

## Systematic Review Orthognathic Surgery

# Surgically assisted rapid maxillary expansion with bone-borne versus tooth-borne distraction appliances—a systematic review

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*T. L. Blæhr, M. Y. Mommaerts, A. D. Kjellerup, T. Starch-Jensen: Surgically assisted rapid maxillary expansion with bone-borne versus tooth-borne distraction appliances—a systematic review. Int. J. Oral Maxillofac. Surg. 2019; 48: 492–501. © 2018 International Association of Oral and Maxillofacial Surgeons. Published by Elsevier Ltd. All rights reserved.*

**Abstract.** The objective was to test the hypothesis of no difference in skeletal and dental arch expansion and relapse after surgically assisted rapid maxillary expansion with a bone-borne compared with a tooth-borne appliance. The PubMed, Embase (Ovid), Cochrane Library, and Google Scholar databases were searched in combination with a hand-search of relevant journals up until December 2017. No language restriction was applied. Two short-term randomized controlled trials with a low risk of bias fulfilled the inclusion criteria. No meta-analysis could be performed due to considerable heterogeneity. There were no statistically significant differences in the skeletal and dental arch expansion and relapse. Dental arch expansion was significantly greater than skeletal expansion with both treatment modalities. However, dissimilar evaluation methods, different outcome measures, unknown vertical level of force application with the bone-borne devices, and various methodological confounding factors posed serious restrictions to reviewing the literature in a quantitative systematic manner. Hence, conclusions drawn from the results of this systematic review should be interpreted with caution. Further well-designed long-term randomized clinical trials including a standardized protocol and three-dimensional analysis of the level of force application and morphological outcome are therefore needed before one treatment modality can be considered superior to the other.

**Key words:** maxillary expansion; orthognathic surgery; skeletal stability; surgically assisted rapid maxillary expansion; systematic review.

Accepted for publication 13 December 2018  
Available online 28 December 2018

Transverse maxillary deficiency in non-syndromic adolescents and adults is often accompanied by a narrow maxillary base, unilateral or bilateral cross-bite, a high narrow palatal vault, and crowded misaligned teeth<sup>1</sup>. A surgical approach is often necessary in order to expand a constricted maxilla after skeletal maturity, due to fusion of the midpalatal and lateral maxillary sutures. The segmental Le Fort I osteotomy is a well-established surgical technique to correct transverse maxillary deficiencies of up to 6–7 mm in adults<sup>1,2</sup>. However, transverse expansion of the maxilla with a segmental Le Fort I osteotomy is often associated with postsurgical instability and relapse<sup>1,3</sup>. Therefore, surgically assisted rapid maxillary expansion (SARME) has become a commonly used surgical technique to treat skeletally mature patients with severe transverse maxillary discrepancies and a closed midpalatal suture<sup>4–7</sup>.

In SARME, a tooth-borne distraction appliance has traditionally been bonded to the maxillary premolars and molars preoperatively. However, dental anchorage may cause buccal tipping, root resorption, or extrusion of the anchor teeth, compression of the periodontal ligament, buccal bone resorption, and bending of the alveolar bone during the distraction phase<sup>6,8–10</sup>. A bone-borne distraction appliance has been advocated to avoid these complications, since the mechanical forces are delivered directly towards the maxillary bone<sup>11</sup>.

Comparisons of the skeletal and dental arch changes following SARME between tooth-borne and bone-borne distraction appliances have previously been reported in the literature, including in systematic reviews and meta-analyses<sup>6,10,12–20</sup>. However, the results have been contradictory and there has been considerable variability in the methods applied to measure the amount of transverse maxillary skeletal and dental arch expansion and relapse. A previously published systematic review and meta-analysis reported that a bone-borne distraction appliance facilitates more skeletal expansion and minimizes dental arch expansion compared with a tooth-borne distraction appliance<sup>19</sup>. However retrospective studies, non-randomized studies, and studies with weak quality assessments were included in that systematic review<sup>19</sup>. In addition, it has been concluded in a systematic review that there is a need for well-designed clinical trials evaluating the effects of tooth-borne and bone-borne distraction appliances, due to limited evidence for less dental tipping with a bone-borne dis-

traction appliance compared with a tooth-borne appliance<sup>6</sup>. Therefore, the objective of the present systematic review was to test the hypothesis of no difference in transverse maxillary skeletal and dental arch expansion and relapse after SARME with a bone-borne distraction appliance compared with a tooth-borne distraction appliance, based on randomized controlled trials with a low risk of bias.

## Materials and methods

### Protocol and registration

The methods used for the analysis and the inclusion criteria were specified in advance and documented in a protocol. The review was registered in PROSPERO, an international prospective register of systematic reviews. The protocol can be accessed at [http://www.crd.york.ac.uk/PROSPERO/display\\_record.asp?ID=CRD42017070301](http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017070301). This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement for reporting systematic reviews<sup>21</sup>. The methodology applied regarding the types of publications, study selection, and assessment of quality and heterogeneity has been described in detail previously<sup>22</sup>.

### Types of studies and outcome measures

The review included randomized controlled trials with a low risk of bias, comparing transverse maxillary skeletal and dental arch expansion and relapse after SARME with a bone-borne distraction appliance compared with a tooth-borne distraction appliance. The outcome measures are outlined in [Table 1](#).

### Information sources

A PubMed (National Library of Medicine, NCBI), Embase (Ovid), Cochrane Library, and Google Scholar search was conducted in collaboration with a senior librarian specialized in health sciences. No date limits or language restrictions were applied. The electronic search was supplemented by a manual search of relevant journals including *British Journal of Oral*

*and Maxillofacial Surgery, International Journal of Oral and Maxillofacial Surgery, Journal of Craniofacial Surgery, Journal of Cranio-Maxillo-Facial Surgery, American Journal of Orthodontics and Dentofacial Orthopedics, Orthodontic and Craniofacial Research, Journal of Oral and Maxillofacial Surgery, Oral and Maxillofacial Surgery, and Oral Surgery, Oral Medicine, Oral Pathology, and Oral Radiology*. The manual search was restricted to publications from 1999 to December 2017. The manual search included the reference lists of articles selected for full-text screening and reviews relevant to the present systematic review. Two of the reviewers (TLB and TSJ) performed the search. Any disagreements were resolved by consensus.

### Search strategy for the identification of studies and study selection

The search focused on the procedure of interest (i.e., SARME and maxillary expansion) and the distraction appliances (tooth-borne, bone-borne, Hyrax, and transpalatal distractor). Free text words and controlled vocabulary terms were used. A detailed description of the search strategy in Embase (Ovid) is outlined in the **Supplementary Material** (Appendix S1). A schematic illustration of the search strategy is presented in [Table 2](#).

Article review and data extraction were performed according to the PRISMA flow diagram ([Fig. 1](#)). Two researchers (TLB and TSJ) selected the studies independently. Any disagreements were resolved by consensus.

### Study eligibility

The PICOS guidelines were used to establish the criteria for the inclusion of studies ([Table 3](#)).

With regard to inclusion criteria, the review exclusively focused on randomized controlled trials with clearly specified inclusion and exclusion criteria. The surgical technique had to be identical for the patients in all of the included studies. In addition, a study sample of at least 10 patients was required, as well as an observation period of at least 3 months.

Exclusion criteria included editorials, PhD theses, case reports, case-series, retrospective studies, non-randomized studies, abstracts, technical reports, conference proceedings, animal or in vitro studies, and literature reviews. Studies with an inadequate description of the surgical procedure, significant dissimilarities in demographic data, a lack of information

*Table 1.* Outcome measures.

Transverse skeletal and dental arch expansion and relapse of the maxilla
Definitive transverse skeletal and dental arch expansion of the maxilla
Frequency of complications
Patient-reported outcome measures

Table 2. Schematic description of the search strategy.

	Block 1	Block 2
Search 1	Palatal* Expansion* Maxilla* Expansion* Arch Expansion* Transvers* Expansion*	oral surgery/ surgery.fs surger* surgic*
Search 2	bone borne boneborne transpalatal distract* bone anchor*	tooth borne toothborne hyrax tooth anchor*
Search 3	SARME SARPE	

on the observation period, and studies involving cleft patients or revision were also excluded.

**Data extraction**

Data were extracted by two researchers (TLB and TSJ) using a data collection form, ensuring systematic recording of the outcome measures. If clarification of certain issues was needed, the corresponding author was contacted by e-mail.

The following items were collected from the included articles and arranged in the following fields: author, patients, type of distractor, method, observation period, skeletal expansion, dental expansion,

skeletal relapse, dental relapse, definitive skeletal expansion, and definitive dental expansion.

**Quality assessment**

The quality assessment was conducted by two researchers (TLB and TSJ) as outlined in Table 4.

**Results**

**Study selection**

A total of 1791 titles were identified and 1264 abstracts were reviewed. The full-text analysis included 23 articles, and two randomized controlled trials were finally

included in the systematic review<sup>10,12</sup>. The manual search provided no additional papers.

The reasons for the exclusion of studies after full-text assessment were as follows: the study could not be excluded before meticulous reading ( $n = 13$ ), insufficient description of the surgical procedure ( $n = 3$ ), and a retrospective or non-randomized protocol ( $n = 5$ ).

**Study characteristics**

The protocols of both studies were approved by relevant ethics committees and written consent was obtained from all patients. A description of the power calculation for the sample size was described in one study<sup>10</sup>. The randomization method was described in both studies and involved opaque sealed envelopes prepared by computer-generated randomization<sup>12</sup> or a computer-generated random sequence<sup>10</sup>. The tooth-borne distraction appliance was anchored to the maxillary first molars and first premolars in both studies<sup>10,12</sup>. The planned postero-anterior location of the bone-borne distraction appliance was described in one study<sup>12</sup>. The transverse skeletal and dental arch expansion,

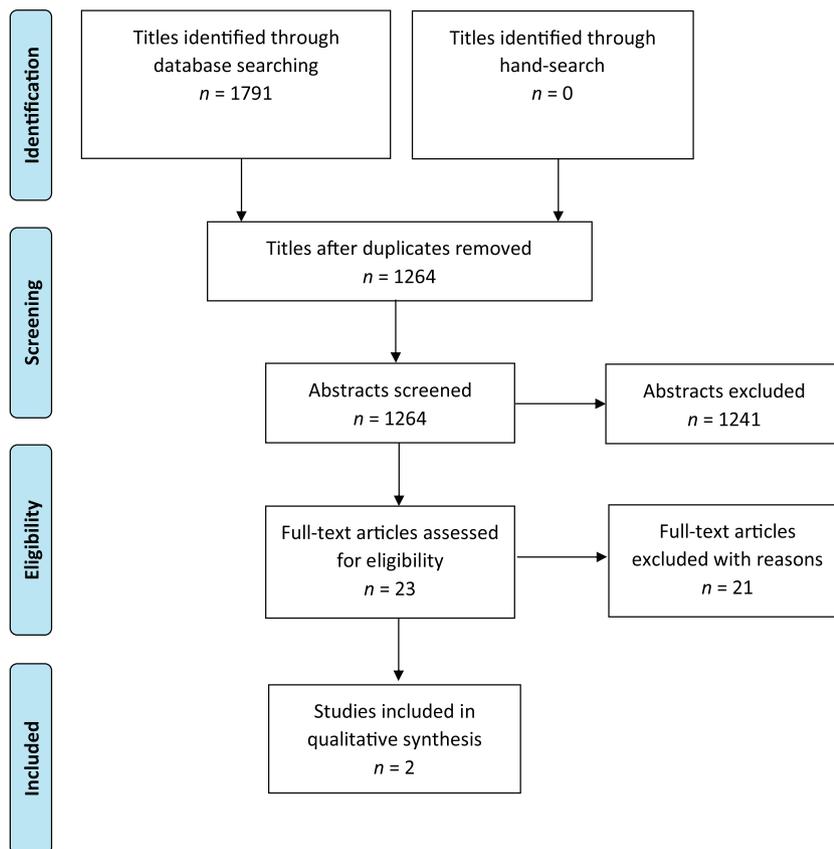


Fig. 1. PRISMA flow diagram demonstrating the results of the systematic literature search.

Table 3. PICOS criteria for the systematic review.

Patient/population (P)	Non-syndromic patients (age $\geq 14$ years) with a transverse maxillary deficiency necessitating SARME
Intervention (I)	Bone-borne SARME
Comparator/control group (C)	Tooth-borne SARME
Outcomes (O)	Transverse maxillary skeletal and dentoalveolar expansion and relapse, frequency of complications, and patient-reported outcome measures
Study design (S)	Randomized controlled trials comparing transverse maxillary skeletal and dentoalveolar expansion and relapse after SARME with a bone-borne distraction appliance compared with a tooth-borne distraction appliance
Focused question	Is there any difference in the transverse maxillary skeletal and dentoalveolar expansion and relapse after SARME with a bone-borne distraction appliance compared with a tooth-borne distraction appliance?

SARME, surgically assisted rapid maxillary expansion.

Table 4. Quality rating system.

Classification of the potential risk of bias:
Random selection in the population (yes/no)
Definition of inclusion and exclusion criteria (yes/no)
Report of losses to follow-up (yes/no)
Validated measurements (yes/no)
Statistical analysis (yes/no)
The included studies were categorized as follows:
<ul style="list-style-type: none"> <li>• Low risk of bias (plausible bias unlikely to seriously alter the results) if all the quality criteria described above were met</li> <li>• Moderate risk of bias (plausible bias that weakens confidence in the results) if one of these criteria was not met</li> <li>• High risk of bias (plausible bias that seriously weakens confidence in the results) if two or more criteria were not met</li> </ul>

sion was reported in both studies<sup>10,12</sup>, while the definitive transverse skeletal and dental expansion and relapse was reported in only one study<sup>10</sup>. The frequency of complications was described in both studies<sup>10,12</sup>, whereas patient-reported outcome measures were not reported in either of the included studies. Neither of the studies described the pre-treatment transverse maxillary deficiency, the amount of intraoperative activation of the distraction appliance, or whether or not a median diastema was achieved.

In the study by Koudstaal et al., 46 patients (23 female, 23 male, age range 16–50 years) were randomly assigned to SARME with a bone-borne distraction appliance (CE 9001, Surgi-Tec, Gent, Belgium, or CE 0297 (Rotterdam Distractor), KLS Martin, Tuttlingen, Germany) or a tooth-borne distraction appliance (Hyrax CE 0297, Forestadent, Pforzheim, Germany)<sup>10</sup>. The patients were treated at the Erasmus University Medical Centre,

Rotterdam, The Netherlands. The demographic data of the study participants were not analysed by statistical methods. Moreover, two different bone-borne distraction appliances were used. The inclusion criteria included non-syndromic patients (16 years or older), with a narrow maxillary arch and the presence of one or more of the clinical signs of transverse maxillary deficiency, such as unilateral or bilateral dental cross-bite, anterior and/or posterior crowding, and clinical evidence of buccal corridors. No information was provided about the number of surgeons involved or their surgical experience with bone-borne SARME. Pterygomaxillary disjunction was not performed. The distraction appliances were placed in the same anatomical location on the palate, without further specification. After a latency period of 7 days, the distraction appliance was activated at a rate of 1 mm/day until the desired expansion was achieved. The consolidation period was 3 months. Fixed orthodontic appliances were placed before surgery or 6 weeks after the end of expansion. No information was provided regarding the onset of active orthodontic treatment.

Postero-anterior cephalograms and dental casts were obtained before treatment, after the distraction phase, and 12 months after SARME. The transverse skeletal expansion and relapse was assessed by linear radiographic measurements of the width of the nasal floor and the most caudal level of the maxilla. Transverse skeletal expansion was estimated by subtraction of the pre-treatment distance from the distance after the distraction phase. Transverse skeletal relapse was estimated by subtraction of the distance 12 months after SARME from the distance after the distraction phase. Definitive transverse skel-

etal expansion was estimated by subtraction of the pre-treatment distance from the distance 12 months after SARME. The transverse dental arch expansion and relapse were assessed using dental cast measurements at the tip of the cusp of the canine, the tip of the buccal cusp of the first premolar, and the tip of the distobuccal cusp of the first molar. Transverse dental arch expansion was estimated by subtraction of the distance after the distraction phase from the pre-treatment distance. Transverse dental arch relapse was estimated by subtraction of the distance 12 months after SARME from the distance after the distraction phase. Definitive dental arch expansion was estimated by subtraction of the pre-treatment distance from the distance 12 months after SARME. Two patients with a bone-borne distraction appliance and two patients with a tooth-borne appliance did not complete the study protocol. Inter-observer and intra-observer reliability was assessed by calculating the intra-class correlation coefficients, which indicated that the measurements were reliable.

In the study by Zandi et al., 30 patients (11 male, 19 female, age range 15–27 years) were randomly assigned to SARME with a bone-borne distraction appliance (TPD, Surgi-Tec, Gent, Belgium) or a tooth-borne Hyrax appliance (Dentaurum, Ispringen, Germany)<sup>12</sup>. No significant difference in demographic data was observed between the two groups. The patients were treated at the Hamedan University of Medical Sciences, Hamedan, Iran. The inclusion criteria were skeletal maturity and the presence of one or more of the clinical signs of transverse maxillary deficiency, such as dental cross-bite, crowded teeth, or a constricted maxillary arch. The surgical procedure was performed by the same surgeon, including pterygomaxillary disjunction. No information was provided about the surgeon's experience with bone-borne SARME. The bone-borne distraction appliance was placed high on the palate at the level of the second premolars. After a latency period of 7 days, the distraction appliance was activated at an approximate rate of 0.5–0.6 mm/day until an overexpansion of 2–3 mm was observed on either side. Afterwards, the distractors were locked and kept in place for a consolidation period of approximately 4 months. It was not stated when the fixed orthodontic appliance was placed or when the active orthodontic treatment was initiated.

The transverse skeletal and dental arch expansion was measured on coronal cone beam computed tomography (CBCT)

images obtained preoperatively and after the end of the consolidation period. The nasal floor width, palatal bone width, interdental root distance, and interdental cusp distance were measured in the first premolar and first molar regions. The pre-treatment distance was subtracted from the post-treatment distance. Two patients with a tooth-borne distraction appliance were excluded because they did not complete the research protocol. Inter-observer and intra-observer reliability was assessed by two blinded observers, indicating good reliability.

### Synthesis of results

Fixed-effects analysis and the test for heterogeneity was inconclusive due to the limited number of studies included. No statistically significant difference in heterogeneity was found between the included studies ( $I^2 = 0\%$ ,  $P = 0.716$ ). The studies revealed considerable variations in design, i.e. different types of distraction appliances, dissimilar rates of distraction, use of pterygomaxillary disjunction, amount of overexpansion, length of the consolidation and observation periods, outcome measures recorded, and methods for evaluating the transverse expansion. Therefore, a well-defined meta-analysis was not applicable.

### Quality assessment

The quality of the included studies is summarized in Table 5. The studies were categorized as having a low risk of bias<sup>10,12</sup>. An explanation of withdrawals and drop-outs was not provided in one study<sup>10</sup>, and blinding of the outcome assessment was not performed in either of the studies.

### Outcome measures

The result of each outcome measure is presented first, and then a short summary is provided. Patient-reported outcome measures were not reported in the studies and are therefore not presented in the following section. All reported numerical values are presented as the mean value with standard deviation (SD), or other

characteristics for reported quantitative numerical values. The main results are described below and outlined in Table 6.

#### *Transverse skeletal and dental arch expansion of the maxilla*

Transverse skeletal and dental arch expansion of the maxilla was reported in both of the included studies<sup>10,12</sup>.

In the study by Zandi et al., CBCT measurements in the region of the first premolar after SARME with a bone-borne distraction appliance revealed a maxillary transverse expansion of 6.73 mm (SD 2.15) at the dental arch, 4.53 mm (SD 2.02) at the palatal bone, and 1.47 mm (SD 0.52) at the nasal floor after 4 months<sup>12</sup>. Measurements in the region of the first molar were 6.53 mm (SD 2.67) at the dental arch, 4.33 mm (SD 1.23) at the palatal bone, and 1.33 mm (SD 0.49) at the nasal floor. SARME with a tooth-borne distraction appliance revealed a transverse expansion of 7.23 mm (SD 2.77) at the dental arch, 4.38 mm (SD 1.75) at the palatal bone, and 1.62 mm (SD 0.65) at the nasal floor in the first premolar region. Measurements in the first molar region were 7.12 mm (SD 2.87) at the dental arch, 3.92 mm (SD 1.48) at the palatal bone, and 1.54 mm (SD 0.52) at the nasal floor. The maxillary transverse expansion at the dental arch after SARME with a bone-borne distraction appliance and a tooth-borne distraction appliance was significantly larger than the skeletal expansion. However, there were no significant differences between the dental and skeletal measurements obtained in the first premolar and first molar regions with the two treatment modalities<sup>12</sup>.

In the study by Koudstaal et al., postero-anterior cephalograms revealed a transverse skeletal expansion of 2.4 mm (SD 1.9) at the nasal floor and 3.1 mm (SD 2.4) at the most caudal level of the maxilla, after SARME with a bone-borne distraction appliance<sup>10</sup>. SARME with a tooth-borne distraction appliance revealed a transverse skeletal expansion of 2.6 mm (SD 1.8) at the nasal floor and 3.1 mm (SD 2.0) at the most caudal level of the maxilla. There was no significant difference in the transverse skeletal expansion between the two treatment modalities<sup>10</sup>. Dental

cast measurements revealed a transverse dental arch expansion of 6.0 mm (SD 3.4) at the canine, 7.0 mm (SD 3.1) at the first premolar, and 5.2 mm (SD 3.4) at the first molar, after SARME with a bone-borne distraction appliance<sup>10</sup>. SARME with a tooth-borne distraction appliance revealed a transverse dental arch expansion of 5.9 mm (SD 3.6) at the canine, 7.1 mm (SD 3.5) at the first premolar, and 6.8 mm (SD 2.9) at the first molar. There was no significant difference in the dental arch expansion between the two treatment modalities<sup>10</sup>.

In summary, the transverse skeletal and dental arch expansion with the two treatment modalities has been assessed in short-term studies using standardized skeletal and dental landmarks on CBCT, postero-anterior cephalograms, and dental casts. No significant difference in transverse skeletal or dental arch expansion of the maxilla was revealed between the two treatment modalities. However, the transverse dental arch expansion was significantly larger compared to the skeletal expansion, irrespective of the type of distraction appliance used.

#### *Transverse skeletal and dental arch relapse of the maxilla*

Transverse skeletal and dental arch relapse of the maxilla was reported in one study, defined as the difference between the distance measured at the end of the distraction phase and the distance measured after 12 months<sup>10</sup>.

The radiographic transverse skeletal relapse was  $-1.0$  mm (SD 0.9) at the nasal floor and  $-0.5$  mm (SD 0.8) at the most caudal level of the maxilla, after SARME with a bone-borne distraction appliance. SARME with a tooth-borne distraction appliance revealed a transverse skeletal relapse of  $-1.4$  mm (SD 1.4) at the nasal floor and  $-0.4$  mm (SD 1.3) at the most caudal level of the maxilla. There was no significant difference in the transverse radiographic skeletal relapse between the two treatment modalities.

Dental cast measurements revealed a transverse dental arch relapse of  $-1.3$  mm (SD 3.2) at the canine,  $-0.1$  mm (SD 2.5) at the first premolar, and  $-0.6$  mm (SD 1.5) at the first molar, after SARME with a bone-borne distraction appliance. SARME with a tooth-borne distraction appliance revealed a transverse dental arch relapse of  $-2.2$  mm (SD 3.8) at the canine and  $-0.5$  mm (SD 1.8) at the first molar, whereas a transverse dental arch expansion of 1.1 mm (SD 2.5) was measured at the first premolar. There was no significant difference in the transverse dental arch

Table 5. Quality assessment of comparative studies.

	Koudstaal et al. <sup>10</sup>	Zandi al. <sup>12</sup>
Random selection in the population	Yes	Yes
Definition of inclusion criteria	Yes	Yes
Report of losses to follow-up	Yes	Yes
Validated measurements	Yes	Yes
Statistical analysis	Yes	Yes
Risk of bias	Low	Low

Table 6. Characteristics of the included studies.

		Koudstaal et al. 2009 <sup>10</sup>		Zandi et al. 2014 <sup>12</sup>	
Number of patients		46		30	
Materials and methods					
Type of distractor		Bone-borne: 25 Tooth-borne: 21		Bone-borne: 15 Tooth-borne: 15	
Method		Dental cast and PAC		CBCT	
Observation period, months		12		4	
Outcome measures (mm)		Bone-borne Tooth-borne		Bone-borne Tooth-borne	
Skeletal expansion	Nasal floor:	2.4	2.6	Palatal bone premolar:	4.53 4.38
	Caudal level of maxilla:	3.1	3.1	Nasal floor premolar:	1.47 1.62
Dental expansion	Canine:	6.0	5.9	Palatal bone molar:	4.33 3.92
	Premolar:	7.0	7.1	Nasal floor molar:	1.33 1.54
	First molar:	5.2	6.8	Premolar:	6.73 7.23
				First molar:	6.53 7.12
Skeletal relapse	Nasal floor:	-1.0	-1.4	NR	
	Caudal level of maxilla:	-0.5	-0.4		
Dental relapse	Canine:	-1.3	-2.2	NR	
	Premolar:	-0.1	1.1		
	First molar:	-0.6	-0.5		
Definitive skeletal expansion	Nasal floor:	1.4	1.1	NR	
	Caudal level of maxilla:	2.7	3.2		
Definitive dental expansion	Canine:	4.7	3.7	NR	
	Premolar:	7.0	8.2		
	First molar:	4.6	6.3		

CBCT, cone beam computed tomography; NR, not reported; PAC, posterior–anterior cephalograms.

relapse between the two treatment modalities.

In summary, the transverse skeletal and dental arch relapse with the two treatment modalities has been assessed in a short-term study using standardized skeletal and dental landmarks on postero-anterior cephalograms and dental study casts. No significant difference in the transverse skeletal or dental arch relapse of the maxilla was disclosed with the two treatment modalities, irrespective of the type of distraction appliance used<sup>10</sup>.

#### *Definitive transverse skeletal and dental arch expansion*

Definitive transverse skeletal and dental arch expansion was reported in one study, defined as the difference between the distance measured before treatment and the distance measured after 12 months<sup>10</sup>.

The definitive radiographic transverse skeletal expansion was 1.4 mm (SD 1.7) at the nasal floor and 2.7 mm (SD 2.2) at the most caudal level of the maxilla, following SARME with a bone-borne distraction appliance. SARME with a tooth-borne distraction appliance revealed a transverse skeletal expansion of 1.1 mm (SD 1.3) at the nasal floor and 3.2 mm (SD 2.2) at the most caudal level of the maxilla. There was no significant difference in the definitive transverse skeletal expansion between the two treatment modalities.

Dental cast measurements revealed a definitive transverse dental arch expansion of 4.7 mm (SD 3.2) at the canine, 7.0 mm (SD 3.5) at the first premolar, and 4.6 mm (SD 3.1) at the first molar, after SARME with a bone-borne distraction appliance. SARME with a tooth-borne distraction appliance revealed a definitive transverse dental arch expansion of 3.7 mm (SD 3.0) at the canine, 8.2 mm (SD 4.1) at the first premolar, and 6.3 mm (SD 3.4) at the first molar. There was no significant difference in the definitive transverse dental arch expansion between the two treatment modalities.

In summary, the definitive transverse skeletal and dental arch expansion was reported in one study, disclosing no significant difference between the two treatment modalities after 12 months<sup>10</sup>.

#### *Frequency of complications*

The frequency of intraoperative and postoperative complications was reported in both of the included studies<sup>10,12</sup>. Oedema and haematoma were observed after SARME with both treatment modalities. Mild extrusion of a first premolar was reported after SARME with a tooth-borne distraction appliance<sup>12</sup>. Endodontic treatment of the right central incisor was performed due to discoloration after SARME with a tooth-borne distraction appliance<sup>10</sup>. Asymmetric transverse expansion was observed in two patients after SARME with a bone-borne distraction appliance<sup>10</sup>.

In summary, the frequency of complications with the two treatment modalities appears to be low and these are not severe.

## **Discussion**

This systematic review revealed no statistically significant difference in the transverse maxillary skeletal or dental arch expansion or relapse after SARME with a bone-borne distraction appliance compared with a tooth-borne distraction appliance. Moreover, the transverse maxillary dental arch expansion was significantly larger compared to the skeletal expansion with the two treatment modalities. The considerable variations in the design of the included studies, the diversity of evaluation methods and outcome measures used, and the various methodological confounding factors were serious restrictions to a review of the literature in a quantitative systematic manner. Hence, the conclusions drawn from the results of this systematic review should be interpreted with caution.

SARME with a tooth-borne or a bone-borne distraction appliance is a well-established surgical technique to correct severe maxillary transverse discrepancies in adolescents and adults. However, there is no clear consensus or strict evidence-based treatment guidelines in the literature regarding the surgical protocol, latency period, distraction rate, or the

consolidation period with the two treatment modalities. Most of the current knowledge about SARME is based on retrospective studies, non-randomized studies, or case-series, and the type of distractor is often chosen non-randomly in comparative studies<sup>14–18</sup>.

The studies included in the present systematic review were subject to several methodological confounding factors including dissimilar distraction rates and consolidation periods, different surgical protocols, different age and sex distributions, variability in the position and design of the bone-borne distraction appliance, and the lack of differentiation between the orthopaedic and the orthodontic expansion effect. Thus, this systematic review clearly demonstrates the need for well-designed long-term randomized controlled trials taking these confounding variables into account.

Dental and skeletal structural changes after SARME have previously been assessed in a systematic review, which revealed that the expansion was largest at the molars and diminished progressively towards the anterior part of the dental arch, with an overall relapse of 0.5–1 mm after 1 year of orthodontic treatment<sup>20</sup>. The studies included used a tooth-borne distraction appliance and the conclusions were based on dental cast measurements and two-dimensional radiographs<sup>20</sup>. These evaluation methods may be imprecise due to superimposition of the anatomical structures and difficulties in landmark identification with high accuracy<sup>10,23–25</sup>. Computed tomography has shown a high degree of accuracy and imaging reproducibility with the possibility of quantitatively evaluating three-dimensional skeletal and dental changes without overlapping of the anatomical structures<sup>14,26–28</sup>. The accuracy and reproducibility of three-dimensional measurements on images obtained from CBCT scans appears to be higher compared to conventional two-dimensional radiographs<sup>29</sup>, and CBCT imaging of the maxillary structures is an accurate and reliable method to evaluate dentoskeletal changes after SARME<sup>27</sup>. Thus, the conclusions drawn from the results of the present systematic review may not reflect the actual relationships, since the transverse maxillary skeletal and dental arch expansion and relapse after SARME were compared using CBCT and conventional postero-anterior cephalograms<sup>10,12</sup>. Moreover, dissimilar radiographic anatomical landmarks were used for the linear measurements of the dentoskeletal anatomical changes. Thus, further randomized controlled trials com-

paring the two treatment modalities should involve computed tomography scans with reproducible anatomical landmarks and three-dimensional volumetric analysis of hard and soft tissue changes to exclude or control confounding variables.

A horizontal V-shaped opening of the midpalatal suture decreasing from anterior to posterior has been reported in several studies in which a bone-borne distraction appliance was used<sup>15,16,30–33</sup>. The studies included in the present systematic review disclosed a parallel opening of the midpalatal suture with the two treatment modalities<sup>10,12</sup>. A frontal V-shaped widening of the maxilla with a significantly larger dental expansion compared to skeletal expansion was observed with the two treatment modalities<sup>10,12</sup>. The expansion pattern described in the present systematic review corroborates the findings of previously published studies<sup>14–16</sup>. However, a parallel expansion in the frontal plane necessitates a high palatal placement of the bone-borne distraction appliance. A parallel movement in the frontal plane can only be accomplished if the expansive force is placed higher than the centre of resistance of the mobilized maxilla. The more inferiorly the distraction appliance is placed, the more dental tipping in the frontal plane is to be expected. The Rotterdam bone-borne distraction appliance was used in one study<sup>10</sup>. This type of bone-borne distraction appliance can only be placed low and more posteriorly in the palatal vault due to its bulkiness. Thus, the reported frontal V-shaped widening of the maxilla was possibly due to the choice of bone-borne distraction appliance<sup>10</sup>. The position of the bone-borne distraction appliance, above or below the centre of resistance of the mobilized maxilla, determines parallel or tipping movement. Neither of the studies in this systematic review described the location of the bone-borne distraction appliance in relation to the centre of resistance of the mobilized maxilla. Therefore, it is very important to identify the site and the amount of transverse maxillary deficiency in order to individualize the surgical technique and select the most appropriate distraction appliance accordingly.

Several factors influence the skeletal and dental expansion pattern, including pterygomaxillary disjunction, surgical expertise, age, skeletal maturity, sex, distraction rate, latency interval, and consolidation period. It has been postulated that a greater posterior expansion is correlated with pterygomaxillary disjunction<sup>34–36</sup>. However, a recent sys-

tematic review and meta-analysis concluded that the scientific literature is inconclusive regarding the effect of pterygomaxillary disjunction<sup>37</sup>. The studies included in this systematic review disclosed a parallel horizontal transverse expansion with both treatment modalities, although pterygomaxillary disjunction was only performed in one of the studies<sup>12</sup>. It has been assumed that SARME without pterygomaxillary disjunction and placement of a bone-borne distraction appliance at the level of the second premolars facilitate a horizontal V-shaped opening with more expansion anteriorly than posteriorly, whereas pterygomaxillary disjunction and placement of the bone-borne distraction appliance at the level of the first molars facilitate a more parallel expansion<sup>6</sup>. In one of the studies included in the present systematic review, the bone-borne distraction appliance was placed high on the palate at the level of the second premolars, demonstrating a parallel transverse expansion with both treatment modalities<sup>12</sup>.

SARME with a bone-borne distraction appliance requires a learning curve to allow the surgeon to acquire the necessary technical expertise. However, neither of the studies included in the present systematic review provided information on the expertise of the surgeons<sup>10,12</sup>.

Age, sex, and skeletal maturity may influence the transverse maxillary expansion and relapse pattern<sup>5</sup>. Fusion of the midpalatal suture begins in the posterior area, progressing from the palatine bone to the maxilla, and presents great variability according to age and sex<sup>38</sup>. The patients included in the two studies in this systematic review had different age and sex distributions, which might be an important confounding variable.

The distraction rate as well as the latency and consolidation periods may also influence the treatment outcome after SARME, and there is no consensus in the literature. Regarding these issues, previously published studies have reported a distraction rate varying from 0.2 mm to 1 mm per day<sup>10–12,14,15,18,30,32,39–52</sup> and a latency period ranging from 5 to 7 days<sup>10–12,14,18,30,32,36,42–44,52</sup>. A consolidation period of 2–12 months is reported in the majority of previous studies<sup>4,10,12,14,15,18,32,40,45,51–55</sup>, while active orthodontic treatment was initiated immediately after surgery in one study<sup>36</sup>. The method of retention is another possible confounding variable<sup>56</sup> and was only described in one of the studies in this systematic review<sup>12</sup>. The distractor was locked after active expansion and a trans-

palatal arch was inserted during the consolidation period of 4 months<sup>12</sup>.

Pre- or postoperative orthodontic treatment and overexpansion may influence skeletal and dental relapse after SARME. In the present systematic review, previous orthodontic treatment was an exclusion criterion in one study<sup>12</sup>, while the other study reported that postoperative orthodontic treatment possibly influenced the final treatment outcome<sup>10</sup>. However, neither of the studies followed the patients until the completion of the orthodontic-surgical intervention<sup>10,12</sup>. Furthermore, overexpansion was performed in one of the studies<sup>12</sup>, while no overexpansion was described in the other<sup>10</sup>. Therefore, long-term studies are needed in order to distinguish between the amount of orthodontic and surgical expansion, as well as overexpansion.

SARME is generally considered a surgical procedure with low morbidity and a limited risk of serious complications, although life-threatening epistaxis, carotid cavernous fistula, and orbital compartment syndrome have been reported<sup>48,57–60</sup>. The most commonly reported complications after SARME include haemorrhage, pain, sinusitis, palatal tissue irritation/ulceration, asymmetrical expansion, nasal septum deviation, damage to teeth and periodontium, periodontal problems, and relapse<sup>48,61–65</sup>. It has been claimed that a bone-borne distraction appliance is associated with less periodontal damage, root resorption, and dental tipping<sup>16,33,66,67</sup>. However, a systematic review concluded that only very weak evidence exists for less dental tipping with a bone-borne distraction appliance<sup>6</sup>. Oedema, haematoma, mild extrusion of a premolar, endodontic treatment, and asymmetrical expansion were reported in the studies included in this systematic review<sup>10,12</sup>. Hence, complications within the studies included seem to be in accordance with the literature.

Patient-reported outcome measures are essentially subjective reports of the patient's perceptions of their oral health status and its impact on their daily life or quality of life. The influence of a bone-borne or a tooth-borne distraction appliance on chewing function, aesthetics, speech, and quality of life during the distraction phase and consolidation period is an essential consideration when selecting the best treatment modality. Tolerance, ease of use, and overall patient satisfaction after SARME with a bone-borne or a tooth-borne distraction appliance has been evaluated previously using a questionnaire. The overall satisfaction was

high and the tolerance was comparable for the two treatment modalities<sup>13</sup>. However, 60% of the patients found the bone-borne appliance easier to use compared with 32% for the tooth-borne device<sup>13</sup>. Neither of the studies included in the present systematic review reported on patient-reported outcome measures.

Meta-analysis was not applicable due to considerable heterogeneity and dissimilar outcome variables. Therefore, the hypothesis of no difference in transverse maxillary skeletal and dental arch expansion and relapse after SARME with a bone-borne or a tooth-borne distraction appliance could neither be rejected nor confirmed due to the considerable heterogeneity, different outcome variables, and the lack of long-term randomized clinical trials. Moreover, the focused question raised by the PICOS criteria could not be answered (Table 3). Hence, well-designed long-term randomized clinical trials including a standardized protocol with emphasis on the placement of the bone-borne distraction appliance above the centre of resistance of the mobilized maxilla and three-dimensional analysis of dental and skeletal changes are needed before one treatment modality can be considered superior to the other.

#### Funding

None.

#### Ethical approval

Not required.

#### Patient consent

Not required.

#### Competing interests

None.

**Acknowledgements.** We thank Pernille Skou Gaardsted, Senior Librarian, Medical Library, Aalborg Hospital Science and Innovation Centre, for assistance with the search strategy, and Ann-Eva Christensen, Biostatistician, Faculty of Medicine, Unit of Epidemiology and Biostatistics, Aalborg University Hospital, for assistance with the statistical analysis.

#### Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.ijom.2018.12.010>

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