

Informed Consent to Participate in a Research Study

25 August 2024

1. Study Title: Accuracy of intraorally scanned denture impressions compared to conventional border molded impressions- in vivo study

The above-mentioned study has been approved by the Dubai Scientific Research Ethics Committee, DHA]

Principal Investigator: Dr. Fatemeh Amir Rad

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Site where the study will be conducted: Dubai Dental Hospital

You are invited to participate in this research study conducted at Hamdan Bin Mohammad College of Dental Medicine/ Dubai Dental Hospital - Dubai Health. Please, take your time to read the following information carefully, before you decide whether you wish to take part in this research study or not. You are encouraged to ask the study investigator if you need any additional information or clarification about what is stated in this form and/or in the research study as a whole. You are also free to take this information sheet and consult with your doctor or other health professionals. Please note that, should you decide to participate, you are free to withdraw at any time without any consequence.

The purpose of the Research Study and Overview of Participation

The purpose of this study is to evaluate the accuracy of an intra oral scanner digital impression in a completely edentulous arch and compare it with a conventional impression.

All patients attending Dubai Dental Hospital for complete denture treatment will be invited to participate in this study.

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What is the duration of the study?

Around two months

Participation in the study – Why participate, what will happen on participation, what is required of the patient.

Participation in this study will provide the investigators with scientific data to validate alternative digital impression obtaining methods.

The process of denture provision will be the same, however, at the impression taking stage, two methods of impression capturing will be performed.

Any Risks as a Result of Participating in the Study

There are no risks associated with participation in the study except for longer chair time which will be communicated to them prior to consenting to participation. Participants will have the right to stop the impression capturing procedure or withdraw from the research at any time.

Any Benefits as a Result of Participating in the Study

The data collection is part of the process of complete denture provision to the patients.

Any Alternative Treatment

N/A

If you agree to take part in this research study, please, be assured that the obtained information will be kept confidential. Unless required by law, only the study investigator or designee, the MBRU-Institutional Review Board (MBRU-IRB), the Dubai Scientific Research and Ethics Committee (DSREC) and/or inspectors from governmental agencies will have direct access to your information.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact Dubai Scientific Research Ethics Committee, DHA on 800 342 or email on DSREC@dha.gov.ae

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Investigator's Statement:

I have reviewed, in detail, the informed consent document for this research study with (name of patient, legal representative, or parent/guardian) the purpose of the study and its risks and benefits. I have answered all the participant's questions clearly. I will inform the participant in case of any changes to the research study.

Name of Investigator or Designee

Signature

Date & Time

Patient's Participation:

I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact Dr. Fatemeh Amir Rad at 04 383 8910 or any of his/her team involved in the study in case I have any questions.

If I feel that my questions have not been answered, I can contact the DSREC (DSREC@dha.gov.ae). I understand that sections of any of my medical notes may be looked at by responsible individuals from Dubai Dental Hospital or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent.

I agree to take part in the above study.

Name of Patient/Legal Representative or Parent/Guardian	Signature	Date & Time

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Name of the Witness (if patient, representative or parent does not read)	Witness's Signature	Date & Time

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