Evaluation of the Rate of En-masse Retraction in Orthodontic Patients with Maxillary Protrusion Using Friction versus Frictionless Mechanics: A Randomized Clinical Trial

Consent Form

Faculty of Oral and Dental Medicine, Future University

Submitted by

Name**: Leena Alaa Shibl**

B.D.S. Future University in Egypt, 2015

(2019)

RESEARCH ETHICS COMMITTEE
Faculty of Oral and Dental Medicine
(REC-FODM)
CONSENT FORM

Title of Research:

Evaluation of the Rate of En-masse Retraction in Orthodontic Patients with Maxillary Protrusion Using Friction versus Frictionless Mechanics: A Randomized Clinical Trial

Part I – Research Participant Information Sheet:

A. Purpose of the Research:

Comparing between two techniques used for en-masse retraction (friction vs. frictionless)

B. Description of the Research:
Randomized Clinical trail

C. Potential Risks and Discomforts:
Pain and discomfort, unwanted tooth movement, pulp pathology, periodontal changes, root resorption and temporomandibular disorders.

D. Potential Benefits:
Getting a complete treatment under the supervision of highly qualified orthodontists.

E. Cost/s 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):

Dorra MHD Izzat Bakhit

00201095956878

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. Dorra MHD Izzat Bakhit and his/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. Dorra MHD Izzat Bakhit has explained to me the nature of the procedures described in the Research Participant Information Sheet as well as any benefits ~~reasonably~~ 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: _____

Title: _____

Date: _____