# Comparison Between the Quality of Finishing and Mini-Esthetics of Three Different Bracket Positioning Techniques Using the ABO Objective Grading System: A Randomized Clinical Trial

ClinicalTrials.gov Study Document

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| **Sponsor:** | Faculty of Oral and Dental Medicine, Future University in Egypt |
| **Principal Investigator:** | Hager Mansour Abdelbasser, BDS |
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# RESEARCH ETHICS COMMITTEE
## Faculty of Oral and Dental Medicine
## (REC-FODM)
CONSENT FORM (#3)

**Title of Research:**
Comparison Between the Quality of Finishing and Mini-Esthetics of Three Different Bracket Positioning Techniques Using the ABO Objective Grading System: A Randomized Clinical Trial

## Part I – Research Participant Information Sheet:

A. **Purpose of the Research** Determining the Quality of Finishing using American Board of Orthodontics (ABO)-Objective Grading System of 3 different bracket positioning techniques.
In addition, to evaluate the mini-esthetics (maxillary gingival display, maxillary incisor display, smile arc, buccal corridor and lip line) of the 3 different bracket positioning techniques using standardized frontal photographs analyzed with Adobe Photoshop CC 2017 software, as a secondary outcome

**B. Description of the Research:** this trial will involve placing orthodontic brackets to compare the quality of finishing and mini-esthetics between three different bracket techniques.

**C. Potential Risks and Discomforts:** pain associated with tooth movement, inflammation of mucosal tissues

**D. Potential Benefits:** orthodontic treatment is done for the patient as indicated, improving patients' esthetics, function and psychology including crowding.

**E. Cost:** To participate in the research you will bear no additional costs or extra loss.

***F.* Compensation / Treatment:**
In the event of injury resulting from participation in this research study, Researcher will make a treatment to you, its facilities and professional attention. Financial compensation from FUE/FODM is not available.

**G. Voluntary Participation:**
Participation in this study is voluntary. You will suffer no penalty nor loss of any benefits to which you are otherwise entitled should you decide not to participate. Withdrawal from this research study will not affect your ability to receive alternative methods of Dental care available at FUE/FODM. Significant new findings developed during the course of the research study which might be reasonably expected to affect your willingness to continue to participate in the research study will be provided to you.

**H. Confidentiality:**

*Your identity and medical* record, as a participant in this research study, will remain confidential with respect to any publications that may result from this study. Furthermore, your Dental/medical record may be reviewed by the Research Advisory Council or the agency sponsoring this research in accordance with applicable laws and regulations.

**I. Contact Person(s):**

_____

_____

**A signed copy of the consent form will be given to you.**

## PART II - Authorization for performance of certain procedures:

**1. I/surrogate authorize Dr. Hager Mansour and her associates to administer the following drugs, use the following devices or perform the following procedures during my treatment (or the treatment of the person named above for whom I am responsible)**

_____

**2. I acknowledge that I have read, or had explained to me in a language I understand, the attached Research Participant Information sheet and that Dr. Hager Mansour has explained to me the nature of the procedures described in the Research Participant Information Sheet as well as any benefits to be expected, possible alternative methods of treatment, the attendant discomforts and risks reasonably to be expected and the possibility that complications from both known and unknown causes may arise as a result thereof. I was given ample opportunity to comprehensively inquire about this study and procedures and all my questions were answered to my satisfaction.**

**3. I understand that I am not entitled for reimbursement for expenses incurred as a result of my participation in this study**

**4. I voluntarily accept the risks associated with the above-mentioned procedures with the knowledge and understanding that the extent to which they may be effective in my treatment (or the treatment of the patient named above, as the case may be) has not been established, that there may be side effects and complications from both known and unknown causes and that these procedures may not result in cure or improvement.**

**5. I understand that I am free to withdraw this consent and discontinue treatment with the above procedures at any time. The consequences and risks, if any, which might be involved in the event I later decide to discontinue such treatment, have been explained to me adequately. I understand that such withdrawal will not affect my ability to receive any dental/medical care made necessary by the performance of such studies or to which I might be otherwise entitled.**

**6. I confirm that I have read, or had read to me, the foregoing authorization and that all blanks or statements requiring completion were properly completed before I signed.**

**Patient Name:**_____

**File #:** _____

**Patient/Surrogate:** (If signed by Surrogate)

Signature Date

**Relationship:**

_____

_____ _____

**7. I confirm that I have accurately translated and/or read the information to the subject or his/her surrogate.**

**Name:**
_____

**Signature:**
_____

**FUE ID #:** _____
**Date:** ___
_____

**8. I have fully explained to the above patient/ relative/ guardian the nature and purpose of the foregoing procedures, possible alternative methods of treatment which might be advantageous, the reasonable benefits to be expected, the attendant discomforts and risks involved, the possibility that complications may arise as a result thereof and the consequences and risks, if any, which might be involved in the event the patient/ relative/ guardian hereafter decides to discontinue such treatment.**
**It is my understanding that the above patient/ relative/ guardian understand the nature, purposes, benefits, and risks of participation in this research before signing ~~of~~ this informed consent. I have also offered to answer any questions the above patient/ relative/ guardian might have with respect to such procedures and have fully and completely answered all such questions.**

**(Signature of Principal Investigator/ Delegate):**
_____

**Print Name: Hager Mansour**

**Title: Master Student at FUE.**

**Date: 1/7/2024**