European Journal of Orthodontics, 2019, 9–20
doi:10.1093/ejo/cjy015
Advance Access publication 28 March 2018

Systematic review

Success of palatal implants or mini-screws placed median or paramedian for the reinforcement of anchorage during orthodontic treatment: a systematic review

Lydia Kakali[1], Majed Alharbi[2], Nikolaos Pandis[2], Nikolaos Gkantidis[2] and Dimitrios Kloukos[1,2]

[1]Department of Orthodontics and Dentofacial Orthopedics, 251 Hellenic Air Force General Hospital, Athens, Greece and [2]Department of Orthodontics and Dentofacial Orthopedics, Faculty of Medicine, University of Bern, Switzerland

Correspondence to: Dimitrios Kloukos, Department of Orthodontics and Dentofacial Orthopedics, University of Bern, Freiburgstrasse 7, Bern, 3010, Switzerland. E-mail: dimitrios.kloukos@zmk.unibe.ch

Summary

Objectives: To assess the failure rates of palatal implants and palatal mini-screws, independently and comparatively, used for supplementing anchorage during orthodontic treatment.
Protocol and registration: The protocol was not registered prior to the study. This study was not registered in any publicly assessable database.
Materials and methods: Screening for inclusion eligibility, quality assessment of studies, and data extraction was performed independently by two authors. The electronic databases MEDLINE, EMBASE, and CENTRAL, as well as unpublished literature, were searched with no restrictions on publication date or language using detailed strategies. The main outcome assessed was palatal implant or mini-screw failure. Randomized controlled trials were evaluated according to the Cochrane risk of bias tool. Prospective and retrospective studies were graded employing the adjusted predetermined criteria of Bondemark.
Results: Twenty-seven studies satisfied the inclusion criteria. Four were RCTs of low risk of bias, 12 were prospective (2 low, 7 unclear, 3 high risk of bias) and 11 were retrospective studies (6 unclear, 5 high risk of bias). Only one retrospective study assessed both palatal implants and mini-screws. Seventeen studies, including the four RCTs, assessed solely palatal implants and nine studies palatal mini-screws. The median failure risk of palatal implants was 6.0 per cent (range: 0.0–26.1%) and of mini-screws 6.1 per cent (range: 0.0–33.3%). The median follow-up period was 17.9 months for palatal implants and 6 months for mini-screws.
Limitations: Significant clinical and methodological heterogeneity among studies and highly variable outcomes.
Conclusions: Both palatal implants and mini-screws have quite low failure rates that are also comparable, though the median follow-up period of palatal implants was quite larger. Therefore, in regular orthodontic cases, the choice between anchoring devices may rely on other factors, such as costs, patient comfort, personal preferences, familiarity with the device, and insertion procedures.

Introduction

Temporary anchorage devices (TADs) are the gold standard in reinforcement of orthodontic anchorage, as they are simple to insert and manage and have low failures (1–3).

TADs can be divided into two main categories: the osseointegrated mini-implants and the mini-screws. Mini-screws are significantly smaller in diameter, they are designed for immediate loading and rely primarily on mechanical stability. On the contrary, palatal implants are larger in diameter, they are placed in the palate, and they usually require a healing period of several weeks for osseointegration, as well as a surgical procedure for insertion and removal (4–7). Recent studies have indicated that palatal implants can also be immediately loaded (during the first week after insertion) with similar success rates to the conventionally loaded (4, 8).

The anterior palate is the ideal area for placement of orthodontic TADs due to the thin soft tissue and the appropriate quality and quantity of cortical bone (9). Besides, in the posterior palate there are several limiting anatomical structures, such as the increased soft tissue thickness composed mainly of adipose tissue and minor salivary glands, and the pathways of the greater palatine arteries, veins, and nerves (9). In adults, the median palatal suture zone is usually the site of choice for placement of palatal implants. In adolescents, however, the paramedian region is preferred to avoid possible growth disturbances of the maxilla in the transverse dimension (10). Regarding mini-screws, they are usually placed paramedian, both in adolescents and adults (11, 12), whereas median insertion is also possible (13). TADs placed in the palate can be used either indirectly, for instance as a part of a transpalatal arch for stabilizing molars while closing spaces after premolar extractions or by applying forces directly from the TADs to the teeth.

A systematic review published in 2012 on bone anchor systems for orthodontic applications showed high success rates of TADs, with some variability, however, between the different anchorage systems: 91–100 per cent for mini-plates, 74–93 per cent for palatal implants, and 61–100 per cent for mini-screws, placed at various sites. The loading period varied from 3 up to 24 months for mini-plates, from 2 to 33 months for palatal implants and from 2 to 22 months for mini-screws (3). Despite the already available systematic evaluations of relevant studies (most recent update: December 2011), the topic of bone anchored devices is of great clinical interest with new appliances coming to the market and various scientific studies published every year. Therefore, an updated systematic review was deemed necessary.

The aim of this review was to provide a comprehensive update of the literature on the failure rates of palatal implants and palatal mini-screws, independently and comparatively, used for supplementing anchorage during orthodontic treatment. As several terminologies for the different types of TADs exist in the literature, a clarification is necessary: in the present systematic review, the term 'palatal implants' will refer to mini-implants with diameter from 3.3 to 4.5 mm placed in the palate. The terms miniscrews, mini screws, mini-pins, and pins will be included in the term 'mini-screws' and will include all mini-screws with diameter from 1.1 to 2 mm, also placed in the palate.

Materials and methods

Protocol and registration

The protocol was not registered prior to the study. This study was not registered in any publicly assessable database.

Selection criteria applied for the review

- Study design: Any study design was considered eligible for inclusion in this review, including randomized clinical trials (RCTs), non-randomized, or quasi-randomized controlled trials, prospective, and retrospective studies.
- Types of participants: Orthodontic patients of any age who received palatal implants or palatal mini-screws for orthodontic anchorage reinforcement.
- Type of intervention: Median and paramedian palatal implants or mini-screws of any diameter or length.
- Primary outcome: Failure/success. Secondary outcome: any adverse events.
- Follow-up: All observation periods were accepted.
- Exclusion criteria: Animal and *in vitro* studies. Case reports or studies reporting less than five palatal implants or mini-screws. Mini-screws placed palatally, albeit with interradicular location.

Search strategy for identification of studies

Detailed search strategies were developed and appropriately revised for each database, considering the differences in controlled vocabulary and syntax rules. The following electronic databases were searched: MEDLINE (via Ovid and Pubmed, Appendix 1, from 1946 to May 2nd, 2017), EMBASE (via Ovid), the Cochrane Oral Health Group's Trials Register, and CENTRAL.

Unpublished literature was searched on ClinicalTrials.gov, the National Research Register, and Pro-Quest Dissertation Abstracts and Thesis database. The search attempted to identify all relevant studies irrespective of language. The reference lists of all eligible studies were hand-searched for additional studies.

Selection of studies

Study selection was performed independently and in duplicate by the first two authors of the review, who were not blinded to the identity of the authors of the studies, their institutions, or the results of their research. Study selection procedures comprised of title-reading, abstract-reading, and full-text-reading stages. After exclusion of non-eligible studies, the full reports considered by either author eligible for inclusion were obtained and assessed independently. Disagreements were resolved by discussion and consultation with the last author. A record of all decisions on study identification was kept.

Data extraction and management

Data extraction was performed independently and in duplicate by the first two authors. The following information was extracted from all eligible studies, if available:

- Methods: Author/title/year of study, design of study
- Participants: Number/age/gender of patients recruited
- Interventions: Type of palatal implant or mini-screw, manufacturer, diameter, length, placement location in the palate, direct or indirect use for anchorage reinforcement, healing period/ timing of loading, observation period (follow-up of patients)
- Outcome: type of outcome(s) and method of outcome assessment

Measures of treatment effect

For dichotomous data, number of TADs with events and total number of TADs in experimental and control groups were considered.

Unit of analysis issues

In all cases, the unit of analysis was the palatal implant or mini-screw placed.

Dealing with missing data

We tried to contact study authors via email to request information where missing. In case of no response or no access of the missing data, only the available data were reported and analyzed.

Assessment of heterogeneity

We assessed clinical heterogeneity by examining the characteristics of the studies, the similarity between the types of participants, the interventions and the outcomes as specified in the inclusion criteria.

Assessment of reporting bias

Reporting biases arise when the reporting of research findings is affected by the nature or direction of the findings. We attempted to minimize potential reporting biases including publication bias, multiple (duplicate reports) publication bias, and language bias in this review, by conducting an accurate and at the same time a sensitive search of multiple sources with no restriction on language. We also searched for ongoing trials.

Data synthesis

We planned to conduct meta-analyses if there were at least two studies of similar comparisons reporting the same outcomes at similar follow-up periods. Risk ratios were to be combined for dichotomous data using the random-effects model.

Quality assessment

Risk of bias assessment was performed by two review authors (L.K., M.A.), independently and in duplicate. Disagreements were resolved through discussion with the last two authors. The methodological quality of RCTs was assessed using the Cochrane risk of bias tool (14). Risk of bias was assessed and judged for seven separate domains and each study received a judgment of low risk, high risk, or unclear risk of bias (indicating either lack of sufficient information to make a judgment or uncertainty over the risk of bias) for each domain. Studies were finally grouped into the following categories:

- Low risk of bias (plausible bias unlikely to seriously alter the results) if all key domains of the study were at low risk of bias.
- Unclear risk of bias (plausible bias that raises some doubt about the results) if one or more key domains of the study were unclear.
- High risk of bias (plausible bias that seriously weakens confidence in the results) if one or more key domains were at high risk of bias.

Prospective and retrospective studies were graded as low, unclear, or high risk of bias according to the following criteria, adapted from the Bondemark scoring system (15):
- Low risk of bias (all criteria should be met):
Randomized clinical study or a prospective study with a well-defined control group.
Defined diagnosis and endpoints.
Diagnostic reliability tests and reproducibility tests described.
Blinded outcome assessment.
- Unclear risk of bias (all criteria should be met):
Cohort study or retrospective cases series with defined control or reference group.
Defined diagnosis and endpoints.
Diagnostic reliability tests and reproducibility tests described
- High risk of bias (one or more of the following conditions):
Large attrition.
Unclear diagnosis and endpoints.
Poorly defined patient material.

Results

Description of studies

In total, 766 studies were identified from the electronic search as relevant. All abstracts were retrieved and the specific inclusion criteria were applied. After exclusion of duplicates and detailed assessment of the abstract and the full text reports, 27 studies were considered eligible for inclusion in this review. Out of the 27 studies, 4 were RCTs, 12 were prospective, and 11 were retrospective studies (Table 1). The process of study inclusion in this review is presented in Figure 1.

Quality assessment

RCTs

The summary of methodological quality of the four included RCTs (4, 16–18) is shown in Figure 2. All studies demonstrated adequate randomization and allocation concealment. Blinding of the clinicians, patients, and assessors was not possible due to the nature of the interventions, but we still considered the possibility of bias as low since palatal implant/mini-screw failure (mobility, loss, etc.) is a hard outcome. Losses to follow-up were appropriately described and there was no evidence of selective outcome reporting and other biases. All four studies were rated at low risk of bias.

Prospective studies

Twelve prospective studies were identified, but only two were judged as low risk of bias (22, 23). None of the rest of the studies met all the necessary criteria outlined by the Cochrane Handbook. Three studies were judged as high risk of bias (6, 31, 32) due to lack of adjusting for confounders, which also had inadequate inclusion criteria. The rest seven prospective studies were rated as unclear risk of bias (5, 19–21, 29, 30, 33). Blinding of the assessors was difficult due to the nature of the interventions. However, as described earlier, it was not considered important because implant failure is a hard outcome (Table 2).

Retrospective studies

Eleven retrospective studies were identified. Five of them (9, 10, 13, 26, 28) were judged as high risk of bias due to lack of appropriate adjustment for confounder and/or inadequate inclusion criteria. The rest six retrospective studies (8, 11, 24, 25, 27, 34) were graded as unclear risk of bias mainly due to inadequate adjustment for confounders (Table 2).

Quantitative synthesis of the included studies

Only one retrospective study evaluated and reported both on palatal implants and mini-screws, among other TAD designs (28). All other included studies assessed, exclusively, either palatal implants or mini-screws. The multiplicity of screw designs and implant locations, however, in this study (28) did not allow for direct comparisons between the two groups. Furthermore, the significant clinical heterogeneity among studies did not allow for meta-analysis.

Table 1. Characteristics of included studies ordered by study design, within anchorage type.

Authors Study design	Study title	Participants (*N*, gender, mean age)	Interventions/comparators (length × diameter)	Outcome/observation period (mean)	Method of outcome assessment
Sandler *et al.* (16) RCT	Palatal implants are a good alternative to headgear: a randomized trial	*N* = 23 (7M, 16F) 15.7 (range: 12–39) years	23 palatal implants (Orthosystem, Straumann) 6.0 × 3.3 mm or 6.0 × 4.0 mm location: median use: direct or indirect loading: 3 months after placement comparator: headgear (*n* = 25)	Success rate 25.8 ± 0.6 months (including healing)	NA (failure of osseointegration)
Feldmann and Bondemark (17) RCT	Anchorage capacity of osseointegrated and conventional anchorage systems: A randomized controlled trial	*N* = 30 (15M, 15F) 14.3 ± 1.73 years	30 palatal implants (Orthosystem, Straumann) 3.3 × 4.0 mm location: paramedian use: indirect loading: 3 months after placement comparators: onplants (*n* = 30), headgear (*n* =30), transpalatal bar (*n* = 30)	Success rate 16.6–18.4 months (including healing)	Mobility
Jung *et al.* (4) RCT	Immediate versus conventional loading of palatal implants in humans: a first report of a multicenter RCT	*N* = 41 (6M, 35F) range: 12–65 years	41 palatal implants (Orthosystem, Straumann) 4.1 × 4.1 mm location: median or paramedian use: direct or indirect loading: 3 months (*n* = 21) or 1 week (18) after placement	Success rate 6 months (during loading)	Mobility
Jackson *et al.* (18) RCT	A comparison of stability between delayed vs immediately loaded orthodontic palatal implants	*N* = 21 (8M,13F) range: 13–48 years	21 palatal implants (Orthosystem, Straumann) 6.0 or 4.0 × 3.3 mm location: median use: direct or indirect loading: immediately loaded vs. not loaded	Success rate 2 months	Mobility
Wehrbein *et al.* (5) Prospective	Palatal implants anchorage reinforcement of posterior teeth: A prospective study	*N* = 9 (gender NA) range: 15–35 years	9 palatal implants (Orthosystem, Straumann) 4.0 × 3.3 mm or 6.0 × 3.3 mm location: median use: indirect loading: 3 months after placement	Success rate 11 ± 0.7 months (during loading)	Mobility
Bernhart *et al.* (6) Prospective	Short epithetic implants for orthodontic anchorage in the paramedian region of the palate	*N* = 21 (6M, 15F) 25.8 ± 9.9 (range: 12.7–48.1) years	21 palatal implants (Brånemark, Nobel Biocare, Sweden) 3.0x3.75 mm or 4.0x3.75 mm location: paramedian use: direct or indirect loading: 4 months after placement	Success rate 11.6 ± 4.9 months (during loading)	Mobility
Tosun *et al.* (19) Prospective	Method for the placement of palatal implants	*N* = 23 (8M, 15F) 22.5 (range: 19.5–25.0) years	21 palatal implants (Frialit-2 Implant System, Synchro Screw implants, Friadent, Mannheim, Germany) 8.0 × 4.5 mm location: paramedian use: indirect loading: 3 months after placement	Success rate NA (whole orthodontic treatment)	Mobility or loss
Crismani *et al.* (20) Prospective	Ninety percent success in palatal implants loaded 1 week after placement: a clinical evaluation by resonance frequency analysis	*N* = 20 (7M, 13F) 26.4 (range 15.3–47.9) years	20 palatal implants (Orthosystem, Straumann, Institut Straumann, Switzerland) 4.0 × 3.3 mm location: median use: direct loading: 1 week after placement	Success rate 3 months (including healing)	Mobility or loss
Männchen *et al.* (21) Prospective	Success rate of palatal orthodontic implants: a prospective longitudinal study	*N* = 70 (14M, 56F) 22.6 ± 10.8 years	70 palatal implants (Orthosystem, Straumann) 6.0 or 4.0x3.3 or 4.0 mm location: median or paramedian use: direct or indirect loading: 2–4 months after placement	Success rate 19 months (during loading)	Mobility
Wehrbein and Göllner (22) Prospective	Do palatal implants remain positionally stable under orthodontic load? A clinical radiologic study	*N* = 22 (8M, 14F) range: 21–62 years	22 palatal implants (Orthosystem, Straumann) 6.0 or 4.0 × 3.3 or 4.0 mm location: median use: direct or indirect loading: 3 months after placement	Success rate 18.2 months (during loading)	Mobility

Table 1. *Continued*

Authors Study design	Study title	Participants (*N*, gender, mean age)	Interventions/comparators (length × diameter)	Outcome/observation period (mean)	Method of outcome assessment
Jung *et al.* (23) Prospective	Success rate of second-generation palatal implants	*N* = 30 (13M, 17F) 19.7 (range: 12–41) years	30 palatal implants (Orthosystem, Straumann) 4.2 × 4.1 mm location: median use: direct or indirect loading: 3 months after placement	Success rate 6 months (during loading)	Mobility or loss
Asscherickx *et al.* (10) Retrospective	Clinical observations and success rates of palatal implants	*N* = 33 (14M, 19F) range: 10.3–53.2 years	34 palatal implants (Orthosystem, Straumann) 4.0 or 6.0 × 4.0 or 3.3 mm location: median (adults) or paramedian (growing) use: direct or indirect loading: 3 months after placement	Success rate 22 ± 7 months (NA)	Mobility or loss or anchorage capability
Arcuri *et al.* (24) Retrospective	Five year of experience using palatal mini-implants for orthodontic anchorage	*N* = 14 (2M,12F) > 20 years	16 palatal implants (Orthosystem, Straumann) 4.0 or 6.0 × 3.3 mm location: median use: direct or indirect loading: 3 months after placement	Success rate 23 months (during loading)	NA (failure of osseointegration)
Göllner *et al.* (8) Retrospective	Immediate vs conventional loading of palatal implants in humans	*N* = 76 (30M, 46F) 18 (range: 12–54)	76 palatal implants (Orthosystem, Straumann) 6.0 or 4.0 × 3.3 mm location: median use: indirect loading: 1 week or 3 months after placement	Success rate NA	Mobility
Jung *et al.* (25) Retrospective	Prognostic parameters contributing to palatal implant failures: a long-term survival analysis of 239 patients	*N* = 239 (81M, 158F) 20.6 (range: 10–65) years	239 palatal implants (Straumann, Basel, Switzerland) 6.0 or 4.0 × 3.3 mm; 4.0 × 4.0 mm; 4.1 × 4.2 mm location: median use: direct or indirect loading: 3 months after placement	Success rate 33 months	Mobility
Krieger *et al.* (26) Retrospective	One palatal implant for skeletal anchorage-frequency and range of indications	*N* = 56 (M22, F34) 19.5 (range: 11–52) years	56 palatal implants (Orthosystem, Straumann) 4.2 × 4.1 mm location: NA use: direct or indirect loading: 3 months after placement	Success rate NA	Mobility
Zuger *et al.* (27) Retrospective	Success rate of paramedian palatal implants in adolescent and adult orthodontic patients: a retrospective cohort study	*N* = 143 (53M, 90F) median: 15.7 (range: 10.2–50.9) years	145 palatal implants (Orthosystem, Straumann) 4.2 × 4.1 mm location: paramedian use: direct or indirect loading: 3 months after placement	Success rate 35.6 (range: 0.1–91.3) months	Mobility
Takaki *et al.* (28) Retrospective	Clinical study of temporary anchorage devices for orthodontic treatment	NA	148 palatal implants (PIAS, Tokyo dental college, Japan), 12 mini-srews (Dualtop autoscrew, Jeil Medical Corp, Korea; OSAS, DEWINED Co., Germany; K1 System, Dentsply-Sankin, Japan) varying diameter and length location: median or paramedian use: direct or indirect loading: 1 month after placement	Success rate NA	Mobility or loss
Gelgör *et al.* (29) Prospective	Intraosseous screw-supported upper molar distalization	*N* = 25 (7M,18F) range: 11.3–16.5 years	25 intraosseous screws (IMF Stryker, Leibinger, Germany) 14.0x1.8 mm location: paramedian use: indirect loading: 2 weeks after placement	Success rate 4.6 (range: 3.0–6.2) months (during loading; until completion of distalization)	Mobility
Gelgör *et al.* (30) Prospective	Comparison of two distalization systems supported by intraosseous screws	*N* = 40 (21M, 19F) range: 11.6–15.4 years	40 intraosseous screws (IMF Stryker, Leibinger, Germany) 14.0 × 1.8 mm location: paramedian use: indirect loading: 2 weeks after placement	Success rate 3–6.6 months (during loading; until completion of distalization)	Mobility

Table 1. *Continued*

Authors Study design	Study title	Participants (*N*, gender, mean age)	Interventions/comparators (length × diameter)	Outcome/observation period (mean)	Method of outcome assessment
Luzi *et al.* (31) Prospective	A prospective clinical investigation of the failure rate of immediately loaded mini-implants used for orthodontic anchorage	*N* = 9 34.3 (gender NA) (range: 13–64) years	Nine mini-screws (Aarhus Mini-Implants®, Medicon, Germany) 9.6 or 11.6x1.5 or 2.0 mm location: NA use: direct or indirect loading: 2–4 weeks after placement	Success rate minimum 4 months (NA)	Mobility or loss
Wu *et al.* (32) Prospective	Factors associated with the stability of mini-implants for orthodontic anchorage: a study of 414 samples in Tawain	*N* = 11 (gender NA) 26.5 ± 8.9 years	11 mini-srews (four types) location: NA use: NA loading: 1–2 weeks after placement	Success rate 6 months (during loading)	Mobility or loss
Kobayashi and Fushima (33) Prospective	Orthodontic skeletal anchorage using a palatal external plate	*N* = 137 (33M, 104F) range: 10–54 years	358 mini-screws (Anchor-Lock, Synthes Co., Solothurn, Switzerland) connected to a titanium plate 8.0 or under to 12.0 or over × 2.0 mm location: paramedian loading: 2 weeks after placement	Success rate 26 months (during loading)	Uncontrollable inflammation or mobility
Kim *et al.* (9) Retrospective	Midpalatal miniscrews for orthodontic anchorage. Factors affecting clinical success	*N* = 128 (27M, 101F) 23.4 ± 8.0 (range: 8.1–56.2) years	197 mini-screws (KLS-Martin, Jacksonville, Fla or Orthoplant, Biomaterials Korea, Seoul, Korea) 5.0 × 1.5 or 2.0 mm location: median or paramedien use: direct or indirect loading: immediately after placement	Success rate 18 months	Mobility
Ziebura *et al.* (34) Retrospective	Mini-implants in the palatal slope-a retrospective analysis of implant survival and tissue reaction	*N* = 41 (19M, 22F) 15.1 ± 4.9 (range: 10–37) years	66 mini-screws (The Jet Screw, Promedia Medizintechnik GmbH, Siegen, Germany) 8.0 × 2.0 mm location: paramedian use: direct or indirect loading: immediately after placement	Success rate 6 months	Mobility
Nienkemper *et al.* (13) Retrospective	Multipurpose use of orthodontic mini-implants to achieve different treatment goals	*N* = 43 (16M, 27F) 14.4 ± 6.6 years	80 mini-srews (Benefit; PSM Medical Solutions, Tuttlingen, Germany) 9.0 or 11.0 × 2.0 mm location: median or paramedian use: direct loading: NA	Success rate 14.4 ± 3.5 or 10.0 ± 4.2 months	Mobility
Karagkiolidou *et al.* (11) Retrospective	Survival of palatal miniscrews used for orthodontic appliance anchorage: A retrospective co-hort study	*N* = 196 (75M, 121F) median: 11.7 (interquartile range: 3.7) years	384 mini-screws (Ortho Easy; Pforzheim, Forestadent, Germany) 8.0 × 1.6 mm location: paramedian use: direct or indirect loading: 1 week after placement	Success rate mean: 5.5 (range: 0.4–23.8) months	Mobility

NA: not Available.

Qualitative synthesis of the included studies

Due to the reasons described above, the qualitative synthesis of the results was limited to failure rates for either palatal implants or mini-screws, separately.

The number of palatal implants or mini-screws per study ranged from 9 to 384 (Table 3). Great differences were observed also in follow-up periods among studies. Züger *et al.* (27), in a retrospective study, demonstrated the greatest follow-up period, which was 35.6 months, whereas Jackson *et al.* (18), in an RCT, study reported only 2 months of follow-up.

Palatal implants

In total, the risk of failure for palatal implants was assessed in 18 studies and ranged from 0.0 per cent (5, 19, 26) to 26.1 per cent (16), with a median risk of 6.0 per cent. The median follow-up period was 17.9 (range: 2.0–35.6) months. Thirty-nine palatal implants failed prior and 12 after loading.

Among the four relevant RCTs the risk of failure for palatal implants ranged from 2.5 per cent (4) to 26.1 per cent (median: 8.8%) (16). Jung *et al.* (4) claimed 2.5 per cent risk of failure for palatal implants with follow-up period of 6 months. Palatal implants

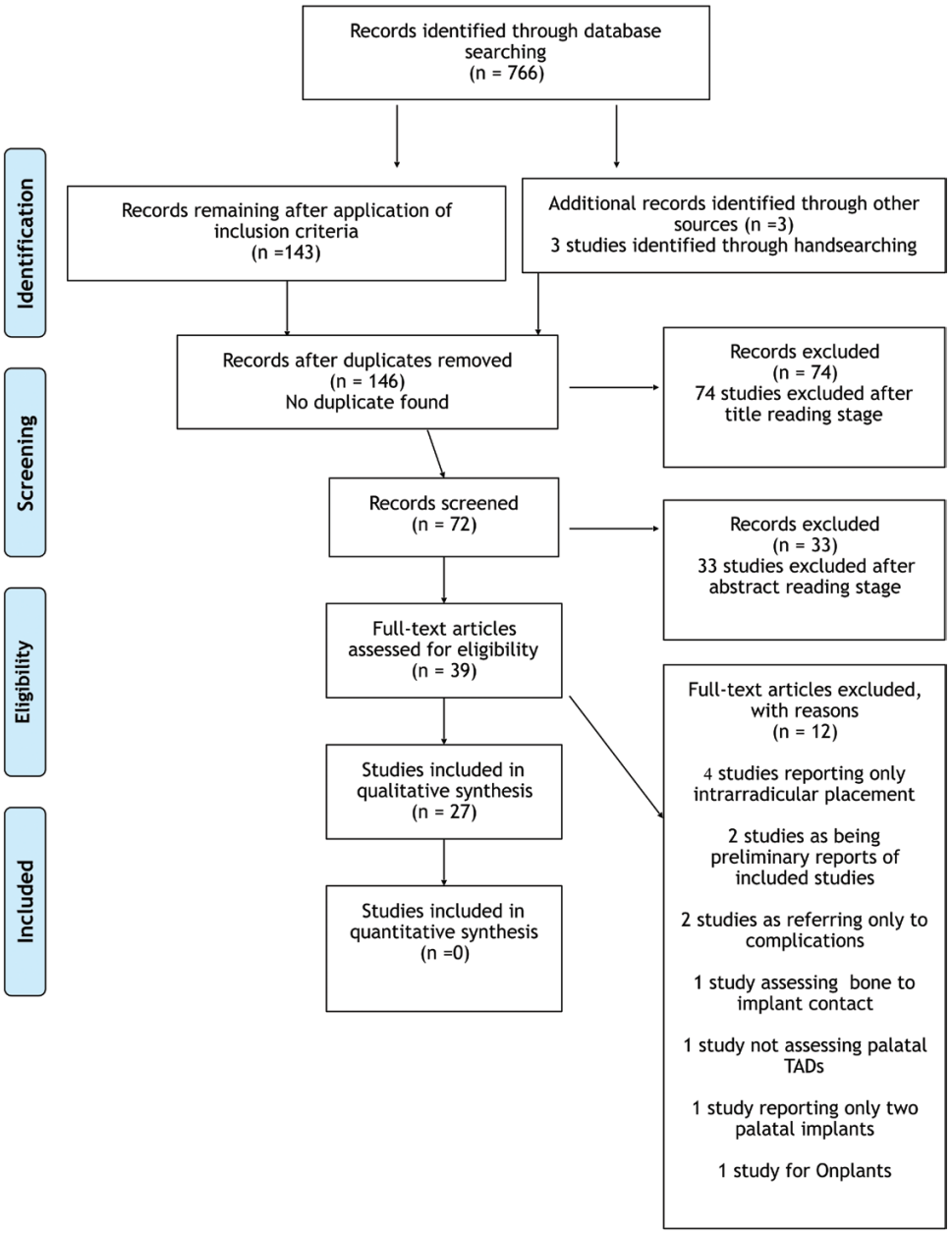

Figure 1. Studies flow diagram.

were used directly or indirectly. Sandler *et al.* (16) reported a 26.1 per cent risk of failure during an observation period of almost 26 months. Feldmann *et al.* (17) reported a risk of failure of 3.3 per cent for 30 palatal implants. The mean follow-up period was 17 months. Finally, Jackson *et al.* (18) showed a 14.3 per cent risk of failure over a 2-month observation period. All except from one palatal implant failed prior to loading.

Among prospective studies (n = 7) the risk of failure for palatal implants ranged from 0 per cent (5, 19) to 14.3 per cent (6) (median: 7.7%). The follow-up period ranged from 3 to 23 (median: 11.3) months. Six palatal implants failed prior to loading and other six after loading.

Among retrospective studies (n = 7) the risk of failure for palatal implants ranged from 0.0 per cent (26) to 21.4 per cent (24) (median: 5.0%). The follow-up period ranged from 22.0 to 35.6 (median: 28.0) months. Twenty-three palatal implants failed prior to loading and other five after loading.

Mini-screws

In total, the risk of failure for mini-screws was assessed in 10 studies and ranged from 0.0 per cent (29, 30, 32) to 33.3 per cent (31), with a median risk of 6.1 per cent. The median follow-up period was 6 (range: 4–26) months. From the studies that reported relevant information, two mini-screws failed prior and 28 after loading.

No RCT assessed failure or success of mini-screws. The risk of failure for mini-screws in the prospective studies (n = 5) ranged from 0 per cent (29, 30) to 33.3 per cent (31) and in the retrospective studies (n = 5) from 2.1 per cent (11) to 16.7 per cent (28).

Discussion

The aim of the present systematic review was to assess the failure risk of mini-screws and palatal implants inserted in the palate,

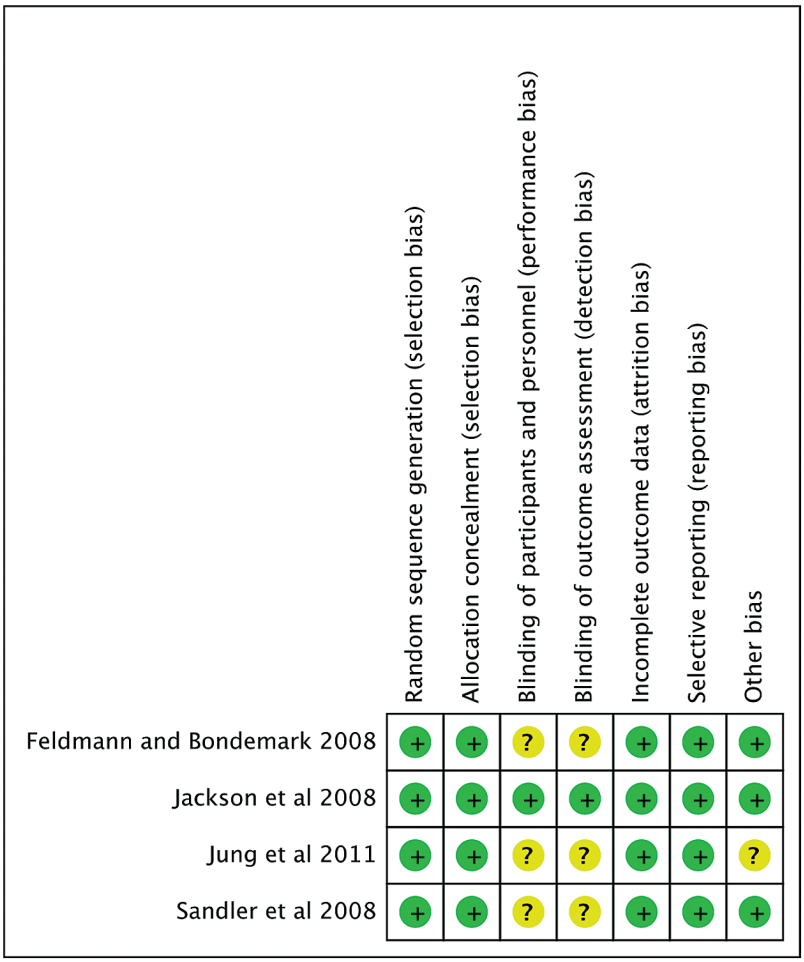

Figure 2. Risk of bias summary for RCTs.

independently, and if possible, comparatively. A comparative evaluation was not possible as all but one (28) of the identified studies did not compare the anchoring devices directly. The methodological and clinical heterogeneity among studies, including considerable variations in participants (sample size, age, sex) as well as in interventions (follow-up, direct/indirect use, study design), precluded a meta-analysis. Furthermore, potential clustering effects due to the use of multiple TADs per patient, which result in unit of analysis errors, were not adequately reported by the authors of the included studies.

As the focus of this review is on the failure risk of orthodontic palatal implants and mini-screws reported in the literature, an explicit definition of failure is appropriate. The most common measure was a palatal implant or mini-screw that showed mobility and thus did not remain stable, fulfilling the clinical requirements during the observation period.

In general, palatal implants were successful in providing the necessary anchorage during orthodontic treatment, with a low median risk of failure (6%) among studies of all designs, although considerable variation was evident (range: 0–26%). The main limitation of palatal implants is that they usually require two surgical procedures. The first is for palatal implant placement and is similar to that of dental implants and the second, more invasive, is sometimes needed for palatal implant removal. Insertion and removal of palatal implants is a technique-sensitive procedure, which requires a specialized periodontist or oral surgeon; thus increasing treatment costs. Furthermore, palatal implants can only be used as non-compliance treatment means for maxillary tooth movements, whereas mini-screws can be also placed in the mandible. The conventional healing period of approximately 12 weeks can also be considered a disadvantage in comparison to immediate loading of mini-screws. Nevertheless, certain recent studies have demonstrated that immediate loading of palatal implants resulted in comparable success with that of conventionally loaded implants (4, 8, 18).

Mini-screws have been favoured in the last decade because they can be inserted and removed easily by the orthodontist, under local or no anesthesia (3). Furthermore, they can also be placed at various locations within the dentoalveolar bone facilitating different treatment needs. The main advantage of mini-screws is the ease of use, although an important consideration is to avoid harming of vital anatomical structures during insertion (12, 35). The median failure risk among studies of all designs was 6.1 per cent, which is quite similar to that of palatal implants. Considerable variation was observed also in this case (range: 0–33%). However, it should be noted that although the median follow-up period for mini-screws was adequate for the needs of regular orthodontic cases (6 months), it was quite smaller than the 18-month median follow-up of palatal implants. Furthermore, the number of mini-screws per patient was not fully reported across studies. In addition, only few of the studies defined which failures concerned single used mini-screws or multiple mini-screws combined in one patient, precluding assessment of unit of analysis errors.

Table 2. Quality assessment for included prospective and retrospective studies.

Authors Study design	Study design and defined control group	Adequately defined patient material	Defined diagnosis and end points	Diagnostic reliability and reproducibility tests	Blinded outcome assessment	Overall risk
Wehrbein *et al.* (5) Prospective	–	+	+	+	+	Unclear
Bernhart *et al.* (6) Prospective	–	–	–	+	+	High
Tosun *et al.* (19) Prospective	–	+	+	+	+	Unclear
Crismani *et al.* (20) Prospective	+	–	+	+	+	Unclear
Männchen *et al.* (21) Prospective	+	+	–	+	+	Unclear
Wehrbein and Göllner (22) Prospective	+	+	+	+	+	Low
Jung *et al.* (23) Prospective	+	+	+	+	+	Low
Gelgör *et al.* (29) Prospective	+	–	+	+	+	Unclear
Gelgör *et al.* (30) Prospective	+	–	+	+	+	Unclear
Luzi *et al.* (31) Prospective	–	–	+	+	+	High
Wu *et al.* (32) Prospective	–	–	–	+	+	High
Kobayashi and Fushima (33) Prospective	+	–	+	+	+	Unclear
Asscherickx *et al.* (10) Retrospective	–	–	+	+	+	High
Arcuri *et al.* (24) Retrospective	–	+	+	+	+	Unclear
Göllner *et al.* (8) Retrospective	–	+	+	+	+	Unclear
Jung *et al.* (25) Retrospective	–	+	+	+	+	Unclear
Krieger *et al.* (26) Retrospective	–	–	–	+	+	High
Zuger *et al.* (27) Retrospective	–	+	+	+	+	Unclear
Takaki *et al.* (28) Retrospective	–	–	+	+	+	High
Kim *et al.* (9) Retrospective	–	–	+	+	+	High
Ziebura *et al.* (34) Retrospective	–	+	+	+	+	Unclear
Nienkemper *et al.* (13) Retrospective	–	–	+	+	+	High
Karagkiolidou *et al.* (11) Retrospective	–	+	+	+	+	Unclear

The findings of our study, in terms of success rate of palatal implant or mini-screws, are in agreement with earlier systematic reviews in the literature. In the systematic review of Schätzle *et al.*, the success rate for mini-screws, placed at different locations, was 85 per cent, with a follow-up observation period ranging from 4 to 36 months, whereas the success rate for palatal implants was 90 per cent, with a follow-up between 3 and 22 months (2). Another systematic review reported 94 per cent success rate for palatal implants. Failures were categorized to three following types: surgery-related 61 per cent, orthodontic-related 19 per cent, and patient-related failures 19 per cent (1).

As far as the risk factors of failure are concerned, no significant effect was identified in various studies for the factors of patient's sex or age. Interestingly, almost all studies included disproportional sex groups, with significantly more female patients. Oral hygiene has proved to be an important predictor of mini-screw or palatal implant success (36). There is evidence that insufficient oral hygiene leads to inflammation of the peri-implant tissues, which can affect the stability of the palatal implants. However, such a conclusion cannot be drawn from the present review since lack of information is present on this respect. In several studies, failure of palatal implants or mini-screws has been attributed to the parafunctional activity of the tongue, though no direct proof was provided. Host parameters that are considered to improve primary and secondary stability of mini implants include increased bone thickness and depth as well as high bone density (12, 35). Thin soft tissue is also considered

Table 3. Outcomes and interventions of included studies ordered by study design, within anchorage type.

Study	Anchorage type	Number of implants/ screws	Number of patients	Direct use	Indirect use	Events of failure	Risk of failure (%)
Sandler *et al.* (16) RCT	Palatal implants	23	23	0	23	6 (prior to loading)	26.1
Feldmann and Bondemark (17) RCT	Palatal implants	30	30	0	30	1 (prior to loading)	3.3
Jung *et al.* (4) RCT	Palatal implants	40	40	11	28	1 (prior to loading)	2.5
Jackson *et al.* (18) RCT	Palatal implants	21	21	10 (11 not loaded)	0	3 (1 after loading)	14.3
Wehrbein *et al.* (5) Prospective	Palatal implants	9	9	0	9	0	0.0
Bernhart *et al.* (6) Prospective	Palatal implants	21	21	6	15	3 (after to loading)	14.3
Tosun *et al.* (19) Prospective	Palatal implants	23	23	0	23	0	0.0
Crismani *et al.* (20) Prospective	Palatal implants	20	20	20	0	2 (after to loading)	10.0
Männchen *et al.* (21) Prospective	Palatal implants	70	70	25	42	3 (1 after loading)	4.3
Wehrbein and Göllner (22) Prospective	Palatal implants	22	22	NA	NA	2 (prior to loading)	9.1
Jung *et al.* 2009 (23) Prospective	Palatal implants	30	30	4	24	2 (prior to loading)	6.7
Asscherickx *et al.* (10) Retrospective	Palatal implants	34	33	13	18	3 (prior to loading)	8.8
Arcuri *et al.* (24) Retrospective	Palatal implants	14	14	4	10	3 (prior to loading)	21.4
Göllner *et al.* 2009 (8) Retrospective	Palatal implants	76	76	0	76	4 (1 prior to loading)	5.3
Jung *et al.* 2012 (25) Retrospective	Palatal implants	239	239	29	201	11 (9 prior loading)	4.6
Krieger *et al.* 2015 (26) Retrospective	Palatal implants	56	56	NA	NA	0 (only loading period evaluated)	0.0
Zuger *et al.* 2014 (27) Retrospective	Palatal implants	145	143	4	134	7 (prior to loading)	4.8
Takaki *et al.* 2010 (28) Retrospective	Palatal implants and mini-screws	148 palatal implants/ 12 mini-screws	NA	NA	NA	16/2	10.8/16.7
Gelgör *et al.* 2004 (29) Prospective	Mini-screws	25	25	0	25	0	0.0
Gelgör *et al.* 2007 (30) Prospective	Mini-screws	40	40	0	40	0	0.0
Luzi *et al.* 2007 (31) Prospective	Mini-screws	9	9	NA	NA	3	33.3
Wu *et al.* 2009 (32) Prospective	Mini-screws	11	NA	NA	NA	0	0.0
Kobayashi and Fushima (33) Prospective	Mini-screws	358	137	NA	NA	11 patients (prior to loading)	NA
Kim *et al.* (9) Retrospective	Mini-screws	197	128	197	0	18 (after loading; placed in 15 patients)	9.1
Ziebura *et al.* (34) Retrospective	Mini-screws	66	41	NA	NA	4 (2 prior to loading)	6.1
Nienkemper *et al.* (13) Retrospective	Mini-screws	80	43	80		5	6.2
Karagkiolidou *et al.* (11) Retrospective	Mini-screws	384	196	376	8	8 (after loading)	2.1

advantageous because it is less vulnerable to inflammation. The median and paramedian regions of the anterior palate possess all those characteristics, as well as the reduced risk damaging tooth roots, and thus, are rightly considered ideal for the placement of TADs. Paramedian regions seem to be preferable for the placement of mini-screws since they demand shorter force arms and they show the greatest palatal cortical bone thickness between the canine and the first premolar. Furthermore, such placement avoids unnecessary trauma to the midpalatal region, which is rich in connective tissue and consequently, potential instability of the implants, especially in young individuals (12).

TADs have a wide spectrum of clinical applications within orthodontics (37, 38). Palatal implants and mini-screws have been used both directly and indirectly. On the whole, 663 palatal implants had

been used indirectly and only 126 directly, whereas, only 78 mini-screws had been used indirectly versus 653 directly. However, since many studies did not clarify if the failed palatal implants or mini-screws were used directly or indirectly, we could not assess in more detail the association between direct/indirect use and success or failure. Finally, it should be kept in mind that some of the TAD designs analysed in the cited studies may have changed over time and may not be commercially available exactly at the same design as at the time the study was published.

Conclusions

This review provides updated information on the failure risk of palatal implants and mini-screws used for orthodontic anchorage. Both palatal implants and mini-screws have quite low failure rates that are comparable, and thus their value as orthodontic anchorage means is not questionable. Based on the available evidence, no clinically meaningful difference in failure risk seems to exist between palatal implants and mini-screws, though the median follow-up period of palatal implants was quite larger. Therefore, in regular orthodontic cases, the choice between anchoring devices may rely on other factors, such as costs, patient comfort, personal preferences, familiarity with the device and insertion procedures.

Conflict of Interest

None to declare.

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