study
Scribante et al. (2018)	In vitro study
Tseng et al. (2016)	In vitro study
Tseng et al. (2017)	In vitro study
Tseng et al. (2017)	In vitro study

Study Characteristics

The characteristics of the included studies are described in Table 4. Selected articles were published between 2009 and 2019. Five studies were CCTs, four^{3,14,15,20} were prospective and one²¹ retrospective. All CCTs investigated interradiographic MIs. Only one²² study was a RCT that investigated extraalveolar MIs.

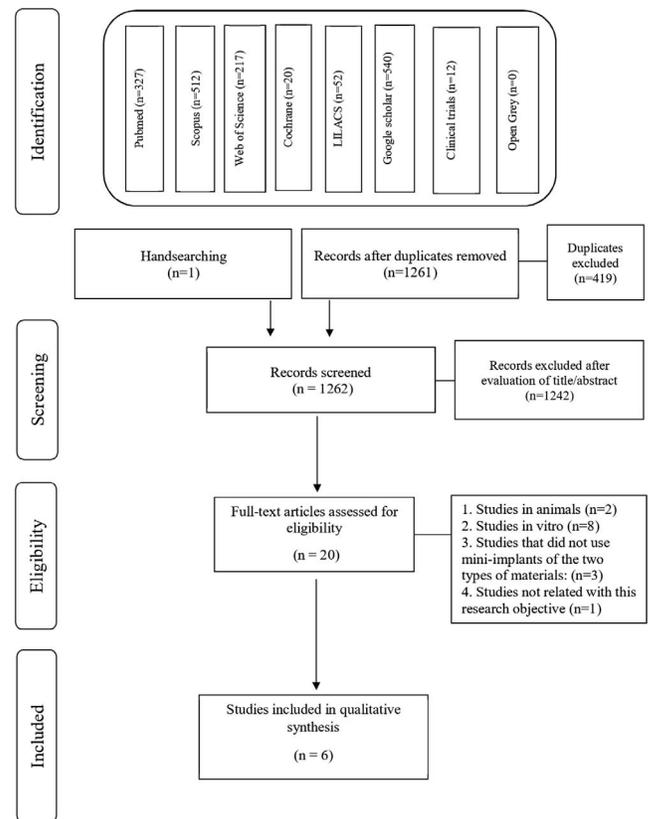
The mean age of participants ranged from 16.2¹⁵ to 29.6²¹ years. Great differences among the articles were observed regarding the number of MIs used that ranged from 10¹⁴ to 386²² per group. Only one study¹⁴ did not describe the number of male/female subjects and the mean age of patients.

In two articles,^{14,15} the MIs were installed mesially to the molars, whereas one²² used extraalveolar MIs in the infrazygomatic crest. It was observed that the loading forces ranged according to the purpose of installation: for maxillary retraction, the highest load used was 227 to 397 g,²² whereas the canine retraction required the lowest forces, 90 to 100 g.¹⁵ Three studies^{3,20,21} did not report the loading forces applied and did not standardize the installation sites and purposes of MI.

In relation to drill type, three studies^{3,15,21} used different types of drills for the titanium and SS groups. One²¹ article used predrilled titanium MIs and self-drilling SS MIs. In another study, titanium MIs were self-drilling, whereas the SS MIs were predrilled¹⁵ In a third study,³ three groups were used, one composed of self-drilling SS MIs, another composed of self-drilling titanium MIs, and a third composed of predrilled titanium MIs. The greatest follow-up period was 12 months,^{14,20} and the lowest was 160.8 days.¹⁵ Only one study did not report the follow-up period.²¹

RoB Within Studies

Regarding the CCTs, two^{15,20} showed moderate RoB as a result of the differences in treatment between

**Figure 1.** Flow diagram of study identification.

groups and the selection of results presented, whereas the other three articles presented a high RoB.^{3,14,21} One²¹ of those was a retrospective study in which important information was lacking such as the force applied, follow-up period, installation purpose, and eligibility criteria. An error in the statistical analysis was found in one study.¹⁴ When the statistical analysis of this article was reevaluated, no differences were detected in any of the following statistical tests: chi-square, which was used in the article; Fisher exact test; G test; binomial; or RR (BioEstat, version 5.3; Mamirauá Institute, Belém, Pará, Brazil). For this reason, the study¹⁴ received a high RoB. Another study³ received a high RoB as a result of discrepancies between MI numbers by group, differences in MI locations, absence of clear eligibility criteria, and poor description of interventions (applied force, purpose of installation).

The RCT²² exhibited a low RoB as a result of an adequate sample along with standardization of the site of installation, the force used, the follow-up time, and the purpose of use for the two groups. The evaluations of RoB for all included studies are presented in Tables 5 and 6.

Results of Individual Studies

The lowest success rate found for SS MIs was 50%,¹⁴ and the highest was 100%.¹⁵ Regarding

titanium MIs, the lowest success rate found was 84.46%,²⁰ and the highest was 100%.¹⁵

Only one study reported that titanium MIs showed higher success rates than SS MIs and that a higher implant failure was found in the upper jaw when compared with the lower jaw.¹⁴ The other five studies—one RCT²² and four CCTs^{3,15,20,21}—did not report statistical differences between the success rates of the two materials. One article did not report MI losses in either group.¹⁵

Age was a determinant factor for MI failures in two studies,^{20,21} but divergent results were found. In one article,²⁰ older patients were more susceptible to MI failures, resulting in a 5% increase in failure risk for every 1-year increase in age among participants older than 30 years, whereas in another²¹ study, patients younger than 35 years presented a higher risk of MI failure than those older than 35 years. In two other studies,^{3,22} age was not a determinant factor. A MI with a longer length²⁰ was cited as more prone to success, whereas another article³ found that diameter and length were not factors associated with MI failure. Installation in the attached gingiva²¹ was also cited as a major factor for MI stability.

Synthesis of Results

A meta-analysis was not performed because of the heterogeneity of methodologies, mainly because of the different sizes and locations of MIs, as well as the amount of force used. The RR for each study was analyzed, and no differences between the groups were found (Table 7).

Assessment of the Quality of Evidence

The evaluation of the evidence according to GRADE is described in Table 8. The quality of evidence was rated as high for the RCT as this work had excellent control of confounding factors, an adequate sample size, and few limitations. For the CCTs, the quality of evidence was rated as moderate because of the limitations of the study designs and differences between the intervention of groups.

DISCUSSION

With the increasing use of MIs in orthodontics, major factors for their stability began to be investigated to decrease the failure rate. It was reported that success rates could be affected by factors such as installation site,¹² root proximity,²³ and surgeon ability¹¹ among others.^{3,20} Nevertheless, the influence of different materials used to manufacture MIs on their stability was not clear.

The most commonly used material for the manufacturing of MIs is titanium,²⁴ which presents better biocompatibility than SS,²⁵ good resistance to corrosion and provide direct contact between the MI surface and the patient's bone (osseointegration).²⁶ It is noteworthy that the degree of osseointegration achieved in orthodontic MIs is lower when compared with dental implants.^{9,27} Among the disadvantages for titanium MIs are the higher price when compared with SS and the need for prior drilling in very dense bone.^{26,28}

SS MIs are also used in orthodontics and present great mechanical properties and better resistance to breakage and penetration capability.^{9,10,26} Some in vitro and animal studies have shown that the two materials present similar results with respect to fracture strength and torsion,²⁹ mechanical stability, and histological responses.⁸

Summary of Evidence

Most of the articles included^{3,15,20–22} found no difference between the two materials. In these studies, the success rate for SS MIs ranged from 74.6%²¹ to 100%¹⁵ and for titanium ranged from 80.9%²¹ to 100%.¹⁵ Only one CCT reported a statistical difference between the groups.¹⁴ Nevertheless, statistical analysis was reevaluated, and no significant difference was detected. Because of this, this study showed a high RoB, and its conclusions should be analyzed with caution.

It is important to emphasize that some studies did not standardize the installation sites and purpose of MIs,^{3,20,21} did not specify the time of follow-up,²¹ and did not measure the forces used.^{3,20,21} If these factors might influence the stability of the MIs, it is essential that they be controlled and standardized between the two groups. Some studies that did not control the confounding factors obtained high rates of failure,^{20,21} whereas those that controlled these factors had success rates above 90%,^{15,22} and in one article there was no loss of MIs in any group.¹⁵ The high success rate found in that study¹⁵ may have been the result of the purpose of the MIs because canine distalization required the use of a lighter force. In addition, the installation occurred in the attached gingiva in patients with good oral health, characteristics that are predisposed to a higher success rate. Some included articles reported that the installation site,²¹ patient age,^{20,21} jaw of insertion,¹⁴ and MI length²⁰ were factors associated with stability. A recent meta-analysis,³⁰ however, showed that MI diameter, length and design, patient age, and jaw of insertion had little effect on the failure rate. Insertion into attached gingiva was strongly related to higher success rates, whereas

Table 4. Summary of the Data From the Studies Included in This Review^a

Author, Year, and Location	Type of Study	Participants (n), M/F (n), and Age (Years)	MIs (n)	Characteristics of MIs (Length, Material)	Loading Force and Healing Time
Chang et al. (2019), Taiwan ²²	RCT	386 76/310 24.3 10.3–59.4	772 386 – SS 386 – Ti	Self-drilling OrthoBoneScrew (Newton's A Ltd, Taiwan). TADs 2 mm × 12 mm	227–397 g; immediate loading
Ashith et al. (2018), India ¹⁴	Split mouth CCT	10 – – 15–25 years	20 10 – SS 10 – Ti	Self-drilling SS MI: (S.K. Surgicals, India) 1.3 mm × 8 mm Self-drilling Ti MI: (Dentos, Korea) 1.3 mm × 8 mm	Initial 50–70 g until 150 g; immediate loading
Bollero et al. (2018), Italy ¹⁵	Split mouth CCT	15 6/9 16.2 ± 4.6	30 15 – SS 15 – Ti	Pre-drilling SS MI: (Leone, Italy) 1.5 mm × 8 mm; Self-drilling Ti MI: (Spider Screw, Italy) 1.5 mm × 8 mm	90–100 g; immediate loading
Tsai et al. (2016), China ²⁰	Prospective CCT	139 25/114 25.7 ± 7.5 12–56	254 151 – SS 103 – Ti	Self-drilling SS MI: (Syntec Scientific Corp, Taiwan) 2 mm x 12 mm; 2 mm x 10 mm; 2 mm x 8 mm. Self-drilling Ti MI: (Huang-Liang Bio-medical Technology, Taiwan) 2 mm x 11 mm, 2 mm x 9 mm; 1.5 mm x 9 mm.	–; early and late loading
Yao et al. (2015), Taiwan ²¹	Retrospective CCT	220 66/154 29.3 –	496 161 – SS 335 – Ti	Self-drilling SS MI: (Kwung-Jer, Taiwan) - Pre-drilling Ti MI: (Leibinger, Germany) -	–; early and late loading
Wu et al. (2009), Taiwan ³	Prospective CCT	166 35/131 26.5 ± 8.9 –	395 20 – SS 375 – Ti	Self-drilling SS MI: (Syntec Scientific Co., Taiwan) 1.5 or 2.0 mm × 10 or 12 mm Pre-drilling Ti MI: (Dentos, Korea) 1.1, 1.2, 1.3, 1.4, 1.5, or 1.7 mm × 7, 8, or 10 mm Self-drilling Ti MI: (Mondel Medical System, Germany) 1.5 or 2.0 mm × of 11 or 13 mm	–; late loading

^a CCT indicates controlled clinical trial; F, female; M, male; MI, mini-implant; NS, not specified; RCT, randomized clinical trial; SS, stainless steel; TAD, temporary anchorage devices; Ti, titanium.

smoking was related to failure. Another meta-analysis¹² concluded that insertion in palatal sites and mainly no contact with roots were both associated with great success rates.

The literature reported that titanium MIs need prior drilling in higher density bones^{26,28} to avoid fractures. However, a meta-analysis³¹ showed no difference in failure rates whether the MIs were self-drilling or

Table 5. Risk of Bias in Nonrandomized Studies Selected

Author	Domains/ROBINS-I Tool							
	Preintervention		Intervention			Postintervention		
	Risk of Bias of Confusion	Risk of Bias in the Selection of Participants	Risk of Bias in the Intervention Classification	Risk of Bias as a Result of Deviation From Planned Intervention	Risk of Bias as a Result of Missing Data	Risk of Bias in the Measurement of Results	Risk of Bias in the Selection of Reported Results	General Judgment of Risk of Bias
Ashith et al. (2018) ¹⁴	Low	Low	Low	Low	Low	High	Low	High
Bollero et al. (2018) ¹⁵	Moderate	Low	Low	Moderate	Low	Low	Low	Moderate
Tsai et al. (2016) ²⁰	Low	Low	Moderate	Moderate	Moderate	Low	Moderate	Moderate
Wu et al. (2009) ³	High	High	High	Moderate	Low	Low	Low	High
Yao et al. (2015) ²¹	Moderate	High	High	Moderate	Moderate	Moderate	Low	High

Table 4. Extended

Location of MI	Follow-Up Period	Purpose of Installation	Statistical Analysis	Methods of Outcome Assessment	Outcomes
Infrazigo-matic crest	6 months	Retraction of entire maxillary arch	χ^2 test	Mobility	Success rate: Overall: 93,7% SS: 93% Ti: 94.3%
Between premolar and molar in maxillary and mandibular arches	12 months or treatment conclusion whichever is earlier	Direct anchorage for en masse anterior retraction	Mann-Whitney test and χ^2 test	Mobility	Success rate: Overall: 70% SS: 50% Ti: 90%
Attached gingiva, mesial to maxillary molars	160.8 ± 23 days	Direct anchorage for canine distalization	–	Mobility	Success rate: Overall: 100% SS: 100% Ti: 100%
Various sites of mandible and maxilla	12 months	Retraction - 152 (61.8%) Protraction - 8 (2.8%) Intrusion - 52 (19.7%) Upright - 26 (10.2%) Reinforced anchorages - 10 (3.1%) BAMP - 6 (2.4%)	Kaplan-Meier survival analyses with log-rank tests and Cox proportional-hazards model	Loosening, pain, infection, or pathologic changes in surrounding soft tissues	Success rate: Overall: 85.82% SS: 86.75%; Ti: 84.46%; Survival rate: Overall: 81.6% SS: 79% Ti: 84.2%
Various sites of mandible and maxilla	NS	NS	X2 test, GEE model and Odds Ratio	Loosening or mobility that could not withstand orthodontic loading	Success rate: Overall: 78,83% First implantation: SS: 74.6% Ti: 80.9%
Various sites of mandible and maxilla	6 months	NS	χ^2 test or Fisher exact test	Mobility	Success rate: Overall: 89.9% SS: 80% Ti: 90.2%

predrilled. Three studies^{3,15,21} included in this review did not use the same type of drilling for both groups. One article,¹⁵ which used self-drilling titanium MIs, obtained a success rate of 100%, the same rate found for predrilled SS MIs. In another article,²¹ titanium MIs were predrilled and SS MIs were self-drilling, and the success rates were the lowest for both materials among the articles included in this review; nonetheless, no differences were found between the groups. A third study used self-drilling SS MIs and both predrilled and

self-drilling titanium MIs and, despite the differences among success rates (80% for SS MIs, 97.2% for self-drilling titanium MIs, 89.4% for predrilled titanium MIs), they were not statistically significant. Therefore, the type of drilling did not seem to be an important factor for the stability of the MIs.

The ROBINS-I tool evaluated the RoB in two studies as moderate^{15,20} and as high in three others^{3,14,21} as a result of limitations such as differences in treatment of groups, selection of reported results, and incorrect

Table 6. Risk of Bias in the Randomized Study

Author	Domains/RoB 2.0					Overall Bias
	Bias Arising From the Randomization Process	Bias as a Result of Deviation From Intended Interventions	Bias as a Result of Missing Outcome Data	Bias in Measurement of the Outcome	Bias in Selection of the Reported Result	
Chang et al. (2019) ²²	Low	Low	Low	Low	Low	Low

Table 7. RR of the Studies^a

Study	MI Type	Failure	Success	Total	RR/CI	P Value
Ashith et al. (2018) ¹⁴	SS	5	5	10	5/0.70–35.50	.0716
	TI	1	9	10		
Bollero et al. (2018) ¹⁵	SS	0	15	15	–	–
	TI	0	15	15		
Tsai et al. (2016) ²⁰	SS	20	131	151	0.85/0.46–1.57	.3706
	TI	16	87	103		
Wu et al. (2009) ³	SS	4	16	20	2.03/0.80–5.13	.1420
	TI	37	338	375		
Yao et al. (2015) ²¹	SS	41	120	161	1.33/0.94–1.88	.0660
	TI	64	271	335		
Chang et al. (2015) ²²	SS	27	359	386	1.23/0.47–1.41	.2774
	TI	22	364	386		

^a CI indicates confidence interval; MI, mini-implant; RR, risk ratio; SS, stainless steel; TI, titanium.

statistical analysis. The RCT²² presented a low RoB mainly because it used an adequate sample size and standardized the site of installation, the force used, the time of follow-up, and the purpose of use for both groups.

The quality of evidence of MI success rate was measured using the GRADE tool and presented results consistent with the assessment of RoB. The quality of evidence was high for the RCT once this article satisfactorily controlled confounding factors and possible bias. This was not seen in most CCTs, generating a moderate quality of evidence. Even with the need for better designed studies, the available evidence indicated that the material used to manufacture MIs appeared not to be an important variable for stability. The RR of included studies ranged from 0.85 to 5, but no statistical difference was found in any article (Table 7), demonstrating that the MI material was not a risk factor for failure.

Limitations

The CCTs^{3,14,15,20,21} included in this review had some limitations in their methodologies and study designs, which impacted their RoB assessment. Factors such as patient hygiene, installation site, and surgeon ability influenced the stability of the MI. Consequently, these factors should be controlled in all studies comparing SS and titanium MIs. Although not all studies did this, the success rates between groups were always close

in almost all of the articles, with the exception of one,¹⁴ which did not present reliable evidence.

Another possible limitation was that the best available article, a RCT,²² evaluated extraalveolar MIs, which were used for different purposes and had different sizes than the interradicular MIs. Therefore, a RCT evaluating interradicular MI is necessary mainly because of the limited quality of the existing CCTs. Nonetheless, the aim of this review was to assess the influence of the material used to manufacturing the MI on its success rate, no matter if it was installed between the roots or in the infrazygomatic crest. In the RCT, there was control of possible confounding factors and randomization of the samples, so any possible difference between the groups would have been a result of the material rather than to other factors.

Clinical Considerations

Considering the available limited evidence, the results showed that the material used, titanium or SS, was not relevant to the stability of MIs. Accordingly, SS MIs are a good option because they have a lower cost and have shown clinical results similar to those made of titanium.

CONCLUSIONS

- Based on the limited scientific evidence, it appears that the material used to manufacture MIs—steel or

Table 8. GRADE Evidence Profile Table

No. of Studies	Study Design	Certainty Assessment				No. of Mini-implants		Certainty	Importance
		Risk of Bias	Inconsistency	Indirectness	Imprecision	Stainless Steel Mini-Implant	Titanium Mini-Implant		
Success rate									
5	Nonrandomized studies	Serious ^a	Serious ^b	Not serious	Not serious	287/357 (80.4%)	720/838 (85.9%)	⊕⊕⊕○ Moderate	Critical
1	Randomized trial	Not serious	Not serious	Not serious	Not serious	359/386 (93.0%)	364/386 (94.3%)	⊕⊕⊕⊕ High	Critical

^a Two studies showed serious ROBINS.
^b There are some heterogeneity in the study sample.

titanium—is not a major factor for their success rate. Therefore, orthodontists must control other factors to achieve better success rates, such as installation site, root proximity, surgeon ability, and patient hygiene.

- High-quality studies are needed to find a definitive answer on this issue.
- With a lower cost than titanium and similar clinical efficiency, SS seems to be a great material for orthodontic MIs.

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