Mestrado Integrado em Medicina Dentária
Faculdade de Medicina da Universidade de Coimbra

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Systematic Review

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Table of Contents

Resumo 6
Abstract 7
1. Introduction 8
2. Materials and Methods 12
2.1. Protocol 12
2.2. Strategy and Study Selection 12
2.3. Data Extraction 14
2.4. Risk of Bias 14
3. Results 15
3.1. Study Selection 15
3.2. Characteristics of the Studies Included in the Review 16
3.3. Risk of Bias 27
4. Discussion 30
5. Acknowledgment 33
6. Reference 34

List of Figures

Figure 1. Flowchart PRISMA 15

List of Tables

Table 1. Search strategy..... 12
Table 2. Characteristics of the *in vivo* studies 17
Table 3. Risk of bias in non-randomized in vivo studies 28
Table 4. Risk of bias in randomized in vivo studies. 29

Resumo

Introdução: Durante o tratamento ortodôntico são geradas forças recíprocas indesejáveis ao movimento dentário, sendo necessário recorrer a estratégias de ancoragem por forma a diminuir os seus efeitos nefastos através de aparatologias intra e/ou extraorais. Os microimplantes são dispositivos intraorais de pequenas dimensões utilizados na ancoragem esquelética temporária e, apresentam facilidade na técnica de colocação e remoção. No entanto, alguns estudos referem efeitos adversos, tais como, inflamação, dor e desconforto.

Objetivo: Esta revisão sistemática tem como objetivo sintetizar as evidências disponíveis sobre a utilização de microimplantes durante o tratamento ortodôntico na perspetiva do doente.

Materiais e métodos: A pesquisa bibliográfica foi realizada com recurso a diversas bases de dados: PubMed via MedLine, Cochrane Library, Web of Science Core Collection e EMBASE. Foi ainda realizada uma pesquisa na literatura cinzenta. Os termos de pesquisa utilizados foram: “Orthodontic Anchorage Procedures”, “mini-implant”, “Mini Dental Implant”, “Miniscrew” e “microimplant”. As ferramentas de risco de viés da Cochrane foram utilizadas para avaliar a qualidade dos estudos incluídos.

Resultados: Os pacientes tendem a superestimar a dor inerente a este procedimento. A inserção de microimplantes é mais aceite que o procedimento de extrações dentárias, com o reporte de dor pós-operatória menor. A localização, técnica cirúrgica e o tipo de anestesia utilizados na colocação dos microimplantes afetam os níveis de desconforto.

Discussão: Os doentes têm tendência a sobrestimar a dor que poderão sentir durante a colocação do microimplante, no entanto, a dor sentida é significativamente menor do que o esperado. Além disso, a execução de uma boa técnica cirúrgica e a capacidade de comunicação do clínico são fatores que condicionam a satisfação e perceção positiva entre os doentes.

Conclusão: As perspetivas dos doentes relativamente à avaliação e caracterização do impacto de doenças bem como o efeito dos tratamentos/intervenções devem ser considerados no planeamento ortodôntico**.**

Palavras-chave: Mini-implante, Microimplante, Dispositivos de Ancoragem Temporários, Procedimentos Ortodônticos de Ancoragem, Ancoragem Esquelética

Abstract

Introduction: During orthodontic treatment, undesirable reciprocal forces are generated during tooth movement, which explains the use of anchorage strategies to minimize their harmful effects through intra and/or extraoral appliances. Miniscrews are intraoral devices used for temporary skeletal anchorage. Miniscrews are small-sized intraoral devices used for temporary skeletal anchorage and are easy to place and remove. However, some studies refer to adverse effects such as inflammation, pain, and discomfort.

Objective: This systematic review aims to synthesize the available evidence on the use of miniscrews during orthodontic treatment from the patient's perspective.

Materials and Methods: The literature search was conducted using various databases: PubMed via MedLine, Cochrane Library, Web of Science Core Collection, and EMBASE.

A search was also carried out in the grey literature.The search terms used were: "Orthodontic Anchorage Procedures," "mini-implant," "Mini Dental Implant," "Miniscrew," and "microimplant." Cochrane risk of bias tools were used to assess the quality of included studies**.**

Results: Patients tend to overestimate the pain inherent in this procedure. The insertion of micro implants is more accepted than the tooth extraction procedure, with less postoperative pain reported. The location, surgical technique and type of anesthesia used in the placement of miniscrews affect levels of discomfort.

Discussion: Patients tend to overestimate the pain they may experience during miniscrew placement; however, the actual pain felt is significantly lower than expected. Additionally, the execution of a good surgical technique and the clinician's communication skills are factors that influence patient satisfaction and positive perception.

Conclusion: Patients' perspectives regarding the assessment and characterization of disease impact, as well as the effect of treatments/interventions, should be taken into account in orthodontic planning**.**

Key-words: Mini-implant, Miniscrew, Temporary anchorage device, Orthodontic Anchorage Procedures, Skeletal anchorage

1. Introduction

The greatest benefit of orthodontic treatment is to improve the aesthetics and function of the teeth, which increases psychosocial well-being and reduces the risk of future problems that may arise from malocclusions, namely tooth wear and gum problems.[1-2]

Traditional treatment ignores the psychological state of the patient. The introduction of the biopsychosocial model of health emerged with the definition of health by the WHO: “not only the absence of infirmity and disease but also a state of complete physical, mental, and social well-being”.[3] Later, The American Dental Association defined evidence-based dentistry (EBD), which includes “patients' treatment needs and preferences”.[4] In this sense, the promotion of evidence-based studies in dental practice should include the patient's perception of health. Recently, the US Food and Drug Administration defined patient-reported outcome measure (PROM) as “any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else”. PROs in orthodontics can be obtained in three ways: by the orthodontist questioning the patient or through diagnostic data (cast models, X-rays, or photographs); by caregivers, especially when the patient is a child; and, by a self-reported.[5]

Nevertheless, the COMET initiative aims to facilitate the development and application of a minimum set of outcomes that must be measured and reported in all clinical trials of a specific disease or trial population. Currently, the final setting of key outcomes for orthodontics includes the impact of self-perceived aesthetics, alignment and/or occlusion, skeletal relationship, stability, patient-related compliance, breakage, and adverse effects on teeth or tooth-supporting structures.[6]

During orthodontic treatment plans and tooth movement, it is necessary to consider the application of Newton's third law of motion: “for every action, there is an equal and opposite reaction”. Thus, for every tooth force, must determine the equal and opposite reaction, considering reciprocal effects on the final molar and canine relation, overjet, overbite, stability, the periodontium and aesthetics. In this way, anchorage control is a key factor to achieve the results intended.[7] Anchorage is defined as the ability to limit the movement of some teeth while achieving the desired movement of other teeth, in other words, it is the ability to resist undesired reactive tooth movements. Conventionally, anchorage orthodontics is obtained by enhancing the number of teeth included in the anchorage unit or by the application of anchorage appliances (eg. headgear or intraoral appliances such as transpalatal arch). However, most of these

appliances rely on the patient's compliance for their effectiveness and only confer relative anchorage.[8] Absolute anchorage can be obtained by using the miniscrews (MI), also known as a temporary anchorage device (TAD). They are placed to control tooth movement during orthodontic treatment, avoiding undesirable forces, and they can be removed when the treatment is completed.[7] These devices provide a skeletal and stationary anchorage and aid in resolving challenging malocclusions that require absolute anchorage, so it has greatly expanded the limit of clinical orthodontics.[9] Miniscrews differ from current dental implants in size, design, surface characteristics, insertion sites, and protocol. They are made with a biocompatible material such as titanium or stainless steel.[10-11] The miniscrews are divided into three parts: the top one (head of miniscrew), which is supra-gingival and allows the anchor; the medium area or neck; and, the third, which provides the mechanic anchor and is inserted inside the bone.[12]

In terms of structural features, the metallic composition and the physical characteristics can vary among different manufacturers. With regard to the diameter, it can be less than 3 mm, as diameter choice depends on the insertion place. Interradicular mini-screws should not exceed 2 mm in order not to damage the roots of adjacent teeth, however, if they are too small, so they should not be smaller than 1.2 mm. It has been shown that diameter does not affect the amount of linear microdamage to bone adjacent to the miniscrew.[13] In terms of length, the third component can vary from 5 to 12 mm, which is determined by anatomical considerations.[14] The head may have the shape of a post or a flat top with a slot designed to insert an archwire if necessary. The size and configuration can be different according to the manufacturer. The miniscrews may be machine or hand driven. As a basic requirement, they should all have: a hole for ligature wire or elastic thread; a collar to attach elastomeric thread, a power chain or coil springs; and, a neck which may vary in size to accommodate the varying thickness of mucosa.[15]

Regarding insertion place, there are three major factors that the clinician should consider. The first factor is related to the exact place where they want to have the source of anchorage in relation to the required tooth movements, so the site and degree of anchorage required is dictated by the malocclusion. The second factor is the quality and quantity of suitable bone. Usually, the thickness of cortical bone should be 1-2 mm. The third factor is the position of the roots of adjacent teeth.[15] Their use is very versatile, since they can be used in all the treatment phases and the indications are numerous, for example, a mid-line or inclined plane alignment, a space opening, to retract teeth, to intrude or extrude teeth, and teeth traction.[16] Furthermore, they can help orthopaedic dentofacial treatments by supporting distraction procedures, maxillary protraction, cleft

segment expansion, stabilization, and tooth movements into narrow alveolar sites.[17] They can also be an option for adult orthodontic patients with a lack of quantity or quality of dental elements or cases with poor patient compliance.[18]

The use of orthodontic miniscrews has some advantages, namely, easiness of placement and removal (frequently only using topical anesthesia), minimally invasive procedure, and a good ratio between costs and benefits of orthodontic treatments.[19]

These aspects are some of the attractive factors that increase patient acceptance of miniscrew treatments.[10] A success rate of 80–90% has been reported. Although failure may be avoided by establishing the right therapeutic protocols, miniscrews failure should not be overlooked. Their failure rate is approximately 10% and occurs mostly in the first week after miniscrew insertion.[12] Additionally, the miniscrews also have some limitations and disadvantages related to the characteristics of the patient, namely, age, the quality of the bone tissue, the characteristics of the oral mucosa, implant site, the state of health of the organism and the quality of oral hygiene.[9]

There are several complications arising from the use of miniscrews such as: trauma to the periodontal ligament or tooth root, miniscrew slippage, nerve involvement, air subcutaneous emphysema, nasal and maxillary sinus perforation, bending, fracture, mobility or migration of miniscrew, stationary anchorage failure, aphthous ulceration, soft tissue inflammation, infection, and peri-implantitis.[20] While most of the soft tissue damage is temporary in most cases, hard tissue damages are irreversible.[21]

Considering the advantages and disadvantages mentioned, it is important to account for the patients' cooperation and perception of the discomfort, trauma, pain, and postoperative complications produced by the insertion and removable of the miniscrews.[19] According to the literature, once the orthodontist proposes the insertion of a miniscrew to the patients, initially most of them are afraid and ask "Is it OK to put a screw through the gingiva? Is it painful?". Most patients do not experience pain during and after placement and removal of the miniscrews. Generally, patients refer to more pain and symptoms such as swelling and discomfort after receiving miniscrews with mucoperiosteal flap surgery, these symptoms can last up to one week after the intervention. On the other hand, patients that had miniscrews placed without flap surgery reported slight pain immediately after the implantation, fewer had pain or symptoms the day after the insertion of the miniscrew and no pain after one week.[21] Pain is a complex and subjective sensation, thus objective quantification is difficult. To measure the pain intensity, Lee *et al* used the visual analogic scale (VAS), a valid and reliable method of measuring discrete pain, which can also assess the relative change in the magnitude of pain overtime on a linear scale. This study showed that the patients who underwent

miniscrews surgery tended to overestimate the pain anticipated by the surgery. Moreover, the pain felt was significantly less than what they had expected and the postinterventional pain decreased continuously. Pain felt one day after miniscrew placement was reported in the literature as being less than one day after extraction of the first premolar for orthodontic purposes or one day after bonding the fixed appliance.[22] Moreover, interdental micro-implants did not produce greater pain than other orthodontic interventions such as the initial tooth alignment phase, tooth extraction procedures, and the insertion of separators.[23]

In recent years, patient-reported measures in orthodontics regarding miniscrews have been reviewed, but studies focus mainly on pain during treatment, quality of life, and expectations of treatment. The objective of this study is to identify, appraise and synthesize all available evidence regarding patient´s perspective on miniscrews. It was designed to increase the understanding of their implications in the quality of life, personal satisfaction, expectations and acceptance in the patients undergoing orthodontic treatment.

2. Materials and Methods

2.1. Protocol

This systematic review was registered in PROSPERO with the ID CRD42023408057 number and was performed according to Preferring Items for Systematic and Meta-Analyses and Meta-Analyses (PRISMA) guidelines. The Population, Intervention, and Outcome (PICO) question was “What is the perspective of orthodontic patients on using miniscrews during the treatment?”.

2.2. Strategy and Study Selection

The research was carried out by searching several databases, namely PubMed (www.ncbi.nlm.nih.gov/pubmed), Cochrane Library (www.cochranelibrary.com), Web of Science Core Collection (webofknowledge.com/WOS), and EMBASE (www.embase.com). ProQuest (Database, EBooks and Technology for Research), HSRProj and Onegrey were also searched as other sources of grey literature. A manual search of the reference list of included studies was performed to assess possible eligibility.

The last search was performed on 29 November 2022, independently by two reviewers, and the language filter applied was: English, Portuguese, Spanish and French. At PubMed database the species filter for humans was also applied. The search strategy is presented in table 1.

Table 1. Search Strategy

Database	Search sentence
PubMed via Medline	(Miniscrew* OR mini-screw* OR mini-implant* OR “mini implant*” OR “Mini Dental Implant*” OR microimplant* OR micro-implant* OR “Dental Implants, Mini” OR “Dental Implant, Mini” OR “Skeletal anchorage” OR “absolute anchorage” OR “Temporary anchorage device*” OR "Orthodontic Anchorage Procedures"[Mesh] OR “Orthodontic Anchorage Procedure*” OR “Anchorage Procedure, Orthodontic” OR “Anchorage Procedures, Orthodontic” OR “Procedure, Orthodontic Anchorage” OR “Procedures, Orthodontic Anchorage” OR “Orthodontic Anchorage Technique*” OR “Anchorage Technique, Orthodontic” OR “Anchorage Techniques, Orthodontic” OR “Technique, Orthodontic Anchorage” OR “Techniques, Orthodontic Anchorage”) AND (''Orthodontics''[Mesh] OR Orthodontic*). The search formula for the Web of Science database was: (Miniscrew* OR mini-screw* OR mini-implant* OR “mini implant*” OR “Mini Dental Implant*” OR microimplant* OR micro-implant* OR “Dental Implants, Mini” OR “Dental Implant, Mini” OR “Skeletal anchorage” OR “absolute anchorage” OR “Temporary anchorage device*” OR “Orthodontic Anchorage Procedure*” OR “Anchorage Procedure, Orthodontic” OR “Anchorage Procedures, Orthodontic” OR

	“Procedure, Orthodontic Anchorage” OR “Procedures, Orthodontic Anchorage” OR “Orthodontic Anchorage Technique*” OR “Anchorage Technique, Orthodontic” OR “Anchorage Techniques, Orthodontic” OR “Technique, Orthodontic Anchorage” OR “Techniques, Orthodontic Anchorage”) AND (Orthodontic*)
Cochrane	(Miniscrew* OR mini-screw* OR mini-implant* OR "mini implant*" OR “Mini Dental Implant*” OR microimplant* OR micro-implant* OR “Dental Implants, Mini” OR “Dental Implant, Mini” OR “Skeletal anchorage” OR “absolute anchorage” OR “Temporary anchorage device*” OR [Orthodontic Anchorage Procedures] OR “Orthodontic Anchorage Procedure*” OR “Anchorage Procedure, Orthodontic” OR “Anchorage Procedures, Orthodontic” OR “Procedure, Orthodontic Anchorage” OR “Procedures, Orthodontic Anchorage” OR “Orthodontic Anchorage Technique*” OR “Anchorage Technique, Orthodontic” OR “Anchorage Techniques, Orthodontic” OR “Technique, Orthodontic Anchorage” OR “Techniques, Orthodontic Anchorage”) AND ([Orthodontics] OR Orthodontic*)
Embase	(miniscrew*:ti,ab,kw OR ‘mini screw*’:ti,ab,kw OR ‘mini implant*’:ti,ab,kw OR ‘mini dental implant*’:ti,ab,kw OR microimplant*:ti,ab,kw OR ‘micro implant*’:ti,ab,kw OR ‘dental implants, mini’:ti,ab,kw OR ‘dental implant, mini’:ti,ab,kw OR ‘skeletal anchorage’:ti,ab,kw OR ‘absolute anchorage’:ti,ab,kw OR ‘temporary anchorage device*’:ti,ab,kw OR ‘orthodontic anchorage’/exp OR ‘orthodontic anchorage procedure*’:ti,ab,kw OR ‘anchorage procedure, orthodontic’:ti,ab,kw OR ‘anchorage procedures, orthodontic’:ti,ab,kw OR ‘procedure, orthodontic anchorage’:ti,ab,kw OR ‘procedures, orthodontic anchorage’:ti,ab,kw OR ‘orthodontic anchorage technique*’:ti,ab,kw OR ‘anchorage technique, orthodontic’:ti,ab,kw OR ‘anchorage techniques, orthodontic’:ti,ab,kw OR ‘technique, orthodontic anchorage’:ti,ab,kw OR ‘techniques, orthodontic anchorage’:ti,ab,kw) AND (‘orthodontics’/exp OR orthodontic*:ti,ab,kw)
Web of Science Core Collection	(Miniscrew* OR mini-screw* OR mini-implant* OR “mini implant*” OR “Mini Dental Implant*” OR microimplant* OR micro-implant* OR “Dental Implants, Mini” OR “Dental Implant, Mini” OR “Skeletal anchorage” OR “absolute anchorage” OR “Temporary anchorage device*” OR “Orthodontic Anchorage Procedure*” OR “Anchorage Procedure, Orthodontic” OR “Anchorage Procedures, Orthodontic” OR “Procedure, Orthodontic Anchorage” OR “Procedures, Orthodontic Anchorage” OR “Orthodontic Anchorage Technique*” OR “Anchorage Technique, Orthodontic” OR “Anchorage Techniques, Orthodontic” OR “Technique, Orthodontic Anchorage” OR “Techniques, Orthodontic Anchorage”) AND (Orthodontic*)

Results from all databases were migrated to Endnote Web Clarivate in order to remove duplicate publications. Then, the titles and abstracts were evaluated independently by two reviewers (I.C. and R.T.) according to the eligibility criteria. In the event of disagreements, a third author (I.F.) was consulted. When the three authors still had doubts about inclusion, the article was collected for reading the full text.

The potentially eligible studies were selected according to the defined inclusion criteria: clinical studies (randomized controlled trials, non-randomized controlled and controlled trials and cohort studies) that reported the patient's perspective on using miniscrews during the orthodontic treatment. Non-clinical studies, cases reports, descriptive studies, animal studies, editorials or studies that did not include the patient’s perspective were excluded.

The full text of eligible publications was screened by two independent reviewers (I.C. and R.T.) and in case of disagreement, a third researcher was consulted (I.F.).

2.3. Data Extraction

For every study included the following information was extracted: first author, year, study design, sample size and characterization (age and sex), intervention performed (location, quantity of miniscrews, function and duration of their use), patient-reported outcome (oral function, orofacial pain, orofacial appearance and psychosocial impact and others) and patient-reported outcome measures (single-item questionnaire, generic multiple-item questionnaires and specific multiple-item questionnaire), results and conclusions.

Data extraction was performed by two authors independently (I.C and R.T.). Any differences in the collection of information between reviewers were resolved by a third reviewer (I.F.). In case of missing data, the authors tried to contact the authors of the articles.

2.4. Risk of Bias

The publications included were evaluated for methodological quality by two independent reviewers (I.C. and R.T.). The Cochrane Risk of Bias Tools were used and depending on the type of study, the corresponding Cochrane Risk of Bias Tool was chosen. A third reviewer solved any disagreements (I.F.). The classification of overall risk was: low- all domains evaluated with low risk of bias; moderate- low or moderate risk of bias for all domains; severe if at least one domain presents a severe risk assessment bias.

3. Results

3.1. Study Selection

The initial search, conducted on the previously mentioned databases, identified 9136 studies. After removing duplicates, 4463 studies were scrutinized by title and abstract, resulting in 65 potentially relevant studies. Finally, those studies were read in full and, considering that 36 articles did not report the patient's perspective on orthodontic treatment with microimplants, only 29 references met the eligibility criteria and were included in this systematic review. The identification, screening, and selection process are summarized in Figure 1.

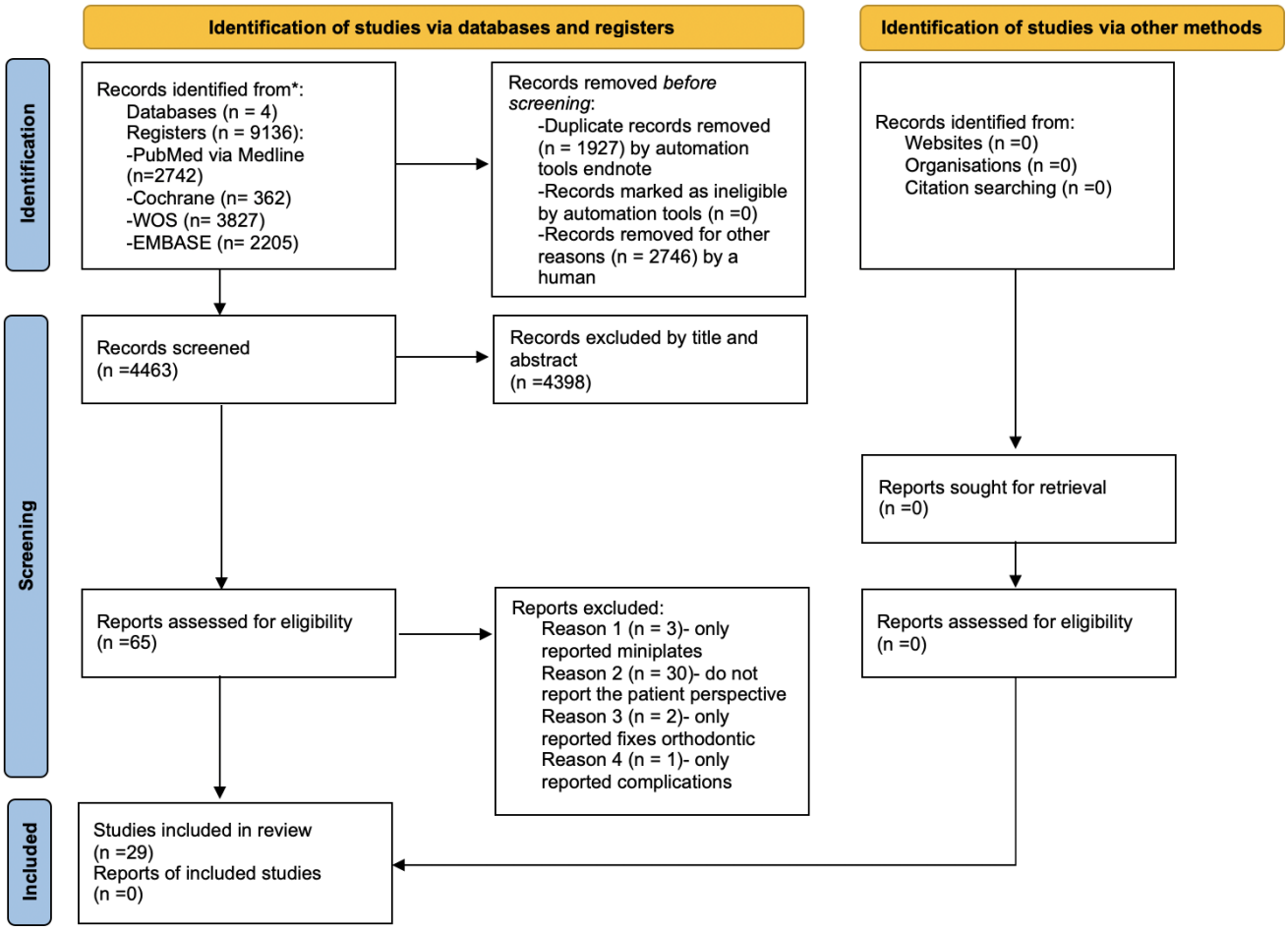

Figure 1. Flowchart PRISMA

3.2. Characteristics of the Studies Included in the Review

Twenty-nine articles analyzed the patient's perspective and experience with orthodontic treatment using miniscrews. Table 2 summarizes the results of the studies included in the present systematic review.

The publication years ranged from 2006 to 2022, being that nine articles were published on the last three years. The studies included are 9 RCTs, 2 pilot, 3 retrospective studies and 15 prospective studies. Concerning the age of participants, 10 studies included patients under 18 years old [24-33] and one included patients since 13 to 54 years old.[34]

With regard to the intervention performed, the number of miniscrews ranged from 4 to 625, with most participants receiving two miniscrews. Self-tapping miniscrews were used in 12 studies. Whereas 11 studies evaluated interradicular miniscrews, 2 studies included miniscrews placed in the infrazygomatic crest, buccal self and on the palatal. The anesthesia used was local and infiltrative in 16 and 10 studies, respectively.

All studies described the pain experienced and discomfort felt by the patients, while eleven also referred to expectations and the level of acceptance of this treatment.[22,26-28,35-41] Furthermore, eight studies assessed the patient's outcome, namely pain and discomfort, in the association of anesthesia during miniscrew placement.[24,26-27,34-35,42-44] There were differences in the patients' perceptions of anesthesia. Lehnen *et al.* reported that patients preferred miniscrews removal without anesthesia.[26] Likewise, Lehnen *et al*. showed that patients preferred manual miniscrew removal.[26-27]

Regarding the patient-reported outcome measurements, questionnaires were used in every study, 18 of which used the visual analog scale, a scale of psychometric response and numeric rating scales usually with 10 points.

The location of the miniscrew influenced the pain experienced, which was smaller in interradicular than in extraalveolar miniscrews (infrazygomatic crest, buccal shelf and palatal). Furthermore, the interradicular miniscrews caused more pain in the mandible.[45-46] Two studies reported that mucoperiosteal incision or flap surgery significantly reduced the patient's pain and discomfort after the intervention.[45, 47]

Three studies showed that the female sex experience more pain and discomfort than the male. Only one study showed that the male sex exhibited a higher sensibility to pain than the female. However, six studies did not observe significant differences.[24,27,34,37-38,43] Most of the studies included did not find an association with age.

Table 2. Characteristics of the in vivo studies

Author, Year	Study Design	Sample characterization (size, age and sex)	Intervention performed	Patient-reported outcome	Patient-reported outcome measures	Results	Conclusions
Zawawi KH. *et al.*, 2014[37]	Prospective	**Patients with MS (n= 83)** (29M / 54F) **Patients without (MS n = 165)** (52M / 113F) Mean age 21.4 ±4.1 y	**Type**: Self-tapping self-drilling **Location and dimension:** Mx - 8x1.8mm Md - 6x1.8mm **Anesthesic:** Local anesthesia **Sugery:** No mucoperiosteal flap and no pilot hole **Load:** Power chains 120 gm	Patient's acceptance Pain Medication Patient's previous knowledge of the devices Recommendation	10-point NRS for pain (total of 17 questions)	Significant relationship between level of education and prior knowledge about MS. 1 analgesic: 59.1%; 2 analgesic: 8.4% ; 0 analgesic: 32.5%. 6 hs post-op: there was a significant difference in pain between M (mean =2.6±2.2) and F (mean =2.1±1.5; P=0.03). 24 hs post-op: there was no difference in pain between M and F. 91.6% patients recommend this procedure.	Patients accept MS as treatment. Post- op pain is significantly low. The acceptance of MS was not related to patient's previous knowledge of the device.
Sreenivasagan S. *et al.*, 2021 [45]	Prospetive	**Patients with (MS n=31)** (15M / 16F) Mean age 27 ± 9 y	**Location and quantity:** n = 59 (12 IZC; 32 IR; 15 BS) **Type:** Self-drilling **Dimension**: EA 12x2mm and IR 1.5x1.3mm **Load:** Immediately with a standardized force of 400 g per side for EA and 250 g for IR	Pain Other problems (deflection of the cheeks and buccal mucosa during placement) Food accumulation Soft tissue entrapment	VAS at 24hs and 1w post-placement	BS caused more pain right after the placement. EA caused more pain, especially in the Md. 1w after the pain score was found to be reduced to baseline values in almost all the cases of IR MS. Patients with IZC MS and BS MS experienced more pain, reported as almost unbearable after the insertion. The EA MS caused more deflection of the cheeks and buccal mucosa, as well as food accumulation and soft tissue entrapment.	Patients placed with EA MS reported more pain than patients with IR.
Kuroda S. *et al.*, 2007[47]	Retrospective	**Patients with MS (n=75)** (12M / 63F) Mean age 21.8 ± 8.2 y	**Dimensions:** 7 or 11x2.0 or 2.3 mm; 6, 7, 8, 10, 12x1.3mm; **Anesthesic:** Local anesthesia **Sugery**: Mucoperiosteal flap and no mucoperiosteal incision or flap **Load:** Elastic chain or nickel-titanium closing coil springs, estimated between 50 and 200 g	Post-op discomfort Pain Swelling Speech difficulty Difficulty in chewing Difficulty in tooth brushing	100-point VAS (after implantation, 1h, 12hs and from 1d to 14ds)	Most patients required medication. The VAS assessments peaked 1 h after surgery (average PI reached 65.7 for type A MS, 66.4 and 19.5 for type B MS). After day 7, no patient with a type B MS reported pain. 10% of the patients with type A MS still reported pain more than 14d after surgery. Difficulty in speech and chewing were correlated with intensity of swelling.	MS placed without a mucoperiosteal incision or flap surgery significantly reduced the patient's pain and discomfort after placement.

(cont.) **Table 2**. Characteristics of the in vivo studies

Author, Year	Study Design	Sample characterization (size, age and sex)	Intervention performed	Patient-reported outcome	Patient-reported outcome measures	Results	Conclusions
Reznik DS. *et al.*, 2009[43]	Prospective randomized	**Patients with MS (n = 17)** (8M / 9F) Mean age 27,18 y	**Type:** Self-drilling, self-tapping, polished titanium screws with a tube and slot on the head **Dimensions:** 7x1.5 mm **Anesthesic**: 20% benzocaine gel (HurriCaine Topical anesthesia GEL, Beutlich LP Pharmaceuticals, Waukegan, Ill). Combination product containing lidocaine 20%, tetracaine 4%, and phenylephrine 2% (TAC 20% Alternate Topical Anesthetic Gel Thick)	Pain	Heft-Parker pain assessment at the placement appointment	The mean pain rating for the topical anesthetic group was 33.12 ± 32.20 SD had significantly lower perceived pain values than the benzocaine group: 92.71 ± 46.14 SD. The success rate for the topical anesthetic group was significantly higher than the benzocaine. There was no significant difference in pain rating or percent pulse rate change between genders and age.	The placement of TAD is well tolerated when a CTA is used. The difference in pain levels experienced was not dramatic enough to elicit a different physiologic response. The topical anesthetic group was shown to significantly decrease pain ratings when compared with 20% benzocaine.
Al-Melh MA. *et al.*, 2021[42]	Prospective randomized	**Patients with MS (n = 20)** Mean age 32.2 ± 5.3 y	**Dimensions**: 6x1.4 mm **Anesthesic:** A quarter of a carpule of the 2.5% lidocaine/2.5% prilocaine L/P topical anesthesia and placebo Vaseline® a quarter carpule of an injection anesthesia containing 2% lidocaine hydrochloride and 1:100,000 epinephrine	Pain Discomfort Numbing effect Presence of lip numbness Effectiveness of the anesthesia Procedural comfort	100-mm horizontal nongraded VAS (after the needle stick and after the MS placement).	The L/P topical anesthesia significantly eliminated the pain from needle stick The injection eliminated the pain from the MS placement better than the L/P topical anestesthetic Patients felt more comfortable with L/P topical anesthesia than injection anesthesia. Pain from needle stick pain was reported to be the most uncomfortable part of the study.	The L/P topical anesthesia efficiently eliminated pain from needle stick. However did not completely eliminate pain from MS placement as the injection anesthesia, but it did reduce pain to tolerable levels.
Azeem M. *et al.*, 2017[24]	Prospective	**Patient for MS PR (n=25)** (12M / 13F) Mean age 16.5 ± 1.3 y **Patients for MS BR (n = 30)** (13M / 17F) Mean age 16.1 ± 1.7 y	**Anesthesic**: PR-topical anesthesia (0.25 g of topical anesthesia containing 20% benzocaine gel and an injection of local anesthesia (0.45 mL of needle-injected anesthesia containing 2% lidocaine hydrochloride with 1:100,000 epinephrine BR-topical anesthesia on one side and topical placebo gel on the other	Pain	100-mm line VAS (before anesthetic, immediately after the anesthetic, immediately after the MS removal and removal procedures)	In the PR group, there were significant differences in mean VAS scores after the MS removal and when the patient combined the anesthesia and MS removal for the topical anesthesia in comparison with needle anesthesia. In the BR group, there were also significant differences in mean VAS scores for the placebo anesthesia in comparison with the topical gel anesthesia.	Topical anesthesia cannot be considered an adequate and comfortable alternative to the injection of local anesthesia for pain control while P MS removal is performed. However, using a topical benzocaine gel, when removing buccal IR MS, is effective in controlling patient discomfort.

(cont.) **Table 2**. Characteristics of the in vivo studies

Author, Year	Study Design	Sample characterization (size, age and sex)	Intervention performed	Patient-reported outcome	Patient-reported outcome measures	Results	Conclusions
Lamberton JA. *et al.*, 2016 [34]	Prospective randomized	**Patients with MS (n=24)** (10M /14F) Mean age 19.9 y	**Type**: Placed with a hand driver **Dimension**: Anterior 6x1.6 mm Posterior 8x1.6 mm **Anesthesic**: CTA compounded mixture of 10% prilocaine, 10% lidocaine, 4% tetracaine, and 2% phenylepherine. The needle-injected anesthesia was 0.45-mL, 2% lidocaine hydrochloride with 1:100,000 epinephrine, topical anesthesia 0.25 g of a single drug, consisting of 20% benzocaine	Pain Discomfort Anesthetic	100-mm VAS at 5 time point	Patients experienced more pain with the CTA during MS placement. The CTA was still viewed as more painful 1mth after the procedures. Significantly more anesthetic failures occurred with the CTA (41.6%) than with the injection (0%).	CTAs provided less predictable, often inadequate, and less comfortable anesthesia than an injection of a local anesthetic for managing patient discomfort during MS placement in buccal sites.
Valieri MM. *et al.*, 2014 [35]	Prospective	**Patients with MS (n = 40)** (17M / 23F) Mean age 26 y	**Type**: Self-drilling **Dimensions**: 6x1.5 mm **Anesthesic**: Infiltration anesthesia-lidocaine hydrochloride+ epinephrine 1:100,000, topical anesthesia gel with 20% lidocaine	Pain Level of acceptance	2 questionnaires (one before and another after MS placement) Pain measured through VAS	The procedure that worried the most the patients was the MS placement (37,5 %) and the infiltrative anesthesia (35 %). 23 patients preferred infiltrative anesthesia,13 patients preferred the topical anesthesia and 4 patients did not have any preference. MS placed with topical anesthesia caused significantly more pain than those placed with infiltrative anesthesia.	Patients considered pressure during MS placement the most unpleasant sensation. Patients had less pain with the use of infiltration anesthesia, and also preferred this type of anesthesia.
Majanni AMR. *et al.*, 2020 [25]	RCT	**Patients with BAIMT (n=28)** (13M / 15F) Mean age 11.49±0.88 y **n = 56** (29M / 27F) Mean age 11.46±0.89 y	**n** = 56 **Location**: Between the roots Md canine and 1st premolar **Dimension**: 8x1.6 mm **Anesthesic**: Local anesthesia **Load**: After 1w of insertion, intermaxillary elastics were applied generating a 125-g force per side of the jaw in the 1w (5/16-inch) followed by 3/16 medium size generating of about 200-g per side until the end of treatment	Pain Discomfort Pressure and tension Difficulty in swallowing Speech impairment Levels of lack of confidence	Sergl questionnaire with 6 questions (1d, 1w, 6ws, 3mths and 6mths)	Patients treated with the BAIMT system had higher levels of pressure, tension ($p<0.001$) and pain ($p<0.001$) compared to those in the control group.	The BAIMT system caused more pain and soft tissue tension the levels of pain gradually decreased especially after 1w following application.

(cont.) **Table 2**. Characteristics of the in vivo studies

Author, Year	Study Design	Sample characterization (size, age and sex)	Intervention performed	Patient-reported outcome	Patient-reported outcome measures	Results	Conclusions
Lehnen S. *et al.*, 2011 [26]	RCT	**Patients with MS n = 25** (11M / 14F) Mean age 15 y	**Location**: IR area of the Mx 2nd premolar and 1st molar **Dimension**: 8.0x1.6 mm **Anesthesic**: No local anesthesia was used 0.2 ml Scandonest® (3% mepivacaine hydrochloride)	Patient's experience Acceptance Preference evaluate Pain Symptoms Treatment expectations	Standardized questionnaire with 11 questions (prior, immediately after, and 1d after the treatment)	The noise associated with the handpiece was found to be unpleasant and tended to lead to more symptoms than when no handpiece was used. During the removal the most severe symptoms were associated with the injection itself. The non-injected side experienced significantly less discomfort and was thus the preferred side in both groups.	The noise associated with the handpiece increased discomfort, manual removal of the MS is preferable. Local anesthesia during removal does not provide a benefit. The most pain was caused by the injection, not by removal of the MS.
Baxmann M. *et al.*, 2010 [28]	RCT	**Patients with MS (n = 28)** (14M / 14F) Mean age 14.94 ± .95 y	**Location**: IR area of the Mx 2nd premolar and 1st molar **Dimension**: 8.0x1.6 mm **Anesthesic**: A superficial injection 0.2 mL Scandonest (3% mepivacaine hydrochloride) **Surgery**: The Tomas punch (diameter, 2.0 mm) was used for gingival tissue removal in the placement area. On the right hand side, the MS was transgingivally placed.	Pain Discomfort	Standardized questionnaire containing 12 items	MS placement produced no pain in 30% of the patients and was described as the least painful procedure (P <0.05). Transgingival MS placement was significantly preferred by all patients (P <0.05).	MS surgery seems to be a well-accepted option. Transgingival placement is clearly favored by patients who do not need tissue removed before placement.
Bud E. *et al.*, 2021 [44]	Prospetive	**Patients with MS (n = 50)** (26M / 24F) Mean age 20.84 ± 3.29 y **Group 1 (n= 28)** Mean age 21.07 ± 3.36 y **Group 2 (n= 22)** Mean age 20.54 ± 3.24 y	**Type**: Self-drilling mini-implant **Location**: 70% MS Mx **Dimension**: 11x1.8 mm **Anesthesic**: Topical use of Lidocaine™ spray and infiltration of 1 mL of articaine hydro-chloride + epinephrine 1:100,000 solution **Load**: Loaded with elastic bands after surgery	Pain (placement MS, removal MS, movement, elastic traction) Anesthetic	Self-report questionnaires (after implantaction, 2mths later, after MS removal) VAS	The maximum PI was recorded during MS placement, which has been associated with a PI of 2.4 ± 0.8, followed by MS removal (PI = 2.36 ± 0.66), gingiva/bone pain around the MS (PI = 2.32 ± 2.58), and elastic traction (PI = 2.26 ± 0.63). M presented a high intensity pain during MS placement (86.3% in Group 2 vs. 3.5% in Group 1, p <0.0001). The age group most sensitive to pain was 18 to 21 y.	Pain perception was significantly higher in M and in the 18–21 years age group. The most painful procedure during surgery was the moment of MS placement, followed by the removal of MS, gingival/bone pain around the MS, and the elastic tractions

(cont.) **Table 2**. Characteristics of the in vivo studies

Author, Year	Study Design	Sample characterization (size, age and sex)	Intervention performed	Patient-reported outcome	Patient-reported outcome measures	Results	Conclusions
Feldmann I. *et al.*, 2012 [32]	RCT	**Patients with MS (n = 30)** (30M / 30F) Mean age 14.3 ± 1.79 y **Total patients (n = 120)**	**Location**: Mx molars **Dimension**: 1.2 mm springhard stainless steel bar anchorage	Pain Discomfort Medication Jaw function impairment	Questionnaires with 17 questions VAS Binary responses	PI as well as tension from jaws and teeth and soreness peaked on day 2 and was almost back to baseline on day 7. Analgesic consumption for all patients followed the pain pattern and demonstrated no significant differences between groups. Limitations in daily life and jaw function were low to moderate and with no differences between anchorage groups.	Skeletal anchorage systems were well accepted by the patients in a long time perspective and can thus be recommended.
Feldmann I. *et al.*, 2017 [33]	RCT	**Patients with hybrid Hyrax expander anchored on 2 MS (n = 25)** (12M / 13F) Mean age 10.0 ± 1.16 y **Total patients (n = 54)**	**Location**: Palate **Dimension**: 8x1.7 mm **Load**: Both expanders were activated two quarter turns per day (0.5 mm)	Pain Discomfort Jaw function impairment	Questionnaires on the 1d and 4ds of treatment VAS Binary Five-point scale	Overall median pain on the 1 day was 13.0 (range 0–82) and 3.5 (0–78) for groups A and B, respectively, with no significant differences in pain, discomfort, analgesic consumption, or functional jaw impairment between groups. Patients with hybrid Hyrax scored significantly lower concerning pain from molars and incisors and tensions from the jaw on day 4 than on the day 1 in treatment.	Although the hybrid RME generally resulted in lower pain and discomfort scores, no statistically significant differences were found between the groups. Age was positively correlated with overall pain and discomfort. Both types of appliances were generally well tolerated by the patients the 1w in treatment.
Ganzer N. *et al.*, 2016 [30]	RCT	**Patients with MS (n = 35)** (11M/ 24F) Mean age 16.3 ± 0.28 y **Patients without MS (n = 38)** (12M / 26F) Mean age 14.9 ± 0.3 y **Total patients (n= 80)**	**Location**: Mx between 2nd premolar and 1st molar **Anesthesic**: Topical anesthesia with 5% lidocaine gel and buccal infiltration of 0.3 mL Xylocaine Dental Adrenalin per site (lidocaine hydrochloride 20 mg/mL, adrenaline 12.5 µg/mL **Load**: Immediate loading as direct anchorage with 150-g closed-coil springs	Pain Discomfort Impact on daily activities Functional jaw impairment	2 Questionnaires (baseline, the evening after TE, 1w after TE, the evening after MS placement, and 1w after MS placement) Horizontal VAS-100 mm and a five-point scale	Patients reported significantly lower levels of pain and discomfort after MS placement compared with PME. There were no significant differences between analgesic consumption after MS placement and PME, although pain levels were significantly lower after MS placement.	Installation of MS causes moderate pain and discomfort. PI and discomfort were significant lower for MS installation than PME. From the perspective of pain and discomfort, the use of MS in adolescents can be recommended.

(cont.) **Table 2**. Characteristics of the in vivo studies

Author, Year	Study Design	Sample characterization (size, age and sex)	Intervention performed	Patient-reported outcome	Patient-reported outcome measures	Results	Conclusions
Feldmann I. *et al.*, 2007 [31]	RCT	**Total patients (n= 120)** (60M/ 60F) **Patients with onplant (n = 30)** (15BM/ 15F) Mean age 14.0 ± 1.6 y **Patients with Orthosystem implant (n=30**) (15M/ 15F) Mean age 14.6 ± 2.0 y	**Location**: ONPLANT-a subperiosteal second premolar ORTHOSYSTEM- approximate level of the first premolar Mx **Dimension**:ONPLANT- diameter 7.7 mm ORTHOSYSTEM- diameter 3.3 mm, length 4 mm; **Anesthesic**: Local anesthesia was injected bilaterally in the palate (1.8 mL of 20 mg/mL lidocaine with 12.5 g/mL epinephrine). **Surgery**: ONPLANT- paramarginal incision, ORTHOSYSTEM- After the mucosa was punched, a specially designed bur created an MS site	Pain Discomfort Medication Daily Activities	Questionnaire VAS binary response	PI following surgical installation of an onplant was comparable to the PI experienced after PME, but there was significantly less pain after surgical installation of an Orthosystem implant compared to installation of an onplant (P = .002) or PME (P = .007). The protective, vacuum-formed stent caused great discomfort, even more discomfort than the surgical sites following installation of the onplant or the Orthosystem implant Onplant patients had taken significantly more analgesics than the patients with the PME on the 1 day. Onplant patients reported disturbed sleep more often than did patients with PME. Speech- less affected in PME patients	PI after surgical installation of an Orthosystem implant was less than after installation of an onplant or PME. The Orthosystem implant was better tolerated than the onplant in terms of pain intensity, discomfort, and analgesic consumption and was the anchorage system of choice in a short-term perspective.
Sreenivasagan S. *et al.*, 2021[46]	Prospective	**Patients with MS (n = 244)** (88M / 156F) **Orthodontists (n=155)** (71M / 83F) Mean age 30 ± 6 years	**Location**: 75% IR, 12% IZC, 9% BS, 8.5% P	Pain Discomfort Swelling Interference with daily activities Medication	Self-Report Questionnaire from patients. Practitioner Assessment Questionnaire VAS using the standard 10 cm metric scale and the Wong-Baker Faces Pain Rating Scale	F subjects had more MS placed, and average pain score was higher than M. The highest pain scores were recorded for P MS with an average score of 36.29 followed by the IZC, the BS and the least for IR MS with an average score of 9.02. Among the subjects, 47.9% of them took analgesics. Swelling and ulceration were resolved with excision of the surrounding soft tissue, composite placement, and palliative care with oral analgesic gels.	F had more MS placed, and higher pain scores than M. P MS caused the highest pain, followed by IZC and the BS. Proper placement techniques and effective palliative care should be utilized to prevent the development of ulceration, soft tissue enlargement, and swelling.

(cont.) **Table 2**. Characteristics of the in vivo studies

Author, Year	Study Design	Sample characterization (size, age and sex)	Intervention performed	Patient-reported outcome	Patient-reported outcome measures	Results	Conclusions
Lehnen S. *et al.*, 2011[27]	RCT	**Patients with (MS n = 30)** (16M/ 14F) Mean age 15.03 ± 0.83 y	**Type**: Group A the MS were inserted manually after pre-drilling with a dental handpiece. In group B self-drilling MS were inserted without pre-drilling **Location**: Mx between 2nd premolar and 1st molar **Dimension**: 8.0x1.6 mm **Anesthesic**: Local anesthesia injected 1.0 ml Scandonest® (3% mepivacaine hydrochloride) and 0.2 ml Scandonest® was injected into the MS insertion area	Anesthetic Discomfort	Standardized questionnaire with 11 questions (Immediately after the treatment and 1d after treatment) VAS divided into 5 scale ranges	There were no significant differences between the two groups in the degree of discomfort. Patients in group A considered the noise from the dental handpiece as the main discomfort factor, patients in group B reported that the pressure applied when inserting the self-drilling MS was the main source of discomfort. Overall discomfort from injections immediately next to the MS insertion area was lower than that resulting from the standard injection methods.	Patients tolerated the various insertion procedures equally well. The patients favored an injection immediately next to the MS insertion area.
Suresh N. *et al.*, 2022[29]	A pilot survey	**Patients with skeletal anchorage MARPE (n = 5)** Total patients (n= 10) (7M / 3F) Mean age 15.8 ± 2.8 y	**Dimension**: 1.8 mm **Load**: Two quarter turns per day (0.5 mm)	Pain Discomfort Medication	Questionnaire using VAS with a score of 1-10	More pain was experienced in the posterior teeth region by patients with MARPE. No significant intergroup difference in pain levels experienced in the anterior region, palatal vault and the head region and analgesic consumption was noted.	Although both Hyrax and MARPE were generally well tolerated there was a significantly higher pain experience in posterior teeth region for subjects treated with MARPE.
Blaya MG. *et al.*, 2010[36]	Prospective	**Patients with MS (n = 30)** (11M / 19F) Mean age 30 y	**Type**: Self-tapping **Location**: Mx **Dimension**: 10x1.2 mm **Anesthesic**: Local anesthesia **Load**: Loaded 2 w after placement. The force applied with the sliding jig mechanics was on average 300 g	Pain Side effects Discomfort (moment of placement, during mechanics and removal of MS)	Questionnaire with 12 questions (immediately after the MS placement, 30ds after placement and immediately after the MS removal)	90% of the patients choose MS over PME. Aphthous ulcer was the side effect most frequent after placement of the MS (30%). The greatest discomfort was felt during infiltration anesthesia (27%), though 23% reported no discomfort during placement. 83% of the patients reported no pain during placement.	MS were well accepted by the patients. The greatest discomfort felt during placement was that of infiltration anesthesia followed by the pressure during MS placement.

(cont.) **Table 2**. Characteristics of the in vivo studies

Author, Year	Study Design	Sample characterization (size, age and sex)	Intervention performed	Patient-reported outcome	Patient-reported outcome measures	Results	Conclusions
Pithon MM. *et al.*, 2015 [57]	Prospective study	**Patients with MS (n=58)**	**n** =132 **Type**: Self-tapping inserted directly into the bone using a manual driver. **Location**: Mx between 2nd premolar and 1st molar **Dimension**: 8x1.6mm **Anesthesic**: Infiltrative local anesthesia with a little less than 1/4 of the anesthesia cartridge **Load**: Loaded using a nickel titanium spring with 100 g force	Pain Discomfort Difficulty cleaning Complaints of aesthetic Difficulty in eating	Questionnaire containing 6 questions	Patients reported pain and discomfort during the MS placement. The mean score for benefits observed was very high, indicating good satisfaction with the end result of the treatment.	MS are recommended for clinical use, since the patients reported a low degree of discomfort and pain during their placement and use, little difficulty with cleaning, minimal complaints of aesthetic compromise and little difficulty with eating.
Tekale PD. *et al.*, 2020 [53]	Prospective	**Patients with MS (n=25)** **Patients without MS (n=25)** Mean age 24.5 y	**Type**: Self-tapping and self-drilling **Location**: Mx between 2nd premolar and 1st molar **Dimension**: 6x1.6mm **Anesthesic**: Topical anesthesia with 5% lidocaine gel and buccal infiltration of 0.3-mL xylocaine dental adrenalin **Load**: Immediate loading with 250-g closed-coil springs (TAD coil spring)	Difficulty in eating Food sticking Interference during tooth brushing Disturbance in chewing	Questionnaire with 5 questions VAS	Patient had difficulty in eating, food sticking around implant, and interference during tooth brushing was moderate, but there was no any anesthesia appearance and disturbance in chewing ability was noted.	The pain experience after MS insertion is significantly low. The peak of the pain and discomfort level was recorded 4 hours to 24 hours following the insertion. MS were found to be an acceptable option.
Lee TCK *et al.*, 2008 [38]	Prospective cohort	**Patients with MS (n=37)** (13M / 24F) Mean age 23.5 ± 10.9 y	**Type**: One-step self-drilling procedure **Dimension**: 7x1.3–1.4 mm **Anesthesic**: 0.5 mL of local anesthesia (2% lidocaine hydrochloride, 3M ESPE)	Pain Acceptance	Diary of VAS Vas 100-mm to rate the pain for 7d. Questionnaire 11 item after 1mth of the treatment	Unlike other orthodontic procedures, patients expected to experience a significantly higher level of pain with MS. The post-op pain decreased continuously from day 1 to day 7 for all orthodontic procedures. The majority of patients (86%) reported food stacking around the microimplants, but fewer complained of speech disturbances (37%)	Patients tended to overestimate the pain. The post-op pain of MS was significantly less than that of initial tooth alignment. Patients accept the surgery and would recommend it to others.

(cont.) **Table 2**. Characteristics of the in vivo studies

Author, Year	Study Design	Sample characterization (size, age and sex)	Intervention performed	Patient-reported outcome	Patient-reported outcome measures	Results	Conclusions
Kaaouara Y. *et al.*, 2018 [39]	Retrospective	**Patients with MS (n=29)** (10M / 19F)	NR	Pain Discomfort Satisfaction	4-page questionnaire divided in 3 sections	The majority of patients reported no pain when the MS were inserted. Post-operative pain decreased steadily between day 1 and day 7. When pain was felt during the 7-day period, it was significantly greater for initial tooth alignment than for MS surgery.	The use of MS is well accepted by patients. Post-operative pain is significantly lower than orthodontic alignment pain.
Kawaguchi M. *et al.*, 2014 [49]	Prospective	**Patients with UB MS (n=14)** (4M / 10F) Mean age 27.8 y **Patients with maxillary mid-palatal MS (n=31)** (3M / 28F) Mean age 23.7 y	**Location and quantity:** n = 76 (27 UB, 49P) **Type**: Self-drilling and a screwdriver **Dimension**: UB 8x1.6 mm P 6x2 mm	Pain Discomfort	Questionnaire survey for 2ws after MS insertion VAS	There were no significant differences in pain and discomfort due to the orthodontic archwire itself, as opposed to the anchorage devices, between all three groups. Although no major differences were found between buccal and P MS in terms of pain level, prolonged discomfort was observed in the P relative to the buccal.	MS should be selected as a first choice because of the milder pain and discomfort after insertion.
Sampson A. *et al.*, 2021 [40]	Prospective	**Patients with MS (n=39)** (15M / 24F) Mean age 33.8 y	NR	Patient perceptions Acceptance Expectations	Questionanaire with 8 questions with "yes", "no" and "I don't know "	Most UK and Brazilian patients want to see their clinician's work online (76.7%) and use SNSs to get information about treatment options.	Patients use SNSs to obtain information about treatments and prefer clinicians to have social media accounts. Patients exposed to TADs on SNSs are more likely to accept them as an OT option.
Brandão LBC. *et al.*, 2008 [41]	Pilot	**Patients with MS (n =10)**	**Location**: Between 2nd premolars and 1st molars **Dimension**: 9x1.5mm	Pain Discomfort Aacceptance Adverse reactions	Questionnaire with 12 questions	Most patients accepted quickly the procedure (90%) with some worries about the surgical procedures (50%) The patients got used to the MS, on average, in 3d, with a time maximum of 10d of adaptation The most unpleasant procedure was the pressure from inserting the MS (40%) the needle (30%) and the feel of numbness (20%)	The MS acceptance level was very prominent. After implantation, 40% did not report any discomfort, and the greatest difficulty was during cleaning (40%), chewing (10%) and some psychological apprehension (10%);

(cont.) **Table 2**. Characteristics of the in vivo studies

Author, Year	Study Design	Sample characterization (size, age and sex)	Intervention performed	Patient-reported outcome	Patient-reported outcome measures	Results	Conclusions
Mohd AND. *et al.*, 2021 [48]	RCT	**Patients with MS (n=39)** (13M / 26F) Mean age 22.13 ± 3.32 y	**Dimensions**: 8x1.8mm	Pain Discomfort Ulceration Quality of life	Questionnaire	The patients that did not have the MS cover showed statistically significant increase in the functional limitation and physical pain domain. Ulceration occurrence was more in the patients that did not have the MS cover than the patients that had the MS covered.	The Oral Health Related Quality of Life was not worsened in the Soft Flow cover. The patients that did not have the MS cover had the most occurrence of ulceration.
Chen CM. *et al.*, 2011 [22]	Retrospective	**Patients with MS (n=25)** (5M / 15F) Mean age 24.3 y	**Type**: Non-self-drilling MI. A low - speed (400– 500 rpm) pilot drill handpiece (diameter, 1 mm) **Location**: Mx **Dimension**: 8x1.2mm **Anesthesic**: Local anesthesia **Load**: Started 3ws after MS placement. A force of 100–200 g was loaded onto an elastomeric chain or NiTi coil spring.	Pain Discomfort	Questionnaire with 10 questions 100-mm VAS. Text 3m after removal of the MS, while wearing the orthodontic appliance.	The mean pain score 1 day after PME was 35.8 mm. The fear of the procedure aggravated the perception of pain. The pain experienced after de MS procedures was less than what patients expected.	Most patients acknowledge pain during OT. 1d after MS placement the VAS score was significantly less than the scores 1d after first PME and 1d after fixed appliance insertion.

BAIMT – Bone-Anchored Intermaxillary Traction, BR - Buccal miniscrew removal, BS – Buccal shelf, CTA – Combination of Topical Anesthetic, d – Day, ds – Days, EA – Extraalveolar, F - Female h – Hour, hs- Hours, IR – Interradicular, IZC – Infrazygomatic crest, L/P - lidocaine/prilocaine, M- Male, Md – Mandible, MS- Miniscrew, mth – Months, Mx – Maxilla, NR- Not reported, NRS - Numeric Rating Scale, OT – Orthodontic Treatment, P – Palate, PI – Pain Intensity, PME – Pre-molar Extraction, PR – Palatal miniscrew removal, Post- op – Post operation, RCT – Randomized controlled trial, TAC - Alternate Topical Anesthetic Gel, TAD – Temporary Anchorange Device, TE – Tooth Extraction, UB – Upper Buccal, VAS- Visual Analog Score, SNSs- Social networking sites, w – Week, ws – Weeks, y – years,

3.3. Risk of Bias

The quality assessment of the non-randomized and randomized studies is summarized in table 3 and 4, respectively.

Concerning non-randomized studies, none of the studies had the potential for confounding the effect of the intervention. Kaaouara *et al*. did not have all the participants filling the questionnaire response and did not report the follow-up of the patients.[39] There are concerns about the measurement of the outcome since the participants themselves assess the outcomes. Furthermore, four studies lack information regarding the selection of the reported results.[38-40,44]

Regarding randomized studies, most of the studies have a moderate risk of bias. Most of the studies face issues regarding the bias in measuring the outcome, since the patients fill the questionnaires and assess the parameters.[25,27-28,30-32,34,48] Four studies did not report how the randomization process was conducted.[27,29,31,48] Additionally, four studies had problems with the selection of the reported results.[25-28]

Table 3. Risk of bias in non-randomized in vivo studies

	Confounding	Selection of the participants into the study	Classification of interventions	Deviations from intended interventioons	Missing data	Measurement of outcomes	Selection of the reported results	Overall
Al-Melh MA. *et al.,* 2021 [42]								Moderate
Kuroda S. *et al.,* 2007 [47]								Moderate
Valieri MM. *et al.,* 2014 [35]								Moderate
Blaya MG. *et al.,* 2010 [36]								Moderate
Bud E. *et al.,* 2021 [44]								Moderate
Pithon MM. *et al.,* 2015 [57]								Moderate
Tekale PD. *et al.,* 2020 [52]								Moderate
Lee TCK. *et al.,* 2008 [38]								Moderate
Kaaouara Y. *et al.,* 2018 [39]								Moderate
Kawaguchi M. *et al.,* 2014 [49]								Moderate
Sampson A. *et al.,* 202 [40]								Moderate
Chen CM. *et al.,* 2011 [22]								Moderate
Sreenivasagan S. *et al.,* 2021[45]								Moderate
Sreenivasagan S. *et al.,* 2021[46]								Moderate
Zawawi KH. *et al.,* 2014 [37]								Moderate
Brandão LBC. *et al.,* 2008 [41]								Moderate

Green- low risk of bias; Yellow- Moderate risk of bias

Table 4. Risk of bias in randomized in vivo studies.

	Randomization process	Deviations from the intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported resullt	Overall
Reznik DS. *et al.,* 2009 [43]						Low
Majanni AMR. *et al.,* 2020 [25]						Moderate
Lehnen S. et al., 2011 [26]						Moderate
Lehnen S. *et al.,* 2011 [27]						Moderate
Baxmann M. *et al.,* 2010 [28]						Moderate
Feldmann I. *et al.,* 2012 [32]						Moderate
Feldmann I. *et al.,* 2017 [33]						Low
Ganzer N. *et al.,* 2016 [30]						Moderate
Feldmann I. *et al.,* 2007 [31]						Moderate
Mohd AND. *et al.,* 2021 [48]						Moderate
Azeem M. *et al.,* 2021 [24]						Low
Lamberton JA. *et al.,* 2016 [34]						Moderate
Suresh N. *et al.,* 2022 [29]						Moderate

Green- low risk of bias; Yellow- Moderate risk of bias

4. Discussion

This systematic review aims to synthesize the current literature regarding patients' perspectives on miniscrews in orthodontic treatment, contributing to an increase in the awareness of their implications in the quality of life, personal satisfaction, expectations and acceptance. Nowadays, the comfort of patients during orthodontic procedures is a concern, thus, considering only functional and biomechanical aspects without subjective experiences of the patient, can lead to unfavorable cooperation and outcomes.

The literature is consensual as to the fact that patients tend to overestimate the pain during insertion and removable of miniscrews, seeing the pain felt is significantly lower than expected.[38] The studies presented several factors that influence discomfort and pain during orthodontic treatment with miniscrews, regardless of interpersonal variations, for example, the location of the miniscrew, the surgical technique to insertion this device, the anesthetic procedure and the use of manual instruments or the handpiece.[26-27] Overrating pain could affect the patient's acceptance, as according to Sergl *et al*., that acceptance of orthodontic appliances and treatment by most patients is directly related to the amount of pain and discomfort initially experienced.[50] However, previous studies in the literature reported an acceptance rate of 86.7% in opting for miniscrews over extractions, although only 12.7% had prior knowledge of screws.[37]

Regarding the location, palatal miniscrews were considered the most uncomfortable, followed by the buccal shelf or in the infrazygomatic crest, depending on the activity. Finally, the interradicular locations were classified as causing the least pain.[45-46] Miniscrew failure occurs mostly in the mandible, as the thickness of the cortical bone is significantly thicker than that of the maxilla.[45,51]

Patients who underwent surgery with mucoperiosteal flap reported more pain (severe or moderate) and discomfort in day-to-day activities, namely, talking, chewing and drinking.[47] In addition, performing a flap decreases the success rate of miniscrews, since this technique is more used in regions with mobile mucosa.[52] Thus, non-traumatic and precise techniques during insertion provide better adhesion of the patient because they reduce side effects, such as inflammation, pain and swelling and had better rates of success.[28,45]

The noise associated with the handpiece is perceived as unpleasant and increases the discomfort of the patient, so manual removal of the miniscrews is preferable.[26-27]

Studies have shown that topical anesthetics did not completely eliminate the pain of miniscrew insertion, but made this pain tolerable and reduced the anxiety of the patient.[42] On the other hand, when infiltrative anesthesia was given, pain and discomfort were effectively eliminated during the insertion of the miniscrews.[35] However, the disadvantage of feeling the prick of the needle was reported. In this way, to eliminate the pain caused by infiltrative anesthesia, most patients felt more comfortable with the topical anesthetic. For very anxious or needle-phobic patients, the results of the studies indicate that the procedure can be performed using only topical anesthesia, although some discomfort can be felt, most patients can tolerate it.[35,42] Combined topical anesthetics (lidocaine, tetracaine and phenylephrine) were considered more effective than the exclusive use of 20% benzocaine.[43] However, Lamberton *et al*. referred that compound topical anesthetics provided less predictable, often inadequate, and less comfortable local anesthesia.[34]

The studies described several postoperative complications, namely swelling of the soft tissues, gingival irritation, and difficulties during oral hygiene, eating some foods and speech, which might be correlated with the intensity of swelling.[53] The type of soft tissue around the miniscrews (attached gingiva or movable mucosa) is related to the success rate since the placement of the miniscrew in the attached gingiva increases the success rate 24 times more than placement in the movable mucosa.[54-55] The placement of mini-screws in keratinized gingiva reduces the probability of developing tissue hyperplasia and inflammation.[54,56]

The patients mentioned that the posterior locations of maxilla and mandible are more difficult to access, so oral hygiene around the miniscrews tends to be worse and those areas are more susceptible to peri-implant inflammation and to infection.[38,47,57] This way, it is crucial for orthodontists to know and convey a cleaning protocol to patients.[53] Mohamed *et al*. investigate the effects of chlorhexidine mouthwash on soft tissues surrounding orthodontic miniscrew and found that the use of chlorhexidine does not significantly improve gingival health and miniscrew survival rate.[58]

According to Sreenivasagan *et al*., half of the patients did not report any swelling or soft tissue overgrowth where the miniscrews were placed.[34, 36, 43] The most common intervention during soft tissue swelling was to remove and reposition the miniscrew and the second most common intervention was to excise the soft tissue, followed by assessing the situation. Gingival inflammation and ulceration are often observed. When this happens, it is advisable to place composite on the head of the miniscrew. Soft tissue overgrowth can be prevented with oral ulcer gel either alone or as an adjuvant, and palliative care with placement of wax on the miniscrew head.[46]

Pain and discomfort were mostly moderate while masticating sticky, fibrous, and firm foods, while mild to moderate pain was mostly reported during tooth brushing. However, no unaesthetic appearance and disturbance in chewing ability have been reported.[44,52] Compared to baseline, the orthodontic treatment did not interfere with leisure-time activities. However, speech and eating habits were substantially affected.[31-32] Comparing with tooth extractions, patients experienced less changes in everyday life and during eating in insertion of miniscrews.[30] The literature reported that the consumption of analgesics was similar after tooth extractions and the placement of miniscrews[32] Patients usually take one single dose of analgesic, while 32.5% of the patients did not require any medication postplacement.[37,47] The most commonly used analgesics were acetaminophen (paracetamol), ibuprofen, aspirin and aceclofenac.[30, 32, 45]

This systematic review has some limitations that may affect the interpretation of the results, namely: 1) some of the studies included have small sample sizes with only 5 participants; 2) absence of groups with an equal number of females and males; 3) the absence of a significant sample that allows assessing the influence of age. However, this work allows understand the patients' opinions regarding the use of miniscrews in orthodontic treatment, helping orthodontists with treatment plans.

Future studies should be blinded randomized controlled trials with control of potential sources of bias, including the randomization process and description of study limitations. In addition, the samples used should be larger and evenly distributed for sex and age. Further investigation should relate the patient´s perspective and the presence of complications and adverse reactions. Additionally, the location of administered anesthesia should be considered in the perception of pain. Furthermore, in future studies, the sensation of pain and discomfort could be related to the patient´s interpretation concerning the importance of using miniscrews in their treatments.

This literature review highlights the importance of considering the patients perspectives when assessing and characterizing the impact of treatments. The Orthodontists should take special care regarding the individual characteristics of the patient, such as their pain tolerance and discomfort, in order to achieve maximum treatment efficacy in miniscrew improving individual adherence.

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