



**Official title of the study:**

# **Factors Associated with Pain Level Experience During Orthodontic Treatment**

**NCT number: Not Available**

**Date of the document: 04 February 2021**

## Research Proposal

Research title	Factors Associate to Pain Level Experience during Orthodontic treatment
Main Investigator	CHIA JUNG, LEE
Abstract	<p>Orthodontic pain has been the primary concern from all patients who requires orthodontic treatment. The design of the study will help us comprehend how patient experienced and managed pain during their orthodontic treatment, average pain level in different orthodontic appliances and factors that could affect pain level experience during treatment, including gender, age, braces types, hygiene level and habitude. With this research, we can interpret the average pain level experience in orthodontic treatment from the survey and clinical data collected and find correlations within each individual respective of different pain level.</p>
Research background & Discussion	<ul style="list-style-type: none"> <li>• Since orthodontic pain has been the primary concern for patient, a thorough investigation for the pain level experience and it's factors related could help us explain to the patient better before starting their treatment, giving information of the general pain level and on what circumstances will patient experience more or less pain.</li> <li>• There are various clinical studies, literature reviews and hypotheses regarding to different factors that could or could not affect the experience the pain level during orthodontic treatment. Factors such as, type of orthodontic appliances (MBT, self-ligated, Invisalign), gender, age, depression history, hygiene level.... were mentioned in different literature that it could affect their pain perception.</li> <li>• This study is to conclude and correlate factors that could affect one's pain perception during orthodontic treatment</li> </ul>
Objective & Hypothesis of the research	<ul style="list-style-type: none"> <li>• The main objective is to compare pain level between different orthodontic appliances (MBT, self-ligated, Invisalign)</li> <li>• The secondary objective is to compare pain level within different factors such as gender, age, history of masticatory pain, history of depression, hygiene level and habitude.</li> <li>• The hypothesis of the research is that different pain level is multifactored and with different appliance, age, gender, the pain level could be more alleviated or intense.</li> </ul>
Methodology	<ul style="list-style-type: none"> <li>• Study type: Observational</li> <li>• Cross-sectional analysis of participants who received orthodontic treatment from UAX Innovation and Advanced Specialty Clinic.</li> <li>• Inclusion criteria: <ul style="list-style-type: none"> <li>-Patient with orthodontic treatment over 2 months and less than 18 months</li> <li>-Patient with braces or Invisalign</li> <li>-Patient who goes to orthodontic visit routinely</li> </ul> </li> <li>• Exclusion criteria: <ul style="list-style-type: none"> <li>-Patient undergoing ONLY orthopaedic treatment (functional appliances, 2x4 braces placement, maxillary expansion device)</li> <li>-Patient who does not understand Spanish</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>-Patient with cognitive impairment</li> <li>-Patient who does not want to participate in the study</li> <li>-Patient who has compete their orthodontic treatment</li> <li>• A simple random sampling of orthodontic patients who attended periodically. Each consultation was carried out by a total of 12 dentist with more than 2 years of clinical practice experiences and who agreed to pass on their patient's clinical reports to gather their information.</li> <li>• The minimum sample size for the study was determined in 150 participants</li> <li>• Consent form (Jotform) and Survey (Surveyhero) was generated as a link and sent to each participant through Whatsapp to complete online.</li> <li>• Questionnaire was assessed through GESIS survey guideline to ensure the efficacy of each questions and quality of the survey data.</li> <li>• The outcome measure of the pain level experience is based on visual analogue scale (VAS)</li> </ul>
Planning for the analysis of the result	<ul style="list-style-type: none"> <li>• Expectation: Study showed that: <ul style="list-style-type: none"> <li>-Invisalign treatment exhibit the least pain out of all kinds of orthodontic appliances.</li> <li>-Women tend to tolerate less the pain (hence higher pain level)</li> <li>-Age has no influence in different pain level experience during orthodontic treatment</li> <li>-History of depression could have higher pain level</li> </ul> </li> <li>• The limitations of the research were: <ul style="list-style-type: none"> <li>-The ethnicity of the participants were mainly Spanish</li> <li>-The participants for Invisalign treatment in general are elder patients, and the older the pain the better pain tolerance they have.</li> <li>-Perception of pain varies between each individual (inter-individual variability), it could be interpreted by different perspective biologically and psychologically.</li> </ul> </li> </ul>
Expectation of the research	<p>Hypothetically based on different studies:</p> <ul style="list-style-type: none"> <li>-Invisalign treatment exhibit the least pain out of all kinds of orthodontic appliances.</li> <li>-Women tend to tolerate less the pain (hence higher pain level)</li> <li>-Age has no influence in different pain level experience during orthodontic treatment</li> <li>-History of depression could have higher pain level</li> </ul>
Bibliographic reference	<ol style="list-style-type: none"> <li>1) Scheurer PA, Firestone AR, Bürgin WB. Perception of pain as a result of orthodontic treatment with fixed appliances. <i>Eur J Orthod.</i> 1996 Aug;18(4):349-57. PubMed 8921656</li> <li>2) Cardoso PC, Espinosa DG, Mecenas P, Flores-Mir C, Normando D. Pain level between clear aligners and fixed appliances: a systematic review. <i>Prog Orthod.</i> 2020 Jan 20;21(1):3. doi: 10.1186/s40510-019-0303-z. PubMed 31956934</li> <li>3) Krukemeyer AM, Arruda AO, Inglehart MR. Pain and orthodontic treatment. <i>Angle Orthod.</i> 2009 Nov;79(6):1175-81. doi: 10.2319/121308-632R.1. PubMed 19852612</li> <li>4) Banerjee S, Banerjee R, Shenoy U, Agarkar S, Bhattacharya S. Effect of orthodontic pain on quality of life of patients undergoing</li> </ol>

	<p>orthodontic treatment. <i>Indian J Dent Res.</i> 2018 Jan-Feb;29(1):4-9. doi: 10.4103/ ijdr.IJDR_113_16. PubMed 29442079</p> <p>5) Kafle D, Rajbhandari A. Anticipated pain and pain experience among orthodontic patients: is there any difference? <i>Kathmandu Univ Med J (KUMJ).</i> 2012 Apr-Jun;10(38):71-3. PubMed 23132480</p> <p>6) Nicotra C, Polizzi A, Zappalà G, Leonida A, Indelicato F, Caccianiga G. A Comparative Assessment of Pain Caused by the Placement of Banded Orthodontic Appliances with and without Low-Level Laser Therapy: A Randomized Controlled Prospective Study. <i>Dent J (Basel).</i> 2020 Mar 4;8(1). pii: E24. doi: 10.3390/dj8010024. PubMed 32143365</p> <p>7) Campbell P, Jordan KP, Smith BH, Scotland G, Dunn KM. Chronic pain in families: a cross-sectional study of shared social, behavioural, and environmental influences. <i>Pain.</i> 2018 Jan;159(1):41-47. doi: 10.1097/j.pain.0000000000001062. PMID: 28937576; PMCID: PMC5737454.</p> <p>8) Fillingim RB. Individual differences in pain: understanding the mosaic that makes pain personal. <i>Pain.</i> 2017 Apr;158 Suppl 1(Suppl 1):S11-S18. doi: 10.1097/j.pain.0000000000000775. PMID: 27902569; PMCID: PMC5350021.</p> <p>9) <a href="https://www.physio-pedia.com/Visual_Analogue_Scale_Description">https://www.physio-pedia.com/Visual_Analogue_Scale_Description</a> The Visual analogue Scale (VAS) for pain assessment</p> <p>10) <a href="https://eu.jotform.com/myforms/">https://eu.jotform.com/myforms/</a>? Description Online consent form for the survey</p> <p>11) <a href="https://www.surveymonkey.com">https://www.surveymonkey.com</a> Description Questionnaire designed and distributed through this website</p>
Research programme	<ul style="list-style-type: none"> <li>• Time frame: From 4<sup>th</sup> of February 2021 to 31<sup>st</sup> of March 2022</li> <li>• Investigator: Chia Jung, Lee</li> <li>• Resources: UAX clinic, Textbooks, Pubmed, Research gate</li> <li>• Auxiliary tools: Jotform (consent form), Surveyhero (questionnaire)</li> <li>• Estimate cost: Around 1700 euros <ul style="list-style-type: none"> <li>-Annual fee for the survey form</li> <li>-Orthodontic cleaning kits (For the raffle)</li> <li>-Fee for ethical committee of Spain approval</li> </ul> </li> </ul>
Appendices	<p>Attachment below:</p> <ul style="list-style-type: none"> <li>• Questionnaire</li> </ul>

# Questionnaire Title: Pain Level Experience during Orthodontic Treatment

## Survey questions:

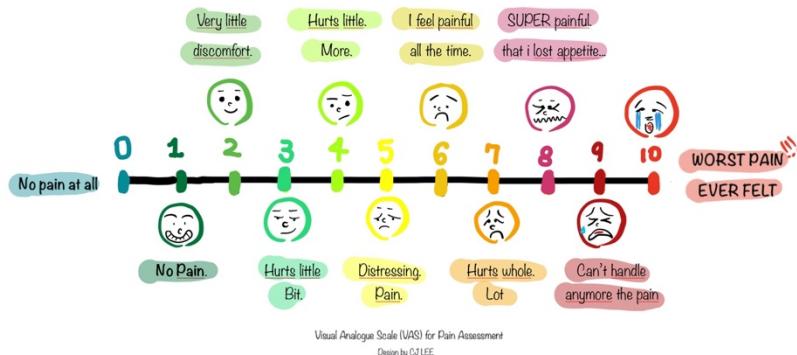
Full Name (First and Last name): \_\_\_\_\_

- 1) What is your gender?
  - a. Male
  - b. Female
- 2) What is your age? \_\_\_\_\_
- 3) What is your estimate orthodontic treatment time?
  - a. 6 months
  - b. 12months
  - c. 18months
  - d. 24months
  - e. 30months
- 4) What kind of treatments are done or expected to be done? (multiple choices)
  - a. Metallic or aesthetic Braces
  - b. Clear aligner (Invisalign)
  - c. Extractions of teeth
  - d. Interproximal reduction (stripping of teeth)
  - e. Elastic placement (Doctor assigned me to do daily)
- 5) Do you have history of anxiety or depression?
  - a. Yes
  - b. No
- 6) Do you smoke?
  - a. Yes
  - b. No
- 7) Are you on prescription of any medication in general? What is the name of the medication? (If you are NOT on any prescription medication you can skip the question). \_\_\_\_\_
- 8) Do you normally have masticatory muscle pain or grind your teeth at night?
  - a. Yes
  - b. No
- 9) On what occasion do you clean your teeth?
  - a. Only in the morning
  - b. Only at night
  - c. Morning & Night
  - d. Morning & Night & every time after meal
- 10) Does your gum bleed while brushing?
  - a. Yes
  - b. Sometime
  - c. No



Option e

11) From 0-10, how was **the initial pain** after the appointment of bracket cementation or your first Invisalign retainer? \_\_\_\_\_



12) Which day after the **INICIAL** braces cementation you experience **the most intense pain**?

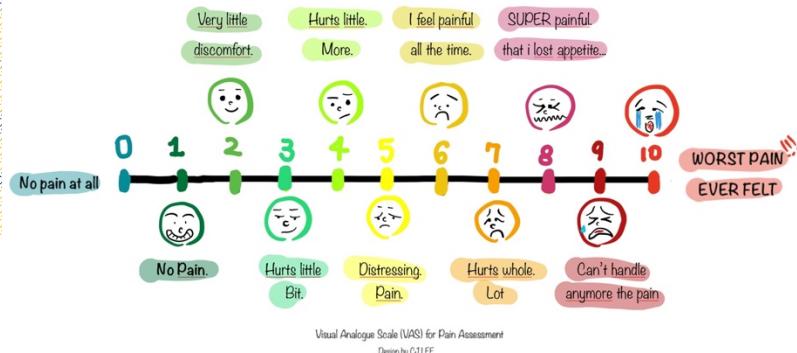
- a. 1<sup>st</sup> day
- b. 2<sup>nd</sup> day
- c. 3<sup>rd</sup> day
- d. 1<sup>st</sup> week in general
- e. 1<sup>st</sup> +2<sup>nd</sup> week

13) Which day after the **INICIAL** braces cementation your pain was **alleviated**?

(The previous question was: Which day after the **INICIAL** braces cementation you experience **the most intense pain**?)

- a. 1<sup>st</sup> day
- b. 2<sup>nd</sup> day
- c. 3<sup>rd</sup> day
- d. 1<sup>st</sup> week in general
- e. 1<sup>st</sup> +2<sup>nd</sup> week

14) From 0-10, how was **the pain after every orthodontic visit** when new arch wires are placed or when new Invisalign retainers are changed? \_\_\_\_\_



15) Which day after the **regular visit** you experience **the most intense pain**?

- a. 1<sup>st</sup> day
- b. 2<sup>nd</sup> day
- c. 3<sup>rd</sup> day
- d. 1<sup>st</sup> week in general
- e. 1<sup>st</sup> +2<sup>nd</sup> week

16) Which day after **the regular visit** your pain is **alleviated**?

(The previous question was: Which day after the regular visit you experience the **most intense pain**?)

- a. 1<sup>st</sup> day
- b. 2<sup>nd</sup> day
- c. 3<sup>rd</sup> day
- d. 1<sup>st</sup> week in general
- e. 1<sup>st</sup> +2<sup>nd</sup> week

17) When you had pain during orthodontic treatment, did you take analgesics?

- a. Yes (Include sometimes)
- b. No

18) At which moment do you normally take the analgesic? (Multiple choices)

(The previous question was: When you had pain during orthodontic treatment, did you take analgesics?)

- a. The first few day (Initial of treatment) after braces were placed
- b. After each regular visits when arch wires are changed or new Invisalign retainer was changed
- c. Other reasons (tooth extractions, headache, back pain, TMJ pain, masticatory muscle pain)

19) If you had taken analgesic, what is the name of the analgesic? \_\_\_\_\_

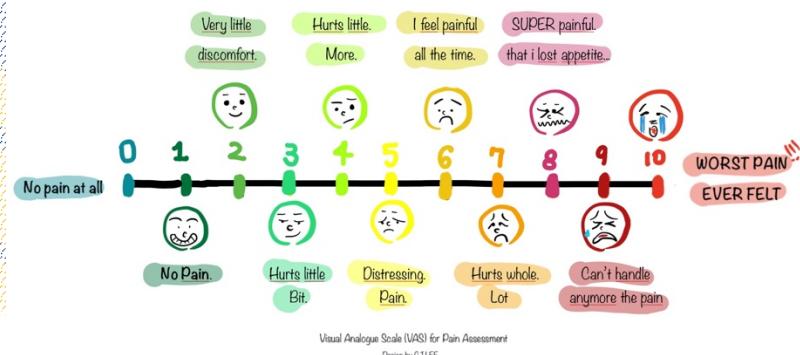
(The previous question was: At which moment do you normally take the analgesic?)

20) Did the pain relieve after intaking the analgesic?

(The previous question was: If you had taken analgesic, what is the name of the analgesic?)

- a. Yes
- b. No

21) In **general** do you find orthodontic a painful treatment? Grade it from 0-10 \_\_\_\_\_



22) Are you satisfied with your orthodontic treatment at the moment? Grade 0-5: \_\_\_\_\_

23) Do you have any suggestions regarding to your orthodontic treatment to help us improve?

24) Would you like to join the raffle and win an orthodontic cleaning kit?

- a. Yes and please inform me!
- b. No, thank you ☺



**Thank you for your participation, we really appreciate you help!**