

## INFORMED CONSENT FORM FOR ACADEMIC STUDY

### Physician's Description:

In the case of complete edentulism of the upper jaw, complete dentures are often applied in clinics. For complete dentures, impressions of the edentulous upper jaw are routinely obtained with traditional methods. Nowadays, with the development of technology, impressions of the edentulous upper jaw can be obtained with digital methods. This study is a research study and aims to compare three different traditional and three different digital impression methods.

The title of the study is "In-Vivo Comparison of Different Impression Methods in the Completely Edentulous Upper Jaw".

We want to include you in this study because you have complete edentulism in the upper jaw and your hard and soft tissues in the upper jaw are healthy. During the course of this study, a total of six different upper maxillary impressions will be taken from you. All impression methods are clinically safe methods and differ in terms of the material used and the technique followed. The measurements and records will not be used for your treatment and will not contribute directly to you. We encourage you to participate in this study, but you are free to decide whether or not to take part. Before you decide, we would like to inform you about the study. Participation in the study is voluntary. You also have the right to withdraw your consent at any stage of the study without any penalty or sanction and without losing any of your rights. If you wish to participate in the study after reading and understanding this information, please sign this form.

Your participation in this study to be conducted at Faculty of Dentistry, Department of Prosthodontics is important for the success of the study. If you agree to participate in the study, your upper jaw examination will be performed. After the examination, measurement procedures will begin. A total of 6 different upper jaw impressions will be taken from you and these impressions will be completed in two sessions. All impression methods and materials have properties that do not damage intraoral tissues and do not cause pain and sensitivity. The first session will not exceed 40 minutes and a total of three different impressions will be taken. The first of these impressions is the traditional impression method and will be completed in one step. Apart from the traditional impression, two different digital impressions will be taken. The digital impressions will be taken with an intraoral scanner (TRIOS3: 3Shape A/S, Copenhagen, Denmark) designed to fit inside the mouth and scan the surface. Three different impressions will be taken during the second session. The duration of this session will not exceed 60 minutes. In this session, two different two-stage traditional impressions and one digital impression will be taken. Traditional and digital impression methods differ in terms of the impression material and technique used.

All measurements will be digitized and compared using a special computer software. Comparison with computer software constitutes the experimental part of this study. The measurements and records to be taken within the scope of the research will not be used for the treatment of volunteers. It will not contribute directly to the volunteers but will contribute to science.

Risks during the study: There is a risk of nausea during impression taking, but this is a risk that may develop during routine impression taking. In other words, it is not directly related to the study. If you encounter a health problem during the study, you can contact us at Faculty of Dentistry, Department of Prosthodontics.

The number of volunteers who will participate in the study has been determined as 15. The time foreseen for you to continue the study is foreseen as 1 hour and 40 minutes in total for two different sessions. In case of severe nausea and burning sensation, anxiety, restlessness, anxiety during the measurement, the procedure will be stopped. If any new information is obtained at any stage of the research that may affect

your willingness to continue the research, this will be shared with you. The results of our study can be used in dental education or scientific publications without revealing your identity. By signing this form, you allow the institutions and organizations related to this research to have access to your original medical records, but your information is completely confidential. During the scope of the research, you volunteers are expected to attend the two different sessions specified on time. You will not be charged for your participation in this study. No additional payment will be made to you for participating in the study. The volunteer's participation in the study will be terminated if the volunteer wishes to leave the study voluntarily, does not attend the specified sessions, or develops a general health problem.

**Declaration of the Volunteer/Patient:**

I was informed Faculty of Dentistry, Department of Prosthodontics and provided me with the above information about this research. After this information, I was invited to participate in such a research as a "participant" (volunteer). I believe that if I participate in this research, my personal information will remain between the physician and me and that the confidentiality of this information will be treated with great care and respect during the research. I have been given sufficient confidence that my personal information will be carefully protected during the use of the research results for scientific purposes.

I can withdraw from the research without giving any reason during the conduct of the project, but I am aware that it would be appropriate to inform the researchers in advance that I will withdraw from the research in order not to leave them in a difficult situation. I may also be excluded from the research by the researcher provided that no harm is caused to my medical condition. I do not assume any monetary responsibility for the expenses to be incurred for the research and I will not be paid.

I have been assured that any medical intervention will be provided in case of any health problem that may arise, whether directly or indirectly, due to reasons arising from the research application. (I will not be under any financial burden regarding these medical interventions.)

If I encounter a health problem during the research, I can contact Faculty of Dentistry, Department of Prosthodontics.

I have read all the explanations in the informed consent form. I have been given written and verbal explanations about the research, the subject and purpose of which are stated above, by the physician mentioned below. I do not have to participate in this study and I may not participate. I have not been subjected to any coercive behavior to participate in the research. I know that if I refuse to participate, this will not harm my medical care and my relationship with the physician. I know that I can leave the study at any time, with or without justification.

I was assured that if at any stage of the research any new information was obtained that might affect my willingness to continue with the research, this would be shared with me.

I have understood all the explanations given to me in detail. As a result of a process of reflection on my own, I have decided to participate voluntarily in the aforementioned research without any pressure or coercion. I gladly and voluntarily accept the invitation made to me in this regard.

I will be given a copy of this signed form sheet.

Date: 09.05.2022 Version: 1.1

Volunteer:

Name-Surname

Address:

Phone Number:

Signature:

Interview Witness:

Name-Surname

Address:

Phone Number:

Signature:

Physician Interviewing the Volunteer:

Name-Surname-Title

Address:

Phone Number:

Signature: