Immunological and Microbiological Assessment of Maxillary Acrylic Resin Complete Dentures Reinforced by Gold Plated Cr-Co Palatal Plate

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1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Digital Occlusal Analysis of Ultra Suction Retained Complete Denture

Principal Investigator: [Shady El Naggar, Removable Prosthodontics Department, Badr University in Cairo]

Co-Investigator(s): [Sherihan M. Eissa, Fixed and Removable Prosthodontics Department, National Research Center]

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

A complete denture will be performed according to your edentulous criteria with supporting device (Ultra Suction Device). Investigations will be performed by occlusal load analysis using Tek-scan device.

1.1 Key Information

Things you should know:

- Biting analysis of conventional complete denture supported by Ultra-suction device.
- If you choose to participate, you will be asked to take apart of all manufacturing visits and follow up investigations for one year.
- Risks or discomforts from this research include mild discomfort with initial commitment of appointments.
- The direct benefits of your participation is having a good manufactured complete denture as best treatment of complete edentulous state.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

Immunological and Microbiological Assessment of Maxillary Acrylic Resin Complete Dentures Reinforced by Gold Plated Cr-Co Palatal Plate

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

1- Age of the selected patients ranged between 40-65 years.

2- The residual alveolar ridges exhibited adequate height and width, with no bony exostosis or, undercuts.

3- The residual alveolar ridges covered with firm fibrous mucoperiosteum. With no signs of inflammation, ulceration or hyperplasia.

4- The selected patients exhibited Angle class I maxillomandibular relationship, and had adequate inter arch space.

5- Patients were free from any systemic diseases or hormonal disorders that may affect the oral condition.

6- Patients were free from any signs of oral pathology.

7- Patients had no history of bad habits as clenching and bruxism, they also had no temporo mandibular joint disorders.

8- Patients were nonsmokers and had no previous denture experience.

9- Patients with excessive salivation were not included in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

- The location where research activities/procedures will take place: National research center, Dokki, Giza, Egypt.
- Biting analysis of conventional complete denture supported by Ultra-suction device.
- If you choose to participate, you will be asked to take apart of all manufacturing visits and follow up investigations for one year.
- Data collection procedures: observational.
- Identification of which procedures are standard and which are experimental
- Conventional complete denture without supporting devices as a standard procedure and conventional complete denture supported by Ultra-suction device as an interventional procedure.
- Randomization procedures: simple randomization.

- Use of medical records: Patient general health will be evaluated through a full medical history as well as laboratory investigations. .

4.2 How much of my time will be needed to take part in this study?

45 days

4.3 If I decide not to take part in this study, what other options do I have?

There may be other ways of treating your condition if you do not want to be in this research study. Check with your health care provider to discuss other options.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

These may be physical, psychological, legal or informational. Breach of confidentiality (i.e., informational risks) is a potential risk in all research that collects or maintains personally identifiable information and may be the only risk in some studies. The researchers will try to minimize these risks

For informational risks state: Because this study collects information about you, [one of the risks/the primary risk] of this research is a loss of confidentiality.

5.1.1 What happens if I get hurt, become sick, or have other problems because of this research?

The researchers have taken steps to minimize the risks of this study. Please tell the researchers if you have any injuries or problems related to your participation in the study. The University may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

5.2 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive [an appropriate compensation] for your participation in the study.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information? Through confidential terms.

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.

8.3 What will happen to the information collected in this study?

We will keep the information we collect about you during the research [for future research projects/for study recordkeeping or other purposes (describe)]. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you.

8.4 Will my information be used for future research or shared with others?

We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

8.4.1 Special Requirements

If your project meets the definition of an NIH clinical trial, include the following required language: A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you will register your project on ClinicalTrials.gov voluntarily or in order to meet journal or other requirements, include the following: This trial will be registered and may report results on www.clinicaltrials.gov. This site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Shady El Naggar

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10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____