

EFFECT OF ACTIVATION PROTOCOL ON MINISCREW- ASSISTED PALATAL EXPANSION: A SYSTEMATIC REVIEW OF CURRENT EVIDENCE

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ABSTRACT

Background and Objectives: The aim of this systematic review was to review the effect of different activation protocols of miniscrew-assisted palatal expanders used in the treatment of maxillary skeletal transverse deficiency.

Material and methods: A search was conducted in MEDLINE via PubMed, Web of Science, Scopus, Cochrane Library till May 2020. The gray literature was also explored via google scholar and Open Gray. Selection criteria included randomized and prospective clinical trials comparing the outcomes of different activation protocols of miniscrew-assisted palatal expansion. Eligibility criteria were applied, and the authors planned to extract relevant data, and assess the risk of bias using the RoB 2 tool for randomized controlled trials and ROBINS-I tool for non-randomized studies, followed by the assessment of the quality of evidence.

Results: As no studies met the inclusion criteria for this review, we discussed the results of prospective clinical trials studying the clinical outcomes of using miniscrew-assisted palatal expansion.

Conclusion: To date, there are no high-quality clinical trials comparing the clinical outcomes of different activation protocols of miniscrew-assisted palatal expansion. There is no clear agreement in the literature on the most efficient activation protocol used with the miniscrew-assisted palatal expanders.

KEYWORDS: palatal expansion techniques, expander, activation, orthodontic anchorage procedures.

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INTRODUCTION

Transverse maxillary discrepancy is a common malocclusion, mostly presented with a unilateral or bilateral posterior crossbite. Previous studies indicate the prevalence of maxillary transverse skeletal discrepancies ranges between 8-22% in different populations.^[1-4] In addition to posterior crossbites, transverse maxillary deficiency can clinically be associated with narrow nasal cavity, arch length discrepancy, alterations in dental axial inclinations, wide buccal corridors, temporomandibular joint dysfunctions, and some Class II and Class III sagittal malocclusions.^[5-10]

Maxillary expansion is the main treatment option for the management of maxillary constriction. The main objective of maxillary expansion is to increase the transverse width of the maxilla through the opening of the mid-palatal suture.^[11, 12] Maxillary expansion can be performed using different ways of expansion (Rapid Maxillary Expansion– RME or Slow Maxillary Expansion– SME, Surgically-Assisted Rapid Maxillary Expansion– SARPE, and Miniscrew-Assisted Rapid Maxillary Expansion– MARPE), and with different appliances, and the choice among these options may affect the skeletal and dental outcomes of the treatment and the post-treatment relapse.^[13]

RME was found to generate forces that exceed the limits of orthodontic tooth movement; which in turn affects the nasomaxillary sutures and, more specifically, the midpalatal suture.^[14, 15] Moreover, RME causes the alveolar processes to bend, and the anchoring teeth to tip, and it induces other skeletal and dental effects, as confirmed by previous studies.^[16, 17] Also, the tipping and extrusion of the posterior teeth and alveolar process bending may be useful in treatment of deep overbite, clockwise rotation of the mandible, but also increases the tendency to relapse due to the resistance to deformation from surrounding structures.^[18, 19] Although RME was reported to produce dentoalveolar changes in

addition to the skeletal changes, it is considered to be a clinically efficient and stable protocol.^[20-22] Other studies reported a significant amount of relapse after the expansion was achieved.^[23, 24] However, the use of tooth-borne RME was less predictable in patients who passed the peak of pubertal growth, leading to more dental than skeletal changes.^[25-29] Furthermore, with tooth-borne RME, skeletal expansion was reported to account for only about 38% of the total expansion,^[13] and the relapse rate was 35%–50%.^[30]

Recently, the introduction of miniscrew-assisted maxillary expansion provided an alternative treatment for adolescent and young adult patients with transverse deficiency.^[31-33] The technique was found to have greater skeletal effects, less dental effects, and fewer side effects than traditional RME.^[34] Although several clinical trials have reported the success of miniscrew-supported palatal expansion in the management of transverse skeletal discrepancies, no clinical evidence exists about the optimal activation protocol.^[7, 35-42] To this end, this systematic review was performed in order to answer the following question: “Do changes in the activation protocol of miniscrew-assisted palatal expansion influence the treatment outcomes?”

MATERIAL AND METHODS

The method used to conduct this systematic review was based on the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.^[43]

Protocol registration

The protocol for this systematic review was prepared *a priori* and registered in PROSPERO (CRD42020142379).

Search methods for identification of studies

In order to track all citations related to our question, four electronic databases used in health

sciences research were accessed: Medline via PubMed, Web of Science, Scopus, and the Cochrane library. Google Scholar was also assessed as part of a gray literature search. The reference lists of relevant articles were manually searched to identify studies that could have been missed in the electronic database searches. The search covered the period up to May 2020. Our search strategy, inclusion/exclusion criteria, and data extraction process were guided by the PICOS question. Finally, when the relevant information was not available in the article, the authors were contacted to obtain further information if applicable. The search strings used were devised with the help of an expert and the search was adapted to the syntax rules of each database. (Table 1)

Criteria for considering studies for this review

We aimed to include prospective clinical trials in this review. The exclusion criteria were studies investigating SARPE, subjects with craniofacial deformities, syndromes, or studies combining miniscrew-assisted maxillary expansion with other treatment, such as facemask. Moreover, the exclusion criteria included systematic reviews and meta-analyses, comprehensive review articles, retrospective clinical trials, case reports, descriptive studies, opinion articles, technical articles, guidelines, animal, and in vitro studies.

Types of participants

We only considered trials in which the participants underwent miniscrew-assisted palatal expansion for correction of maxillary transverse discrepancy. There were no restrictions regarding the gender nor the age of participants.

Types of intervention and comparator

We included studies in which a specific miniscrew-assisted maxillary expansion protocol was compared to a different one for correction of maxillary transverse skeletal discrepancy.

Types of outcome measures

Primary outcomes

Our primary outcome was the correction of the transverse discrepancy, including the dental and skeletal changes at the end of the expansion period

Secondary outcomes

Our secondary outcomes were as follow:

- Expansion duration
- Retention duration

Data collection and analysis

Study Selection and data extraction process

Title and abstract screening were conducted by two reviewers (YMY and MGH) by grading studies as 'included', 'not-included', or 'Unclear' based on the information provided by the title and abstract. The full text was located for all articles graded with 'included' or 'unclear'. A preset template was designed to extract information from the included studies. From each study, the following data were extracted: author, population, intervention, comparison, type of study, protocol of expansion, and expansion duration, and clinical outcomes. All the data were extracted by the same two reviewers (YMY and MGH). Disagreements between the two investigators were resolved by a third independent reviewer (ARZ).

Risk of bias in individual studies

The two reviewers (YMY, MGH) planned to extract relevant data, and assess the risk of bias using the RoB 2 tool for randomized controlled trials and ROBINS-I tool for non-randomized studies, followed by the assessment of the quality of evidence. With the use of these two tools, reviewers could determine selection bias, performance bias, detection bias, attrition bias, reporting bias, and bias from other sources within the included studies.^[44,45]

Measures of treatment effect

The authors planned to calculate the odds ratio for dichotomous outcomes, and the mean difference for continuous outcomes.

Data synthesis

The authors planned to combine the results in a meta-analysis if the studies showed statistical homogeneity. In case of statistical heterogeneity, narrative synthesis would be performed. In case of absence of eligible studies, an empty descriptive systematic review was planned.^[46]

RESULTS

Results of the search

The authors identified 948 records through database searching (Medline n=358, Scopus n=278, Cochrane n=40, Web of Science n=272), plus 82 records identified through other sources (Google Scholar). Following duplicate removal, 499 records remained. The authors excluded 386 articles by title and/or abstract. Full texts of 113 potentially eligible articles were retrieved. After applying the eligibility criteria, all articles were excluded. Hence, the authors proceeded to perform an empty descriptive systematic review. The articles were excluded for the following reasons: retrospective studies, case reports and case series; in-vitro studies; animal studies; guidelines; opinion articles; technical articles; narrative reviews; systematic reviews and meta-analyses; and for including adjunctive treatments in addition to maxillary expansion. The process of literature searching is displayed in (Figure 1).

INCLUDED STUDIES

No studies met the inclusion criteria. However, a total of 11 prospective clinical trials reporting the activation protocol were identified. None of the trials compared the outcomes of different activation protocols of miniscrew-assisted palatal expansion.

Risk of bias in included studies

As no studies met the inclusion criteria, risk of bias, as well as quality assessment were not performed.

Effects of interventions

As no studies met the inclusion criteria, no meta-analysis was performed.

Characteristics of the identified prospective studies

The characteristics of the excluded studies including the activation protocols are summarized in (Table 2). Seven studies were randomized controlled trials,^[7, 38, 47-51] two studies were prospective non-randomized controlled trials,^[40, 52] and two studies were prospective non-randomized uncontrolled trials.^[53, 54] Only four studies reported sample size calculations.^[48, 50, 51, 54]

Characteristics of the participants

Collectively, the samples comprised adolescents in the 11 trials. The average age at the beginning of orthopedic expansion in the samples ranged from 9 to 17 years. Between 13 and 62 patients were selected for each study, with a median of 25-28 patients.

Results of individual studies

Although none of the 11 studies directly investigated the effect of changing the expansion protocol on the skeletal and/or dental outcomes of mini-screw assisted palatal expansion treatment, two different expansion protocols have been identified. The appliance was activated once every other day (0.2 mm) in two studies,^[7, 38] twice daily (0.5 mm) in eight studies,^[40, 47-53] and the expansion protocol in the remaining study was unreported.^[54]

Miniscrew-assisted slow maxillary expansion

As far as post-retention results are concerned, several maxillary skeletal, dental, and airway clinically relevant differences were identified. Two trials^[7, 38] showed that slow activation of bone-borne

expanders once every other day was associated with statistically significant differences for transverse and vertical dimensions and dental inclinations ($P < 0.001$), but not the anteroposterior dimension ($P = 0.244$), nor the airway measurements ($P > 0.05$) after a 6 months retention period. The statistically significant differences were related to maxillary first molars, premolars and central incisor apices ($P < 0.001$). For dental inclination, only angles related to maxillary first molars had significant differences among groups ($P < 0.001$).

Miniscrew-assisted rapid maxillary expansion

Measurements of skeletal changes immediately following MARPE showed a significant increase in the facial ($p = .002$) and maxillary widths ($p = .039$).^[40] Significant increase in maxillary width ($p = .003$) was also evident 3 months after the expansion.^[50] In addition, a significant sutural opening was evident immediately after expansion ($p < .001$)^[53] and 6 months after the expansion ($p < .001$), which accounted for approximately 70% of the total expansion achieved.^[48] Regarding the changes in the nasal cavity, one study did not find a significant change ($p = .500$) in the nasal cavity width immediately post-expansion.^[40] On the other hand, a significant increase in the nasal cavity width was found immediately post-expansion ($p = .001$)^[53], 3 months after the expansion ($p = .034$)^[50], and 6 months after the expansion ($p < .001$).^[48] The skeletal changes induced by the rapid activation of the miniscrew-assisted palatal expanders were found to significantly improve the nasal airflow immediately post-expansion ($p < .05$),^[47,53] and after 5 months of retention ($p < .05$).^[53]

The dental buccal inclination was investigated using CBCT and digital models immediately after expansion,^[40] 3 months after the expansion,^[50] and 6 months after the expansion.^[48,51] However, the results of the studies were widely divergent. The amount of dental tipping was not significant

in the bone-borne expander immediately post-expansion as well as after 6 months.^[51] On the other hand, significant premolar and molar tipping was observed with the hybrid expander.^[51] Three studies investigated the effect of rapid expansion of the miniscrew-assisted appliances on the alveolar bone following retention, and found it to preserve the buccal alveolar bone especially at the premolar area.^[48,50,52]

One study^[49] evaluated pain following miniscrew-assisted rapid maxillary expansion, and found that pain from molars and incisors was significantly less ($p = .042$ and $p = .024$, respectively) on the fourth day of appliance activation compared to the first day of activation. Pain, discomfort and analgesic consumption did not differ between miniscrew-assisted rapid maxillary expansion and conventional rapid maxillary expansion.

Endpoint of expansion

Overcorrection was achieved in five studies,^[7,47,49,50,52] four studies^[38,40,51,53] did not define the criteria of transverse correction, and the remaining two studies^[48,54] did not report the extent of correction.

Expansion duration

As a whole, in seven studies^[7,38,47,49,52-54] the active expansion duration was not reported. The average of the orthopedic expansion using miniscrew-assisted palatal expansion in the samples using rapid protocol ranged from 11 to 20 days.

Retention duration

Eight studies^[7,38,48,50-54] reported the duration of the retention phase following the active expansion. Between three to six months of post-expansion retention duration were applied in each study, with a median of four months. The remaining three studies^[40,47,49] did not report the retention duration.

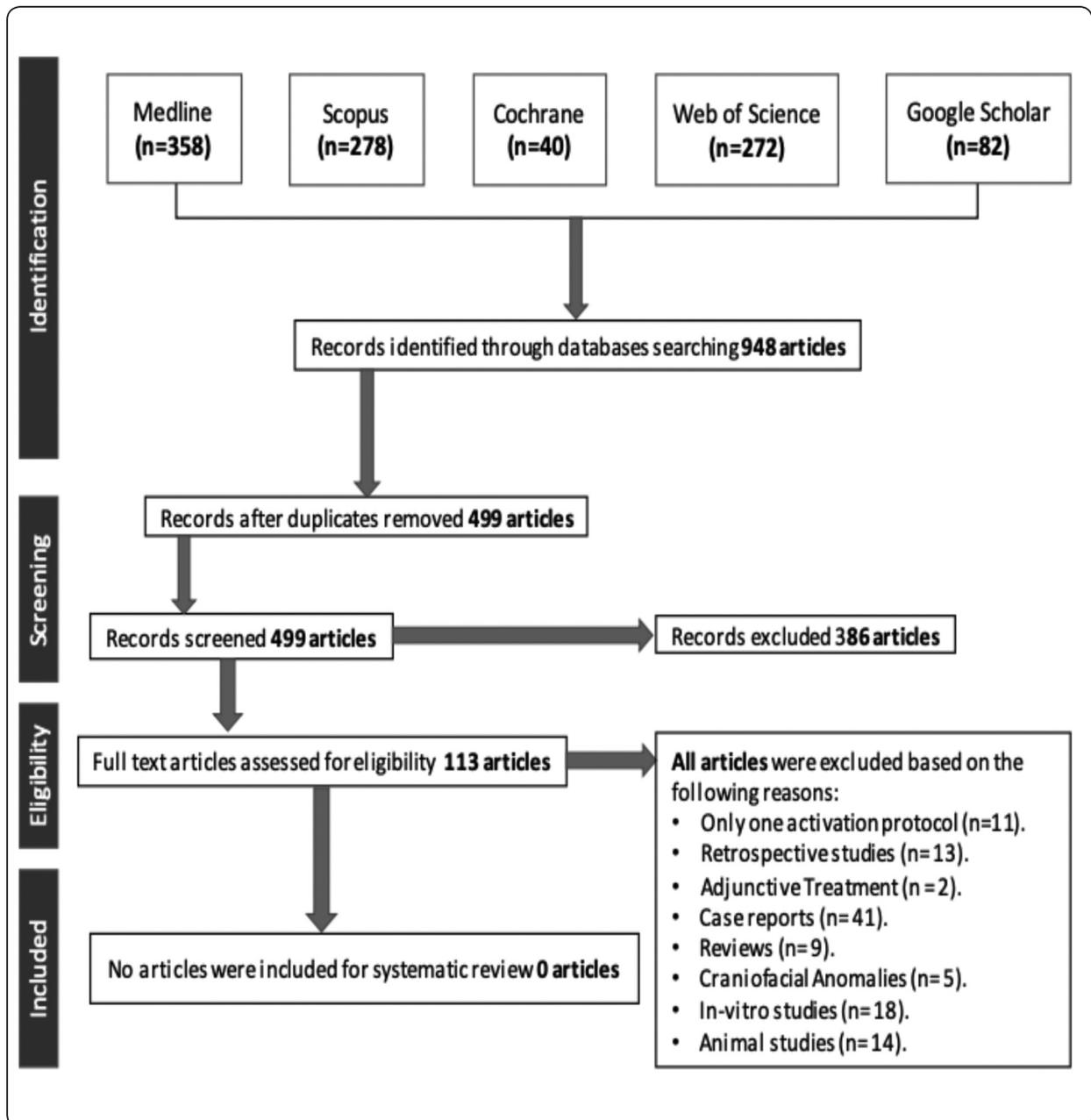


Figure 1. PRISMA flow chart for identification and selection of included studies.

TABLE (1) Search strategies in the electronic databases (last search date: May 1st, 2020)

Database	Search strategy	Hits
MEDLINE (via PubMed)	Search #1 “palatal expansion technique”[MeSH Terms] OR maxillary expan*[Title/Abstract] OR palatal expan*[Title/Abstract]	3201
	Search #2 “orthodontic anchorage procedures”[MeSH Terms] OR miniscrew-supported[Title/Abstract] OR miniscrew-assisted[Title/Abstract] OR miniscrew*[Title/Abstract] OR mini-screw*[Title/Abstract] OR mini-implant*[Title/Abstract] OR microimplant*[Title/Abstract] OR micro-implant*[Title/Abstract] OR bone-borne[Title/Abstract] OR bone-anchor*[Title/Abstract] OR skeletal anchorage[Title/Abstract] OR skeletally-anchored[Title/Abstract]	5095
	Search #3 #1 AND #2	358
Scopus	Search #1 TITLE-ABS-KEY (“maxillary expan*” OR “palatal expan”*)	3392
	Search #2 TITLE-ABS-KEY (“miniscrew-supported” OR “miniscrew-assisted” OR miniscrew OR “mini screw” OR “mini implant” OR microimplant OR “micro implant” OR “bone borne” OR “bone anchor*” OR “skeletal* anchor”*)	4994
	Search #3 #1 AND #2	278
Cochrane	Search #1 [mh “palatal expansion techniques”] OR maxillary NEXT expan*:ti,ab,kw OR palatal NEXT expan*:ti,ab,kw	335
	Search #2 [mh “orthodontic anchorage procedures”] OR miniscrew-supported:ti,ab,kw OR miniscrew-assisted:ti,ab,kw OR miniscrew:ti,ab,kw OR miniscrews:ti,ab,kw OR mini-screw:ti,ab,kw OR mini-screws:ti,ab,kw OR mini-implant:ti,ab,kw OR mini-implants:ti,ab,kw OR microimplant:ti,ab,kw OR microimplants:ti,ab,kw OR micro-implant:ti,ab,kw OR micro-implants:ti,ab,kw OR bone-borne:ti,ab,kw OR bone-anchored:ti,ab,kw OR skeletal anchorage:ti,ab,kw OR skeletally-anchored:ti,ab,kw	460
	Search #3 #1 AND #2	40
Web of Science	Search #1 maxillary-expan* OR palatal-expan*	2160
	Search #2 miniscrew-supported OR miniscrew-assisted OR miniscrew OR mini-screw* OR mini-implant* OR microimplant* OR micro-implant* OR bone-borne OR bone-anchor* OR skeletal anchorage OR skeletally-anchored	4790
	Search #3 #1 AND #2	272
Google scholar	allintitle: “maxillary OR palatal expander OR expansion” AND (miniscrew OR mini-screw OR mini-implant OR microimplant OR micro-implant OR bone-borne OR bone-anchored OR bone-anchorage OR skeletal-anchorage OR skeletally-anchored)	82

Table 2. Characteristics of prospective studies studying miniscrew-assisted palatal expansion

Study	Design; Setting; Country ^s	Patients (MF); age in years	Intervention; duration [#]	Activation protocol	Appliance retention	Sample size calculation
Bazargani 2018	RCT; Uni; SWE	EG1: 19 (11/8); 9.7 EG2: 21 (10/11); 10.2	EG1: TB RME; NR EG2: Hybr. RME; NR	2x/day until upper molar's palatal cusp contacts lower molar's buccal cusp	NR	
Canan and Senesik 2017	RCT; Uni; TUR	EG1: 16 (8/8); 12.63 ± 1.36 EG2: 16 (7/9); 12.92 ± 1.07 EG3: 15 (7/8); 13.41 ± 0.88	EG1: TB RME; 13.31 days EG2: BB RME; 12.44 days EG3: Hybr. RME; 14.13 days	2x/day until appropriate expansion	EG1: 6 mo EG2: 6 mo EG3: 6 mo	√
Celenk-Koca 2018	RCT; Pract; NLD	EG1: 20 (7/13); 13.81 ± 1.23 EG2: 20 (8/12); 13.84 ± 1.36	EG1: BB RME; 19.7±3.8 days EG2: TB RME; 19.7±3.8 days	2x/day	EG1: 6 mo EG1: 6 mo	√
Chane-Fane 2010	Non-RCT; Uni & Pract; FRA	EG1: 9 (1/8); 15.5 EG2: 7 (2/5); 14.1	EG1: Hybr. RME; NR EG2: TB RME; NR	2x/day until upper molar's palatal cusp contacts lower molar's buccal cusp	EG1: 4 mo EG2: 4 mo	
Feldmann 2017	RCT; Uni; SWE	EG1: 25 (12/13); 9.7 ± 1.39 EG2: 25 (12/13); 10.0 ± 1.16	EG1: TB RME; NR EG2: Hybr. RME; NR	2x/day until upper molar's palatal cusp contacts lower molar's buccal cusp	EG1: NR EG1: NR	
Gunyuz Toklu 2015	RCT; Uni; TUR	EG1: 13 (5/8); 14.3 ± 2.3 EG2: 12 (6/6); 13.8 ± 2.2	EG1: TB RME; 19.2 days EG2: Hybr. RME; 20.2 days	2x/day until upper molar's palatal cusp contacts lower molar's buccal cusp	EG1: 3 mo EG1: 3 mo	√
Kabalan 2015 *	RCT; Uni; CAN	Total 61 patients EG 1: NR EG 2: NR CG: NR	EG 1: TB RME; NR EG 2: BB; NR CG: delayed for 6 months; NA	EG 1: 2x/day until appropriate expansion EG 2: 1x/every other day until appropriate expansion	EG1: 5.5 mo EG2: 4 mo	

Lagravère 2010	RCT; Uni; CAN	EG1: 20 (5/15); 14.1 ± 1.4 EG2: 21 (8/13); 14.2 ± 1.3 CG: 21 (6/15); 12.9 ± 1.2	EG1: TB RME; NR EG2: BB; NR CG: delayed for 12 months; NA	EG1: 2x/day until posterior dental cross bite overcorrection EG1: 1x/every other day until posterior dental cross bite overcorrection	EG1: 6 mo EG2: 6 mo
Mosleh 2015	Non-RCT; Uni; EGY	EG1: 10 F; 12.0 ± 0.6 EG2: 10 F; 12.0 ± 0.6 (both groups together are 12.0 ± 0.6)	EG1: TB RME; 11 days EG2: BB RME; 11 days	2x/day	EG1: NR EG1: NR
Storto 2019	Prospective Uncontrolled Clinical Trial; Uni; BRA	EG1: 20 (7/13); 17.1 CG: No Comparison	EG1: Hybr. RME; NR	2x/day until necessary expansion achieved	EG1: 5 mo
Yildirim 2019 *	Prospective Uncontrolled Clinical Trial; Uni; TUR	EG1: 20 (9/11); 14.31 ± 1.36 CG: No Comparison	EG1: BB on one side & TB on other side; NR	NR	EG1: 3 mo √

Duration of active transverse expansion in days

\$ Countries are given with their ISO-3 code

Ix one time, *2x* two times, *4x* four times, *BB* bone-borne, *CG* control group without expansion, *EG* experimental group with expansion, *F* female, *Hybr* hybrid (tooth-bone-borne), *M* Male, *NR* not reported, *Pract* practice, *RCT* randomized clinical trial, *RME* rapid maxillary expansion, *TB* tooth-borne, *Uni* university.

* Emails were sent to ask about missing information. No reply was received.

DISCUSSION

Our search identified no prospective clinical trials studying the effect of different activation protocols of miniscrew-assisted palatal expansion on the treatment outcomes. Hence, our review was based on ineligible prospective clinical trials using miniscrew-assisted palatal expansion for the treatment of maxillary transverse discrepancy. This approach may aid in identifying knowledge gaps and gaining new insights.^[46]

Prospective clinical trials were carefully explored. A total of 11 publications including a total of 339 participants in need of miniscrew-assisted maxillary expansion were analyzed in details. Although we identified seven RCTs, they were comparing between either tooth-borne expanders and tooth-bone-borne or bone-borne expanders, two of them most probably used the same sample.^[7, 38] Furthermore, the heterogeneity among studies, in terms of using different reference points and different measurements made the comparison difficult. Dental, skeletal and airway measures varied widely, as follows; skeletal maxillary width,^[7, 40, 48, 50, 52] amount of midpalatal suture opening,^[48, 53] alveolar tipping,^[50] alveolar bone thickness,^[48, 50, 52, 53] intermolar distance,^[7, 40, 48, 50, 52, 53] inter-premolar distance,^[7, 40, 48, 50, 52, 53] dental tipping,^[40, 48, 50, 51, 53] sagittal/vertical tooth movements,^[7] root resorption,^[48, 54] nasal airflow/resistance,^[38, 47, 53] nasal cavity width,^[7, 40, 48, 50, 52, 53] and pain assessment.^[7, 49]

Although it was evident that the different activation protocols of the miniscrew-assisted palatal expanders produced significant expansion in the mid-palatal suture, expansion protocols and duration varied widely across the studies. Few studies reported the reason behind adopting a specific protocol. Lagraverre et al.^[7] claimed that slow activation protocol (once every other day) might prevent possible palatal-shelf fracture for the bone. Other retrospective studies^[42] reported that semi rapid expansion protocol (one turn per

day) might be efficient with miniscrew-supported expander supported by monocortical miniscrews to overcome the greater stress at the implant-bone interface.

The end-point of activation was another interesting finding of this review. Overcorrection of the posterior crossbite is recommended by some investigators due to the molar's buccal inclination, which is usually a common consequence of tooth borne and/or hybrid expanders.^[33, 55] The philosophy of overcorrection assumes that molars tend to relapse to their original position after retention is discontinued, which is not going to happen if overexpansion was performed. Five of the excluded studies^[7, 47, 49, 50, 52] expanded the maxilla until the crossbite was overcorrected in all groups. Other investigators claim that overcorrection might be unnecessary, since expansion without overexpansion was found to be stable on the long-term.^[56]

This review has potential limitations. Many factors can affect the efficiency of the miniscrew-assisted palatal expansion such as the patient age and appliance design. In the case of age, It is widely believed that the midpalatal suture becomes more resistant to opening as patients grow older. The age range in the reviewed articles was 9 to 17. All the studies with participants younger than 17 years reported 100% success rate except one study^[50] that reported 96% success rate. Although the mean age was comparable, Wilmes et al.^[39] using tooth-bone-borne expander anchored with 2 miniscrews and 2 molars activated by 2 turns/day could overcorrect the transverse discrepancy in a mean duration of 8.7 days, while Arman-Ozcirpici et al.^[57] in a different study using bone-borne expander anchored with 4 miniscrews reported 97.1 days of expansion duration activating the expander twice a day in the first 7–10 days, then continued 3 times a week until the desired expansion was achieved. Previous studies^[35, 36, 58–60] using samples of mean age over 20 years showed a varying success rate ranging between

84% and 100% although they adopted nearly the same expander design. The main difference across these studies was the expansion protocol. This wide difference in expansion duration and success rate highlights the possible effect of altering appliance design and/or expansion protocol on the treatment outcomes.

The expander design could affect the efficiency of the miniscrew-assisted maxillary expansion. None of the 11 studies reported specific guidelines for the selection of expander design, some studies used bone-borne expanders while others used tooth-borne expanders. Furthermore, some studies [40, 47, 49] used only molars as anchor units, while other investigators [31, 35, 58, 59] used both the first premolars in addition to the molars. The authors did not explain the reasons for choosing one design over the other. However, we could assume that teeth are included in the miniscrew-assisted expander when dental effects are desired besides the skeletal correction of the transverse discrepancy.^[33, 55]

CONCLUSION

Despite general clinical agreement justifying miniscrew-assisted palatal expansion, as a legitimate treatment for skeletal transverse discrepancy, firm and robust conclusions regarding the optimal activation protocol cannot be deduced from the available evidence. It is highly desirable that further research on this issue be undertaken based on calculated sample size and randomized controlled trial (RCT) designs to ameliorate the conclusions of the current literature.

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