EFFECTS OF NON-COMPLIANT INTRAORAL DISTALIZERS ON THE SOFT TISSUE PROFILE, A SYSTEMATIC REVIEW

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ABSTRACT

Effects of non-compliant intraoral distalizers on the soft tissue profile,

A systematic review

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Background: Practicing orthodontists have special interest in Class II malocclusion cases as they constitute a significant percentage of the cases they treat. Maxillary molar distalization is the most frequently used nonextraction treatment in the correction of Class II malocclusion to establish a Class I molar and canine relationships. The common and unwanted side effect of these intraoral methods is the mesial shift of premolars and incisors leading to anchorage loss which might affect the profile and soft tissues of the patient.

Aim: The objective of this systematic review is to look at the soft tissue effects associated with the use of non-compliant intraoral distalizers for the correction of Class II malocclusion.

Materials and Methods: The systematic search included Cochrane Library, PubMed, Scopus and Ovid journals identifying 4 prospective or retrospective studies matching the inclusion criteria. The inclusion criteria considered were Class II malocclusion cases using non-compliant intraoral tooth-borne distalizers, a control group of untreated Class II patients or non-compliant intraoral skeletal-borne distalizers. The main outcome assessed were the soft tissue effects including the nasolabial angle, upper and lower lips to E-plane. Secondary outcomes included the degree of incisor anchorage loss. Appliances with conventional or skeletal anchorage designs were considered for the review. The Final articles included were three non-randomized retrospective studies and one prospective study. The date of the last search was May 15, 2021. The methodological index of non-randomized studies (MINORS) was used to assess the articles included. The studies had close results and assessed to have high risk of bias.

Results: In total, 436 studies were identified for screening, and 4 studies were eligible.
The mean change in the upper lip to E-plane varied from 0.1mm to 0.7mm. The mean change in lower lip to E-plane varies from 0.0mm to 0.6mm. While the mean change in nasolabial angle showed an increase of 1.7 (15.5) degrees. Dental changes were also assessed. The SN-upper incisor mean change ranged from 0.1 degrees with the use of distal screw appliance to 5.0 with the use of the pendulum. The mean change in the overjet was 0.0mm with the use of bone anchored pendulum appliance BAPA. The values increased with the use of other types of distalizers with the highest value of 1.5mm with the use of the distal jet.
The first premolars can also be affected with the use of distalizers. However, using a skeletally anchored distalizer can lead to distalization of the first premolars as reported by (Polat-Ozsoy, 2008) with the use of BAPA with a mean change of -2.7mm when measured from a vertical plane. Mesialization of the first premolars happened when a conventional pendulum appliance was used with a mean change of 4.0mm.

Conclusion: There is no significant difference in the nasolabial angel, upper lip and lower lip positions, and hence the soft tissue profile of the patient with the use of various types of non-compliant intraoral distalizers when treating Class II malocclusion cases. The use of skeletally anchored distalizers had fewer side effects on the soft tissue measurements, however these differences were not significant.

DEDICATION

This study is dedicated:

To my father, Zouheir Hameed Kaouche who spent his life supporting me and encouraging me in every stage of my life. Without him I wouldn’t have been The man I am now.

To my loving mother and siblings, for their continuous support and love.

My friend Sami who was a great help and motivation during my unexpected times.

To my professors, who were a continuous support and motivation throughout this journey.

And to “Allah” who gifted and blessed me with all of this, thank you for giving me the strength and guidance to see this through.

DECLARATION

I hereby declare that the dissertation entitled "Effects of non-compliant intraoral distalizers on the soft tissue profile, a systematic review" submitted by me for the partial fulfillment of the Master of Science in Orthodontics at the Hamdan Bin Mohamed College of Dental Medicine (HBMCDM), Mohammed Bin Rashid University of Medicine and Health Sciences (MBRU) is my original work under the direct supervision of Dr. Samira Diar Bakirly, and that the thesis has not previously formed the basis for the award to me of any degree, diploma, fellowship or any other title in this university or any other institution.

Name: Zahir Zouheir Kaouche

Signature:

ACKNOWLEDGMENT

First and foremost, I thank Allah who enabled me to finish my thesis. Then, I would like to submit my heartiest gratitude to my respected Associate Professor Ahmed Ghoneima and Doctor Samira Diar-Bakirly for their guidance and help to complete this project.

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1. INTRODUCTION:

Class II malocclusion can be caused by various skeletal and dental discrepancies (Cozza, 2006). Practicing orthodontists have special interest in Class II malocclusion cases as they constitute a significant percentage of the cases they treat. Maxillary molar distalization is the most frequently used nonextraction treatment in the correction of Class II malocclusion to establish a Class I molar and canine relationships (Mohamed, 2018). The common and unwanted side effect of these intraoral methods is the mesial shift of premolars and incisors leading to anchorage loss which might affect the profile and soft tissues of the patient (Kinzinger, 2008). The use of non-compliance intramaxillary molar distalization appliances all act by distalizing molars with a concomitant and unavoidable loss of anchorage, as seen in the mesial movement of incisors and premolars (Antonarakis, 2008). Few studies considered the effects on the soft tissues with the use of non-compliance intraloral distalizers and found no significant changes in the facial profile with the use of such appliances (Reis, 2019).

1.1. Class II malocclusion:

Edward Angle introduced the term "malocclusion" derived from the term occlusion, which means any deviation from ideal occlusion considering both esthetics and function. (B, 1965). In 1899 he based his classification on the relationship of the maxillary first molar's mesiobuccal cusp and the mandibular first molar's buccal groove (Hurt, 2012).

Practicing orthodontists have special interest in Class II malocclusion cases as they constitute a significant percentage of the cases they treat. Cases of Class II malocclusion are common in western societies and Caucasian patients of Northern European descent. The incidence is up to

25% as reported in 12 years old in the UK (Holmes, 1992) and 15% of 12–15 year old in the USA (Proffit, 1998).

It is not uncommon to find Class II malocclusion in most developed countries. The features of Class II malocclusion can be seen even in the primary dentition. Such cases usually present with an increased overjet, which usually is a cause of concern to both the patients and their parents, and as a result, a specialist opinion is frequently needed.

Class II malocclusion in the primary dentition has early traits. Distal terminal plane of the second deciduous molars, distal canine relation, large overjet, and large overbite are the occlusal traits of Class II malocclusion in the primary dentiton stage (Varrela, 1998). British children were reported to have a 38.8% prevalence of distal step of the second primary molars and a 59% of Class II primary canine relationships from 2.5 to three years (Foster TD, 1969). The same respective values were reported as 43.3% and 68.1% in Finnish children (Keski-Nisula K, 2003).

Full Class II malocclusion in the primary dentition is never self-correcting in growing children. Beshara et al also reported that, during the transition from the primary to the mixed dentition, a distal-step relationship of the second primary molars leads to a Class II relationship of the first permanent molars in 100% of the cases (Bishara SE, 1988).

A Class II skeletal pattern can be established early in the primary dentition due to maxillary protrusion. This remains unmodified during the transition to the mixed dentition stage. A correlation exists between this skeletal maxillary protrusion and sucking habits indicating a need for interceptive treatment (Antonini A, 2005).

Prominence of the maxillary anterior teeth in Class II malocclusion is a problem affecting around one fourth of children aged 12 years in the UK. This condition requires orthodontists' attention because prominent upper front teeth are more likely to be injured as well as their emotional impact on children. The orthodontist has to decide whether to treat early or wait till the early adolescence stage. The evidence suggests that there is a significant reduction in the incidence of upper incisor injury when treated in two phases (early treatment) compared to late treatment (early adolescence) (Thiruvenkatachari B, 2013).

1.2. Treatment Options of Class II Malocclusion:

Treatment options in Class II malocclusion patients vary depending on the stage of growth and whether the problem is dental or skeletal. In general, treatment options range from growth modification, camouflage and extractions or orthognathic surgery. Growth modification is indicated in growing patients with functional appliances, in case of mandibular deficiency and a headgear in case of maxillary excess. Beneficial skeletal changes can be produced with the use of these appliances during growth stages. Class II growth modification is most effective during the adolescent growth spurt. (William Proffit, 2018).

Class II camouflage treatment is acceptable only if the facial appearance, dental alignment and occlusion are satisfactory. Less severe Class II malocclusion cases can be treated by tooth movement in order to camouflage the discrepancy between the jaws. However, patients with more severe Class II problems and those who are done with growth will require surgical mandibular advancement. Teeth movement to correct Class II cases can be used in three major ways including distalization of the upper molars, using extraction spaces for differential anteroposterior tooth movement and nonextraction treatment consisting of primarily forward movement of the lower arch. (William Proffit, 2018)

1.2.1. Removable Appliances

In cases of increased overjet in the mixed dentition, a removable appliance with an activated labial bow can be of benefit. This treatment modality is effective if the upper incisors are spaced and proclined as the the labial bow of the appliance will retrocline the teeth by tipping them. In cases of increased overbite, an anterior bite plane can be added to help reduce it. A headgear can also be used. However, it is not appropriate in cases with a Class II skeletal relationship and mandibular retrognathism as dentoalveolar tipping will be unlikely to produce reasonable result.

1.2.2. Functional Appliances

The use of functional appliances is an effective way to reduce increased overjet in the mixed dentition. These orthodontic appliances were developed in the early twentieth century in Europe (DiBiase, 2015). They were developed to affect facial growth. There are many available designs and systems which all work by posturing the mandible forward to achieve several things including: changing the soft tissue environment and as a result alters forces that influence the position of the dentition, exerting direct force on the teeth via the appliance, from the forces generated by the stretch of the muscles controlling the mandible trying to return to their resting length. In most of the cases, this results in a distalising force on the upper jaw and the maxillary dentition and a mesialising force on the mandible and the lower dentition. Some bony remodelling at the condyle and glenoid fossa has also been suggested.

1.2.3. Headgear

Headgear can be used with a removable or functional appliance, or on its own, for the treatment of Class II malocclusion. It has been shown to be effective at overjet reduction in the mixed dentition.

1.2.4. Fixed Appliances

Fixed appliances can be used to reduce overjet in certain cases. This can be done with the use of Class II elastics along with the fixed orthodontic appliances, which is one of the most widely used modalities in the treatment of Class II malocclusion. Class II elastics are effective in correcting Class II malocclusions, and their effects are mainly dentoalveolar. These effects include lingual tipping, extrusion, and retrusion of the maxillary incisors; labial tipping and intrusion of the mandibular incisors; and mesialization and extrusion of the mandibular molars. Therefore, in the long term, Class II elastics are similar to the effects of fixed functional appliances (Janson, 2013).

1.3. Distalization

Molar distalization has been advocated as one of the strategies to treat molar relationship in Class II patients into Class I molar relationship, especially in patients with a normal position of the mandible and maxillary dento-skeletal Class II malocclusion, during the growing period (Quinzi V, 2020). Molar distalization is also recommended in patients after the pubertal growth stage, with

Class II malocclusions characterized by dento-skeletal protrusion of the upper dental arch and normal position of the lower arch. This can be done with various types of distalization devices.

Several methods had been proposed to distalize the molars, consequently, to aid in retroclination of maxillary incisors and decreasing the overjet. Amongst these methods, some distalizers are fixed on the buccal side while others are fixed at the palatal side. The Distal Jet, the First Class appliance, the Pendulum and the Carriere 3D motion are fixed on the upper dental arch only. The Distal Jet and the First Class get their anchorage from a palatal button transmitting the force to the anterior teeth. The Distal Jet consists of two Ni-Ti coil springs positioned in the palatal side of the teeth, to be near the center of resistance of the teeth.

The First Class consists of two coil springs in stainless steel that are positioned on the vestibular side of the molars, between the upper first molars and the first upper bicuspids. The Carries 3D motion has a bar that is placed in the vestibular side of the upper first molar and the canine. The Pendulum appliance is anchored to the upper dental arch, and its distalization force is generated by a wire toe (Quinzi V, 2020) (Sandler, 2018).

1.3.1. Types of distalizers:

1.3.1.1. Tooth borne distalizers:

Maxillary molars distalization is often indicated for correcting distal tooth malposition and/or gaining space in the upper dental arch during the course of orthodontic treatment. There are multiple appliances and treatment methods described in the literature for molar distalization. Since the end of the 1970s, a trend has been seen which favors distalization appliances with intramaxillary anchorage in addition to the traditionally used headgear types and removable active plates. Compliance is not an issue with such innovative appliances. There are two essential elements in these appliances including the active distalization component which that applies a distal force to the molars and an anchorage component that dissipates the generated reciprocal forces. The anchorage, which is a combination of soft tissue rests and dental anchorage, is almost similar in non-compliance intraoral molar distalization appliances. Other appliances have been described which incorporates absolute and supportive anchorage designs with palatal implants and mini-screws. (Männchen, 1999; Byloff *et al.*, 2000; Karaman *et al.*, 2002; Kinzinger and Diedrich, 2002, Favero *et al.*, 2003; Keles *et al.*, 2003; Kyung *et al.*, 2003; Gelgör *et al.*, 2004; Kinzinger *et al.*, 2004b, 2006; Kircelli *et al.*, 2005; Escobar *et al.*, 2007; Öncag *et al.*, 2007).

The pendulum appliance described by Hilgers (1992) has active components which are two pendulum springs anchored to the dorsal portion of the button, made of 0.032 inch titanium molybdenum alloy wire inserted in the pre-activated state into palatal sheaths of the molar bands. Modifications of the appliance to make tooth movement as translatory as possible and to counteract tipping and palatal movements were reported. (Byloff *et al.*, 1997; Kinzinger *et al.*, 2000, Kinzinger and Diedrich, 2007)

Distalization appliances with magnets depends on two homopolar samarium/cobalt magnets which apply forces of repulsion between them (Itoh *et al.*, 1991; Bondemark and Kurol, 1992). Ribbon arches are used to place the magnets buccally. The distal magnet is placed directly to the first molar headgear tube. Bondemark *et al.* (1994), Bondemark and Kurol (1998), and Bondemark (2000) used the Nance button with open nickel titanium springs (NiTi) which are placed on arch sections on the vestibule.

The Jones Jig appliance (Jones and White, 1992) consists of NiTi coil springs are placed on an arch section that is attached to the molars buccal tubes.

While in the distal jet (Carano and Testa, 1996; Bowman, 1998), the component that apply forces, unlike the Jones Jig, is placed on the palatal side. Two tubes that are incorporated bilaterally into the Nance button are end points to open NiTi coil springs which, through a bayonet bend, can deliver a distalization force to the tubes located palatally on the upper molar bands. The Jones Jig and the distal jet, considering their main components, can be considered to be different based on design. The difference is mainly the site of the applied force (buccally in Jones Jig and palatally in the distal jet).

The first class appliance (Fortini *et al.*, 1999) has a special design. It has a distalizing component consisting of a screw that is positioned buccally to the molar tubes and premolars. There are NiTi springs fitted palatally to spring-loaded splints acting to prevent the rotational moments. Another component is the Nance button which is butterfly-shaped and fitted to premolar and molar bands.

1.3.1.2. Skeletal borne distalizers:

Skeletal anchorage system (temporary anchorage device or skeletally anchored distalizers) is defined as a device that is fixed in bone temporarily to reinforce orthodontic anchorage (Singh, 2010). They permit orthodontists to predictably move maxillary molars distally in non-growing patients. This has become a common treatment alternative in some patients with Class II malocclusions. Their use minimizes the need to extract premolars. Sfondrini et al found that most noncompliant appliances were associated with mesial movement or tipping of the incisors indicating loss of anchorage (Sfondrini MF, 2002).

However, temporary anchorage skeletal devices are stable and considered to provide absolute anchorage. Many distalization appliance designs incorporating temporary anchorage skeletal devices have been developed. They include the skeletal anchorage system (SAS) with miniplates positioned in the zygomatic region in the maxilla or the mandibular retromolar region and appliances supported by a single orthodontic implant in the palate.

Orthodontic distalization reinforced with the temporary anchorage skeletal devices are effective in molar distalization. They also appear to produce fewer unwanted side effects (Fudalej P, 2011).

The skeletal anchorage system is a viable noncompliance option to distalize maxillary molars. This helps in correcting maxillary protrusions and malocclusions including maxillary incisor crowding (Sugawara J, 2006).

All previously mentioned appliances can achieve successful upper arch molar. However, success should not be judged by the space gained between the first molar and the second premolar or a primary molar. Orthodontists must be aware of the reaction forces created as a side effect of the appliances to the anchorage unit. Mesialization occurs as a side effect on the anchorage unit resulting in anchorage loss. The anchorage unit could be either could be the premolars or primary molars depending on the stage of development of the dentition. Anterior teeth can also be affected either directly or indirectly by anchorage loss leading to other soft tissue changes. The distalized molars are also prone to tipping, intrusion, and extrusion as a result of the direction of the force applied (Gero S. M. Kinzinger, 2008).

1.3.2. Effects of Distalizers:

Side effects usually occur at the same time during molar distalization. These side effects result in unwanted effects on active distalization unit as well as the anchorage unit. Molars may show tipping and movement in the vertical dimension including intrusion or extrusion. Modifying the appliances can lead to almost bodily movement of the molar.

Reported anchorage loss is more marked in the area of the incisors compared with that of the first premolars.

There are minor effects on the vertical aspects in relation to the molars, premolars, and incisors, such as intrusion and extrusion (Gero S. M. Kinzinger, 2008).

Molar distalization with minimal distal tipping can be effectively done with miniscrew-supported appliances. They also can be used to achieve premolar distalization without anchorage loss (Mohamed RN, 2018).

The mode of action of noncompliance intramaxillary molar distalization appliances used for the correction of Class II molar relationships is the distalization molars. These appliances are associated with unavoidable anchorage loss.

- Distal crown tipping movement help achieve molar distalization.
- Anchorage loss results in mesial movement of the premolar and mesial crown and tipping movements of the incisors.
- Vertical movements are also observed, and extrusion of incisors and premolars can occur.
- Palatal acting appliances result in less tipping movements compared to Buccal acting appliances

as they act more closely to the center of resistance of the teeth.

- Friction-free appliances (pendulum appliance) seem to be associated with a large amount of distal molar movement and concomitant substantial tipping when no therapeutic uprighting activation is applied. (Antonarakis GS, 2008)

The currently available systematic reviews looked at the dentoalveolar and skeletal effects of distalization. One of these systematic reviews done by (Al-Thomali, 2017) stated that the use of pendulum appliance lead to anchorage loss specifically in the areas of the incisors compared with that of the premolars, leading to maxillary incisors proclination. Another systematic review by (Soheilifar S, 2019), reported that there is no difference in the amount of molar distalization and tipping between TAD-supported and conventional distalization. The objective of this systematic review is to look at the soft tissue effects associated with the use of non-compliant intraoral distalizers for the correction of Class II malocclusion.

2. AIM

The objective of this systematic review is to look randomized and non-randomized retrospective and prospective studies to assess the soft tissue effects associated with the use of non-compliant tooth-borne intraoral distalizers, comparing it to no treatment or non-compliant skeletal-borne intraoral distalizers, for the treatment of patients with Class II malocclusion.

3. MATERIALS AND METHODS

3.1. Eligibility criteria

This systematic review was performed in accordance with the PRISMA statement for reporting systematic reviews of health sciences (Liberati et al., 2009). It was not published or registered in any protocol. Both prospective and retrospective clinical studies were included: randomized controlled trails, nonrandomized controlled clinical trials. The selection criteria that were applied for the inclusion of articles is shown in Table 1. A study was considered eligible if it reported Class II malocclusion treatment using tooth borne non-compliant intraoral distalizers compared to treatment with skeletal borne non-compliant intraoral distalizers or no treatment of Class II patients in randomized or non-randomized clinical trials. After removal of all duplicates, the articles were screened based on the title and abstract. Full text articles were screened when screening the titles and abstract were insufficient to decide. Reasons for excluding potentially **eligible articles are shown in Table 2.**

3.2. Information sources and search

Four electronic databases were systematically searched including Cochrane Library, PubMed, Scopus and Ovid journals. No limits were applied for language or publication year. no additional data were found with manual search or grey literature. The date last searched was up to May 15, 2021. After removal of all duplicates, the articles were screened based on the title and abstract. Full text articles were screened in case screening the titles and abstract were insufficient to decide. The search was performed by two investigators (Z.K and S.A). Disagreement among studies to be included were resolved by discussion between the reviewers until a final consensus is reached.

The following search terms were used in our search: maxillary molar distalization, molar distalization, distal jet, distal jet appliance, jig appliance, Jones, pendulum, jones jig, hybrid pendulum, pendex, Intraoral distalizing devices, miniscrew, miniscrew implants, temporary anchorage device, intraoral extradental anchorage system, Class II malocclusion, Class II, Angle Class II, soft tissue effects, soft tissue changes, soft tissue, skeletal changes, skeletal effects, dental changes, dental effects, Search strategy in the pubmed database is shown in (Table3). An adjusted form of that search strategy was applied to the other databases.

3.3. Data collection process and data items

Data were extracted independently by two reviewers (Z.K and S.A). The collected data included: publication details (authors, titles and year), sample size, mean age, gender, intervention, control group, treatment duration, soft tissue and dental outcomes (**Table 4**). Any disagreement about extracted data were resolved by discussion between the reviewers until final consensus was reached.

3.4. Outcome

The primary outcome were soft tissue changes recorded in the lateral cephalogram after distalization. Secondary outcome included amount of anchorage loss for each intervention recorded by the incisor dental measurements on lateral cephalogram after the use of distalizers.

3.5. Risk of bias assessment of individual studies

The Cochrane Risk of Bias Tool was used to analyze the risk of bias in each RCT study included with the following criteria for assessment: random sequence, generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and other sources of bias. The overall risk of bias was judged as high, low or unclear for randomized studies. For non-randomized comparative trials, the methodological index of non-randomized studies (MINORS) was used to assess these trials with the following criteria for assessment: a clearly stated aim, inclusion of consecutive patients, Prospective collection of data, endpoints appropriate to the aim of the study, unbiased assessment of the study endpoint, follow-up period appropriate to the aim of the study, loss to follow up less than 5%, prospective calculation of the study size, an adequate control group, contemporary groups, baseline equivalence of groups and adequate statistical analyses. Each item is scored from 0 to 2. 0 indicating that it was not reported in the article evaluated, 1 indicating that it was reported but inadequately and 2 indicating it was reported adequately. The global ideal score is 24.

3.6. Summary measure

All outcome measurements used to evaluate the soft tissue effects were considered as primary outcomes. These include upper and lower lip to E line(mm), nasolabial angle, Ls-VR and Li-VR (mm). Moreover, all outcome measurements used to evaluate the dental effects were considered as secondary outcomes, these include SN-U1, SN-U4, PTV-U1(mm), PTV-U4(mm), PPU1(mm), PPU4(mm), overjet (mm), overbite(mm), 1-SN, 4-SN, 4-PTV, 4-PP, 1-PTV, 1-PP, OLp-is, PTV-11 CEJ, OLp-ii, Difference OLp-is - OLp-Ii (overjet), U1-HR. U4-HR, U1-VR and U4-VR. List of abbreviations is shown in table 5.

3.7. Synthesis of results:

Due to heterogeneity in the appliance type, duration of treatment and activation protocol, pooling of outcome data and metanalysis could not be performed.

Table 1

Participants	Patients with Class II malocclusion
Intervention	Non-compliant intraoral tooth borne distalizers
Control	Non-compliant intraoral skeletal borne distalizers or untreated Class II patients
Outcome	Primary outcome: soft tissue effects Secondary outcome: degree of incisor anchorage loss

Selection criteria for inclusion of articles

Table 2

Reason for Exclusion	Excluded articles
Excluded due to inadequate control group	(Fontana et al., 2012), (de Almeida-Pedrin et al., 2009),(Pinzan-Vercelino et al., 2009),(Mossaz et al., 2007),(Kaya et al., 2013),(Chiu et al., 2005),(Angelieri et al., 2008),(Paul et al., 2002),(Sar et al., 2013),(Mayara Paim Patel et al., 2009),(Gelgor et al., 2007),(Sa'aed et al., 2015),(Zhao & Liu, 2005),(Pupulim et al., 2019),(Mayara Paim Patel et al., 2020),(Marure et al., 2016),(Brickman et al., 2000),(Acar et al., 2010),(Ferguson et al., 2005) and (Fontes et al., 2020),(Polat-Ozsoy et al., 2008)
Excluded due to absence of a control group	(Kinzinger et al., 2009) ,(Cambiano et al., 2017), (Kilkis et al., 2016) ,(Ba-Yazed et al., 2014) ,(Fuziy et al., 2006),(Bolla et al., 2002),(Bussick & McNamara, 2000) ,(M P Patel et al., 2009),(Escobar et al., 2007),(Kook et al., 2014) and (He et al., 2004)
Excluded due to soft tissue changes not being recorded	(Papadopoulos et al., 2010) and (Cozzani et al., 2014)
Excluded because the control group consisted of subjects with normal occlusion	(Ramon Pujols et al., 2020)
Excluded because measurements were not done immediately after distalization	(Vilanova, 2018), (Patel, 2013)
Excluded because of not using non-compliance appliances	(Altug-Atac, 2007)
Article could not be retrieved	(Reis RS, 2019)

Reasons for excluding potentially eligible articles

Table 3

PubMed	**((“maxillary molar distalization” OR “molar distalization” OR ”Distal jet” OR ”distal jet appliance” OR ”jig appliance” OR ”Jones” OR ”pendulum” OR ”jones jig” OR ”hybrid pendulum” OR ”pendex” OR ”Intraoral distalizing devices” OR ”miniscrew” OR ”miniscrew implants” OR ”temporary anchorage device” OR ”intraoral extradental anchorage system”) AND (”Class II malocclusion” OR ”Class II” OR ”Angle Class II”)) AND (”soft tissue effects” OR ”soft tissue changes” OR ”soft tissue” OR ”skeletal changes” OR ”skeletal effects” OR ”dental changes” OR ”dental effects”)**

Search strategy in Pubmed database

Table 4

study	sample size /Gender	age (intervention)	age (control)	intrervetion	control	duration after distalization only
(Mariani, 2014)	N= 57 not specified	13.3 ± 2.3 years	12.8 ± 1.7 years	MGBM system (n=30)	pendulum (n=27)	MGBM : 8±2 months, pendulum 9±3 months
(Caprioglio, 2015)	N= 43 19 ♂, 24 ♀, Pendulum (10 ♂, 14 ♀), Distal Screw (9 ♂, 10 ♀)	12.2 ± 1.5 years	11.3 ± 1.9 years	Pendulum (n=24)	distal screw appliance (n=19)	Pendulum 7 mo ± 2 mo (5 mo – 11 mo), Distal Screw 9 mo ± 2 mo (4 mo – 12 mo)
(Polat-Ozsoy, 2008)	N=39 BAPA group 15 ♀, 7 ♂, CPA 10 ♀, 7 ♂	13.61 ± 2.01 years	13.62 ± 2.07 years	BAPA (bone anchored pendulum	CPA (convectional pendulum	(T2-T1) BAPA 6.8 ± 1.7 months, CPA 5.1 ± 0.9 months

				appliance) (n 22)	appliance) (n 17)	
(Reis, 2019)	N=44 Distal Jet 5 ♂ 17 ♀ (total 22), Control 13 ♂ 9 ♀ (total 22) (P 0.06)	initial pretreatment age Distal Jet 12.7 ± 1.2 (P 0.145)	initial pretreatment age Control 12.2 ± 0.8 (P 0.145)	Distal Jet (n=22)	no treatment (n=22)	Mean period of distalization of 1.2 years (SD = 0.3, range 0.6 to 1.6 years), Control followed by a mean period of 1.2 years (SD= 0.3) (P= 0.986)

Data extracted from articles, MGBM= G.B Maino, A. Giannelly, R. Bernard, P. Mura, BAPA= bone anchored pendulum appliance, CPA= conventional pendulum appliance.

Table 5

Abbreviation	**Meaning**
NLA	Nasolabial Angle
Ls-VR	Labial superior to Vertical Reference (mm)
Li-VR	Labial inferior to Vertical Reference (mm)
SN-U1	Sella Nasion to Upper first incisor (degrees)
SN-U4	Sella Nasion to Upper first premolar (degrees)
PTV-U1	Pterygoid Vertical to upper incisor (mm)
PTV-U4	Pterygoid Vertical to Upper first premolar (mm)
PPU1	Palatal Plane to Upper incisor (mm)
PPU4	Palatal Plane to Upper first premolar (mm)
1-SN	Upper incisor to Sella Nasion (degrees)
1-PTV	Upper incisor to Pterygoid Vertical (degrees)
4-PTV	Upper first premolar to Pterygoid Vertical (degrees)
1-PP	Upper incisor to Palatal Plane (degrees)
4-PP	Upper first premolar to Palatal Plane (degrees)
OLp-is	Perpendicular Occlusal Plane to Upper incisal edge (mm)
OLp-ii	Perpendicular Occlusal Plane to Lower incisal edge (mm)
PTV-11 CEJ	Pterygoid Vertical to Upper incisor CementoEnamel Junction (mm)
Difference OLp-is - OLp-Ii	Overjet
U1-HR	Upper incisor to Horizontal Plane (degrees)
U4-HR	Upper first premolar to Horizontal Plane (degrees)
U1-VR	Upper incisor to Vertical Plane (mm)
U4-VR	Upper first premolar to Vertical Plane (mm)

List of abbreviations

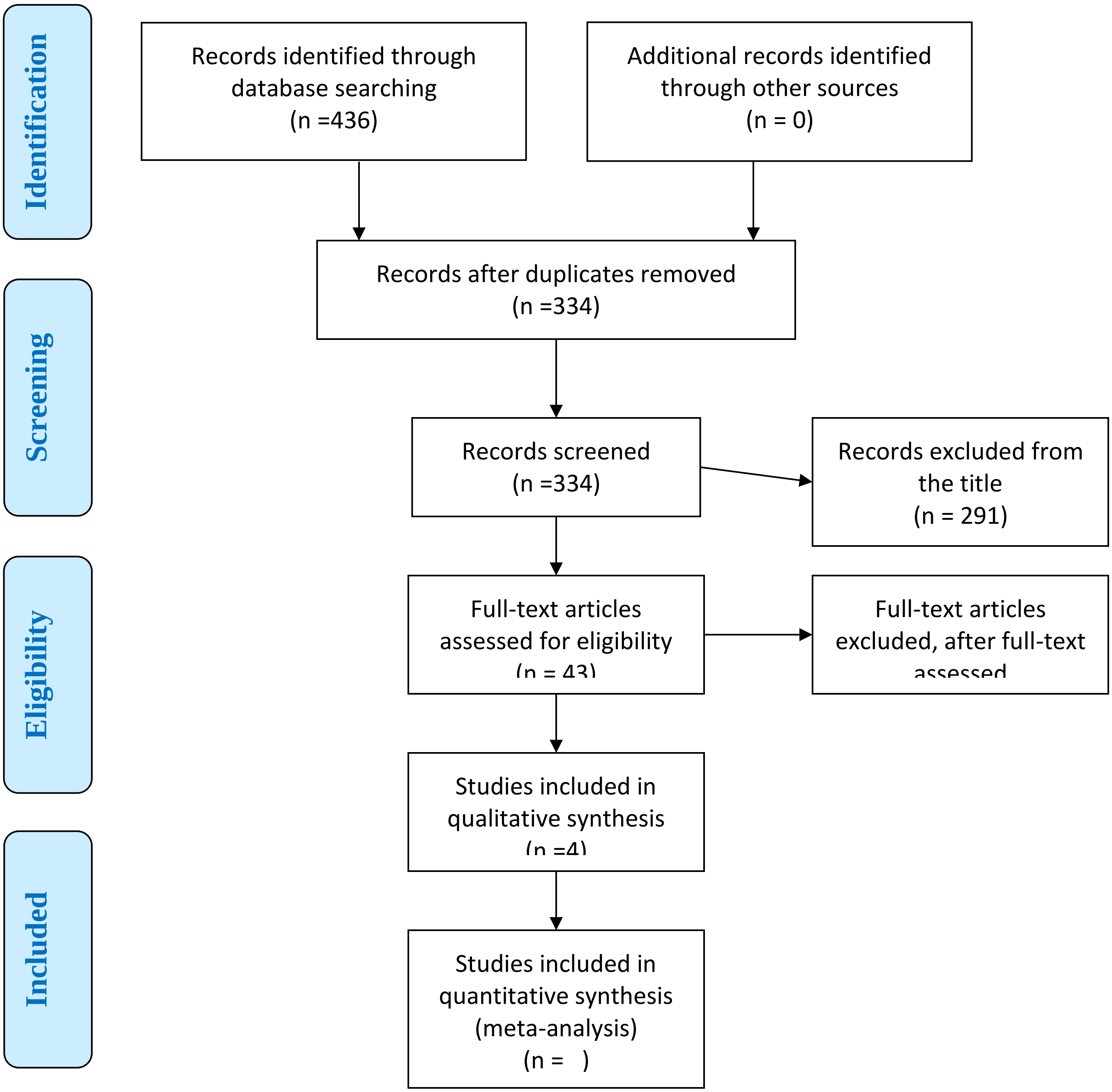
4. RESULTS

4.1. Study Selection:

Four hundred thirty-six articles were identified initially through electronic search. No additional records were identified through other sources. After exclusion of duplicates, three hundred thirty-four articles remained. A total of forty-three articles remained after screening based on the title and abstract. A total of four articles were included after full-text assessment of eligibility. Three articles (Mariani, 2014), (Caprioglio, 2015), (Polat-Ozsoy, 2008) compared skeletal and conventional intraoral anchorage. While one article (Reis, 2019) compared conventional intraoral anchorage to no treatment. Two articles were excluded as measurements were not done after distalization (Vilanova, 2018), (Patel, 2013).

One article was excluded as it could not be retrieved, the author was not contacted (Reis RS, 2019). Figure 1 shows the study selection flow diagram of the systematic review.

Fig. 1



Identification
Screening
Eligibility
Included
Records identified through database searching (n =436)
Additional records identified through other sources (n = 0)
Records after duplicates removed (n =334)
Records screened (n =334)
Records excluded from the title (n = 291)
Full-text articles assessed for eligibility (n = 43)
Full-text articles excluded, after full-text assessed
Studies included in qualitative synthesis (n =4)
Studies included in quantitative synthesis (meta-analysis) (n =)

4.2. Study Characteristics:

Three studies compared skeletal to conventional intraoral anchorage. While one study compared conventional intraoral anchorage to no treatment.

(Mariani, 2014) in his retrospective study evaluated the dentoalveolar and skeletal effects of the MGBM system (MGBM= G.B Maino, A. Giannelly, R. Bernard, P. Mura) (intervention) and the pendulum appliance (control) in Class II malocclusion patients. The sample consisted of skeletal Class I or II malocclusion (angle classification) and bilateral full cusp or end-to-end Class II molar relationship with moderate space deficiency in the maxillary dental arch, minimal or no crowding in the mandibular arch. The sample size was 57 patients. The MGBM group consisted of 30 patients with a mean age of 13.3 ± 2.3 years. While the Pendulum group consisted of 27 patients with a mean age of 12.8 ± 1.7 years. Gender within the groups were not specified by the author. The mean duration of distalization of the MGBM group was 8±2 months. While the same of the pendulum appliance group was 9±3 months. The MGBM system anchorage was provided by a TPA connecting the first premolars and to which two miniscrews inserted between the first molars and second premolars bilaterally are connected. Distalization was achieved by a compressed SENTELLOY coil spring (200gm) in a sectional wire 0.016 × 0.022 SS from the first premolars to the first molar. In case of presence of fully erupted second molars, a shape memory 0.018 × 0.025 Neo Sentalloy wire is inserted between the second molar and the first premolar, looped vertically for 6 mm in the buccal fold. The pendulum was activated with a TMA wire by 90 degrees. In case of presence of the second molars, the pendulum springs were inserted in the second molars. The main outcome measures assessed on the cephalograms were distal movement and distal tipping of maxillary first molars and anchorage loss (anterior movement and proclination of maxillary first premolars and maxillary central incisors).

(Caprioglio, 2015) did a retrospective study to compare the dentoalveolar and skeletal changes produced by the pendulum appliance (intervention) and the distal screw appliance (control) in Class II patients. The sample included cases with skeletal Class I or mild Class II malocclusion and a bilateral full cusp or end-to-end Class II molar relationship. The sample size consisted of 43 patients including 19 men and 24 women. The group of the pendulum appliance had 24 patients (10 men and 14 women) with a mean age of 12.2 ± 1.5 years. The distal screw appliance group had 19 patients (9 men and 10 women) with a mean age of 11.3 ± 1.9 years. The mean period of active distalization was 7 ± 2 months (standard deviation 5 − 11 months) in the Pendulum group. The same was 9 ± 2 months (4 − 12 months) in the distal screw group. The pendulum consisted of a nance button placed on the anterior vault of the palate as anchorage, adding arms on the first premolars and occlusal rests on the second premolars. The 0.032-inches titanium-molybdenum alloy (TMA) springs were bent parallel to the palatal midline and placed in the lingual sheaths on maxillary first molar bands, exerting approximately 230 g of distalizing force per side, activation was done every 6 weeks. The distal screw appliance was modified distal jet with a Nance button. It was supported by four miniscrews. The two miniscrews (one for each side) were placed in the paramedian region of the anterior palatal vault along a line connecting the first premolars. The superelastic springs were compressed until a force of 240 g was obtained. Reactivation was carried out at 4-week intervals.

(Polat-Ozsoy, 2008) compared, in a retrospective study, the dentoalveolar and skeletal effects obtained with a bone-anchored pendulum appliance (BAPA) (Intervention group) and a conventional pendulum appliance (CPA) (control group). Sample included Class II molar relationship with moderate space deficiency in the maxillary dental arch, and minimal or no crowding in the mandibular arch. His sample size was 39 patients (25 girls, 14 boys) with Angle Class II molar relationships. The BAPA group size was was 22 patients (15 girls, 7 boys) with a mean age of 13.61 ± 2.01 years. While the CPA group had 17 patients (10 girls, 7 boys) with a mean age of 13.62 ± 2.07 years. The mean duration of distalization was 6.8 ± 1.7 months for the BAPA group and 5.1 ± 0.9 months for the CPA group. Anchorage for the BAPA group was provided by titanium intraosseous screws (2.0mm diameter, 8 mm length). Screws were placed in the anterior paramedian region of the median palatal suture, 4 to 6 mm posterior to the incisive foramen and 3 to 4mm lateral to the median line. Nine patients had only one screw. While eleven patients had two screws. The acrylic plate was connected to the screw head by using cold-curing, methyl methacrylate-free acrylic resin. Activated 0.032-in titanium molybdenum alloy springs were placed in the lingual sheaths on the first molar bands. One week after screw placement the springs were activated 60° to 70° for approximately 230 g of distalizing force. In the CPA, Palatal acrylic button was anchored to the maxillary first and second premolars by using occlusal rests. Bilateral 0.032-in TMA springs were placed in the lingual sheaths on the first molar bands. Initial activation of 60° to 70° was made. Reactivation was made monthly when needed.

(Reis, 2019) did a prospective study and evaluated the dental, skeletal and soft tissue effects in Class II malocclusion patients treated with Distal Jet appliance (intervention), compared to an untreated control group. The sample consisted of a total of 44 patients. The distal jet group had 22 patients (5 males, 17 females) with an age of 12.7 ± 1.2 years. Four patients presented 1/4 cusp Class II molar relationship, 16 presented 1/2 cusp Class II and 2 presented 3/4 cusp Class II molar relationship. While the control group had a total of 22 patients (13 males, 9 females) with an initial age of 12.2 ± 0.8 years. The mean period of distalization was 1.2 years (SD = 0.3). The control was followed by a mean period of 1.2 years (SD= 0.3). Distal Jet appliance consisted of bands that were fitted on the maxillary first molars and maxillary first premolars. Coil springs were activated every 4 to 6 weeks. The forces generated by the NiTi coils were of 240g.

Details on the characteristics of the studies are provided in table 4 in the materials and methods section.

4.3. Risk of Bias within Studies:

Risk of bias assessment was done based on the methodological index of non-randomized studies (MINORS). The studies had close results based on the scoring done. (Mariani, 2014) had a score of 15. (Caprioglio, 2015) was given the highest score of 17. While (Polat-Ozsoy, 2008) scored 16, (Reis, 2019) was given the lowest score of 14. Details on the scoring is summarized in table 6.

Table 6

Methodological Items	**Study and score**			
	(Mariani, 2014)	(Caprioglio, 2015)	(Polat-Ozsoy, 2008)	(Reis, 2019)
Clearly stated aim	2	2	2	2
Inclusion of consecutive patients	2	2	1	2
Prospective collection of data	1	1	1	1
Endpoints appropriate to the aim of the study	2	2	2	2
Unbiased assessment of the study endpoint	1	1	1	1
Follow up period appropriate to the aim of the study	0	0	0	0
Loss to follow up < 5%	0	1	1	1
Prospective calculation of the study size	1	1	1	2
An adequate control group	2	2	2	0
Contemporary groups	2	1	1	0
Baseline equivalence of groups	2	2	2	2
Adequate statistical analysis	1	2	2	1
Total Score	15	17	16	14

Risk of bias assessment

4.4. Results of Individual Studies:

The results obtained from (Mariani, 2014) show that after distalization, significant anchorage loss was found in the incisors with increased proclination in the pendulum group however, no significant difference was found in the loss of anchorage in the first premolars. A certain amount of anchorage loss occurred in both groups even though the MGBM protocol made provision for skeletal anchorage. For the esthetic variables, no significant difference observed in the lips position after distalization.

(Caprioglio, 2015) found a significant difference in the anchorage loss. The first premolar showed a mesial movement and a mesial tipping in the PA group, whereas a slight distal movement and distal tipping was noted in the DS group. No significant change was described at the maxillary incisor in the DS group, whereas a significant proclination was reported in the PA group. The distal screw caused premolar distal movement during the distalization phase, possibly positively influencing the total treatment time. No significant difference in lip position between the two groups after distalization.

(Polat-Ozsoy, 2008) found an absence of anchorage loss, significant spontaneous distal premolar movement, slight distal incisor movement, and the possibility of less total treatment time with BAPA compared to CPA. No significant difference in the upper and lower lip positions between the BAPA and CPA groups.

It was shown by (Reis, 2019) that the distal jet causes mesialization of the maxillary first premolars, and increase in labial inclination and protrusion of the maxillary incisors, leading to an increase in the overjet. However, there were no significant changes in the facial profile. Table 7 shows the measurements obtained after distalization in each study.

4.5. Data Synthesis:

Metanalysis was not done as pooling the data from these 4 reports was deemed not suitable because of clinical and methodologic heterogeneity across the trials.

Table 7

Study	Type of measurement	Measurement after distalization (Standard Deviation)		
(Mariani, 2014)		MGBM	Pendulum	P value
	Angular Dental measurements			
	SN^1.1 axis	1.4 (2.5)	4.7 (3.9)	p=0.000
	PP^1.1 axis	1.2 (3.0)	4.9 (4.5)	p=0.000
	SN^1.4 axis	2.5 (4.3)	1.9 (6.6)	p=0.479
	Linear dental measurements			
	OLp-is	1.6 (2.0)	2.9 (2.0)	p=0.043
	PTV-11 CEJ	1.0 (1.8)	1.5 (2.8)	p=0.523
	OLp-ii	0.2 (3.1)	1.8 (2.2)	p=0.421
	Difference OLp-is - OLp-Ii	1.1 (2.4)	1.0 (2.0)	p=0.213
	PTV-1.4 centroid	1.8 (2.0)	2.7 (3.3)	p=0.242
	Soft tissues			
	UL-E plane	0.7 (0.9)	0.5 (1.4)	p=0.347
	LL-E plane	0.5 (1.3)	0.6 (1.5)	p= 0.479
(Caprioglio, 2015)		Pendulum	Distal Screw Appliance	P value
	Angular Dental measurements			
	SN-U1 (o)	5.0 ± 3.6	0.1 ± 3.5	<0.001
	SN-U4 (o)	3.6 ± 1.6	5.1 ± 2.0	<0.001
	Linear dental measurements			
	PTV-U1 (mm)	1.7 ± 2.7	0.1 ± 1.5	0.279
	PTV-U4 (mm)	2.7 ± 3.3	1.9 ± 1.7	<0.001
	PP-U1 (mm)	0.5 ± 1.4	0.5 ± 0.6	0.584
	PP-U4 (mm)	1.4 ± 1.9	1.3 ± 2.0	0.193
	Overjet (mm)	1.3 ± 1.2	0.9 ± 1.1	0.096
	Overbite (mm)	0.4 ± 1.9	0.1 ± 1.3	0.704
	Soft tissues			
	Upper lip to E-plane (mm)	0.7 ± 1.3	0.1 ± 1.7	0.069
	Lower lip to E-plane (mm)	0.6 ± 1.5	-0.1 ± 1.2	0.079
(Polat-Ozsoy, 2008)		BAPA	CPA	
	Angular Dental measurements			
	U1-HR	-1.7 ± 2.9	0.9 ±2.4	.035

	U4-HR	-7.7 ± 5.1	6.9 ± 4.1	.000
	U5-HR	-9.9 ± 5.2	3.8 ± 2.7	.000
	Linear dental measurements			
	U1-VR	-0.1 ± 1.7	1.2 ± 1.7	.034
	U4-VR	-2.7 ± 1.6	4.0 ± 2.7	.000
	U5-VR	-4.1 ± 2.1	2.3 ± 2.1	.000
	Overjet	-0.0 ± 0.8	0.9 ± 1.0	.025
	Overbite	-0.3 ± 0.9	-0.6 ± 1.5	—
	Soft tissues			
	Ls-VR	0.3 ± 2.0	0.4 ± 2.2	—
	Li-VR	0.1 ± 1.6	0.4 ± 2.3	—
(Reis, 2019)		Distal Jet	No treatment	
	Angular Dental measurements			
	4.SN	-0.3 (3.3)	-0.8 (2.8)	0.597
	4-PTV	3.4 (1.1)	0.9 (1.6)	0.000
	4-PP	1.6 (1.4)	0.8 (1.1)	0.070
	1.SN	4.3 (4.7)	-0.3 (3.0)	0.000
	1-PTV	2.4 (1.7)	1.0 (1.4)	0.004
	1-PP	0.4 (1.2)	0.4 (0.8)	0.954
	Linear dental measurements			
	Overjet	1.5 (1.1)	-0.0 (0.7)	0.000
	Overbite	-0.4 (1.3)	-0.2 (1.2)	0.542
	Soft tissues			
	NLA	1.7 (15.5)	0.9 (7.2)	0.842
	UL-E	0.1 (1.3)	0.5 (0.7)	0.235
	LL-E	-0.0 (1.4)	0.5 (0.8)	0.105

Measurements obtained after distalization. SN^1.1 = sella-nasion to central incisor axis, PP^1.1 = palatal plane to central incisor axis, SN^1.4 = sella-nasion to first premolar axis, OLp = perpendicular occlusal plane passing for sella point, PtV = pterygoid vertical, is = upper incisor, li = lower incisor, UL-E = upper lip to E-plane, LL-E = lower lip to E-plane, HR= a horizontal reference plane constructed 7° to the sella-nasion plane, VR = vertical reference plane constructed perpendicular to the horizontal reference line at the T point (the most superior point of the anterior wall of sella turcica at the junction with the tuberculum sella).

5. DISCUSSION

This systematic review was conducted to find out the soft tissue effects associated with the use of non-compliant intraoral distalizers for the correction of Class II malocclusion. The upper lip to E-plane, lower lip to E-plane, upper lip to VR (vertical plane), lower lip to VR and the nasolabial angle were looked at. The side effects of these appliances including the loss of anchorage of the first premolars, second premolars and incisors were also taken into consideration.

5.1. Effects on the soft tissues:

In the present review, the nasolabial angle was only looked at by (Reis, 2019) which showed a mean change of 1.7 (15.5) degrees as a result of distalization with the distal jet. However, the mean change with no treatment was 0.9 (7.2) degrees showing that there is no significant change. The upper lip to E-plane was assessed by multiple studies with a mean value varying from 0.1mm to 0.7mm. The highest effect was observed by (Caprioglio, 2015) and (Mariani, 2014) with a mean value of 0.7mm using the pendulum appliance and the MGBM respectively. The lowest effect on the upper lip to E-plane was observed (Reis, 2019) and (Caprioglio, 2015) with a mean value of 0.1mm using the distal jet and the distal screw appliance respectively. The highest mean change of 0.6mm for the lower lip to E-plane was reported by (Caprioglio, 2015) and (Mariani, 2014) where the pendulum appliance was used. While the lowest mean change was 0.0mm which was reported by (Reis, 2019) with the use of the distal jet. (Polat-Ozsoy, 2008) used the vertical plane as a reference to assess changes in the upper and lower lips. The mean change was 0.4mm in both the upper and lower lips with the use of conventional pendulum appliance which are slightly higher compared to the use of bone anchored pendulum appliance (0.3mm for the upper lip and 0.1mm for the lower lip). All of the previously mentioned studies showed that there is no significant difference in the lips position between the intervention and control groups.

(Ghosh, 1996) evaluated the effects of pendulum appliance on the soft tissues after distalization and found an increase in the mean change of 0.31mm and 0.95mm for the upper and lower lips from the E-plane respectively. These results match those of the pendulum of (Mariani, 2014) who got 0.5mm for the upper lip and 0.6mm for the lower lip, and (Caprioglio, 2015) who got 0.7mm 0.6mm for the same. The upper lip and lower lip to E-plane were also assessed by (Chiu, 2005). After distalization, it was found that the mean change in the upper lip to E-plane was 0.9mm using the distal jet and 0.3mm using the pendulum. While the mean change in the lower lip to E-plane was 2.1mm with the distal jet and 0.5 with the pendulum. The mean change found by (Reis, 2019) was 0.1mm for the upper lip and 0.0mm for the lower lip using the distal jet. The pendulum was used by (Caprioglio, 2015) and found close results to those of (Chiu, 2005) with values of 0.7mm for the upper lip and 0.6mm for the lower lip to E-plane.

Several dental angular and linear measurements can be taken to evaluate the non-compliant intraoral distalizers effects on the anchorage unit. These are taken into consideration as they might affect the lip position and facial profile of the patient. The SN-upper incisor mean change ranged from 0.1 degrees with the use of distal screw appliance to 5.0 with the use of the pendulum (Caprioglio, 2015). This supports the idea that skeletally anchored distalizers has less side effects on the anchorage unit. The mean change in the overjet can be used as an indicator to loss of anchorage. The mean change in the overjet was 0.0mm with the use of bone anchored pendulum appliance BAPA (Polat-Ozsoy, 2008). The values increased with the use of other types of

distalizers with the highest value of 1.5mm with the use of the distal jet (Reis, 2019). By looking at the results in table 5, a correlation can be noted between the mean change in overjet and the position of the lips. The amount of increase in the upper lip to E-plane and the increase in overjet in (Caprioglio, 2015) were higher in the pendulum group compared to the distal screw group. Another correlation can be noted from the results obtained from (Reis, 2019) between the increase in the overjet in the distal jet group (1.5mm) and the increase in the nasolabial angle (1.7 degrees). The correlation is not so apparent in (Polat-Ozsoy, 2008), where the the difference in the increase in the overjet and the upper lip is not significant between the BAPA and the CPA groups.
The first premolars can also be affected with the use of distalizers. However, using a skeletally anchored distalizer can lead to distalization of the first premolars as reported by (Polat-Ozsoy, 2008) with the use of BAPA with a mean change of -2.7mm when measured from a vertical plane. Mesialization of the first premolars happened when a conventional pendulum appliance was used with a mean change of 4.0mm.

(Ghosh, 1996) used the pendulum appliance in his study and found an increase in the mean change of the SN-incisor axis angle of 2.4 degrees which matches with the results of the pendulum group of our studies including (Mariani, 2014) who found 4.7 degrees increase, (Caprioglio, 2015) and (Reis, 2019). In another systematic review done by (Al-Thomali, 2017), it was found that the use of pendulum appliance lead to anchorage loss which occurred more markedly in the areas of the incisors compared with that of the premolars, leading to proclination of the maxillary incisors. To minimize this side effect, palatal implants were used along with pendulum appliance. (Onçag G, 2007) noticed labial tipping of incisor in the pendulum group and palatal tipping in the implant group. Premolars tipped mesially in the pendulum group, with significant loss of anchorage and distally in implant group, with no anchorage loss. Others who used BAPA, similar to (Polat-Ozsoy, 2008), include (Kircelli BH, 2006) and (Sar C, 2013) who reported premolar distalization of 1.75–5.4 mm and distal tipping of 6.04 – 16.3 degrees. (Al-Thomali, 2017) concluded that Molar distalization, as well as premolar distalization, was achieved with BAPA without anchorage loss. In another systematic review by (Soheilifar S, 2019), it was reported that there is no difference in the amount of molar distalization and tipping between the conventional and TAD-supported distalization. However, TADs would minimize the loss of anchorage by limiting premolar mesial movement.

The overall risk of bias was assessed to be high in the reviewed studies. Lack of randomization and blindness would make it impossible to draw a definite conclusion based on the reviewed studies.

5.2. Limitations:

This systematic review is based an extensive unrestricted literature search of available evidence and clear inclusion and exclusion criteria. However, the limited number of the articles reviewed and their heterogeneity resulted in high risk of bias. This can be considered as the main limitation of the study. The included articles were non-randomized and did not report any blinding of the operator performing the intervention and the operator responsible for collecting outcomes.

5.3. Funding:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

6. CONCLUSIONS

From this systematic review and with the level of evidence available, it can be concluded that there is no significant difference in the nasolabial angel, upper lip and lower lip positions, and hence the soft tissue profile of the patient with the use of various types of non-compliant intraoral distalizers when treating Class II malocclusion cases. The use of skeletally anchored distalizers had fewer side effects on the soft tissue measurements, however these differences were not significant.

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