The Effect of Different Head Positions on Occlusal Contacts

Informed Consent Form

*Hacettepe University Clinical Research Ethics Boards
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Clinician's Description:

Interocclusal registration is defined as a record of the positional relationship of opposing teeth and jaws. Restorations with occlusal incompatibility produced using inaccurate interocclusal records result in increased chairside restoration fitting time or the need for restoration replacement. This is time consuming and costly for both the physician and the patient. This study is a research study and aims to compare the different tooth contact points obtained in three different head positions.

The title of the study is "Digital Evaluation of Changes in Interocclusal Contact Points in Different Head Postures: An In Vivo Study".

The reason we want to include you in this study is that you do not have any missing teeth, have a normal relationship between the jaws or have any obstacles to your jaw bite for any reason. During this study, we will take digital measurements of your upper and lower jaws, digital bite recordings in three different head-neck positions, and digital facial arch recordings so that the jaws can be positioned appropriately in the digital environment. All recording methods to be used are clinically safe. We encourage you to participate in this study, but you are free to decide whether or not to take part. We would like to inform you about the study before you make your decision. Participation in the study is voluntary and you have the right to refuse. 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. (16) 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 Hacettepe University Faculty of Dentistry, Department of Prosthodontics is important for the success of the study. If you agree to participate in the study, your examination will be performed. After the examination, digital recording procedures will begin. Records determining the closure of the jaws and the contact points of the teeth in the closure in a total of three different head-neck positions that are within natural limits and do not pose a risk to healthy individuals will be taken from you and will be completed in two sessions.

All recording methods have features that do not damage the oral tissues and do not cause pain and sensitivity. The first session will be completed within 10 minutes and a total of three different records will be taken. First, a surface scan will be performed with an intraoral scanner for your upper and lower jaw and will be completed within three minutes. Then direct digital closure recordings will be taken and repeated for three different head-neck positions. The upper and lower jaw scans and digital interocclusal records will be taken using an intraoral scanner (TRIOS4: 3Shape A/S, Kopenhagen, Denmark) designed to fit inside the mouth. In the second session, your digital facial arch will be recorded so that the jaws can be positioned appropriately in the digital environment. The surface scans obtained for upper-lower jaw and bite registration will be digitized and compared using a computer software (zebris WINJAW+; zebris Medical GmbH, Germany).

Comparison with the computer software and statistical evaluation constitute the experimental part of this study. Your personal data will not be included in any software to be used during the study. Your personal data will not be shared with anyone and will be kept only with the physician. The surface scans and recording process will not directly benefit the participants but will contribute to science.

Risks during the study: There is a risk of nausea during surface scanning and closure recording, but this is a risk that can develop during routine scans. It is not directly related to the study.

The number of participants to take part in the study has been set at 36. The time for you to continue with the study is estimated to be 25 minutes in total for two sessions. In case of severe nausea, anxiety, restlessness, anxiety during surface scanning and contact point recording, the procedure will be stopped. The results of our study can be used in dental education or scientific publications without revealing your identity. By signing this form, you consent to the right of access to your original medical records by monitors, surveyors, the Ethics Committee, the Ministry and other relevant health authorities related to this research, but your information is under the guarantee of complete confidentiality.

You will not be asked to pay any fee for taking part in this study. You will not receive any additional payment for taking part in the study.

Declaration of the Patient:

Researchers informed me that a medical research would be conducted at Hacettepe University Faculty of Dentistry, Department of Prosthodontics and provided me with the above information about this research. After this information, I was invited as a "participant" (volunteer) to such a research. 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.

During the execution of the project, I can withdraw from the research without giving any reason, 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 given the necessary assurance 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, at any time, I would like to inform researchers at 03123052240 and Hacettepe University 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 am not obliged to participate in this research 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 research at any time, with or without justification. (24) I have been given the necessary commitment that if any new information is obtained at any stage of the research that may affect my willingness to continue the research, this situation will be shared with me.

I have understood all the explanations given to me in detail. After 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.

Volunteer	**Interview Witness**
Name-Surname:	Name-Surname:
Address:	Address:
Phone Number:	Phone Number:
Signature:	Signature:

Clinician Interviewing the Volunteer:

Name-Surname-Title:

Address: Hacettepe University Faculty of Dentistry Department of Prosthodontics Altındağ/ANKARA

Tel: 03123052240

Signature:

Name-Surname / Signature of the Principal Investigator