



Complications reported with the use of orthodontic miniscrews: A systematic review

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Objective: The aim of this systematic review was to evaluate the complications and side effects associated with the clinical use of orthodontic miniscrews by systematically reviewing the best available evidence. **Methods:** A survey of articles published up to March 2020 investigating the complications associated with miniscrew insertion, in both the maxilla and mandible, was performed using 7 electronic databases. Clinical studies, case reports, and case series reporting complications associated with the use of orthodontic miniscrew implants were included. Two authors independently performed study selection, data extraction, and risk-of-bias assessment. **Results:** The database survey yielded 24 articles. The risk-of-bias assessment revealed low methodological quality for the included studies. The most frequent adverse event reported was root injury with an associated periradicular lesion, vitality loss, pink discoloration of the tooth, and transitory loss of pulp sensitivity. Chronic inflammation of the soft tissue surrounding the miniscrew with mucosal overgrowth was also reported. The other adverse events reported were lesion of the buccal mucosa at the insertion site, soft-tissue necrosis, and perforation of the floor of the nasal cavity and maxillary sinus. Adverse events were also reported after miniscrew removal and included secondary bleeding, miniscrew fracture, scars, and exostosis. **Conclusions:** These findings highlight the need for clinicians to preliminarily assess generic and specific insertion site complications and side effects.

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INTRODUCTION

Anchorage management is a key factor for success in clinical orthodontics, as it is essential to maximize desired tooth movements and mitigate unwanted forces.¹ Many anchorage devices, both intraoral and extraoral, have been proposed and used for more than a century.¹ Orthodontic implants or temporary anchorage devices (TADs) are a compliance-free alternative to conventional anchorage systems. Current literature suggests that TADs can provide more stable anchorage than do traditional methods.² Skeletal anchorage, in the form of implants or miniscrews fixed to the bone, can be used to enhance support to the reactive unit (indirect anchorage) or to fix the anchor unit (direct anchorage).³ Nowadays, TADs are widely used in daily orthodontic practice to increase the effectiveness of dental movement (protraction, retraction, intrusion, or uprighting) or the effectiveness of orthopedic appliances, in the form of hybrid or bone-borne designs.⁴⁻⁶ Nevertheless, the clinical use of miniscrews is associated with potential side effects (i.e., unwanted effects that are generally predictable and expected) and complications (i.e., unwanted and unexpected events due to treatment, and recognized as events that can happen), which can occur during their insertion, use, or removal.⁷

Many studies have evaluated the clinical applications and effectiveness of orthodontic miniscrews, but few have evaluated the side effects and complications related to their clinical use. Moreover, most of these studies in the literature are case reports, and studies covering and discussing the documented side effects and complications related to the usage of TADs are scarce.

Therefore, the aim of this systematic review was to evaluate the side effects and complications associated with the clinical use of orthodontic miniscrews by systematically reviewing the literature for the best available evidence.

MATERIALS AND METHODS

Protocol and registration

The present systematic review was performed according to the guidelines provided by the Cochrane Handbook for Systematic Reviews of Interventions (version 5.1.0) and was reported according to the PRISMA statement.^{8,9} The protocol of this systematic review was preliminarily registered on PROSPERO (ID: CRD42020142774). Two authors independently carried out study selection, data collection, and risk-of-bias assessment. Any disagreement was resolved by discussion with a third author. The level of agreement between the two reviewers was assessed using Cohen kappa statistics.

Information sources and search

A survey of articles published up to March 2020 about the complications associated with miniscrew insertion in both the maxilla and mandible was performed using 7 different electronic databases (Table 1). A specific search strategy was developed for each database, as shown in Table 1. The research strategy was not restricted by language, publication year, or status, and articles in foreign languages were translated when required. The reference lists of the articles eligible for inclusion were also manually reviewed. Previous systematic reviews and meta-analyses on this topic were also identified and their reference lists were scanned to identify additional studies.^{7,10,11}

Study selection

Duplicated reports were preliminarily excluded. All retrieved records were screened on the basis of titles and abstracts, and the full text of the remaining articles was assessed for eligibility before inclusion in the final analysis. Studies were considered eligible if they met the inclusion criteria, which were reported according to the PICO format (Table 2).

Data extraction and management

A data extraction form was developed to collect the characteristics of (study design, sample size, age, sex, insertion site, type of miniscrews, type of complication, observation period, and surgical insertion procedure) and outcomes from the included studies. The primary outcomes were the complications, which were unwanted and unexpected events due to treatment, generally related to improper use of orthodontic miniscrews, and could lead to permanent biological damage. In contrast, the secondary outcomes were side effects, which could occur regardless of how miniscrews were used and generally did not lead to permanent biological damage.

Risk-of-bias assessment

The risk-of-bias of the included studies was assessed using the Newcastle-Ottawa Scale (NOS), as recommended by the Cochrane Collaboration.¹⁰ The NOS consists of 8 multiple-choice questions that address subject selection (4 questions), comparability (1 question), and outcome assessment (3 questions). High-quality responses would be awarded up to 9 points (the comparability question earns up to 2 points). No risk-of-bias assessment was planned for case reports and case series.

RESULTS

Study selection

Among the 1,980 initially identified articles, 1,487 remained after the removal of duplicates. On the basis

Table 1. Databases screened, search strategies, and results

Database	Search strategy	Results
MEDLINE via PubMed searched on March 19, 2020, via www.ncbi.nlm.nih.gov/sites/entrez/	(((((orthodont*) OR (tooth movement*) OR (malocclusion*)) AND ((implant*) OR (miniscrew*) OR (mini screw*) OR (mini implant*) OR (miniscrew implant*) OR (mini screw implant*) OR (microscrew*) OR (micro screw*) OR (microimplant*) OR (micro implant*) OR (micro screw implant*) OR (osseointegrat*) OR (absolute anchorage) OR (skeletal anchorage) OR (stationary anchorage) OR (infinite anchorage) OR (temporary anchorage) OR (temporary anchorage devices) OR (TAD) OR (TADs) OR (temporary absolute anchorage) OR (temporary skeletal anchorage) OR (temporary stationary anchorage) OR (screw* AND orthodontic anchorage) OR (implant* AND orthodontic anchorage) OR (implants orthodontic anchorage) OR (screws orthodontic anchorage)))))) AND (Complication* OR Side effect* OR Adverse effect* OR Negative Effect* OR Root resorption* OR Root damage* OR Root perforation* OR Tissue scarring OR Mucosal lesion* OR Gingival tissue proliferation*)	994
Cochrane Database of Systematic Reviews via The Cochrane Library searched on March 19, 2020, via www.thecochranelibrary.com	(((((orthodont*) OR (tooth movement*) OR (malocclusion*)) AND ((implant*) OR (miniscrew*) OR (mini screw*) OR (mini implant*) OR (miniscrew implant*) OR (mini screw implant*) OR (microscrew*) OR (micro screw*) OR (microimplant*) OR (micro implant*) OR (micro screw implant*) OR (osseointegrat*) OR (absolute anchorage) OR (skeletal anchorage) OR (stationary anchorage) OR (infinite anchorage) OR (temporary anchorage) OR (temporary anchorage devices) OR (TAD) OR (TADs) OR (temporary absolute anchorage) OR (temporary skeletal anchorage) OR (temporary stationary anchorage) OR (screw* AND orthodontic anchorage) OR (implant* AND orthodontic anchorage) OR (implants orthodontic anchorage) OR (screws orthodontic anchorage)))))) AND (Complication* OR Side effect* OR Adverse effect* OR Negative Effect* OR Root resorption* OR Root damage* OR Root perforation* OR Tissue scarring OR Mucosal lesion* OR Gingival tissue proliferation*)	44
Cochrane Central Register of Controlled Trials via The Cochrane Library searched on March 19, 2020, via www.thecochranelibrary.com	(((((orthodont*) OR (tooth movement*) OR (malocclusion*)) AND ((implant*) OR (miniscrew*) OR (mini screw*) OR (mini implant*) OR (miniscrew implant*) OR (mini screw implant*) OR (microscrew*) OR (micro screw*) OR (microimplant*) OR (micro implant*) OR (micro screw implant*) OR (osseointegrat*) OR (absolute anchorage) OR (skeletal anchorage) OR (stationary anchorage) OR (infinite anchorage) OR (temporary anchorage) OR (temporary anchorage devices) OR (TAD) OR (TADs) OR (temporary absolute anchorage) OR (temporary skeletal anchorage) OR (temporary stationary anchorage) OR (screw* AND orthodontic anchorage) OR (implant* AND orthodontic anchorage) OR (implants orthodontic anchorage) OR (screws orthodontic anchorage)))))) AND (Complication* OR Side effect* OR Adverse effect* OR Negative Effect* OR Root resorption* OR Root damage* OR Root perforation* OR Tissue scarring OR Mucosal lesion* OR Gingival tissue proliferation*)	96
Web of Science searched on March 19, 2020, via www.webofknowledge.com	(((((orthodont*) OR (tooth movement*) OR (malocclusion*)) AND ((implant*) OR (miniscrew*) OR (mini screw*) OR (mini implant*) OR (miniscrew implant*) OR (mini screw implant*) OR (microscrew*) OR (micro screw*) OR (microimplant*) OR (micro implant*) OR (micro screw implant*) OR (osseointegrat*) OR (absolute anchorage) OR (skeletal anchorage) OR (stationary anchorage) OR (infinite anchorage) OR (temporary anchorage) OR (temporary anchorage devices) OR (TAD) OR (TADs) OR (temporary absolute anchorage) OR (temporary skeletal anchorage) OR (temporary stationary anchorage) OR (screw* AND orthodontic anchorage) OR (implant* AND orthodontic anchorage) OR (implants orthodontic anchorage) OR (screws orthodontic anchorage)))))) AND (Complication* OR Side effect* OR Adverse effect* OR Negative Effect* OR Root resorption* OR Root damage* OR Root perforation* OR Tissue scarring OR Mucosal lesion* OR Gingival tissue proliferation*)	654
LILACS searched on March 19, 2020, via http://bvsalud.org/en/	(tw:(miniscrews)) OR (tw:(mini implants)) OR (tw:(miniscrew implants)) OR (tw:(TADs)) OR (tw:(temporary anchorage)) OR (tw:(skeletal anchorage)) AND (tw:(complications)) OR (tw:(side effects)) OR (tw:(negative effects)) OR (tw:(adverse effects))	115

Table 1. Continued

Database	Search strategy	Results
BBO searched on March 19, 2020, via http://pesquisa.bvsalud.org/portal/advanced/?lang=en .	(tw:(miniscrews)) OR (tw:(mini implants)) OR (tw:(miniscrew implants)) OR (tw:(TADs)) OR (tw:(temporary anchorage)) OR (tw:(skeletal anchorage)) AND (tw:(complications)) OR (tw:(side effects)) OR (tw:(negative effects)) OR (tw:(adverse effects))	73
Clinical Trials. searched on March 19, 2020, via http://clinicaltrials.gov/ct2/home		4

Table 2. Eligibility criteria according to the PICO format

Field	Inclusion criteria	Exclusion criteria
Patient	Healthy human subjects treated with orthodontic miniscrews	Syndromic patients, orthognathic surgery
Intervention	Miniscrews inserted for orthodontics purpose	First generation miniscrews, miniplates
Comparison	Not applicable	Not applicable
Outcome	Soft and hard-tissue complication related to the use of orthodontic miniscrews	Complication related to the orthodontic treatment
Study design	Case reports, RCTs, PCTs, retrospective longitudinal studies, case series	Abstract, <i>in-vitro</i> studies, descriptive studies, review, and meta-analysis

RCTs, randomized controlled trials; PCTs, prospective clinical trials.

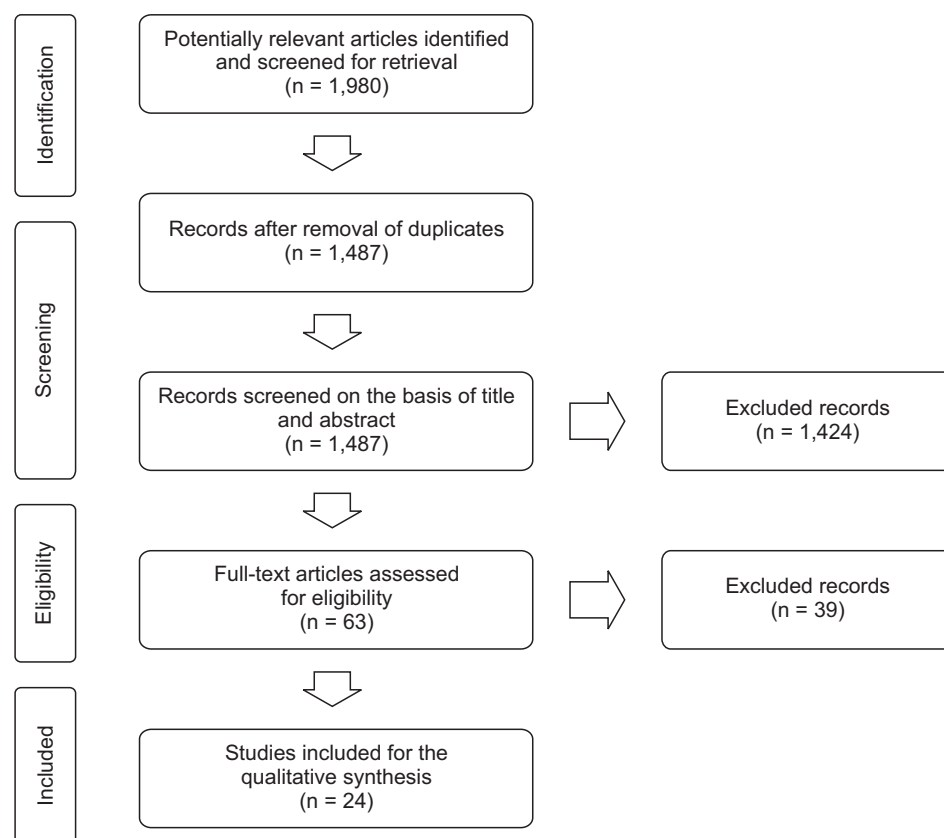


Figure 1. Flow chart showing the selection of studies performed according to the PRISMA guidelines.

of an analysis of the titles and abstracts, another 1,424 articles were excluded. Among the remaining 63 articles, 39 were further excluded after evaluating their full texts; nevertheless, 3 of those studies were meta-analyses, and hence, their reference lists were scanned to identify additional studies.^{7,11,12} Therefore, 24 studies were finally selected for the qualitative and quantitative synthesis. Figure 1 shows the flow diagram for the selection of studies. Table 3 lists the excluded articles together with the reason for exclusion.

Study characteristics

The characteristics of the 24 studies included in the systematic review are summarized in Table 4. All studies reported side effects and complications associated with the use of orthodontic miniscrews. The studies, as summarized in Figure 2, were identified as follows: 11 case reports,¹³⁻²³ 8 retrospective longitudinal studies,²⁴⁻³¹ 3 prospective controlled trials,³²⁻³⁴ 1 preliminary study,³⁵ and 1 case series.³⁶ All studies were conducted in a university setting and included both male and female participants. The reported average age of the patients ranged from 11 to 52 years old. Self-drilling titanium orthodontic miniscrews were used in 7 different studies,^{15,23,26,28-30,32} whereas non-self-drilling screws were used in 4 studies.^{19,24,25,27} The other studies did not specify the type of miniscrew inserted. The miniscrews used among the studies differed in terms of manufacturer and dimensions (such as diameter and length of the miniscrew). The diameters ranged from 1.2 mm^{13,14,21} to 3 mm,³⁵ and the length ranged from 2.3 mm³⁵ to 14 mm.²⁸

Table 3. Number of excluded studies and the reasons for exclusion

Exclusion reason	Articles excluded on the basis of title and abstract	Articles excluded after full-text evaluation
Not compatible methodology	81	4
Expert opinions	11	3
Abstract	60	
Review and meta-analysis	93	4
Descriptive studies	64	6
Different topic	688	5
Different evaluated outcome	305	15
Animal studies	67	
<i>In-vitro</i> studies	54	2
Trial in progress	1	
Total	1,424	39

All the miniscrews were surgically inserted according to the protocol suggested by the respective manufacturer. According to each orthodontic treatment plan, the miniscrews were positioned both in the maxilla and in the mandible, in the interradicular area,^{13,15,18,19,21-24,32,33,36} palatal zone,^{16,17,25,26,31} infrazygomatic crest,^{28,36} ascending ramus,²⁶ or buccal shelf.^{20,26,29}

The adverse events associated with the use of orthodontic miniscrews are summarized in Tables 5 and 6, after dividing them into complications and side effects, and reported separately with the relative information about the insertion site. Seven studies reported root perforation,^{18,19,21,23} with an associated periradicular lesion,¹⁶ loss of tooth vitality,²⁷ pink discoloration of the crown, and transitory loss of vitality.²² Three studies reported contact of the miniscrew with the root of the adjacent tooth.^{21,33,34} Three studies also reported the perforation of the maxillary sinus,^{28,32,36} and one study reported the perforation of the nasal cavity floor.²⁵

Some complications occurred immediately after the removal of the miniscrew, such as secondary bleeding,²⁵ fracture of the miniscrew,^{21,25,26} or loss of bone tissue around the insertion site.¹⁷ However, other complications occurred later, such as scars^{15,29} or exostoses.¹³ Other complications described were inflammatory lesions,^{26,30,31,35} necrosis of the buccal or palatal mucosa at the insertion site level,²⁵ or traumatic sores on the soft tissue in direct contact with the miniscrew.^{14,20} The patient's pain, during and after the insertion of the miniscrews, was reported in two different studies.^{14,25}

Risk-of-bias assessment

The risk-of-bias of the 8 included retrospective studies was assessed using the NOS.²⁴⁻³¹ The scores of the studies ranged from 3 to 5 stars, as reported in Table 7. The interreviewer agreements for study selection, data extraction, and risk-of-bias assessment were suitable, with kappa values of 0.931, 0.988, and 0.943, respectively.

DISCUSSION

To the best of our knowledge, this is the first systematic review that specifically investigated the current literature on the complications associated with the usage of orthodontic miniscrews. However, a meta-analysis could not be performed because of the high heterogeneity and differences in design among the selected studies.

According to the results of this systematic review, the insertion of miniscrews as TADs can be characterized by the onset of immediate or delayed complications associated with both the soft and hard tissues.

One of the most commonly reported complications was the contact of the miniscrews with the root of the tooth adjacent to the insertion site. This undesired event

Table 4. Characteristics of the selected studies

Study	Study design	Sample size	Mean age	Sex	Insertion site	Complication type	Observation period	Type of implant	Surgical insertion procedure
Agrawal et al. ¹³ (2013)	Case report	1	16	F	Buccal alveolar bone between roots of maxillary central and lateral incisors on both sides	Alveolar bone exostoses	2 months	1.2 mm diameter and 8 mm length	-
Al-Kharsa and Masoud ¹⁴ (2017)	Case report	1	-	-	Lingual alveolar bone between the roots of 46-47	-	-	-	-
Chen et al. ²⁴ (2011)	Retrospective study	20	24.3	15 F/5 M	Interradicular bone between the bilateral maxillary second premolar and first molar	Pain following microimplant treatment	3 months	1.2 diameter and 8 length. Non self-drilling. Absoanchor; Dentos, Daegu, Korea	Low-speed (400-500 rpm) pilot drill handpiece (diameter, 1 mm) used to penetrate the cortical level of bone only
Choi et al. ¹⁵ (2015)	Case report	1	20	F	Interdental alveolar bone, distal to the maxillary canines at the mucogingival junction	Scar lesion at the miniscrew removal site	3 months	Two self-drilling orthodontic miniscrews (1016107; Ortholution, Seoul, Korea)	-
Er et al. ¹⁶ (2011)	Case report	1	22	F	Bilaterally behind the incisive canal in the palatal interradicular spaces between the lateral incisor and canine	Periradicular lesion caused by unintentional root damage	10 months	Aarthus Anchorage System; MediconeG, Tuttlingen, Germany. 1.5 mm in diameter and 10 mm in length	-
Fabbroni et al. ³⁴ (2004)	Prospective study	55	16-52	54 M/1 F	Interradicular space in mandible and maxilla	Minor and major contact of adjacent teeth; loss of vitality, granulation tissue	7 months	Transalveolar screws: 2.0 mm titanium capstan headed screws	-

Table 4. Continued

Study	Study design	Sample size	Mean age	Sex	Insertion site	Complication type	Observation period	Type of implant	Surgical insertion procedure
Fäh and Schätzle ²⁵ (2014)	Retrospective study	146	19.5 years (implantations); 22.8 years (explantations)	104 (33 M/ 71 F); 44 (9 M/35 F)	Median and paramedian	Complication associated with the implantation: no primary stability, prolonged pain, secondary bleeding, perforation of nasal floor, necrotic mucosa, sensory impairment Complication associated with the explantation: disturbed wound healing, perforation of nasal floor, secondary bleeding, fracture of the implant	-	Palatal implant (Orthosystem; Institut Straumann AG, Basel, Switzerland). Self-tapping	Placed according to the Straumann guidelines for respective palatal implants. After local anesthesia, the palatal mucosa was either removed with a punch and an elevator or by open flap technique. After marking the center of the site with round drill, the hole was drilled by spiral drills. The self-tapping implant was inserted by hand with a ratchet. After the orthodontic treatment the palatal implant was removed using trephin
Ghislanzoni et al. ¹⁷ (2016)	Case report	1	11	M	Insertion of palatal miniscrew at the height of the second palatal rugae	Anchorage and bone loss around insertion site	14 months	6 mm miniscrew (3M Unitek, Monrovia, CA, USA)	-
Gracco et al. ³⁶ (2010)	Case series	4	24.3	3 F/1 M	Buccal insertion either between the second premolar and the first molar or between the first and second molars, at a 45° angle to the occlusal plane	Protrusion of the screw into sinus	-	Orthodontic miniscrews (Vector TAS; Ormco, Brea, CA, USA) of different lengths and diameters	-

Table 4. Continued

Study	Study design	Sample size	Mean age	Sex	Insertion site	Complication type	Observation period	Type of implant	Surgical insertion procedure
Gurdan and Szalma ²⁶ (2018)	Retrospective study	47	-	F	Palate, buccal fold, ascending ramus	Peri-implant inflammation in bone and in soft tissue, screw fracture	2 years	One or more self-drilling mini-screws (Jeil Dual Top Anchor System; Jeil Medical Corp., Seoul, Korea) with a dimension of 1.6 mm × 8 mm	Every screw was placed hand driven with the screwdriver tool of the mini-implant system
Hourfar et al. ²⁷ (2017)	Retrospective study	284	14.4 years (± 8.8)	182 F/102 M	Paramedian insertion in the anterior palate: at second rugae (76); between second and third rugae (24); at third rugae (468)	Loss to pulp sensibility testing (PST) of maxillary front teeth	-	OrthoEasy [®] , Forestadent, Pforzheim, Germany (1.7 mm diameter, length 8 mm); anodized surface and features a self-tapping and cutting design (Ti-6Al-4 V)	OMIs inserted without soft tissue incision or pre-drilling, perpendicular to the bone surface, using a motorised dental handpiece at an insertion speed of 60 RPM. Torque limitation was 30 Ncm
Hwang and Hwang ⁸ (2011)	Case report	1	46	M	Interradicular area between the central and lateral incisors	Root perforation of mandibular lateral incisor	1 year		
Jia et al. ²⁸ (2018)	Retrospective study	32	28 ± 6 years	10 M/22 F	Infrazygomatic crest	Penetration of infrazygomatic crest miniimplants into the sinus	13 months	Self-drilling mini-implants (A1, Penghua, Taiwan; stainless steel, 2 mm in diameter, 12-17 mm in length according to the individual anatomic variation). The mean length of the mini-implant was 14 mm, and the mean embedded angulation was 29.6°	Incision in the buccal keratinized gingiva near the mucogingival junction of the maxillary first molar, limited to less than 2 mm. A hand screwdriver used for mini-implant insertion

Table 4. Continued

Study	Study design	Sample size	Mean age	Sex	Insertion site	Complication type	Observation period	Type of implant	Surgical insertion procedure
Jung et al. ²⁹ (2015)	Study cohort	66	F: 28.5 ± 10.02 years; M: 28.9 ± 8.87 years	52 F / 14 M	Buccolingual insertion sites: maxillary buccal and mandibular buccal (within the attached gingiva, at the mucogingival junction, or within the alveolar mucosa), palatal slope, and midpalatal regions	Soft tissue scarring	6–58 months	Two types of selfdrilling Miniscrew: cylindrical type (1.5 mm in diameter, 7 mm in length; ACR OAS-T1507, Biomaterials Korea, Seoul, Korea) or combined cylindrical and tapered type (1.8 mm in diameter, 7 mm in length; Orlus Classic IO18107, Ortholution, Seoul, Korea)	Hand driver used to insert and remove miniscrew
Lee et al. ¹⁹ (2016)	Case report	1	21	F	Interradicular area, mesial and apical to the left maxillary second premolars	Root perforation	3 years	1.5 × 8.0 mm, Biomaterials Korea, Seoul, Korea. Miniscrew's sharp drilling tip	-
Lim et al. ²³ (2013)	Case report	1	44	M	Buccal and palatal interradicular attached gingiva between the left maxillary first and second molars	Root damage	3 years	1.8 mm in diameter and 7-mm long (Orlus IO18107; Orlus Korea, Seoul, Korea)	Miniscrews inserted using the self-drilled manual method

Table 4. Continued

Study	Study design	Sample size	Mean age	Sex	Insertion site	Complication type	Observation period	Type of implant	Surgical insertion procedure
Marquezan et al. ²⁰ (2012)	Case report	1	-	-	Interradicular between the maxillary central incisors	Traumatic lesion in the frenulum	-	-	-
McCabe and Kavanagh ²¹ (2012)	Case report	1	25	F	Interradicular area between the maxillary second premolar and first molar tooth	Root perforation, miniscrew's tip fractured	5 years	Two self-screwing 8-mm long 1.3-1.2 mm tapered miniscrews	Round bur used to mark the attached buccal mucosa and cortical bone
Motoyoshi et al. ³² (2015)	Prospective study	45	23.3 ± 8.9 years	28 F/17 M	Maxillary alveolar bone between second premolar and first molar	Maxillary sinus perforation	-	Self-drill miniscrews (ISA orthodontic anchor screw; diameter, 1.6 mm; length, 8 mm; Biodent, Tokyo, Japan)	A hand screwdriver used to place the miniscrew without a pilot hole so that it was inclined at 40° to 60° from vertical to the adjacent tooth axis
Qin et al. ²² (2016)	Case report	1	23	F	Between the root apices of the maxillary central incisors	Pink discoloration of the tooth and no response to EPT suggesting pulp necrosis	15 months	One 6-mm-long, 1.6-mm-diameter 'Tomas' miniscrew implant	-
Shinohara et al. ³³ (2013)	Prospective study	50	21.8 ± 5.7	35 F/15 M	Buccal alveolar bone between roots of maxillary central and lateral incisors on both sides	Root contact by mini implants	-	Commercial mini-implants (diameter, 1.6 mm; length, 8 mm; ISA orthodontic mini-implants; Biodent, Tokyo, Japan)	A pilot hole drilled in the buccal alveolar bone between the second premolar and the first molar of the maxilla or the mandible without creation of a flap. The pilot hole inclined 45° to 60° vertically to the adjacent tooth axis

Table 4. Continued

Study	Study design	Sample size	Mean age	Sex	Insertion site	Complication type	Observation period	Type of implant	Surgical insertion procedure
Takaki et al. ³⁰ (2010)	Retrospective study	455	M: 23.8 ± 9.2 years; F: 26.2 ± 9.9 years	97 M/358 F	Mini and microscrew: mandible (anterior alveolar region, posterior alveolar region, external oblique ridge, retro-molar region), maxilla (anterior alveolar region, posterior alveolar region, posterior alveolar palate region, median suture, paramedian suture, maxillary zygomatic buttress); PIAS: mandible (posterior alveolar region, retro-molar region), maxilla (anterior alveolar region, median suture, paramedian suture)	Acute and chronic inflammation (granulation tissue) of the soft tissue surrounding implant	-	Two different self-drilling titanium miniscrew implant systems (Dualtop autoscrew; Jeil Medical Corp., Seoul, Korea; OSAS; DEWIMED Co. Ltd., Tuttingen, Germany), one pre-drilling microimplant system (KI system; Dentsply-Sankin, Tokyo, Japan) and a palatal implant anchorage system (PIAS, Tokyo Dental College, Tokyo, Japan)	Micro- and mini-implants inserted into the gingival or palate and placed according to their manufacturers' protocols

Table 4. Continued

Study	Study design	Sample size	Mean age	Sex	Insertion site	Complication type	Observation period	Type of implant	Surgical insertion procedure
Wang et al. ³⁵ (2010)	Preliminary report	54	21.8 years	34 F/20 M	Buccal alveolar bone between the second premolar and first molar, between the first and second molars, between the second and third molars. Three angulations: 10–30°, 30–60°, 60–80°. Two different occlusogingival position: less than 3 mm from the mucogingival line, more than 3 mm from the mucogingival line	Buccal mucosal lesion and trauma associated to miniscrew	5 years	Aarhus miniscrews (prism shaped head, 3 mm in diameter and 2.3 mm long)	-
Ziebur et al. ³¹ (2012)	Retrospective study	41	15.1 years	19 M/22 F	Recommended location and slight deviation: half of the distance of the perpendicular line segment from raphe to the palatal cusp tip of the first bicuspid	Overgrowth, defined as the partial or complete covering of the implant head by soft tissue, palatal mucosa	6 months	Screws with necks of 3 or 5 mm; thread 8 mm long and 2 mm in diameter	Insertion using a surgical handpiece

F, female; M, male; OMI, orthodontic miniscrew implant; EPT, electric pulp testing.

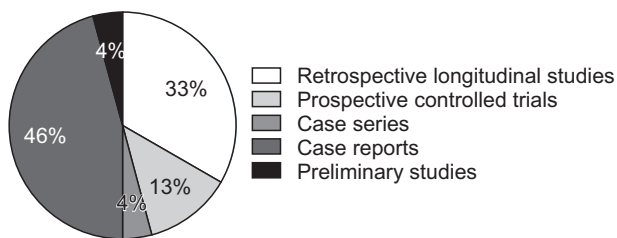


Figure 2. Pie chart showing the proportion of the selected study designs.

had a greater incidence in the interradicular insertion sites, mainly in the posterior region of both the arches, with a similar incidence in both the maxilla and the mandible.

Miniscrew-tooth contact can contribute to the loss of the miniscrew,^{37,38} or can determine tooth vitality loss.²⁷ Miniscrews placed in a narrow space, such as the interradicular space, can cause iatrogenic damage to the root and the periodontium, and the extent of damage may vary depending on the extent of penetration of the miniscrew. However, if the miniscrew invades the space limits of the periodontal ligament, its prompt removal will promote rapid tissue healing without further complications.^{34,39,40}

If the cementum is mechanically damaged, multinucleated cells will colonize the denuded dentin in contact with the miniscrew, resulting in root resorption. If the damage is limited to the surface area of the root, it can be replaced by cementum-like tissue within 2–3 weeks after miniscrew removal or even without removal.^{41,42} Root injury that affects the pulp tissue can cause periodontal ligament destruction and tooth vitality loss. Moreover, this adverse event will necessitate not only endodontic treatment of the injured tooth but also surgical repair of the root.¹⁸ The interradicular placement of the miniscrews also necessitates an appropriate radiographic evaluation to guide the clinician in determining the safest site for miniscrew insertion.^{43,44}

Therefore, clinicians should be aware that the greatest amount of interradicular bone in the buccal maxillary region is between the second premolar and the first molar, 5–8 mm from the alveolar ridge.^{45,46} In addition, in the mandibular buccal region, the greatest amount of bone is between the second premolar and the second molar. Thus, these regions are the most favorable ones for the buccal intraalveolar placement of orthodontic miniscrews. However, during the insertion procedure in the posterior region, operators have a strong tendency to change the insertion angle by bringing the handpiece toward them, and this maneuver can increase the risk of root injury and miniscrew fracture.⁴⁷

During the insertion procedure, if the miniscrew

Table 5. Complications – Part I (interradicular insertion sites)

Jaw	Anterior region		Lateral region		Posterior region										
	Maxilla	Mandible	Maxilla	Maxilla	Maxilla	Maxilla	Maxilla	Maxilla	Maxilla	Mandible	Mandible				
Sample	1 F	2 M	1 F	1 F	15 F 5 M	1 F	1 F	1 F	28 F 17 M	35 F 15 M	1 M	52 F 14 M	1 M	52 F 14 M	35 F 15 M
Miniscrew	1	1/2	2/2	1/2	NA	1/2	1	8/82	68	68	2/2	68/122	1/2	17/62	79
Complication	Crown pink discoloration, no response to EPT ²²	Exostoses ¹³	Root perforation ¹⁸	Scar lesion ¹⁵	Pain ²⁴	Protrusion into the sinus ⁶	Root perforation & miniscrew fracture ²¹	Maxillary sinus perforation ³²	Root contact ³³	Root contact ³³	Protrusion into the sinus ³⁶	Scar lesion ²⁹	Root damage ²³	Scar lesion ²⁹	Root contact ³³

F, female; M, male; NA, not applicable; EPT, electric pulp testing.

Table 6. Complications – Part II (extraalveolar insertion sites)

	Infrazygomatic crest		Palate		Ascending ramus		Buccal shelf				
Sample	2 F 10 M	22 F 47	52 F 14 M	22 F 19 M	1 F	1 M	106 F 42 M	47	1		
Miniscrew	2/2	47/60	4/17	8/66	1/2	1	31/148	2/3	3/24	1	
Complication	Protrusion of the screw into the sinus ³⁶	Penetration into the sinus ²⁸	Inflammation ²⁶	Overgrowth ³¹	Periradicular lesion ¹⁶	Bone loss around the insertion site ¹⁷	Loss of response to PST ²⁷	Pain, bleeding, nasal floor perforation, necrotic mucosa, sensory impairment, disturbed wound healing, miniscrew fracture ²⁵	Miniscrew fracture, inflammation ²⁶	Inflammation ²⁶	Traumatic lesion ²⁰

F, female; M, male; NA, not applicable; PST, pulp sensibility test.

Table 7. Risk-of-bias assessment

Studies	Selection			Comparability		Outcome		
	Representativeness of the exposed cohort	Selection of the non exposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at start of study	Comparability of cohorts on the basis of the design or analysis	Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of follow up of cohorts
Chen et al. ²⁴	★	-	-	★	-	★	-	-
Fäh and Schätzle ²⁵	★	★	-	★	-	★	-	-
Gurdan and Szalma ²⁶	★	-	★	★	-	★	★	-
Hourfar et al. ²⁷	★	-	★	★	-	★	-	-
Jia et al. ²⁸	★	-	★	★	-	★	-	-
Jung et al. ²⁹	★	-	★	★	-	★	★	-
Takaki et al. ³⁰	★	-	★	★	-	★	-	-
Ziebur et al. ³¹	★	-	★	★	-	★	★	-

The Newcastle-Ottawa Scale consists of 8 multiple-choice questions that address subject selection (4 questions), comparability (1 question), and outcome assessment (3 questions). High-quality responses would be awarded up to 9 points (the comparability question earns up to 2 points).

contacts the periodontal ligament, the patient may experience increased sensitivity even under topical anesthesia.^{44,48} In case of contact with dental roots, the miniscrew may stop or require greater insertion force.⁴⁸ Increased torsional stress during the insertion procedure could lead to flexion or fracture of the miniscrew.^{21,26} Miniscrew fracture often occurs in the cervical part, because during the insertion procedure, mechanical stress is concentrated at that point.⁴⁹ Self-drilling miniscrews are associated with increased torque during placement.^{50,51} This is beneficial for primary stability but could increase the risk of miniscrew fracture upon insertion, especially in high-density bone.⁵²

In the analyzed studies, the palatal site was less affected by complications. Taken together with the current literature, our findings suggest that the anterior region of the palate is the most appropriate insertion site owing to the high success rate and ideal anatomical characteristics.⁵³⁻⁵⁶ However, unintentional injuries to the roots of the anterior teeth were reported in 2 studies.^{16,27} In these studies, root damage occurred because of improper positioning, with the placement of the miniscrews at the second palatine rugae or ahead. In this regard, previous evidence suggests that the miniscrews should be placed posteriorly at the level of or behind the third palatine rugae.⁵⁷

Several researchers have recommended the infrazygomatic crest as a useful site for miniscrew insertion, since this area provides two cortical plates (i.e., the buccal cortical and maxillary sinus floor) that can ensure great primary stability.⁵⁸ However, the main complication related to the use of the infrazygomatic crest or the posterior region of the maxilla as a miniscrew insertion site is the perforation of the maxillary sinus. This complication was reported in 3 studies.^{28,32,38} Jia et al.²⁸ reported the perforation of the maxillary sinus in 78.3% of the miniscrews inserted in the infrazygomatic crest. Motoyoshi et al.³² reported the perforation of the maxillary sinus in 9.8% of the miniscrews inserted in the posterior region of the maxilla. However, maxillary sinus perforations ≤ 1.5 mm in depth are unlikely to affect screw stability.⁵⁹ Even if perforation occurs, interruption of orthodontic treatment and miniscrew removal are not needed. This is because small, uncomplicated perforations of the maxillary sinus by miniscrews may heal spontaneously.⁶⁰

One of the most frequently reported complications in the present review was related to the soft tissues surrounding the implant. Miniscrew placement can stimulate the surrounding soft tissues and evoke tissue inflammation, small infections, and periimplantitis, especially when placed through the non-keratinized or mobile gingiva. Tissue overgrowth, defined as a partial or total covering of the implant head by the surrounding

soft tissues, was reported by Ziebur et al.³¹ as the most common complication associated with miniscrews placed on the palatal site. To avoid this, several authors have proposed covering the miniscrew head with a healing abutment, wax pellet, or large separation elastic. For the same reasons and to avoid traumatic injuries caused by the miniscrews, Al-Kharsa and Masoud¹⁴ proposed covering the head of the miniscrew with a composite resin. Two studies reported soft-tissue scars after miniscrew removal.^{15,29} The removal procedure is almost atraumatic but leaves a small, transient, full-thickness wound that heals via secondary intention. Intrinsic factors, such as the patient's age and flat gingival biotype, or miniscrew-related factors, such as the insertion of the miniscrews in the attached gingiva or the mucogingival junction, especially at the maxillary buccal region, can represent risk factors for scar development. Therefore, the application of appropriate postoperative/removal care may be necessary to promote favorable healing.

CONCLUSION

The insertion of orthodontic miniscrews is a widely described and relatively safe therapeutic procedure; however, it is not free from possible complications and side effects.

The most frequently reported complication was the occurrence of lesions at the roots during miniscrew interradicular insertion. The main side effects found in this review were pain, soft- and hard-tissue inflammation, hypertrophy of the gingival tissues surrounding the miniscrew, and perforation of the maxillary sinus and nasal cavity walls.

Clinicians should preliminarily assess generic and specific insertion site complications and side effects.

There is a lack of clinical studies that specifically evaluate the complications and side effects associated with miniscrew insertion. Future studies are needed to address this scarcity of evidence.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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