Céline Audrey Flore VÉDRENNE

# Initial discomfort and pain perception related with orthodontic aligners and fixed appliances : a systematic review

Universidade Fernando Pessoa

Faculdade Ciências da Saúde

Porto, 2020

**ABSTRACT**

*Aims:* To compare the initial discomfort between the two orthodontic methods, with pain measurements, control of the frequency of taking analgesics, and changes in daily routine.

*Materials and methods:* The article searches were mainly carried out on the Pubmed and ResearchGate websites, using the following keywords: "invisalign", "fixed appliance", "pain", "analgesics", "discomfort", "impact on daily performance", in addition to an in-depth study of the bibliographies.

*Results:* Eight studies were deemes relevant to our work.

*Conclusion:* With a lower certainty, the pain in patients using aligners seems to be less intense than in patients with fixed applainces and the use of analgesic is therefore more important for the fixed group. These two parameters follow a gradual decrease during the first week of treatment. Chewing, speaking and general activity can be affected by the treatment.

*Keywords:* Orthodontic appliances, Fixed, Removable, Invisalign, Pain, Analgesics.

**RESUMO**

*Objetivos:* Comparar o desconforto inicial entre os dois métodos ortodônticos, com medições da dor, controlo da frequência da toma de analgésicos e alterações da rotina diária.

*Materiais e métodos:* As pesquisas de artigos foram realizadas principalmente nos sites Pubmed e ResearchGate, utilizando as seguintes palavras-chave: "invisalign", "aparelho fixo", "dor", "analgésicos", "desconforto", "impacto no desempenho diário", para além de um estudo aprofundado das bibliografias.

*Resultados:* Oito estudos foram considerados relevantes para o nosso trabalho.

*Conclusão:* Com uma certeza menor, a dor nos pacientes que utilizam alinhadores parece ser menos intensa do que nos pacientes com maçãs fixas, pelo que a utilização de analgésicos é mais importante para o grupo fixo. Estes dois parâmetros seguem uma diminuição gradual durante a primeira semana de tratamento. A mastigação, a fala e a actividade geral podem ser afectadas pelo tratamento.

*Palavras-chave:* Aparelhos ortodônticos, Fixos, Removíveis, Invisalign, Dor, Analgésicos.

**ACKNOWLEDGMENT**

To my parents for their trust, love and support. To my mother for being my inspiration all my life.

To my grandparents for their kindness and belief in me.

To my partner, who supported me and always motivated me.

To my advisor, Professor Telmo Moreira, for guiding me throughout this work, I express my deepest gratitude.

To all the teachers for the transmission of their knowledge.

To all the university officials.

**INDEX**

**INDEX OF FIGURES**

# I. INTRODUCTION

## 1. History

In 1728, a French dentist, Pierre Fauchard, explained for the first time how to straighten teeth with the help of ligatures or a small metal plate clamped to the teeth. At the beginning of the 20th century, braces were made of large wires, attached to the teeth and held by two rings sealed to the molars. But a new material appears: vulcanite, which allows for appliances that fit better to the teeth and that the patient can remove for cleaning.

Edward Angle, considered to be the “father of modern orthodontics”, came up with the idea in 1928, of putting a ring on every tooth with a mortise attachment, in which a wire is embedded, which has been given the shape of an ideal arch, also allowing the root of the tooth to be moved, if necessary. The Edgewise appliance was born. (SFODF, 2020).

Starting in the 1980s, the problem of the visibility of orthodontic appliances arose, particularly with the development of adult orthodontics, which became incompatible with vestibular metal arches and brackets. Solutions were then proposed as early as the late 1970s, such as lingual face attachments by Craven Kurz and Kynia Fujita. Lingual orthodontics was born but met with laborious success. The ceramic brackets that appeared in 1988 were to occupy the central place in aesthetic orthodontics for more than a decade. (Baron, 2014)

Harold Kesling proposed in 1945 the "tooth positioning appliance", a flexible appliance made of ebonite rubber, intended for finishing orthodontic treatments with braces. In 1964, Nahoum developed the first vacuum thermoformed gutter used for closing anterior spaces and for correcting minor rotations.

Mac Namara, in 1985, introduced the first pressure-formed orthodontic aligners (Biostar ® system). He was inspired by the work of Ponitz, who developed the invisible retainer in 1971 for restraint.

In 1995, Sheridan developed the ESSIX® system based on the same principles as Kesling's, but with the addition of "divots" that create a force to push a particular tooth and "windows" that create spaces for the tooth to move through. However, only small amounts of movement are possible with a single aligner, and at each stage of processing, an impression is required to make a new set-up.

In 1997, a new company, Align Technology, appeared in the United States and developed the Invisalign® system. This is the result of the joint use of two techniques: CAD-CAM, which allows the digitization by tomography of the impressions in order to obtain a 3D set-up and

thus virtually pre-visualize the entire process step by step; and liquid resin stereolithography for industrial purposes, which allows the manufacturing of a series of aligners from their 3D images. Despite a difficult start, this technique has evolved to be able to treat complex malocclusions. (BloomSquare, 2020).

In addition to a new technique, this is a new operator in the world of orthodontics who will address patients directly with a large number of advertising campaigns. Indeed, their strategy is as follows: "Multi-channel, integrated media approach to reach consumers anywhere, anytime and on any device; Utilize mass reach media via TV to drive overall awareness and purchase intent, especially with women; Generate earned media via PR, Social and Digital to drive peer-to-peer awareness, purchase intent and action". (Align Technology, 2014).

Thus Align Technology's advertising is based on creating the public's desire to find an easy way to get straight teeth. Invisalign is therefore part of a modern approach to its communication with patients. The website presents all the information about the system, a "smile evaluation" is even proposed, as well as a summary of the most frequent questions/answers. The company has also developed the "My Invisalign Smile" application which accompanies the patient throughout his treatment. (Invisalign, 2020)

As patents expire or are successfully challenged, competitive companies and orthodontists themselves begin to produce their own clear aligners. Companies such as SmileDirectClub even offer to send a kit directly to the patient's home, so that the patient can do the entire treatment from home, and no longer have to travel to the office. (Smiledirectclub, 2020)

## 2. Nowadays

For several years now, a new type of orthodontics has seen the light of day with the arrival of aligners on the market, motivated by a growing demand for discretion on the part of patients. Indeed, this technique has many advantages, among which we can cite its discretion due to its transparent material, a lower average cost than a traditional treatment, and a lower number and length of appointments with the practitioner as well. During this treatment, the patient has to remove his or her mouth trays to eat and brush their teeth, thus allowing the maintenance of a normal diet and simplified dental hygiene. In spite of these many advantages, his technical skills have not yet completely replaced the classical method via a fixed device.

The older ones also try to be more discreet, such as with ceramic rings or lingual appliances. These types of treatments also have their own advantages such as speed and the ability to correct much more complex cases.

As a professional, we therefore have several treatment options available to us when we have to choose the most suitable method to correct the defects in this case. Of course we have to select the one that we think is best for our patient, but we also have to discuss it with the patient, because he is the main actor, we have to know that we are motivated and invest 100%.

That's why we have to present him with all the characteristics of the different techniques .

In order for the patient to feel at ease with the treatment, awareness of the treatment's imperatives through enlightened information is essential and can modify his choice. Indeed, his lifestyle, his availability and ease in coming to the firm, his financial possibilities, his motivation, his rigour, and his level of oral hygiene, are among the factors that he must take into account.

But beyond these practical aspects, it is necessary to have absolute transparency towards him regarding also the various inconveniences that these treatments may have, such as pain, discomfort, and disturbances in daily life, however subjective they may be. According to the official definition of the International Association for the Study of Pain (IASP), "pain is an unpleasant sensory and emotional experience associated with, or described by, actual or potential tissue damage". (IASP, 2020)

Pain is therefore above all a personal feeling, and is therefore difficult to quantify. However, questionnaires and scales can allow the patient to tell us how intense it is. For adults, the most commonly used scale is the Visual Analogue Scale (VAS). [Annex 1] It is presented as a horizontal line graduated from 0 for no pain, to 10 for maximum imaginable pain; 1 to 3 representing mild pain, 4 to 7 moderate pain and 8 to 10 severe pain. For children, on the other hand, a ladder with faces is most commonly used.

## 3. Objective

Thus, this systematic review was undertaken in order to compare, within the two major orthodontic methods, the initial discomfort felt by the patient as well as the changes he may have to adopt within his daily routine; as well as his degree of perception of pain, in conjunction with the frequency of taking analgesics. The ultimate goal is to be able to advise and prepare the patient as well as possible for his future treatment.

## 4. Materials and methods

To achieve this work, a systematic research was undertaken in order to identify all the articles that may be relevant to our study.

Studies were eligible for inclusion based on the following criteria.

1. Primary studies that used an experimental or observational study design (randomized controlled trial, cohort/longitudinal study, case-control study, cross-sectional study).
2. At least one type of contemporary orthodontic appliance was used as either the main sample population or as a comparison/control group with in the study.
3. The study included human subjects of any age, sex and ethnicity.
4. The study measured pain/discomfort outcome related with the orthodontic appliance, the usage of analgesics, impact on daily routines performance, or any other orthodontically related outcome.

Narrative reviews, case reports and case series studies were excluded from review. Animal studies were also excluded, because the goal of this systematic review was to analyze trends in the use of clear aligners and conventional fixed appliances with in the pain or discomfort experience as it pertains to human subjects.

A comprehensive electronic search to identify relevant publications was conducted in February 2020 in the PubMed database. Research Gate was also used. The search was developed and performed by the author, assisted and supported by the supervisor. The search included MeSH terms to locate relevant orthodontic studies. No language restrictions were used. The bibliographies of the included studies were also used to identify additional studies for possible inclusion.

The selection process is illustrated in the PRISMA Flow Diagram [Figure 1].

Studies were screened with the previously stated inclusion criteria at the title and abstract level by the author and by the supervisor to reduce bias. A high level of agreement was obtained at the two stages. The studies were them reviewed at the full-text level.

Of these, 11 were excluded because 10 did not have a control or an intervention group, and 1 was not related to the objectives of this systematic review.

One customized data abstraction form was used to extract data from each study. The following variables were recorded : author, year, country of study ; design of the study ;

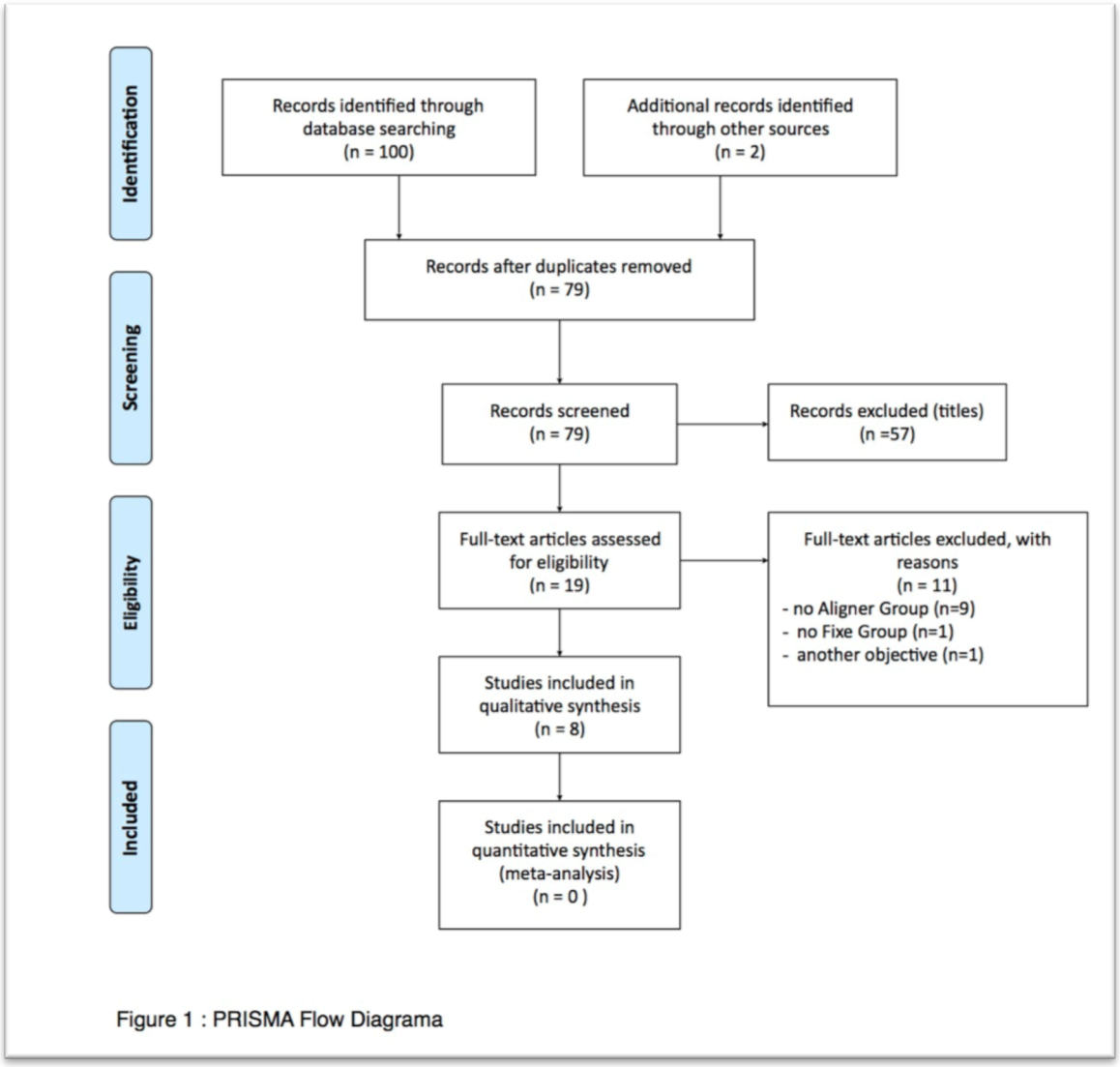



Figure 1 : PRISMA Flow Diagrama

number, gender, age of participants, research instrument, results, authors conclusions, level of evidence.

## II. DEVELOPMENT

In the end, eight studies were deemed relevant to our work.
Among those, two are randomized clinical trials (Diddige *et al.*, 2020, White *et al.*, 2017), five are prospective non-randomized clinical studies (Almasoud, 2018, Fujiyama *et al.*, 2014, Masi-Damois, 2015, Miller *et al.*, 2007, Shalish *et al.*, 2012), and the last is a retrospective study (Alajmi *et al.*, 2019).
The articles are dated from 2007 (Miller *et al.*), to 2020 (Diddige *et al.*).

In one study, treatment of patients with aligners was carried out with Smile Align (Diddige *et al.,* 2020), all the others used Invisalign technology.
However, there was greater heterogeneity in the choice of types of fixed appliances. We thus find Damon (Almasoud, 2018, Diddige *et al.*, 2020, Masi-Damois, 2015, Shalish *et al.*, 2012), Edgewise (Fujiyama *et al.*, 2014), Speed (Masi-Damois, 2015), GAC and Incognito (Shalish *et al.*, 2012), Radiance and Alexander (White *et al.*, 2017). Two studies did not provide information (Alajmi *et al.*, 2019, Miller *et al.*, 2007).
We observe that among the participants, there are on average more women than men.
The average age of the different groups varies from 16 to 40 years (Masi-Damois, 2015, Miller *et al.*, 2007), however two studies (Diddige *et al.*, 2020, White *et al.*, 2017) did not provide this information.
For two studies, a reference survey was carried out before the start of the treatment (Miller *et al.*, 2007, Masi-Damois, 2015). For five studies, the assessment was about the first week after delivery of the equipment (Alajmi *et al.*, 2019, Almasoud, 2018, Diddige *et al.*, 2020, Fujiyama *et al.*, 2014, Masi-Damois, 2015, Miller *et al.*, 2007, Shalish *et al.*, 2012, White *et al.*, 2017). Two studies have collected informations on the 14th day (Masi-Damois, 2015, Shalish *et al.*, 2012). For the Masi-Damois, 2015 study, this 14th day corresponding to the change of aligners, and was moved to the 4th week for fixed appliances. In one study, patients also completed a daily diary for 4 days after each of their next adjustment appointments, after 1 and 2 months (White *et al.*, 2017). A study continued its evaluation during the 3rd and 5th week post pose (Fujiyama *et al.*, 2014). For one study, the evaluation focused on 4 different phases of treatment: when the first, then the 4th, the 7th and finally the 10th aligner were put in the mouth; in parallel, this chronology corresponded to the change of wires every 6 weeks for the fixed appliances. (Masi-Damois, 2015)
All studies have used a VAS to quantify pain (Aljami, Almasoud, 2018, Diddige *et al.*, 2020,

Fujiyama *et al.*, 2014, Masi-Damois, 2015, Miller *et al.*, 2007, Shalish *et al.*, 2012, White *et al.*, 2017); two studies used a daily report (White *et al.*, 2017, Miller *et al.*, 2007) [Annex 2], one study used a specific questionnaire to specific phases of treatment (Masi-Damois, 2015); three studies have used the Oral Health Related Quality of Life (Alajmi *et al.*, 2019, Diddige *et al.*, 2020, Shalish *et al.*, 2012) [Annex 3]. Consumption of analgesics based on patient reports has been requested for seven studies (Aljami, Almasoud, 2018, Diddige *et al.*, 2020, Masi-Damois, 2015, Miller *et al.*, 2007, Shalish *et al.*, 2012, White *et al.*, 2017).

## III. DISCUSSION

### 1. Pain and discomfort

All studies have evaluated pain and discomfort the week after placement.

Two studies (Almasoud, 2018, Masi-Damois, 2015) noted that the number of patients with pain in the Aligners group was lower than that in the fixed group. However, for one study (Shalish *et al.*, 2012), the number of patients with severe pain in the fixed group was lower than that in the aligners group. Six studies (Almasoud, 2018, Diddige *et al.*, 2020, Fujiyama *et al.*, 2014, Masi-Damois, 2015, Miller *et al.*, 2007, White *et al.*, 2017) found that the intensity of pain in the aligners group was less than the number of patients in the fixed group. In one study (Fujiyama *et al.*, 2014), the number of days of pain was lower in the aligners group than in the fixed group.The duration of pain per day was lower in the aligners group compared to the fixed group in a study (Masi-Damois, 2015). This same study also noted that the pain was greatest in the teeth in the two groups, and in the soft tissue in the fixed group.

Right after the pose, the pain seems to be weak (White *et al.*, 2017), a study noted that the first appearance of pain was 4 hours later (Diddige *et al.*, 2020). One study noted that more people felt pain at this moment. (Almasoud, 2018).

Four studies found a peak in pain intensity 24 hours later (Almasoud, 2018, Diddige *et al.*, 2020, Fujiyama *et al.*, 2014, Masi-Damois, 2015).

On day 1, the pain increased for both groups (Miller *et al.*, 2007, White *et al.*, 2017), especially in the fixed group where it was intensely felt during chewing and bitting on the front teeth, this phenomenon being identical on days 2 and 3 (White *et al.*, 2017). Pain also increased on day 2 in both groups, and only in the fixed group on day 3 (White *et al.*, 2017). Day 4 marks the end of pain in a study (Fujiyama *et al.*, 2014) (IG / EIG). Day 5 marks the end of pain in two studies (Fujiyama *et al.*, 2014) (EG), aligners (Miller *et al.*, 2007). The 7th day, represents the end of the painful episodes for two studies (Diddige *et al.*, 2020, Masi-Damois, 2015). For two other studies, it’s the day when the number of patients is at its lowest (Almasoud, 2018), but it is not the end of the painful episodes (Miller *et al.*, 2007)

In all studies, the pain seems to decrease gradually during the first week (Diddige *et al.*, 2020, Fujiyama *et al.*, 2014, Masi-Damois, 2015, Miller *et al.*, 2007, Shalish *et al.*, 2012, White *et al.*, 2017).

In Alajmi *et al.*, 2019's study, patients with Invisalign experienced more pressure-like pain, whereas patients with conventional fixed appliances reported more throbbing and dull pain

In addition, some studies have not only analyzed data from the first week, but have gone beyond that. Thus, we note that the pain decreases over the phases (Masi-Damois, 2015, White *et al.*, 2017) and it ends at an earlier stage in the post-treatment week. (Fujiyama *et al.*, 2014, White *et al.*, 2017)

**2. Analgesics**

Seven studies have evaluated taking pain relievers.

The group of patients treated with a fixed appliance, took more painkillers during the week in order to calm the pain as we can see in four studies (Aljami, Almasoud, 2018, Miller *et al.*, 2007, White *et al.*, 2017). Only one study tells us the opposite (Shalish *et al.*, 2012).

During the 1st day, a study shows a peak in the number of aligners patients at 5h and at 24h for the fixed group (Masi-Damois, 2015); another study shows a peak at 24 hours for the two groups (Almasoud, 2018). A peak on the first global day is indicated for both groups in a study, which extends to the second day in the fixed group (White *et al.*, 2017). There was an increase in the use of painkillers in the aligners group from day 1 to day 5, then a rate of 0% on day 6 (Shalish *et al.*, 2012). In this same study, the rate of 0% is reached in the fixed group on day 4 for patients with an oral appliance, and is not reached on the 7th day in patients with a lingual appliance.

A study indicates that on day 7 the group of patients treated with Aligners no longer takes painkillers while some patients treated with a fixed appliance continue (Almasoud, 2018).

For five studies, the patient's need for analgesics seems to decrease progressively during the first week (Almasoud, 2018, Diddige *et al.*, 2020, Miller *et al.*, 2007, Shalish *et al.*, 2012, White *et al.*, 2017).

**3. The disturbances of daily life**

Four studies have evaluated the disturbances of daily life.

In the group of patients treated with a fixed appliance, there are limitations or pain during chewing (Alajmi *et al.*, 2019, Masi-Damois, 2015), consequently influencing the diet. It doesn’t return to completely normal after two weeks (Shalish *et al.*, 2012); there may also be a restriction on the quantity and type of food (Alajmi *et al.*, 2019). General activity also appears to be impacted and constantly decreasing (Diddige *et al.*, 2020, Miller *et al.*, 2007), as is the speech, which for its part returns to its basic state at the end of the week (Diddige *et al.*,

2020). This group has ulcers in the mucosa. (Alajmi *et al.*, 2019).
In the group of patients treated with the aligners there are difficulties with speech until the 7th day (Diddige *et al.*, 2020); as well as limitations on the desire to speak and changes (Alajmi *et al.*, 2019). Pain is present the first 3 days during chewing (Masi-Damois, 2015). General activity is also reduced, up to the 7th day in some patients (Diddige *et al.*, 2020), or stops on the 4th day in others (Miller *et al.*, 2007).
Dietary limitations seem to be greater in the fixed patient group (Alajmi *et al.*, 2019, Diddige *et al.*, 2020) as well as the impact on quality of life (Masi-Damois, 2015), the general activity, and oral symptoms (Shalish *et al.*, 2012).

## 4. Satisfaction

Three studies have evaluated the satisfaction.
Aligners patients seem to be more satisfied with the appearance of their appliance (Alajmi *et al.*, 2019, Diddige *et al.*, 2020), although patients in both groups recommend their own appliance and are not interested in the other option (Alajmi *et al.*, 2019).
The satisfaction level of the aligners group is high throughout the week, while in the patient group with a fixed appliance, it evolves positively over the days (Miller *et al.*, 2007).

## 5. Limitations of the studies

### 5.1 Age

Information on the age of participants is not complete in all studies, especially in White *et a.l*'s (2017) study which does not even mention this parameter.
For the studies that provide this information, the average age of the entire study ranges from 16 (Masi-Damois, 2015) to 30.3 years (Shalish *et al.*, 2012), which is a big difference. Some studies include patients from 11 years old (Masi-Damois, 2015) while others do from 18 years old (Alajmi *et al.*, 2019, Diddige *et al.*, 2020, Fujiyama *et al.*, 2014, Miller *et al.*, 2007, Shalish *et al.*, 2012); the age limit also varies from 30 (Diddige *et al.*, 2020, Masi-Damois, 2015) to 60 (Shalish *et al.*, 2012).
The mean age, when indicated, of the Invisalign groups (27.42) is slightly higher than that of the fixed group (24.32), but remains fairly similar.
On the one hand, the lack of information, and on the other hand the age difference between

the different studies, this can represent a risk of bias.
Brown and Moerenhout (1991) reported a variation in pain ratio between adolescents, pre-adolescents and adults during orthodontic treatment, with more intense pain reporting in adolescents. Therefore, one would expect a higher perception of pain in studies with an average age closer to 15-16 years (Masi-Damois, 2015), in comparison with studies including patients only from 18 years old (Alajmi *et al.*, 2019, Diddige *et al.*, 2020, Fujiyama *et al.*, 2014, Miller *et al.*, 2007, Shalish *et al.*, 2012)
However, Scott *et al.* (2008) and Ngan *et al.* (1989) Demonstrated that there was no relationship between age and the perception of pain.
We cannot therefore conclude to date that this parameter represents a limitation or a risk of bias in comparing the different studies.

### 5.2 Analgesics

Only one study (Fujiyama *et al.*, 2014) did not compare the use of painkillers between the two groups, which represents a lack of essential information. Indeed, the purpose of taking pain relievers being to prevent or reduce the sensation of pain, this can have serious consequences on the validity of interpretation of the results.

### 5.3 Randomization

Within the eight studies represented in this systematic review, only two are randomized (Diddige *et al.*, 2020, White *et al.*, 2017) and by definition, therefore have more reliable results, since their design has made it possible to limit certain biases that could distort the results of the research. However, Diddige *et al.*, (2020) spoke of the fact that random assignment of treatment could also have a negative effect, as choosing the best equipment for a specific age group and gender could help reduce the pain level for most people. patients.
In the other studies, the means of allocating treatment between groups remains rather vague; we can assume that, starting on an equal footing with the inclusion criteria, treatment was not imposed on them but it was they who chose the one they preferred.

### 5.4 Removable

Another limitation within this systematic review is the fact that one of the essential

characteristics of aligners is that they are removable. This can therefore represent a bias within studies at several levels. First of all we have to take into account the fact that the gutter must be systematically removed during meals, oral hygiene, as well as in patients who smoke. This represents approximately 22 hours of wearing the tray over 24 hours, so patients undergoing treatment with aligners are subject to a shorter potential duration of onset of pain than patients under fixed treatment. In addition, we can assume that patients may have removed their gutters for a period of time due to the pain, or for some other reason other than those recommended. Thus, it could distort the results.

### 5.5 Cultural, religious, ethnic, and socio-economic differences

Several studies (Edwards *et al.*, 2001; Krupić *et al.,* 2019; Cleland *et al.* 2005; Wandner *et al.*, 2012) have shown that there are differences between ethnic, cultural and religious groups in their relationship to pain, as much in the intensity felt as in the will to express it. However, in the studies of this systematic review, we find no details on this aspect but six countries are represented: Canada, India, Israel, the USA, Saudi Arabia, Japan.

Furthermore, as demonstrated in Dorner *et al.*'s study (2011), the socio-economic level can influence the level of pain, with an inversely proportional evolution between pain and socio-economic status; but only the studies of Miller *et al.*, (2007) and Shalish *et al.*, (2012) took patients from private and university clinics, allowing to have a larger socio-economic panel leading to a reduction of a potential bias. Alajmi *et al.*, (2019) also showed, however, that there was no significant difference in socio-economic status between his patients. On the contrary, the studies of Almasoud, (2018) and Fujiyama *et al.*, (2014) include only patients coming from private clinics, and we can therefore expect a lower level of pain than in the studies of Masi-Damois, (2015) and White *et al.*, (2017 which recruited their patients only in university clinics.

Miller *et al.*, (2007), having recruited in both types of clinics, was able to observe that the patients treated with Invisalign had greater incomes and 78% came from the private clinic against 44% for the fixed group.

### 5.6 Equipment

We were able to note a great diversity of material selected for the fixed devices during the different studies. However, research has shown that this parameter can influence pain.

Thus, patients treated with CuNiTi seem to experience greater pain than those treated with NiTi (Papageorgiou *et al.,* 2014) ; patients in the Almasoud, (2018), Diddige *et al.*, (2020), and Masi-Damois, (2015) studies should therefore have greater pain intensity than those in the Alajmi *et al.*, (2019) and Shalish *et al.*, (2012) studies. This parameter could be an explanation for the constantly contrary results of Shalish *et al.*, 's study (2012).
In addition, those treated with superelastic NiTi experience greater pain than those treated with multistranded stainless steel (Sandhu, 2013) over the 1st day period, so patients in the Alajmi *et al.*, (2019) study should experience greater pain than those from the Masi-Damois study (2015).

For aligners only one study used the Smile Align brand and not Invisalign (Diddige *et al.*, 2020). Besides the brand, we have no other information as to the characteristics of the gutters; however research (Hahn *et al.,* 2009 ; Kwon *et al.*, 2008) has shown that characteristics such as the thickness of the gutter can influence the force exerted and therefore cause more or less pain. We can however assume that Invisalign has more setbacks because it is the first to have marketed these gutters; they could therefore be more successful and provide less pain than other brands.

5.7 Inclusion criteria

Another point that can influence the adequate comparison of our studies is the inclusion criteria. Even if they remain fairly similar overall, some studies have developed them less than others, notably the study by Shalish *et al.*, (2012), who counted as an only criterion for inclusion, an age between 18 and 60 years. Studies by Alajmi *et al.*, (2019), Diddige *et al.*, (2020), Masi-Damois (2015) and White *et al.*, (2017) required treatment without extraction, while in Miller *et al.*,'s study (2007), patients with pre-molar or incisor extractions were accepted. Not specified in the inclusion criteria, extractions were made in the Fujiyama *et al.*,study (2014), and were not similar in the different groups, which could have resulted in a difference in pain feeling following the surgery. Likewise, Fujiyama *et al.*, (2014), Miller *et al.*, (2007) and Shalish *et al.*, (2012) did not necessarily want a full arch. The Angle Class of the molar relationship was not specified for the studies of Fujiyama *et al.*, (2014), Miller *et al.*, (2007) and Shalish *et al.*, (2012). Light to moderate congestion was requested only in the studies of Alajmi *et al.*, (2019), Almasoud (2018), Diddige *et al.*, (2020) and White *et al.*, (2017). In Masi-Damois's study (2015), the lack of precision in the latter criterion caused an

inequality of overlap between the two groups.
These different studies include patients with dental characteristics that are not all identical, so we can expect results that are not entirely comparable.

## 5.8 Gender

On average, the number of female participants represented 64% in each study. In the Invisalign group, they were in majority with 66%; and in the fixed group also with 63%.
On average, in the two groups and in all of the studies, they were therefore in the majority, but sex could have an influence on the perception of pain.
Indeed, according to (Bartley and Fillingim, 2013 ; Scheurer *et al.,* 1996 ; Pieretti *et al.,* 2016) women can experience more severe pain, indeed they seem to be more sensitive to it than men
In contrast, according to Jones (1984), and Fleming *et al.* (2009) it would have no significant gender differences in the perception of pain.
We cannot therefore conclude that this inequality between the two sexes is a bias in comparing these studies.

## 5.9 Sample size

As mentioned in the studies by Almasoud (2018) and Diddige *et al.*, (2020), the size of the samples seems to be too small and therefore necessarily representative.

## IV. CONCLUSION

As a conclusion of this systematic review, we can say that in a majority of studies, pain in patients using gutters seems to be less intense than in patients with fixed appliances, the analgesic intake, as a consequence of this, is more important for the fixed group. Pain and analgesic intake follow the same pattern for both types of devices, i.e. a gradual decrease.

In everyday life, both groups seem to be disturbed in activities such as chewing, speech and activity in general.

Patients treated with gutters seem to be more satisfied, but patients treated with fixed appliances gradually adjust to their new appearance and eventually become satisfied as well.

The use of more detailed and comparable methodologies should be considered in all orthodontic trials.

## BIBLIOGRAPHY


1. Alajmi, S., Shaban, A., & Al-Azemi, R. (2019). Comparison of short-term oral impacts experienced by patients treated with Invisalign or conventional fixed orthodontic appliances. *Medical principles and practice : international journal of the Kuwait University, Health Science Centre*, 10.1159/000505459.
2. Almasoud N. N. (2018). Pain perception among patients treated with passive self-ligating fixed appliances and Invisalign®aligners during the first week of orthodontic treatment. *Korean journal of orthodontics*, *48*(5), pp. 326–332.
3. Baron P. (2014). Les appareils orthodontiques invisibles et presque invisibles [Invisible and almost invisible orthodontic appliances]. *L' Orthodontie francaise*, *85*(1), pp. 59–91.
4. Bartley, E. J., & Fillingim, R. B. (2013). Sex differences in pain: a brief review of clinical and experimental findings. *British journal of anaesthesia*, *111*(1), pp. 52–58.
5. Brown, D. F., & Moerenhout, R. G. (1991). The pain experience and psychological adjustment to orthodontic treatment of preadolescents, adolescents, and adults. American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics, 100(4), pp. 349–356.
6. Cleland, J.A., Palmer, J.A., & Venzke, J.W. (2005). Ethnic differences in pain perception. *Physical Therapy Review, 10* (2), pp. 113-122.
7. Diddige, R., *et alii*. (2020). Comparison of pain levels in patients treated with 3 different orthodontic appliances - a randomized trial. *Medicine and pharmacy reports*, *93*(1), pp. 81–88.
8. Dorner, T. E., *et alii*. (2011). The impact of socio-economic status on pain and the perception of disability due to pain. *European journal of pain (London, England)*, *15*(1), pp. 103–109.
9. Edwards, C. L., Fillingim, R. B., & Keefe, F. (2001). Race, ethnicity and pain. *Pain*, *94*(2), pp. 133–137.
10. Fleming, P., *et alii*. (2009). Pain experience during initial alignment with a self-ligating and a conventional fixed orthodontic appliance system. A randomized controlled clinical trial. *The Angle orthodontist*, *79*(1), pp. 46–50.
11. Fujiyama, K., *et alii*. (2014). Analysis of pain level in cases treated with Invisalign aligner: comparison with fixed edgewise appliance therapy. *Progress in orthodontics*, *15*(1), p. 64.

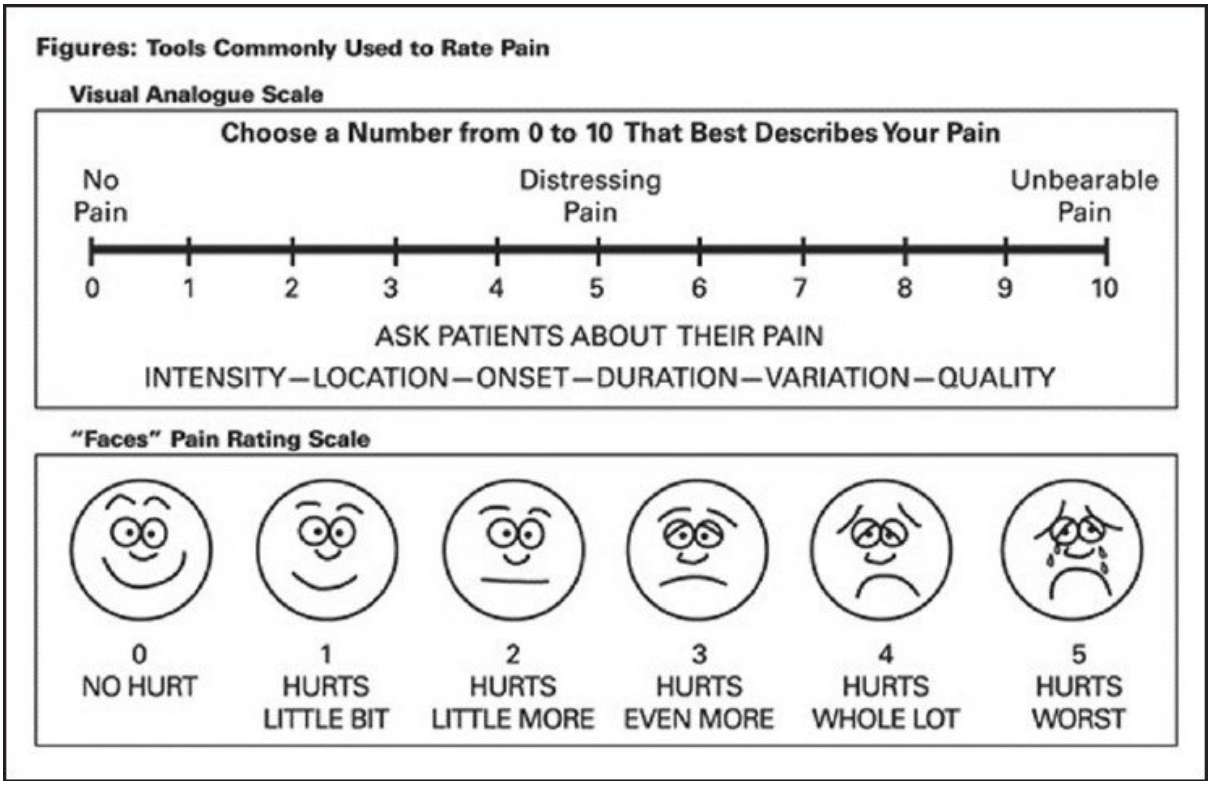
12. Global growth strategy [Online]**.** Available on <http://investor.aligntech.com/static-files/4ce29ad2-255d-4e4c-9806-14ba06ea3a8c>. [Consulted the 13/04/2020]
13. Hahn, W., et alii. (2009). Influence of thermoplastic appliance thickness on the magnitude of force delivered to a maxillary central incisor during tipping. American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics, 136(1), 12.e1–13.
14. Histoire de l'orthodontie [Online]. Available on <http://www.sfodf.org/avada_portfolio/histoire-de-lorthodontie/>. [Consulted the 13/04/2020]
15. How it works [Online]. Available on <https://smiledirectclub.co.uk/en-gb/>. [Consulted the 13/04/2020]
16. Invisalign® [Online]. Available on <https://www.invisalign.com>. [Consulted the 13/04/2020]
17. Jones M. L. (1984). An investigation into the initial discomfort caused by placement of an archwire. *European journal of orthodontics*, *6*(1), pp. 48–54
18. Krupić, F., *et alii*. (2019). Ethnic differences in the perception of pain: a systematic review of qualitative and quantitative research. *Medicinski glasnik : official publication of the Medical Association of Zenica-Doboj Canton, Bosnia and Herzegovina*, *16*(1), pp. 108–114.
19. Kwon, J. S., et alii. (2008). Force delivery properties of thermoplastic orthodontic materials. American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics, 133(2), pp. 228–328.
20. Les origines des traitements orthodontiques par gouttières [Online]. Available on <https://www.bloomsquare.com/2019/09/03/blog-1/ >. [Consulted the 13/04/2020]
21. Masi-damois C. Comparaison de la perception de la douleur entre le traitement orthodontique avec Invisalign® et le traitement avec fils et boîtiers fixes; 2015.
22. Miller, K. B., et alii. (2007). A comparison of treatment impacts between Invisalign aligner and fixed appliance therapy during the first week of treatment. American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics, 131(3), p. 302.
23. Ngan, P., Kess, B., & Wilson, S. (1989). Perception of discomfort by patients undergoing

orthodontic treatment. American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics, 96(1), pp. 47–53.

24. Papageorgiou, S. N., *et alii.* (2014). A systematic review and meta-analysis of experimental clinical evidence on initial aligning archwires and archwire sequences. *Orthodontics & craniofacial research*, *17*(4), pp. 197–215.
25. Pieretti, S., *et alii*. (2016). Gender differences in pain and its relief. *Annali dell'Istituto superiore di sanita*, *52*(2), pp. 184–189.
26. PRISMA flow diagram [Online]. Available on <http://www.prisma-statement.org>. [Consulted the 14/11/2019]
27. Sandhu, S. S., & Sandhu, J. (2013). A randomized clinical trial investigating pain associated with superelastic nickel-titanium and multistranded stainless steel archwires during the initial leveling and aligning phase of orthodontic treatment. *Journal of orthodontics*, *40*(4), pp. 276–285.
28. Scheurer, P. A., Firestone, A. R., & Bürgin, W. B. (1996). Perception of pain as a result of orthodontic treatment with fixed appliances. *European journal of orthodontics*, *18*(4), pp. 349–357.
29. Scott, P., *et alii*. (2008). Perception of discomfort during initial orthodontic tooth alignment using a self-ligating or conventional bracket system: a randomized clinical trial. *European journal of orthodontics*, *30*(3), pp. 227–232.
30. Shalish, M., *et alii*. (2012). Adult patients' adjustability to orthodontic appliances. Part I: a comparison between Labial, Lingual, and Invisalign™. *European journal of orthodontics*, *34*(6), pp. 724–730.
31. The international association for the study of pain [Online]. Available on <https://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1698#Pain>. [Consulted the 28/02/2020].
32. Wandner, L. D., *et alii*. (2012). The perception of pain in others: how gender, race, and age influence pain expectations. *The journal of pain : official journal of the American Pain Society*, *13*(3), pp. 220–227.
33. White, D. W., *et alii*. (2017). Discomfort associated with Invisalign and traditional brackets: A randomized, prospective trial. *The Angle orthodontist*, *87*(6), pp. 801–808.

**ANNEX**

Annex 1 : Visual Analog Scale



## Annex 2 : Daily report

**Instructions:** Please complete the following survey about how your teeth or orthodontic appliances (braces or aligners) have affected your life since you started treatment. Answer only what you feel and have experienced, not what you think is the right answer. There are no right or wrong answers to these questions.

**1. Please circle one response for each of the following questions.**

| **In the past 24 hours, how often:** | Always | Often | Some-times | Seldom | Never |
|---|---|---|---|---|---|
| a. did you limit the kinds or amounts of food you eat because of problems with your mouth, teeth, or orthodontic appliances? | 1 | 2 | 3 | 4 | 5 |
| b. did you have trouble biting or chewing any kinds of food, such as firm meat or apples? | 1 | 2 | 3 | 4 | 5 |
| c. were you able to swallow comfortably? | 1 | 2 | 3 | 4 | 5 |
| d. did your teeth or orthodontic appliances prevent you from speaking the way you wanted? | 1 | 2 | 3 | 4 | 5 |
| e. were you able to eat anything without feeling discomfort? | 1 | 2 | 3 | 4 | 5 |
| f. did you limit contact with people because of the condition of your teeth or orthodontic appliances? | 1 | 2 | 3 | 4 | 5 |
| g. were you pleased or happy with the looks of your teeth or orthodontic appliances? | 1 | 2 | 3 | 4 | 5 |
| h. did you use medication to relieve pain or discomfort from around your mouth? | 1 | 2 | 3 | 4 | 5 |
| i. were you worried or concerned about the problems with your teeth or orthodontic appliances? | 1 | 2 | 3 | 4 | 5 |
| j. did you feel nervous or self-conscious because of problems with your teeth or orthodontic appliances? | 1 | 2 | 3 | 4 | 5 |
| k. did you feel uncomfortable eating in front of people because of problems with your teeth or orthodontic appliances? | 1 | 2 | 3 | 4 | 5 |
| l. were your teeth sensitive to hot, cold, or sweets? | 1 | 2 | 3 | 4 | 5 |
| m. did your orthodontic appliances cause discomfort to your cheeks, lips, or tongue | 1 | 2 | 3 | 4 | 5 |

**2. Please mark an "X" on the line below to indicate how severe your discomfort has been within the last 24 hours:**

_____

**No pain** **Severe Pain**

**3. Please indicate what time of the day you are filling out this survey:**

_____:_____ **AM/PM**

**hh mm**

**4. A) Have you taken any medications today? Y/N (please circle)**

**B) If so, please write in which medications you took today:**

_____

**5. Are you having any other problems or concerns about your teeth or orthodontic appliances since your last orthodontic visit? If so, please describe.**

_____

_____

Annex 3 : Oral Health Related Quality of Life

*OHRQoL Questionnaire*

You have received an orthodontic appliance. To improve the quality of care, it is important for us to know how the appliance has affected you. Please take a few moments to complete this survey. Please choose the number that corresponds to your assessment over the last week. Rate the worst pain you have felt during last week on a scale of 1–10 (1 – not at all, 10 – very much). Have you taken any medication to relieve pain? (0 = no, 1 = yes). For the following questions, please use this rating: 1 = no instances, 2 = few instances, 3 = some instances, 4 = several instances, 5 = numerous instances. Has it been difficult to speak? Has it been difficult to swallow? Has it been difficult to open your mouth? Were there any foods that you could not eat? Have you enjoyed your food? Have you noticed a change in your sense of taste? Was it difficult to sleep? Does the appliance disturb you at work or when studying? Has it been difficult to continue your daily activities? Do you have sores on your tongue? Do you have sores on your cheeks? Do you have sores on your lips? Have you had a bad taste or bad smell in your mouth? Has there been any food debris under the appliance?