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Changes in Soft tissue profile of Class II division 1 malocclusion treated with and without extraction – A systematic review and meta-analysis.

Ramya Krishna M, BDS[a], Maria Kuriakose, MDS[b], Parvathy Ghosh, MDS[c], Sapna Varma N.K, MDS[d]

[a] Post Graduate Student, [b] Professor, [c] Assistant Professor, [d] Professor and Head, Department of Orthodontics and Dentofacial Orthopaedics, Amrita School of Dentistry, Amrita Vishwa Vidyapeetham, Kochi, Kerala, India.

Running title: Soft tissue changes in extraction & non-extraction

Corresponding author:

Dr Ramya Krishna M

Post Graduate Student Department of Orthodontics and Dentofacial Orthopaedics, Amrita School of Dentistry, Amrita Vishwa Vidyapeetham, Kochi, Kerala, India – 682041.

Email: ramyaculgil@gmail.com

ABSTRACT:

Objective: The objective of this systematic review and meta-analysis is to evaluate the changes in the soft tissue profile of Class II division 1 malocclusion patients treated with and without extraction.

Methods: Databases were searched and supplemented by hand searching as well. Studies with prospective or retrospective and randomized or non-randomized design and Class II division 1 malocclusion patients receiving orthodontic treatment with extraction compared to patients treated without extraction were included. Outcomes assessed were changes in soft tissue linear and angular cephalometric measurements. Included studies were retrieved and assessed for Risk of Bias based on a validated checklist. Meta-analyses were done to summarize the overall effects and a Random-effects model was applied.

Results: Ten studies fulfilled the eligibility criteria and seven were eligible for quantitative synthesis. Meta-analysis showed a significant increase in Nasolabial angle in both extraction groups (four premolar and two premolar), a significant decrease in overjet in the non-extraction group compared to four premolar extraction, and significant a decrease in overjet in the non-extraction group compared to two premolar extraction. While there was no significant difference regarding the upper lip to E line and lower lip to E line.

Conclusion: A significant increase in the nasolabial angle is associated with both extraction (four premolar and two premolar) protocols while the decrease in overjet and overbite was significant in non-extraction protocols when compared to four and two premolar extraction respectively.

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Keywords: Extraction, Facial profile, Soft tissue changes, Cephalogram, Class II division 1.

Main Points:

- Significant increase in nasolabial angle was seen in both extraction treatment protocol.
- Significant decrease in overjet and overbite was seen in non-extraction treatment.
- Evidence based clinical practice should be followed instead of opinion based practice.

INTRODUCTION:

The main aim of orthodontic treatment is to create and maintain the best possible occlusal relationship within the framework of acceptable aesthetics and occlusal stability. A balanced face is the outcome of the intricate proportion and balance between hard tissues and their soft tissue drape (1). Malocclusion has physical, psychological, and social consequences that affect the oral health-related quality of life (2). Irregularities in the position of the teeth and jaws have a significant impact on the attractiveness and aesthetics of the smile and quality of life (3). Severe malocclusion is likely to be considered as a "Social Handicap" and one of the reasons people seek treatment is to reduce the psychological and social problems related to their appearance (4). Hence, Patient-centered treatment that keeps the patient's point of view in mind, both when treatment is planned and when its success is evaluated has to be implemented. With this in mind, the concept of soft tissue paradigm is used where jaws and teeth are placed in a functional occlusion within the framework of ideal soft tissue proportion and adaption. The success of the orthodontic treatment is closely related to the improvement of soft tissue profile and is critical in decision making (4).

Class II division 1 malocclusion can be treated by several means and one such method is Fixed appliance therapy with or without extraction of teeth. Many factors like space requirements in the arch, patient's profile, age, type of growth, Leeway space and sexual dimorphism influence the extraction or non-extraction decision (5). The choice to extract teeth might have a substantial impact on various parameters such as vertical dimension, treatment stability, perioral soft tissues, arch width, and facial convexity (6). Some experts believe that non-extraction gained popularity due to concerns of condylar displacement, dished in profile with extraction, and suboptimal mandibular growth (7).

The debate whether to extract or not to extract is still going on and some clinicians believe that extracting four first premolars will compromise post-treatment by "dishing" the profile whereas others believe that a non-extraction approach places the teeth in an unstable position (8).

The current trend in the delivery of health care is "Evidence-based". There must be a focus on evidence-based rather than opinion or leader based decisions on how to treat a particular problem. There are few systematic reviews and meta-analysis (6,9,10) published in the literature regarding the dilemma of extraction and non-extraction treatment approaches and its effects on soft tissue profile, but a lacuna exists mainly in the treatment of Class II division 1

malocclusion patients. Hence, this systematic review and meta-analysis were conducted to compare the changes in the soft tissue facial profile of Class II division 1 malocclusion patients treated with and without extractions.

METHODS:

This Systematic Review and Meta-analysis was registered at "International Prospective Register Of Systematic Reviews (PROSPERO), Center of Reviews and Dissemination, University of York" under a registration number of CRD42020205271.

Questions

The "Population, Intervention, Comparison, Outcome, Study design (PICOS)" format was applied in this review. 1) Population - Angle's Class II division 1 malocclusion patients of any age, gender, or ethnicity. 2) Intervention - Comprehensive orthodontic treatment with extraction of permanent teeth. 3) Comparison – Comprehensive orthodontic treatment without the extraction of permanent teeth for treatment. 4) Outcome - changes in both linear and angular cephalometric measurements of soft tissue profile. 5) Study design – Randomized and Non-Randomized clinical trials, Retrospective, and Prospective cohort studies.

Search strategy

An electronic search was conducted in PubMed and Scopus databases and hand-searched for additional studies up to July 2019. The search was done using the keywords 'Orthodontic', 'soft tissue', 'profile', 'facial', 'Esthetics', 'Class II', 'nasolabial ', 'malocclusion', 'Cephalometric' and 'extraction' and the Boolean operators with the search strategy ((((((((((orthodon*[title/abstract]) AND extract*[title/abstract]) OR removal) AND soft AND tis sue) OR profile) OR lip) OR nasolabial) OR mentolabial) AND cephalomet*)) AND malocclusi*).

Eligibility criteria

Studies that did not have only Class II division 1 malocclusion patients, patients treated with orthognathic surgery or for cleft lip or palate, Case reports, Case series, Letters to the Editor, Expert's Opinions, Reviews and Systematic reviews, studies that did not report the type of extraction, studies with no control group, studies conducted in animals and studies published in any language other than English were excluded.

Study selection

To identify eligible articles and to remove duplicates, primary screening of title and abstract was conducted by two researchers independently (Kappa = 0.90) using Rayyan QCRI software (11). The inter-examiner conflicts were cleared by a third researcher. The selected and doubtful articles from the primary screening were retrieved and secondary screening of full-text was done by two researchers (Kappa = 0.95) supervised by a third researcher.

Assessment of Risk of Bias

The Risk of Bias (ROB) of the eligible studies was conducted using the Downs and Black checklist (12). The Downs and Black checklist comprised a total of 27 items. All items in the

checklist were scored 0 or 1, except item 5 (reporting of confounders) scored 0 to 2 and item 27 (power of study) scored 0 to 5. The item Power of the study was scored based on their sample size (N) per group as (10) 0 ($N \leq 20$), 1 (N – 21 to 24), 2 (N – 25 to 28), 3 (N – 29 to 31), 4 (N - 32 to 34) and 5 ($N \geq 35$). Studies with combined scores <17 were judged as low quality, 17-25 as moderate quality, and >25 as high-quality studies (10).

Data extraction

Custom made data extraction table was used for this review and included the author's name, year, total sample, participants per group, gender, mean age, extraction type (four premolars, two premolars), and soft-tissue measurements. Cephalometric measurements included in this review were (13,14) Nasolabial Angle (NLA), Labrale superioris / Upper lip to E line (UL-E line), Labrale inferioris / Lower lip to E line (LL-E line), Overjet, Overbite (7).

Statistical analysis

All the measurements were reported as continuous variables. The treatment effect estimate was summarized as Mean Difference (MD) with 95% Confidence Interval (CI). The tests of overall effects were performed by meta-analysis and were calculated using "Review Manager software, version 5.3 (Cochrane Collaboration, Boston, MA)". Heterogeneity among the studies was assessed using I^2 test and a random-effects meta-analysis model was applied. Based on the availability of data, sub-group analysis was planned for the type of extraction wise comparisons.

RESULTS:

The PRISMA(15) (Preferred Reporting Items for Systematic reviews and Meta-Analysis) flow chart presents the process of the search for this review (Figure-1). After the electronic database search, 2,944 records were retrieved and exported to the Rayyan software (11) and two records were identified from other sources. After the removal of duplicates, a total of 1,908 records were screened for title and abstract. After the preliminary screening, 1,851 records were excluded and a total of 57 full-text articles were assessed for eligibility. Among these 57 full-text articles, 47 were excluded and 10 articles (7,16–24) were included for qualitative synthesis.

All the studies included (n=10) in this review were retrospective design. All the studies had 16 to 44 patients in the extraction group and 19 to 47 in the non-extraction group. In the extraction group, the age of the patients before treatment ranged from 8 to 17 years while in the non-extraction group ranged from 7.9 to 14.9 years. Among the ten studies included, five studies had all four first premolar extractions (7,16,17,19,20), two studies had two maxillary first premolar extractions (18,21), two studies had both the types of extraction groups (22,24) and one study had molar extraction group along with premolar extraction groups (23).

The treatment of the patients in the extraction group of the studies includes using the Edgewise technique in six studies (17–21,24), Begg's technique in one study (16), Andrew's straight wire technique in one study (23), multiband appliance in one study (22), and unclear in one study (7). While in the non-extraction group Edgewise technique was used in five studies

(17,19–21,24), Andreson activator in two studies (16,22), Frankel appliance (FR1 or FR2) in one study (18), Andrew's straight wire technique in one study (23) and unclear in one study (7).

According to the risk of bias assessment given by Down and Black (12) (Table-1), six studies were of low quality (16–19,21,24), four studies were of moderate quality (7,20,22,23) and none of the studies were of good quality.

For quantitative synthesis (Meta-analysis) seven studies (7,16–18,21,22,24) were included. Two studies (19,23) did not report standard deviation and one study (20) reported the outcomes separately based on gender rather than extraction and non-extraction groups and were excluded from the meta-analysis. Meta-analyses were conducted for overbite, overjet, UL-E line, LL-E line, and NLA comparing four premolar extractions versus non-extraction and two premolar extractions versus non-extraction (Table-2).

The decrease in overjet after treatment was more in the non-extraction as compared to four premolar extraction (7,16,17,24) and was significant ($p=0.002$) (Figure-2). The increase in NLA was more in both the two premolar (18,22,24) ($p<0.001$) and four premolar extraction (16,17,22,24) ($p=0.04$) which was significant when compared to non-extraction (Figure-3).

The decrease in overbite was significant in the non-extraction when compared to two premolar extraction only (21,24) ($p=0.02$) (Figure-4). The change in UL-E line and LL-E line showed no significant difference in non-extraction when compared to two premolar extraction (18,21,22) ($p=0.66$ and $p=0.69$ respectively), or four premolar extraction (7,17,22) ($p=0.26$ and $p=0.35$ respectively).

DISCUSSION:

This systematic review and meta-analysis were aimed to compare the soft tissue changes between extraction (four premolars and two maxillary premolars) and non-extraction protocols in the treatment of class II division 1 malocclusion. Several soft tissue variables were reported in the included studies and the most frequently used variables like NLA, distance from upper and lower lips to E-plane, overjet, and overbite were selected for meta-analysis.

The changes in the UL-E line and LL-E line showed no significant difference between extraction and non-extraction groups. These results were partly following Konstantonis et al.,(6) where there was no difference between non-extraction and two premolar extraction groups for the changes in the UL-E line and LL-E line. A systematic review by Almurtadha et al.,(10) reported significant changes in the UL-E line and LL-E line favoring the extraction group. Variations in the results of these reviews were mainly due to different eligibility criteria and different comparison groups.

Following orthodontic treatment in the class II division 1 patients, the increase in NLA was more in extraction (both four and two premolar groups) than non-extraction patients. This finding was not in accordance with the systematic review conducted by Konstantonis et al.,(6) who reported the increase in NLA in non-extraction patients as compared to the extraction of four premolar patients. A sensitivity analysis was conducted to compare the changes of NLA between four premolar extraction and non-extraction groups. When one study, Weyrich and

Lisson (22) was removed from the meta-analysis the heterogeneity (I^2) became 0% and was more significant (p=0.001) favoring extraction.

Only two studies (16,17) evaluated the Upper Lip Thickness (ULT) and Lower Lip Thickness (LLT) and two studies (18,21) evaluated Upper Lip Prominence (ULP) and Lower Lip Prominence (LLP) but the authors used different landmarks. Hence, these studies couldn't be combined to perform a meta-analysis. Upper Lip Length (ULL) and Lower Lip Length (LLL) was reported in only one study (16) in four premolar extraction group and one study (18) in two premolar extraction group compared with the non-extraction group. Similarly, one study (7) measured Z-angle comparing four premolar extraction and non-extraction groups, and one study (21) comparing the Z-angle between two premolar extraction and non-extraction patients. Due to a lack of studies, a meta-analysis was not conducted.

Holdaway angle or H-angle is another important measurement in assessing the soft tissue change after orthodontic treatment. In this review four studies measured H-angle and we couldn't perform a meta-analysis because one study (19) hadn't reported standard deviation, one study (23) hadn't given post-treatment values and two studies (7,17) used different landmarks. In this review labiomental angle was measured in two studies, one study (16) comparing four premolar extraction and non-extraction, and one study (18) compared labiomental angle between two premolar extraction and non-extraction. Hence, due to the lack of a minimum number of studies, we couldn't perform a meta-analysis.

Among the ten studies included in this review, only one study (20) reported soft tissue changes in the extraction and non-extraction groups separately for males and females. Hence, a sub-group analysis based on gender could not be performed. Also, none of the studies included mentioned the method of adequate sample size calculation, sampling methodology, and selection of the samples. The present review was based on retrospective studies. There was no Randomized Controlled Trial (RCT) eligible for this review. Well-conducted RCT with a large sample size are highly recommended but in many situations raise ethical or practical concerns. Some studies reported many variables to assess the changes in soft tissue, while in recent studies the number of variables assessed was comparatively less. A comparison group was required for the observed soft tissue changes to be evident. The extraction patients were compared to non-extraction patients with different treatment approaches like fixed appliances, headgear, and functional appliances. Hence, treatment in the comparison groups was not homogenous. For each outcome, the number of studies combined was few and the effects of extraction on soft tissue profile changes were considerably heterogeneous. Sensitivity analysis was conducted to explain some heterogeneity and should be taken into consideration in decision making. Some studies reported high standard deviation values more than the mean, showing a wide and skewed distribution. Hence, caution should be used in the application of the results.

Soft tissue changes can be assessed using various methods (25) among which a lateral cephalogram can be used for evaluating skeletal relationships, growth patterns, facial soft tissues for quantitative analyses and measurements (26). This review included the changes assessed using cephalometry only for uniformity. This review included studies that were conducted in

class II division 1 patients only and included all the studies from the literature during preliminary screening without time limitation. A sensitivity analysis was conducted to identify the study which causes the most heterogeneity and to confirm whether that study was able or unable to change the outcome and significance.

CONCLUSION:

A significant increase in the Nasolabial angle was seen in both extraction protocols. While a significant decrease in the overbite and overjet was seen in non-extraction compared to two premolar extraction and four premolar extraction protocols respectively. No difference was obtained regarding the UL-E line and LL-E line. When the extraction is suggested for treatment, care should be taken to assess, if the soft tissue changes will be favorable or unfavorable.

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Table 1: Risk of Bias of the included studies

Author	Year	Reporting	External Validity	Internal Validity-Bias	Internal Validity-Confounding	Power	Total	Quality
Looi	1986	5	0	2	0	3	10	Low
Finnoy	1987	5	1	3	1	3	13	Low
Battagel	1989	7	0	3	0	4	14	Low
Akin	1993	6	1	3	1	0	11	Low
Bishara	1995	8	1	3	0	5	17	Moderate
Basciftci	2003	7	1	3	1	5	17	Moderate
Janson	2007	9	1	3	1	1	15	Low
Weyrich	2009	7	1	3	1	5	17	Moderate
Mc Guinness	2011	8	1	3	2	5	19	Moderate
Janson	2015	7	1	3	0	3	14	Low

Table 2: Summary of meta-analyses.

Outcome	**Group**	**Studies**	**MD**	**95 % CI**	**P-value**	**Favours**	**I^2**
Overbite	4 Premolar Extraction vs. Non Extraction	4	0.94	-0.09 to 1.96	0.07	None	81%
	2 Premolar Extraction	2	0.46	0.07 to	**0.02 ***	Non-	11%

	vs. Non Extraction			0.84		extraction	
Overjet	4 Premolar Extraction vs. Non Extraction	4	0.97	0.37 to 1.58	**0.002 ***	Non-extraction	41%
	2 Premolar Extraction vs. Non Extraction	3	0.19	-0.04 to 0.42	0.11	None	0%
UL-E line	4 Premolar Extraction vs. Non Extraction	2	0.41	-0.30 to 1.13	0.26	None	46%
	2 Premolar Extraction vs. Non Extraction	3	-0.38	-2.09 to 1.32	0.66	None	93%
LL-E line	4 Premolar Extraction vs. Non Extraction	3	-0.13	-0.41 to 0.15	0.35	None	0%
	2 Premolar Extraction vs. Non Extraction	3	-0.43	-2.56 to 1.69	0.69	None	94%
NLA	4 Premolar Extraction vs. Non Extraction	4	1.40	0.06 to 2.73	**0.04 ***	Extraction	50%
	2 Premolar Extraction vs. Non Extraction	3	3.01	1.89 to 4.14	**<0.0001 ***	Extraction	0%

CI – Confidence Interval, LL-E line - Lower lip to E line, MD – Mean difference, NLA - Nasolabial Angle, UL-E line - Upper lip to E line, ,

* significant

Figure 1: PRISMA flow diagram for the identification and selection of studies.

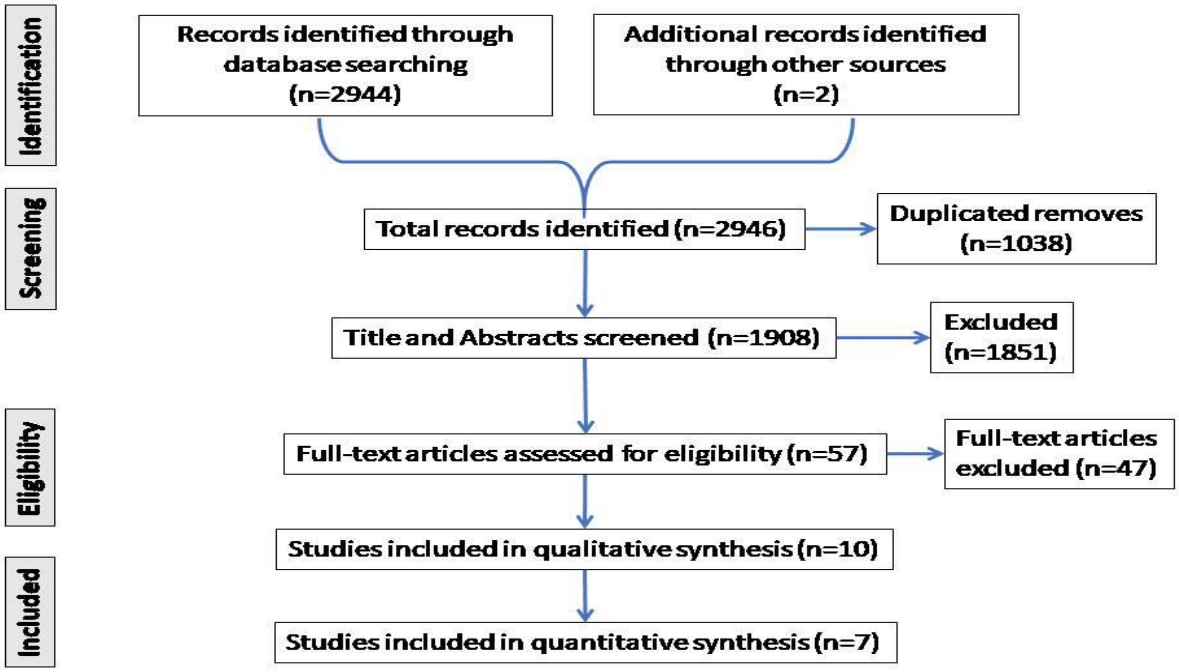

Figure 2: Forest plot on the change of overjet comparing four premolar and two premolar orthodontic extractions vs non-extraction treatment.

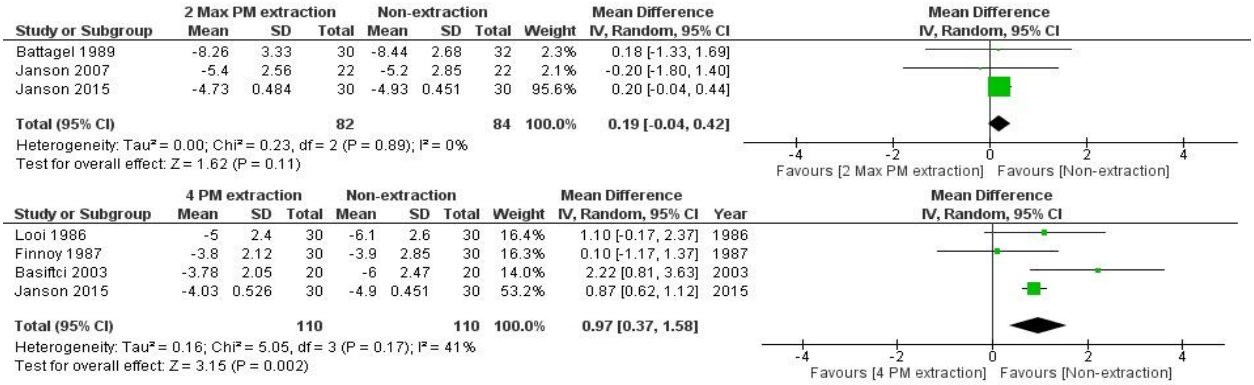

Figure 3: Forest plot on the change of Nasolabial angle comparing four premolar and two premolar orthodontic extractions vs non-extraction treatment.

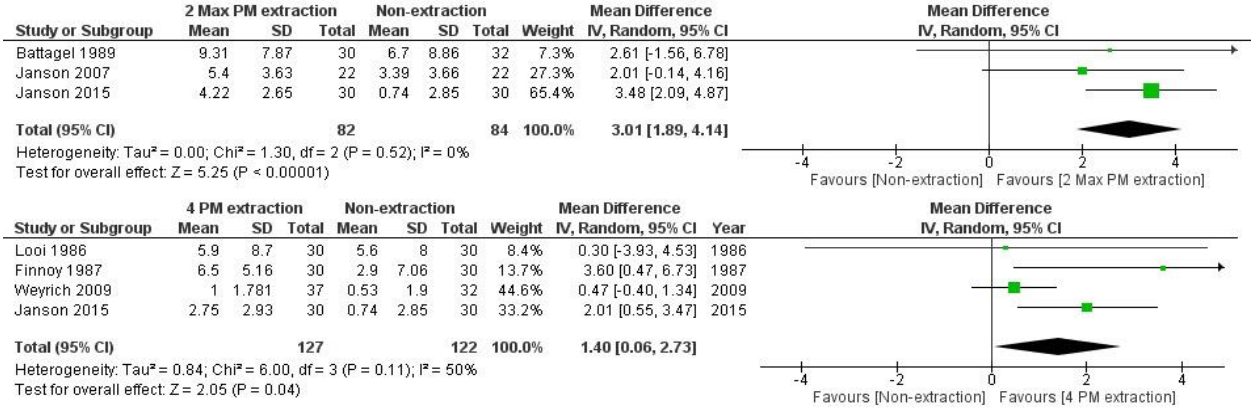

Figure 4: Forest plot on the change of overbite comparing four premolar and two premolar orthodontic extractions vs non-extraction treatment.