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Anchorage methods and treatment outcomes in the treatment of Bimaxillary Protrusion: A Systematic Review and Meta-Analysis

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Keywords: Systematic Review; Meta-Analysis; Bimaxillary Protrusion; Treatment time; TADs; Anchorage loss; Treatment outcomes.

Abstract

Aim

This systematic review aimed to identify the most effective anchorage methods producing better skeletal, dental, aesthetic and patient experience outcomes in the treatment of bimaxillary protrusion.

Methods

Electronic databases (Pubmed, Medline, Scopus, and Cochrane library) were searched without language restrictions. Unpublished studies were searched for on clinicaltrials.gov. Search terms included bimaxillary proclination, bimaxillary dentoalveolar protrusion, biprotrusion, bimaxillary prognathism, bimaxillary protrusion, and bidental. Treatment studies on patients with bimaxillary protrusion were included. Relevant articles were assessed for quality according to Cochrane guidelines and the data extracted for statistical analysis. Using predefined forms two authors assessed eligibility for inclusion in the study and any disagreement was discussed. Cochrane Risk of Bias tool was used for quality assessment and GRADE was used to assess the quality of the evidence.

Results

Four studies met the inclusion criteria while thirty-two were excluded based on study design and /or no outcome of interest reported. Only three studies were included in the random effects metaanalysis. There was some evidence to suggest that use of TADs resulted in less anchorage loss than traditional anchorage techniques (mean difference 2.38mm; 95% CI, -3.89 to -0.88; P=0.002). There was a significant difference in treatment duration with use of TADs (mean difference 0.92 months; 95% CI -1.64 to- 0.21; P= 0.01).

Conclusion

There is very low quality evidence to suggest TADs provide better anchorage and shorter treatment duration in the orthodontic treatment of bimaxillary protrusion.

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Introduction

Bimaxillary protrusion is defined as a condition where upper and lower incisors are proclined (bimaxillary proclination) and the lips are procumbent [1]. However, bimaxillary protrusion may also include cases with bimaxillary prognathism. It has been shown to have a high prevalence in African-American [2], Asian [3], and Caribbean ethnic groups [4] and is present to some extent in nearly all ethnic groups.

The aetiology of bimaxillary protrusion is multi-factorial and includes genetic and environmental factors. Genetic factors include ethnicity and skeletal pattern both vertically and anteroposteriorly. Environmental factors include the soft tissues, particularly the lips and tongue. It is thought that tongue volume and tongue pressure [1, 5] are key aetiological factors.

Patients with bimaxillary protrusion often seek orthodontic treatment to improve facial aesthetics with a goal of reduction of the protrusion. Orthodontic treatment of bimaxillary protrusion is usually by a combination of extractions and fixed appliances, with maximum anchorage [6]. Maximum anchorage aims to use all of the available extraction space for anterior teeth to be retracted and so reduce the convexity of the face and achieve the desired treatment outcomes.

Methods to support anchorage include traditional appliances such as headgear, transpalatal arches and Nance buttons[7, 8]. Their efficiency is challenged by complicated designs, elaborate wire bending and patient compliance. They are therefore associated with loss of anchorage and variable treatment outcomes[9-11].

To overcome these shortcomings orthodontic mini-screws and mini-plates (temporary anchorage devices (TADs)) have been recently used for maximum anchorage cases. TADs provide skeletal / absolute anchorage and so potentially allow closing of spaces completely by anterior tooth retraction[12]. They are easily placed and removed and reduce the need for patient compliance compared to wearing headgear which can be very demanding for patients and this lack of need for patient cooperation is an important factor for their effectiveness[13, 14].

To date there is no consensus in the literature or any systematic review that has adequately focused on the crucial question of the most effective way to provide the maximum anchorage required to treat bimaxillary protrusion cases and achieve optimal outcomes. Two previous systematic reviews have assessed soft tissue changes with treatment [15] and the effectiveness of en masse retraction [16]. One systematic review which was recently conducted [17] included retrospective and low quality studies, and a GRADE assessment was not done, therefore the conclusions from this review are not reliable. Therefore, there is a need to undertake a systematic review of the relevant literature with a focus on identifying the best anchorage method for this common problem.

Objective

This review aims to identify the most effective anchorage method in the treatment of bimaxillary protrusion and asses treatment outcomes through undertaking a systematic review and meta-analysis.

Material and Methods

Protocol and Registration

The protocol for this systematic review on treatment of bimaxillary protrusion was registered on the National Institute of Health Research Database (<u>www.crd.york.ac.uk/prospero,registration</u> protocol: CRD42019136179).

This study was performed according to PRISMA guidelines and the main research question was defined in PICO format (Table 1).

Eligibility Criteria

The following selection criteria were applied for articles to be included in the review:

- 1. Participants: Subjects with bimaxillary protrusion undergoing orthodontic treatment
- 2. Intervention: Orthodontic treatment
- 3. Comparison: Other orthodontic or other non-surgical treatment
- 4. Outcomes: Skeletal and dental changes (from cephalometric measurements), aesthetic assessments, patient experience, stability
- 5. Study Design: Prospective controlled / comparative clinical trials
- 6. Exclusion criteria: Treatment with orthognathic surgery

Information sources, search strategy, and study selection

The following electronic databases were searched up to 25th February 2019 and updated on 21st October 2019- PubMed, Medline, Scopus, and the Cochrane Library. Language restrictions were not applied. Table 1 shows search terms used to search electronic databases. Unpublished and incomplete studies were searched for electronically using Clinical Trials website (<u>www.clinicaltrials.gov</u>) and with the broad search terms treatment and bimaxillary. Reference lists of included studies were screened for relevant research.

Two investigators (T.H and D.B) who were not blinded to the authors or the results of the research, assessed articles for inclusion in the review, undertook assessment of risk of bias, and extraction of data independently. Disagreements were resolved by discussion between both authors.

Data items and collection

The Cochrane data extraction form [18] was used to record type of orthodontic treatment, methods (allocation, blinding, duration, treatment type), participants (sample size, age of participants at the beginning of treatment, sex) interventions, and outcome data of interest.

Risk of bias/ quality assessment in individual studies

Using the Cochrane Collaboration Risk of Bias assessment tool [18]six criteria were analysed to assess the risk of bias in each study. Two review authors assessed the risk of bias in included studies, independently and then in duplicate. The criteria were

- Adequate sequence generation: was the allocation sequence adequately generated?
- Allocation concealment: was allocation adequately concealed?
- Blinding of outcome operators, assessors, participants: was knowledge of the allocated intervention adequately prevented during the study?
- Incomplete outcome data: were incomplete outcome data adequately addressed
- Selective outcome reporting: were reports of the study free of suggestion of selective outcome reporting?
- Other sources of bias: was the study apparently free of other problems that could put it at a high risk of bias?

An overall assessment of risk of bias (high, low, unclear) was then made. A judgement of unclear indicated either lack of sufficient information to make a judgement or uncertainty over the risk of bias.

Summary measures and approach to synthesis

Clinical heterogeneity of the included studies was assessed by looking at the treatment protocoltreatment mechanics and materials used, measurement techniques and data collection.

Methodological heterogeneity was assessed by looking at differences in study design and methodological quality (risk of bias).

Statistical heterogeneity was assessed by I^2 statistic and inspecting a graphic display of estimated treatment effects in conjunction with emphasis on the overlap of 95% confidence intervals. I^2 values above 50% would mean moderate to high heterogeneity. The chi square test was also used to test for heterogeneity. A p value below 0.1 also means significant heterogeneity is present.

Mean difference and 95% confidence intervals (CI) were calculated for each outcome and combined using a random effects model which was considered most appropriate in view of the variation between studies.

GRADE

The quality of evidence was assessed by using the Grading of Recommendation Assessment, Development and Evaluation (GRADE) system producing a GRADE evidence profile table [19].The GRADE system was used to assess the overall body of evidence. The quality of evidence can be classified as:

High quality: Further research is very unlikely to change our confidence in the estimate of effect Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

Very low quality: We are very uncertain about the estimate

Results

Study Selection and Characteristics of Included Studies

Six hundred and eighty-five studies were identified as being relevant to the review from the electronic database searches which reduced to one hundred and ninety-eight after duplicates were excluded. Sixty- eight were screened by title and abstract. After reading abstracts thirty- six records were assessed as potentially satisfying the inclusion criteria and full texts of the articles were obtained and reviewed. Thirty– two of these were excluded, leaving four studies that were finally included [12, 20-22]. The process is summarized in the PRISMA flowchart (Figure 1). Three of the included articles were prospective clinical trials and one was a randomized clinical trial. The details of these studies are shown in the characteristics of included studies in Table 2. Three studies were included in the quantitative synthesis (meta- analysis).

Risk of Bias Within Studies

Similar answers were given for all six criteria used to assess risk of bias in all the studies (Figure 2). Only Upadhyay et al, (2008) was a randomized clinical trial. No study had blinding of participants and operators because the researchers were the ones placing the appliances. Only Upadyay et al,(2008) had blinding of assessors and had a low risk of bias for allocation concealment, incomplete outcome data, free from other bias and adequate sequence generation,[12]. The other studies had high risk of bias with allocation concealment. In Chen et al, (2015) patients chose their anchorage device, so there was no randomization or allocation concealment, sequence generation or blinding[21]. Mitra et al(2011) was a split mouth design where participants may have been blinded but the operator was not blinded and this negates the importance of the randomization procedure [22].

In Chopra et al (2017) there was no sequence generation or allocation concealment reported [20]. It was also unclear how incomplete data was addressed.

Therefore, three studies were considered appropriate for quantitative synthesis Mitra et al [22]was the only study that assessed rate of space closure and was therefore omitted from the quantitative synthesis.

Meta-analysis

Three studies were included in the meta-analysis[12, 20, 21]. Three random effects models were generated, for the outcomes anchorage loss, incisor retraction and treatment time (Figures 3,4,5). In total 58 patients were included in the TADs group and 59 in the other anchorage techniques group.

The first model (Figure 3) shows less anchorage loss with TADs compared to conventional anchorage methods and the difference was statistically significant (p=0.002, 95%CI -3.89 to - 0.88). The mean difference for anchorage loss was 2.38mm. The confidence interval did not include zero, indicating that there is a significant difference between anchorage loss with TADs versus other anchorage techniques. The test for heterogeneity confirmed that for this outcome there was a high level of heterogeneity between the three studies with $I^2 = 93\%$; chi-squared =27.71 p<0.00001. The statistical heterogeneity was at an unacceptable high level. The high value of I² indicates that although overall mean difference in anchorage loss is statistically significant, for TADs there is a wide variation between the studies in how much more effective TADs are compared to each of the other anchorage devices.

The second model (Figure 4) shows that the incisor retraction was greater with TADs compared with other anchorage techniques, however the difference was not statistically significant (p=0.10, 95% CI -2.95 to 0.26). The mean difference for incisor retraction was 1.35mm. The confidence interval does include zero, indicating there is no significant difference between TADs and other anchorage devices for incisor retraction. The test for heterogeneity $I^2 = 64\%$; p=0.06 chi square=5.52 showed moderate heterogeneity.

The third model (Figure 5) shows that treatment time was reduced with TADs and the difference was statistically significance (p=0.01, 95% CI -1.64 to -0.21. The mean difference was 0.92 months. Statistical heterogeneity was at an acceptable level ($1^2 = 0\%$; chi-square=1.77, p=0.41). The confidence interval did not include 0, indicating that in certain cases a difference is expected in treatment time between TADs and other anchorage techniques.

Statistical analysis of publication bias was not indicated because there were less than 10 studies in the meta-analysis.

GRADE analysis

The assessment of the quality of the collected evidence, according to GRADE, regarding, anchorage loss, incisor retraction and treatment time of TADs versus other anchorage techniques indicated that the level of evidence contributing to the conclusions was very low (Table 3). This suggests that we are very uncertain about the estimate.

Discussion

Summary of Evidence

Despite an extensive search of the literature only four studies were identified that met the inclusion criteria. They looked at different treatment mechanics for bimaxillary protrusion. Only one was a randomized clinical trial. Three studies looked at anchorage reinforcement, treatment time, incisor retraction and one looked at rate of space closure only and therefore, only three studies provided data for meta-analysis.

Risk of bias was high in all the studies identified except the randomized clinical trial and this high risk of bias would affect the confidence in the findings of the systematic review [23] as shown by the GRADE ratings. Therefore, more randomized clinical trial studies are desirable for more robust conclusions in the future.

Inherent bias formed part of some studies especially where patients were allowed to select the device. The effect that bias has on systematic reviews has been documented [24]. The Cochrane assessment tool was used to assess risk of bias. For reliable quality evaluation it had six main aspects. The randomization method of Upadhay et al (2008) [12] was the only trial with a robust randomization. Mitra et al(2011) [22] was a split mouth design which offers concurrent experimental and control assignment but was not included in the meta-analysis because it only looked at rate of space closure. Chopra et al (2017) alternately assigned patients to groups [20] which resulted in a high risk of bias. Blinding of operators and participants was assigned a high risk of bias in all studies because it was impossible to blind operators and participants except in Upadhay et al (2008) who made up for this by blinding assessors, which can compensate for non blinding of patients. Noteworthy, was that other studies did not mention

blinding of assessors.

More scrutiny to RCT guidelines is needed in future studies, since two studies were regarded as of high risk of bias for randomization, and allocation concealment.

The GRADE analysis on the quality of evidence was evaluated to be very low due to all the shortcomings of the research included in the meta-analysis and qualitative synthesis. The studies showed a lot of clinical heterogeneity due to the different types of orthodontic treatment mechanics that were used. All three studies involved extraction of all four first premolars so the studies were comparable in this aspect.

Anchorage loss

Bimaxillary protrusion cases are very anchorage demanding. Therefore, elimination of undesired mesial molar movement is key in these cases. The conventional anchorage techniques include intraorally, transpalatal arches, Nance arch, and headgear. The results of this systematic review and meta-analysis provide evidence that anchorage loss is less with TADs in bimaxillary protrusion cases and in all three studies it was statistically significant. Upadhyay et al (2008) [12] also demonstrated anchorage gain may also be achieved with temporary anchorage devices in bimaxillary protrusion cases. The other techniques such as the transpalatal arch have biomechanical deficiencies and headgear use is not tolerated well by patients. Therefore, in general TADs allow for better anchorage preservation than other techniques.

Incisor Retraction

Meta-analysis showed more retraction of incisors may be achieved with TADs in all three studies but this was not statistically significant. The dimensions of working arch wires used ranged from 0.017x0.025[12] to 0.019x0.025[20]. Also both MBT[20, 21] and Roth prescriptions [12] were used. This alteration in incisor torque prescription could have had an effect on the amount of retraction achieved. Also, the studies showed heterogeneity because all studies used different reference planes to assess retraction.

Treatment time

In all studies the treatment time was minimally shorter with TADs but this was statistically significant. The shorter treatment time observed may be due to use of a one-step retraction technique with TADs versus two-step with conventional techniques. Methodological heterogeneity between studies was also seen as the Upadyay et al (2008) reported treatment time at the end of space closure (12) as opposed to Chen et al and Chopra et al [20, 21] who reported total treatment time . Noteworthy is that more anchorage loss is seen in conventional techniques and this is possibly responsible for some of the space closure thereby providing a deceptive shorter treatment time [25]. Other factors that may affect treatment time include patient compliance, skill of the operators and the closing mechanics deployed.

Conclusion

On the basis of this systematic review, we conclude:

- The use of TADs in bimaxillary protrusion cases showed statistically significant less anchorage loss than traditional anchorage reinforcement techniques
- The use of TADs showed shorter treatment time in bimaxillary protrusion case sand this was statistically significant
- The difference in incisor retraction achieved with TADs in bimaxillary protrusion cases was not statistically significant
- There is a lack of high quality evidence for clinicians managing anchorage in this condition to base clinical decisions on.
- Evidence quality was assessed as very low therefore the results have to be interpreted with caution as they are likely to change with more evidence.

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Population	Intervention	Comparison	Outcome
Bimaxillary	Orthodontic Treatment	No treatment	Aesthetics/esthetics
Proclination			
Bimaxillary Protrusion			Patient Experience
Bimaxillary			Stability
dentoalveolar			
Protrusion			
Bidental			Relapse
Bimaxillary			SNA
Prognathism			
Biprotrusion			SNB
			Overjet
			Anterior Posterior
			Vertical
			Interincisal
Bimax*	Ortho*		Lower Facial Height
Bimaxillary*			Maxillo-Mandibular
-			Planes Angles
			Frankfort-Mandibular
			Planes angle

Table 1 PICO format and associated search terms

Author(s) Year	Design	Participants	Interventions	Outcomes
Chopra et al (2017) ⁹	Comparative Clinical trial (CCT)	50 participants 13 to 17 years. 24 males and 26 females	Group 1 received conventional anchorage with Nance button or lingual arch. Group 2 received Orthodontic implants	 Anchorage loss Treatment time Incisor retraction
Chen et al, (2015) ¹⁰	Comparative Clinical trial (CCT)	31 participants 13 men 18 women 25.87±3.37 years Group 1=15 Group 2=16	Group 1 micro implant Group 2 headgear anchorage	 Anchorage loss Treatment time Incisor retraction.
Mitra et al, (2011) ¹¹	Comparative Clinical trial (CCT)	30 participants 13-17 years	Right side of the mouth elastic chain E- chain was used for space closure, on the left side of the mouth stretched elastomeric module with steel ligature	1.Rate of space closure
Upadhyay et al (2008) ¹²	Randomized clinical trial (RCT)	36 participants (Group 1-18 Group 2-18) Minimum age 14 years. Group 1mean age 17.6years. Group 2 mean age 17.3years	Group 1 mini-implants used Group 2 conventional methods used (transpalatal arch, banding second molars, and headgear)	 Anchorage loss Treatment time Incisor retraction

Table 2. Data on Studies included in the Review

Table 3 Summary of Findings (SOF) table according to GRADE

Pubmed search strategy

- 1. Bimaxillary Proclination (tiab)
- 2.Bimaxillary dentoalveolar protrusion (tiab)
- 3. Bidental (tiab)
- 4. Bimaxillary protrusion (tiab)
- 5. Bimax*(tiab)
- 6. Bimaxillary*(tiab)
- 7. 1or2or3or4or5or6
- 8. Orthodontic treatment (tiab)
- 9. Brackets (tiab)
- 10. Orthodontic treatment with extractions (tiab)
- 11. Orthodontic treatment without extractions (tiab)

- 12. Ortho*(tiab)
- 13. 8or 9 or10 or 11or12or 13or 14
- 14. Aesthetics/ esthetics
- 15. Patient experience
- 16. Cephalometric measurements
- 17. Overbite
- 18. SNA
- 19. SNB
- 20. Overjet
- 21. AP/anterioposterior
- 22. Vertical
- 23. Interincisal angle
- 24. LFH/ lower face height
- 25. MMPA/ maxillomandibular planes angle
- 26. FMPA
- 27. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
- 28.7 AND 15 or 29

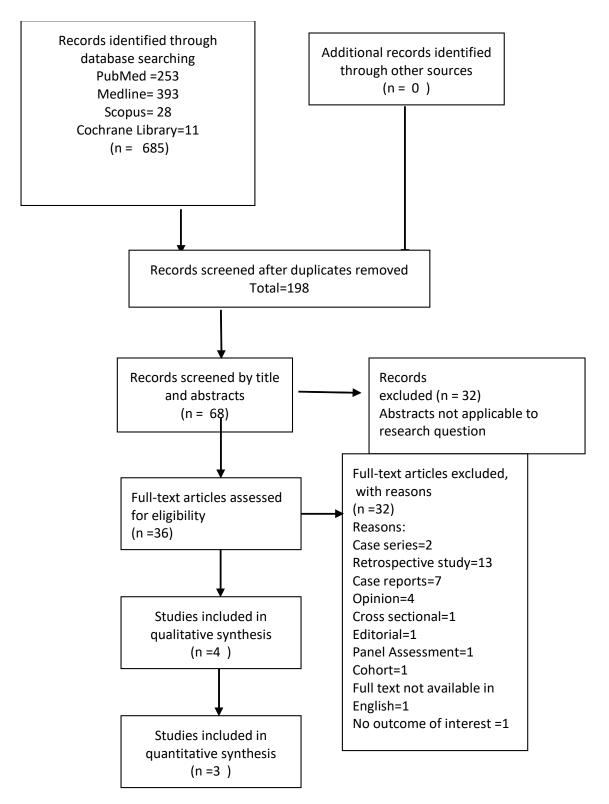


Figure 1. Prisma flow diagram of article retrieval

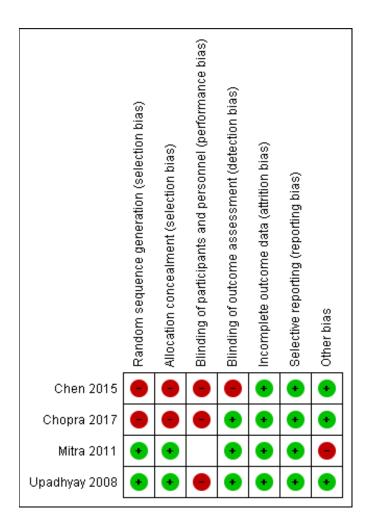


Figure 2. Risk of bias summary outlining judgement of risk of bias items for studies included in the quantitative synthesis

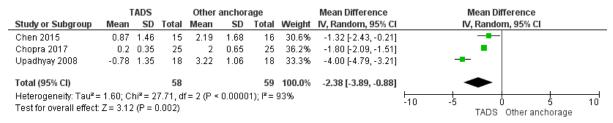


Figure 3. Random-effects meta-analysis for anchorage loss

	1	TADS			Other anchorage			Mean Difference		Mean Difference			
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	I\	IV, Random, 95% Cl			
Chen 2015	-10.27	3.51	15	-6.88	2.55	16	26.8%	-3.39 [-5.56, -1.22]					
Chopra 2017	8.36	2.252	25	8.68	2.8	25	37.5%	-0.32 [-1.73, 1.09]			_		
Upadhyay 2008	-7.22	2.07	18	-6.33	2.57	18	35.7%	-0.89 [-2.41, 0.63]		-	-		
Total (95% CI)			58			59	100.0%	-1.35 [-2.95, 0.26]					
Heterogeneity: Tau ² = 1.27; Chi ² = 5.52, df = 2 (P = 0.06); l ² = 64% Test for overall effect: Z = 1.65 (P = 0.10)								⊢	0 TADS	5 Other Ancho	orage	10	

Figure 4. Random -effects meta-analysis for incisor retraction

	I	ADS		Other anchorage				Mean Difference	Mean Difference			
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl		IV, Random, 95% 0	3	
Chen 2015	21.93	3.1	15	23.88	2.68	16	12.1%	-1.95 [-4.00, 0.10]				
Chopra 2017	21.16	1.62	25	21.76	1.54	25	65.9%	-0.60 [-1.48, 0.28]				
Upadhyay 2008	8.61	2.2	18	9.94	2.44	18	22.0%	-1.33 [-2.85, 0.19]				
Total (95% CI)			58			59	100.0%	-0.92 [-1.64, -0.21]		•		
Heterogeneity: Tau ² = 0.00; Chi ² = 1.77, df = 2 (P = 0.41); l ² = 0% Test for overall effect: Z = 2.54 (P = 0.01)							-10	+ -5 0 TADS Other Ar	5 nchorage	10		