



# Systematic Review Effects of Surgically Assisted Rapid Palatal Expansion on Facial Soft Tissues: A Systematic Review

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Abstract: Surgically assisted rapid palatal expansion (SARPE) is a successful method for treating transverse discrepancies in adult patients. The relocation of maxillary segments may induce changes at the surrounding soft tissues as well. The aim of this systematic review was to examine the possible effects that SARPE may have in the soft tissues of the face. Our search strategy included electronic databases (Pubmed, Scopus, ProQuest, Google Scholar, Cochrane Library) and a hand search of the reference list of found reviews. A priori definition of inclusion and exclusion criteria was made. Finally, 15 articles were included in qualitative synthesis. Risk of bias was generally high among the included studies. Study outcomes included nasal, labial, nasolabial and other facial soft tissue measurements. The evaluation of the changes was two-dimensional in six studies, and three-dimensional in nine studies. Meta-analysis was unfeasible due to lack of standardization, important methodological limitations, and shortcomings of the studies. A post-surgical increase in the dimensions of the alar width and the alar base width was commonly reported among the included studies. However, the above should be considered with caution due to the high risk of bias and the inability for quantitative synthesis.

Keywords: expansion; distraction osteogenesis; soft-tissue; SARPE

# 1. Introduction

Orthodontists are often challenged to deal with transverse maxillary deficiency (TMD). Treatment of TMD depends on its nature, i.e., dentoalveolar or skeletal, as well as the level of skeletal maturation of the patient. A dentoalveolar TMD can be treated with several different techniques to correct the position of the affected teeth. However, when the discrepancy is due to a skeletally narrow maxilla, the treatment is oriented to orthopedic rapid palatal expansion, surgically assisted rapid palatal expansion, or segmented Le Fort I osteotomies [1]. The decision is primarily based on the level of skeletal maturation. Many clinicians have suggested a certain age as the determining factor of treatment selection, yet this approach is probably vague because of the low correlation of skeletal maturation and chronological age [1,2].

Interdigitation of the palatal suture used to be a relevant criterion for treatment decisions; however, several studies suggest that this suture does not offer much resistance to expansion [1,2]. Further research has shown that the zygomatic buttress and the pterygomaxillary junction are the critical areas of resistance. Surgically assisted rapid palatal expansion (SARPE) has been highly recommended for treating TMD, and osteotomies are



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**Copyright:** © 2022 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). performed in order to decrease the resistance resulting from the consolidation of facial and skull joints [3–5].

Generally, surgical expansion is indicated in skeletal mature patients with a severe constricted maxillary arch, and can be performed with two different techniques: SARPE or segmental osteotomy of the maxilla with a wider repositioning of the two halves. Bailey et al. recommended that the latter technique can be chosen when the patient's skeletal problems are to be addressed with a single maxilla-mandibular surgical procedure to correct discrepancies in the sagittal and the vertical dimensions as well. On the other hand, SARPE is preferred when the patient's skeletal discrepancy is isolated on the transverse dimension [6].

The first to propose SARPE to address TMD was Brown (1938) [7]. SARPE is based on the principles of distraction osteogenesis described by Ilyzarov (1987) [8]. The distraction force is transferred and applied to the bone via tooth-borne or bone-borne devices. It is a reliable method of treating TMD with clinically efficient long-term dental and skeletal changes [9–11]. These changes are reflected in the facial soft tissue as well. An increased projection of the cheek area in the lateral direction and widening of the nose were most commonly reported [12]. Treatment varies in terms of the surgical technique, the appliance used to achieve the expansion, and the expansion protocol. Recently published systematic reviews seem to reach different conclusions concerning the necessity of pterygoid plate separation [10,13]. Furthermore, the effect of SARPE on nasal airway volume was recently reviewed as well [14]. The authors of this study reported a significant increase in nasal cavity volume and no increase in oropharyngeal volume. Accordingly, SARPE cannot be suggested as part of the treatment of respiratory dysfunctions [14].

Although several papers investigate the dental and skeletal effects of SARPE, its potential outcome on facial soft tissues has not been reviewed yet. The aim of this article is to systematically search the literature and review the effects that it may have on the soft tissues of the face.

#### 2. Materials and Methods

## 2.1. Search Strategy

A computerized search was conducted using Medline (1970–June 2022), Google Scholar (1950–June 2022), Cochrane Library, Pro Quest, and Scopus. Terms that were used in this literature search were "SARME" or "surgically assisted rapid maxillary expansion", "SARPE" or "surgically assisted rapid palatal expansion", "surgically assisted palatal suture expansion", and "surgical palatal suture expansion". The search strategy and appropriate modifications were applied to fit for each database (Table 1).

Database		MESH Terms	Limits
	1	orthodont *	
	2	SARPE	
	3	SARME	
	4	"surgically assisted rapid palatal expansion"	
MEDLINE via PubMed	5	"surgically assisted rapid maxillary expansion"	NoLimits
	6	"surgically assisted palatal suture expansion"	
	7	"surgical palatal suture expansion"	
	8	"transpalatal AND distract *"	
	9	2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8	
	10	1 AND 9	-

Table 1. Search strategy. \* replaces one or more characters at the end of the search term.

Table 1. Cont.

Database	MESH Terms	Limits
Scopus	9	No Limits
Google Scholar	10	English
Cochrane library	9	No Limits
ProQuest	10	No Limits

#### 2.2. Study Selection and Eligibility Criteria

After removing the duplicates, two authors (F.V. and P.R.) independently screened all candidate articles using pre-specified inclusion and exclusion criteria. These authors excluded the articles that did not fulfill the criteria based on the titles, the abstracts, and the full texts, sequentially. Studies published in languages other than English were excluded during the abstract and full-text screening. Finally, all reference lists of the included studies and the identified systematic reviews and meta-analyses were hand searched for further candidate studies. In the case of disagreement, the two authors reached a consensus after discussion with another author (G.P.). The a priori eligibility criteria were organized within the PICO framework in order to increase precision (Table 2).

Table 2. A priori inclusion and ex	clusion criteria.
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Category	Inclusion Criteria	Exclusion Criteria		
Danticinanto	Human studies on healthy participants of any age,	Craniofacial syndromes, cleft lip and palate		
Participants	gender, angle classification, and skeletal pattern	Systematic disease		
Intervention	SARPE as a surgical method	Combination of surgical procedures		
	Any other type of treatment as a control group (e.g., orthodontics without SARPE)			
Comparison	Untreated control groups	<ul> <li>No exclusion criteria concerning the "comparisons"</li> </ul>		
	No control groups (before–after studies, repeated measures designs)			
Outcome	Facial soft tissue evaluation on any plane of space	Only hard tissue evaluation		
Principal Outcome Measure	Measurements concerning soft tissue changes via photographs, cephalometrics, CBCTs, etc.	Lack of records prior to or post SARPE		
	Randomized clinical trials	Congress material		
	Non-randomized clinical trials	Expert opinions		
	Retrospective cohorts	Comments		
	Case-control studies	Letters to the editors		
Study design	Prospective before-after studies	In vitro studies		
		Animal studies		
		Case reports		
	Retrospective before-after studies	Narrative reviews *		
		Systematic reviews *		
		Meta-analyses *		

\* Excluded after screening their reference lists for additional candidate studies.

#### 2.3. Data Extraction

Two authors (P.R. and F.V.) independently used the same pre-specified data extraction forms to retrieve data of interest from all included studies. Finally, they compared their results, and in the case of disagreement, they reached a consensus after discussion. The items of the pre-specified data extraction form were as follows: study design, eligibility criteria, sample size, age and gender sample distribution, a minute description of the undertaken orthognathic procedure, the type of the applied expander, the expansion protocol, the comparator, the outcomes assessed, the methodology, and finally, the time of each record relative to the interventions for each study.

### 2.4. Assessment of Risk of Bias (RoB)

Two review authors (P.R. and I.D.) independently assessed risk of bias of all included studies by means of "ROBINS-I" (RoB) assessment tools suitable for each one based on the study design. Randomized clinical trials were assessed using the "Risk of bias assessment tool for Randomized Clinical Trials" [15]. Non-randomized studies were evaluated using the RoB assessment tool [16]. Finally, uncontrolled studies were assessed using the Risk of bias tool for studies with no control group (NHLBI, RTI International, Quality Assessment Tool for Before–After (Pre–Post) Studies with No Control Group). Once again, a consensus was reached after discussion in the case of disagreement.

### 2.5. Heterogeneity Assessment

Two authors (P.R. and I.D.) assessed clinical heterogeneity taking the PICO framework into account; intervention characteristics were considered, namely features of both the orthognathic procedure and the expansion protocol, to contribute to the overall clinical heterogeneity. The same features were evaluated for the comparators. Finally, the heterogeneity on the outcomes was assessed, in view of time of measuring, method of imaging and/or measuring, and the outcome measures. Methodological heterogeneity was assessed both in terms of study design and in terms of risk of bias. Statistical heterogeneity was assessed only between comparable studies. The tools for this purpose were Cochran's Q, while the impact of statistical heterogeneity was assessed with the I2 statistic.

#### 3. Results

#### 3.1. Flow Diagram

The results of the search are shown in the flow diagram (Figure 1). The initial number of combined hits of the electronic databases and hand search was 2536. After the removal of duplicates, 1318 articles remained, while after the application of the eligibility criteria, 15 studies were included in the present systematic review [17–31]. Two studies shared the same samples, but they evaluated different soft tissue characteristics.

## 3.2. Study Characteristics

Out of the 15 studies, 1 was a randomized clinical trial [17], 2 were prospective nonrandomized controlled clinical trials [18,19], 8 were retrospective cohorts [20–22,28–31], and 5 were uncontrolled studies [23–27] (specifically 1 retrospective before–after study [23], 2 prospective studies with a repeated measures design [24,25], and 2 retrospective studies with a repeated measures design [26,27]). Study design, eligibility criteria, and sample characteristics of the included studies have been uploaded separately as supplementary files (Supplementary Table S1).



Figure 1. PRISMA study flow diagram.

Seven studies included pterygomaxillary disjunction in their surgical technique [17–19,23,25,28,31], while remaining seven studies did not [20–22,24,27,29,30]. Bita et al. did not clarify whether this procedure was included in the surgical technique [26]. Four studies applied alar cinch sutures [17,23,26,31], five studies applied alar base V-Y sutures [17,20,23,26,27], one study applied both alar cinch and alar base V-Y sutures [21], two studies applied neither alar cinch nor alar base V-Y sutures [24,25], while the remaining studies did not clarify whether they included these techniques in the surgery. Eight studies used a tooth-borne expander [21–30], three used a bone-anchored appliance [25,28,31], three used both [18–20], and one was unclear in relation to the expander [17]. Seven studies included a comparator [17–22,31]. Two studies compared SARPE with rapid maxillary expansion (RME) [21,22], one compared different sutures within the framework of SARPE [17], one compared two dissection tools [17], and four studies compared two types of expanders (again, within the framework of SARPE) [18–21]. The details of the undertaken orthognathic procedures, the expander, and the expansion protocols as well as the comparison groups have been uploaded separately as supplementary files (Supplementary Table S2).

As far as the study outcomes are concerned, three studies included nasal measurements [26,27,30], four included nasolabial measurements [20–24], one included labial measurements [17], five studies included various facial measurements [18,19,22,25,28] and two studies included various nasal and soft tissue measurements [29,31]. The evaluation of the changes was two dimensional in six studies [17,21,22,26,27,29] and three dimensional in nine studies [18–20,23–25,28,30,31]. The outcomes were measured clinically with a caliper in two studies [26,27], via laser scan in one study [25], via three-dimensional photogrammetry in three studies [19,23,28], via lateral cephalometric analysis in one study [21], via calibrated two-dimensional photography in one study [22], via CBCT in five studies [20,24,29-31], and via a combination of lateral cephalometric analysis and clinical evaluation with a caliper in two studies [17,19]. All studies included measurements before intervention. Post-SARPE soft-tissue evaluations were carried out at 2 months in three studies [24,25,31], at 6 months in seven studies [17,23,25–27,29], at 12 months in two studies [25,26], and at 24 as well at 36 months in one study [27]. Three CBCT studies re-evaluated the patients after 18 [24] or 22 months [18,19]. One study measured the outcomes at specific stages of orthodontic treatment [22]. One study had a minimum of 6 months follow up [20] and three studies did not specify the time of re-evaluation [21,28,30]. The details of the studies' outcomes, outcome measures, and time of measuring are presented in Table 3.

Study	Outcomes	Outcome Measures	Outcome Time of Measuring Measures	
Bita et al., 2011 [26]	Transversal nasal measurements	Alar width measured directly with a caliper	T0: preoperative T1: at 2 months T2: at 6 months T3: at 12 months postoperatively	Postoperative growth of the alar base ranging from 3.12 to 3.48 mm for females and from 3.43 to 3.65 mm for males. The nasolabial angle grew by about 2 degrees.
Ramieri et al., 2008 [25]	Facial soft tissue measurements on all 3 planes of space	Various linear and angular measures via 3D facial laser scanning	T0: before transverse palatal distraction (TPD) T1: 6 months T2: 1 year after TPD	TPD produces mean facial changes (1–2 mm) in the cheek and paranasal areas as well as in the nasal base in the transverse plane only. Changes are more evident at 6 months and remain stable at 1 year postoperatively.
Metzler et al., 2014 [23]	Nasolabial measurements on all 3 planes of space	Various liner and angular measurements via 3D photogrammetry	T0: preoperative T1: at least 6 months postoperatively	<ol> <li>Significant decrease in nasofrontal angle and upward rotation of nasal tip.</li> <li>Significant increase in alar width, alar base width and nasal sill width.</li> <li>Stable lip dimensions.</li> </ol>
Rubim de Assis et al., 2010 [27]	Transversal nasal measurements	Alar width measured directly with a caliper	T0: preoperative T1: 2 months T2: 6 months T3: 24 months T4: 36 months postoperatively	No statistically significant differences.
Gungor et al., 2012 [21]	Sagittal nasolabial measurements	Measurements on lateral cephalometric radiographs	T0: before expansion T1: after expansion (unspecified)	Significant postoperative decrease in soft tissue convexity angle; significant increases in upper and lower nasal width as well as in the anterior face height.

Table 3. Outcomes, outcome measures, time of measuring, and main findings of the included studies.

Study	Outcomes	Outcome Measures	Time of Measuring	Main Findings
Filho et al., 2002 [20]	Nasolabial measurements on all 3 planes of space	Various lateral vertical or sagittal cephalometric measurements; clinical transversal measurements (caliper): alar base	T0: immediately preoperative T1: minimum 6 months postoperatively	<ol> <li>SARPE tends to position the upper lip posteriorly, without important vertical alterations.</li> <li>The V-Y suture seems to minimize this effect.</li> <li>Absence of alar base suture widens the nasal base, regardless of the type of suture applied over the mucosa.</li> </ol>
Berger et al., 1999 [22]	Vertical and transverse facial soft tissue measurements	All measurements made on calibrated photographs	T0: before any treatment was rendered T1: bonding; immediately after the appliance was bonded and before any expansion T2: end of expansion; on the day of completion of orthopedic or surgical expansion T3: debonding; immediately after removal of the appliance T4: retention; 1 year after appliance removal	<ol> <li>Soft tissue nasal width increased by 2.0 mm during treatment. Both the orthopedic and surgical groups maintained this increase throughout the whole length of the observation period.</li> <li>Overall face height, intercanthal distance, average eye width, and nose length did not change over time.</li> </ol>
Magnusson et al., 2013 [24]	Nasolabial measurements on all 3 planes of space	Measurements from various nasolabial landmarks on CBCT	T0: 1 week before surgery T1: at the end of the active orthodontic treatment phase (on average, 18 months postoperatively)	<ol> <li>Significant widening and overall anterior and inferior displacement of all nasomaxillary soft tissues.</li> <li>Various displacements that rounded the shape of the nose in the frontal view.</li> <li>Significant widening of the nostrils and an increase in nostril area.</li> </ol>
Nada et al., 2013 [18]	3D evaluation of maxillary soft tissue measurements	Measurements from various nasolabial landmarks on CBCT	T0: before treatment T1: after the 1st and before the 2nd surgical procedure (22 $\pm$ 7 months after T0)	<ol> <li>SARME with tooth-borne or bone-borne expansion appliances induced comparable orofacial soft tissue changes.</li> <li>Slight postoperative retro-positioning of the upper lip and increased projection of the cheeks.</li> </ol>
Nada et al., 2013 [19]	Transversal nasal measurements	Alar width measured on 3-D photographs	T0: before treatment T1: after the 1st and before the 2nd surgical procedure (21.7 $\pm$ 6.6 months for the Hyrax group and 22.6 $\pm$ 6.9 months for the TPD group)	No statistically significant differences.
Antonini et al., 2013 [17]	Sagittal and vertical labial measurements	Measurement on lateral cephalometric radiographs and clinically via a caliper	T0: preoperative T1: 6 months postoperatively	<ol> <li>Upper lip shortening.</li> <li>Thinning of the upper portion.</li> </ol>
Zupan et al., 2022 [28]	3D evaluation of maxillary soft tissue measurements	Measurements from various anatomical landmarks (cephalometric points) and regional best-fit method (forehead, supraorbital, and nasal root regions were selected for the superimposition) from 3D scans	T0: preoperative T1: postoperative	<ol> <li>Increase in the paranasal and cheek areas.</li> <li>Increased nasal width.</li> <li>Decreased upper-face height with an unchanged lower height.</li> <li>Increased vertical philtrum height.</li> <li>Increased nasolabial angle.</li> <li>Increase in the facial profile angle, resulting in an increased facial convexity and anterior displacement of the upper-lip area.</li> </ol>

# Table 3. Cont.

Study	Outcomes	Outcome Measures	Time of Measuring	Main Findings
Karabiber and Yilmaz, 2021 [29]	Soft tissue assessment; Anterior nasal airway	Linear soft tissue measurements on tereophotogrammetric images for soft tissue assessment; measurements using cone beam computed tomography (CBCT) to evaluate the anterior nasal airway.	T0: before treatment T1: 6 months after expansion	<ol> <li>Soft tissue distances of the alar base and alar to midsagittal plane (MSP) were increased on the cross bite (C) side.</li> <li>A significant decrease in the distance from the lower nostril point to the midsagittal plane (MSP) on the non-cross bite (NC) side compared to a significant increase on the C side.</li> <li>Significantly higher changes on the C side for all parameters except the upper nostril point to the MSP distance. Cheek volume was significantly higher on the C side.</li> <li>Volume changes of the anterior nasal airway were significantly increased on the C side.</li> </ol>
Dias et al., 2021 [30]	Nasal septum measurements	Various linear nasal septum measurements	T0: preoperative T1: immediately postoperative T2: late postoperative	No statistically significant differences.
Jesus et al., 2021 [31]	Soft tissue nasomaxillary measurements	Various nasal soft tissue measurements using CBCT	T0: before expansion T1: 1 to 2 months after stopping the active expansion of MARPE	<ol> <li>MARPE uniformly increased the anterior and posterior widths of the nasal cavity.</li> <li>Nasal width did not differ significantly between the groups.</li> </ol>

## Table 3. Cont.

# 3.3. Risk of Bias

The quality assessment of all included studies lacking a control group (before–after studies and repeated measures designs) is depicted in Table 4.

 Table 4. Risk of bias for uncontrolled studies, i.e., before-after studies and repeated measures designs.

Studies	Bita et al., 2011 [ <mark>26</mark> ]	Ramieri et al., 2008 [25]	Metzler et al., 2014 [23]	Rubim de Assis et al., 2010 [27]	Magnusson et al., 2013 [24]
Criteria					
1. Was the study question or objective clearly stated?	Yes	Yes	Yes	Yes	Yes
2. Were eligibility/selection criteria for the study population pre-specified and clearly described?	No	Yes	Yes	Yes	Yes
3. Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?	Yes	Yes	Yes	Yes	Yes
4. Were all eligible participants that met the pre-specified entry criteria enrolled?	CD	CD	CD	CD	CD
5. Was the sample size sufficiently large to provide confidence in the findings?	CD	CD	CD	CD	CD
6. Was the test/service/intervention clearly described and delivered consistently across the study population?	Yes	Yes	Yes	Yes	Yes

# Table 4. Cont.

Studies	Bita et al., 2011 [26]	Ramieri et al., 2008 [25]	Metzler et al., 2014 [23]	Rubim de Assis et al., 2010 [27]	Magnusson et al., 2013 [24]
7. Were the outcome measures pre-specified, clearly defined, valid, reliable, and assessed consistently across all study participants?	Yes	Yes	Yes	Yes	Yes
8. Were the people assessing the outcomes blinded to the participants' exposures/interventions?	No	No	No	No	No
9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?	CD	CD	CD	CD	CD
10. Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests conducted that provided <i>p</i> values for the pre-to-post changes?	No	Yes	Yes	Yes	No
11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?	No	No	No	No	No
12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.), did the statistical analysis take into account the use of individual-level data to determine effects at the group level?	NA	NA	NA	NA	NA
Yes/No/Other (CD, NR, NA) *					

\* CD—cannot determine; NA—not applicable; NR—not reported.

The results of the assessment of risk of bias for non-randomized studies are displayed in summary in Table 5, while those for the randomized study are presented in Table 6 and Supplementary Figure S1.

Table 5. Risk of bias summary of non-randomized studies.

Studies	Gungor et al., 2012 [21]	Filho et al., 2002 [20]	Berger et al., 1999 [22]	Nada et al., 2013 [ <mark>18</mark> ]	Nada et al., 2013 [19]	Zupan et al., 2022 [28]	Karabiber et Yilmaz 2021 [29]	Dias et al., 2021 [30]	Jesus et al., 2021 [31]
Bias due to confounding	Serious	Serious	Serious	Moderate	Serious	Serious	Serious	Serious	Serious
Bias in selection of participants for the study	Low	Low	Low	Low	Low	Low	Low	Low	Low
Bias in classification of interventions	Low	Low	Low	Low	Low	Low	Low	Low	Low
Bias due to departures from intended interventions	Low	Low	Low	Low	Low	Low	Low	Low	Low
Bias due to missing data	Low	Low	Low	Low	Low	Low	Low	Low	Low
Bias in measurement of outcomes	Low	Low	Low	Low	Low	Low	Low	Low	Low
Bias in selection of the reported result	Low	Low	Low	Low	Low	Low	Low	Low	Low
Overall RoB	Serious	Serious	Serious	Moderate	Serious	Serious	Serious	Serious	Serious

Study	Antonini et al., 2013 [17]
Random sequence generation (selection bias)	Low
Allocation concealment (selection bias)	Unclear
Blinding of participants and personnel (performance bias)	Unclear
Blinding of outcome assessment (detection bias)	Unclear
Incomplete outcome data addressed (attrition bias)	Low
Selective reporting (reporting bias)	Low
Summary	Unclear

Table 6. Risk of bias of the randomized clinical trial.

#### 3.4. Heterogeneity Assessment

As an overall assessment, only the measurement of alar base width is common in methodologically similar studies [23,27,28] that share the type of expander (tooth-borne), the time of measurement (6 months), and the type of surgical technique (Le Fort I osteotomy with V-Y suture, except the part of disjunction of the pterygoid plates that was performed in the study by Metzler et al. [23] but not included in the study by Rubim de Assis et al. [27]). Despite the similarities that the study by Filho et al. [20] has with the above studies, several unclear details of the surgical procedure (performance of V-Y suture and alar cinch suture) as well as the vague definition of the time of measurement (at least six months) does not render it comparable with the above. A meta-analysis was not performed because of the high risk of bias of the respective studies and due to the heterogeneous data of the included studies.

## 4. Discussion

Several studies aimed at investigating the effect of various orthognathic procedures on the soft tissues. However, the available systematic reviews addressing this issue concluded that better designed studies are needed in order to draw definitive conclusions regarding the effect of the orthognathic procedures on the appearance of the face [32–34]. The present study agrees with this conclusion.

The variability of the soft tissues' response to surgical procedures requires careful consideration during research protocol development. Predictor variables of the soft tissue changes after maxillary advancement can be categorized in relation to the surgery as presurgical, intrasurgical and postsurgical [34]. Presurgical variables may include soft tissue characteristics such as lip tone, length, and thickness. Intrasurgical variables may include the magnitude of the surgical trauma and the formation of edema or hematoma, surgical bone recontouring, magnitude and direction of maxillary movement, soft tissue manipulation techniques, and type of suture. Postoperative variables include magnitude of bone remodeling, relapse, healing, scarring and contraction, postsurgical infection, magnitude and direction of postoperative orthodontic movements, and hard and soft tissue stability [34]. These predictors may explain soft tissues changes after SARPE and should be controlled for either in the design of the study or in the statistical analysis; otherwise, they may bias the study results. Unfortunately, it is not possible to control all these factors in a randomized clinical trial (RCT).

From the included studies, the RCT of Antonini et al. [17] used the presence of all anterior teeth as an inclusion criterion in their study. Absence of maxillary anterior teeth might bias the results decreasing lip support. The studies by Ramieri et al. [25] and Antonini et al. [17] were the only ones to use the history of facial trauma as an exclusion criterion; facial trauma can alter the effect of SARPE on the facial soft tissues via its subsequent scaring. No other potential predictors mentioned above were considered in the included studies. On the other hand, Nada et al. [18] were the only authors to control for some of the above-mentioned variables in their analysis. They tested for 3D upper lip and cheek changes, controlling for age, gender, amount of expansion, and upper incisor inclination. They found that age and upper incisor inclination affected the upper lip, whereas the

amount of total expansion affected the cheeks. Moreover, studies without control groups should at least control the amount of expansion in their analysis, since the reported facial soft tissue changes are additionally influenced by the orthodontic movements. This fact renders the pure SARPE effect impossible to quantify [23–30]. Studies with treated controls may also benefit from controlling the total amount of surgical expansion for two reasons: primarily, because the latter could be a confounder as indicated by Nada et al. [18], and secondarily, because it would be of clinical interest to quantify the expected facial soft tissue changes for the individual patient considering, among other things, the amount of expansion. On the other hand, as the number of variables increases, the required sample size also grows. Power analysis is a key component for planning prospective studies in the future.

Both Gungor et al. and Berger et al. compared SARPE versus RME [21,22]. The age discrepancy between the compared groups introduces bias in the estimation of difference between the two treatment effects. Therefore, the comparison of their reported results should be interpreted with caution.

A noticeable difference was also found in the distribution between the males and the females in the samples of three studies. The females included were 12 against 3 males in the study by De Assis et al. [27], 14 against 4 in the study by Ramieri et al. [25], and 10 against 4 in the study by Gungor et al. [27]. The comparison of their results should be interpreted with caution due to the lack of knowledge regarding sexual dimorphism in SARPE effects on soft tissues.

High clinical heterogeneity was observed among the included studies regarding the surgical technique: the inclusion of pterygoid plate separation, V-Y suture, and alar cinch may influence the soft tissues response. High heterogeneity was also found in the type of expander, the outcome measurements, and the time of measurement. The expansion protocol was vaguely described (or remained unspecified) among the studies since the termination of expansion was set at the correction of the cross bite of each patient, not at the same predetermined distance between the patients. The above is logical when clinical efficiency is concerned, but it encapsulates the bias of result assimilation between patients with high and low needs for expansion.

The most widely used outcome measures relate to the transverse dimension and include alar width, alar base width, and intercanthal distance. At the sagittal level, the distances between subnasale and pronasale, between labiale superius and tragus, and between pronasale and tragus were measured in two studies [20,23]. No vertical measurements were common between the studies. Nasolabial angle was measured in two studies as well [20,23].

Alar width is defined as the distance between the right and the left alar. Nada et al. did not report a statistically significant increase either in tooth-borne or bone-borne expanders [18,19]. Ramieri et al. found a statistically significant increase of 1.4 mm one year after surgery [25], whereas Metzel et al. found the same increase of 1.4 mm 6 months post surgery [23]. Magnusson et al. found a median increase of 1.66 mm 18 months postoperatively while Zupan et al. found a decrease of 1.7 mm postoperatively [24].

Alar base is defined as the distance between the most lateral right and left points of the alar base. Magnusson et al. found a median increase of 3.09 mm about 18 months post-operatively [24]. An increase of 1.69–2.0 mm was reported 6 months post surgery [23,27], which remained stable even after 36 months [27]. Filho et al. found an increase of 4.2 mm when conventional suturing of the upper lip was used and 3.5 mm when patients received the simple V-Y suture of the upper lip [20].

Intercanthial distance (the distance between the right and left endocanthion) was measured in two studies [22,25]. Non-significant differences ( $\pm 0.2$  mm) were reported during the expansion and retention phase (1 year after SARPE) [22,25].

The distance between subnasale and pronasale defines the length of the base of the nose. Ramieri et al. found a non-significant decrease of 0.8 mm 1 year after the surgery. The

same distance was measured by Magnusson et al., who found a non-statistically significant increase of 0.18 mm 18 months postoperatively [24,25].

The measurement from labiale superius to tragus expresses the projection of the labiale superius. It is defined by the distance between the midpoint of the upper vermilion line and the notch in the upper margin of the tragus. Ramieri et al. found a non-significant decrease of 0.7 mm while Metzler et al. found an increase of 0.9 mm [23,25]. Additionally, these two studies measured the pronasale-tragus distance, between the most protruded point of the apex nasi and the notch in the upper margin of the tragus [23,25]. This measurement expresses the projection of the nasal tip. Statistically significant differences were obtained: a decrease of 0.9 mm and an increase of 0.7 mm. The explanation for these contradictory results may be the fact that these studies evaluated different surgical techniques: Metzler et al. [23] used an alar cinch and V-Y suture whereas Ramieri et al. did not [25]. Nevertheless, the changes were small and clinically insignificant. Nasolabial angle is another important parameter in determining the attractiveness of facial profile. This angle is formed by labiale superius, collumela peak, and subnasale. Metzler et al. found a non-significant median decrease of 2.0 degrees [23]. Filho et al. found a median decrease of 0.04 degrees in the group that had conventional suturing of the upper lip, practically reporting no change. However, the group that had a simple V-Y suture of the upper lip exhibited a decrease of 2.6 degrees [20].

The strengths of the present review include a methodology following clear-cut guidelines. The search strategies employed were exhaustive, covering electronic, manual, and gray literature material up to November 2020. Their character was comprehensive, including every available study in English, irrespective of date and status of publication. Every effort to decrease bias in the methodology employed was made. As a result, screening, verification of eligibility, abstraction of information, and assessment of risk of bias and of the quality of evidence were all performed in duplicate, and any disagreement was resolved by discussion or consultation until a final agreement was achieved.

The gold standard of study design is the RCT. The comparator in an RCT evaluating SARPE would include either non-surgical approaches, e.g., orthodontics only, or another intervention group, i.e., different techniques still within the context of SARPE, such as using different expanders. The two types of comparators would provide insight into different effects and answer different research questions; the first would estimate the effect of SARPE on the facial soft tissues, whereas the second would compare these effects between two or more different approaches to SARPE. However, studies of inferior study design (nonrandomized studies (NRS) and uncontrolled studies) were additionally included in the present systematic review for various reasons. First and foremost, RCTs cannot answer the first question, as it is unethical to randomly assign a patient presenting skeletally narrow maxilla to the orthodontics-only control group. Consequently, we resort to NRSs and uncontrolled studies as the only means of assessing the effect of SARPE on facial soft tissues. In contrast, RCTs are the ideal design to answer the second question, i.e., which SARPErelated treatment benefits the patients more, since it is ethically acceptable to randomize a patient in need of SARPE to either of the SARPE-related treatment groups. The second reason to include NRSs is the general lack of RCTs available in the literature on this subject. Finally, future research will benefit from the evaluation of the weaknesses of the available studies. Another potential source of bias in the present review could be the exclusion of articles in non-English language. Further limitations in this study arise from the nature and the characteristics of the data retrieved during the review process. Most of the included studies were nonrandomized trials except for one [17], with different surgical/expansion protocols. In some of the studies, these protocols were vaguely described. Additionally, the control groups differed between the eligible studies.

It is evident that more high-quality prospective studies with respect to the clinical outcomes of SARPE on facial soft tissues need to be carried out in the future. A standardized methodology, including control samples, would be valuable in obtaining comparative results.

## 5. Conclusions

- Detailed prediction of soft tissue outcomes remains unreliable after surgically assisted rapid palatal expansion.
- High heterogeneity and risk of bias was observed among the available studies.
- As an overall assessment, only the measurement of alar base width is common in methodologically similar studies.
- A postoperative increase of the alar base was reported by most studies.
- High-quality prospective studies with respect to the clinical outcomes of SARPE on facial soft tissues need to be carried out in the future.

**Supplementary Materials:** The following supporting information can be downloaded at https:// www.mdpi.com/article/10.3390/app122211859/s1. Table S1: Study design, study-specific eligibility criteria, and sample characteristics of the included studies; Table S2: The orthognathic procedures, the expanders, and the expansion protocols as well as the comparison groups for all the included studies. Figure S1: Graphical summary of the bias analysis for the RCT [17].

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