The Effect of Different Head Positions on Occlusal Contacts

Clinical Research Plan

*Hacettepe University Clinical Research Ethics Boards
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Importance of the study

Head posture varies according to the physiologic and functional activity of the individual. Head postures are divided into 'active feeding position', 'head up position', and 'extended head position'. (1,2) The position in which the head extends 30° forward during feeding is known as the 'active feeding position'. (2) This posture causes the mandible and mandibular closure pathways to be positioned more anteriorly than normal. During drinking, the head extends 45° backwards and the mandible moves posteriorly. (3) Any change in head posture causes the muscles attached to the mandible to stretch and lengthen, resulting in a change in mandibular position. Changes in mandibular position result in changes in occlusal contact points and the occlusal forces generated at these points. The literature supports the relationship between head posture and occlusal contact points. (4,5)

Micron-sized changes in occlusal contacts can trigger severe dysfunction and pain in the temporomandibular joint (TMJ). Therefore, it is important to obtain accurate interocclusal records and to detect occlusal interferences. The interocclusal record is defined as a record of the positional relationships of opposing teeth and jaws. (6) Interocclusal records facilitate the assessment of occlusion for diagnostic or treatment planning purposes. Restorations with occlusal incompatibility produced using inaccurate interocclusal records result in increased adjustment time of the restoration or the need for restoration replacement. This is time-consuming and costly for both the clinician and the patient. Therefore, reliable interocclusal records obtained by providing appropriate occlusal records directly affect the success of prosthetic or indirect restorative procedures. (7)

With digitalization, the use of intraoral scanners has enabled dental impressions and interocclusal records to be obtained digitally. After the scanning of both dental arches is completed with intraoral scanners, the interocclusal record begins. Right and left interocclusal records are taken. After ensuring that the patient closes the teeth in the appropriate position, the intraoral scanner head is positioned to see the buccal surfaces of the teeth on the relevant side. The scanner is moved anteriorly starting from the most posterior tooth. The images captured during scanning are matched with the full arch scans through the software and the upper and lower jaw scans are brought to closure. The same process is repeated for the other side. Thus, the interocclusal registration is completed. Digital interocclusal records have the advantages of being obtained in a shorter time and in a more comfortable way for both clinician and patient, easy and error-free transfer to the laboratory, and the ability to obtain dynamic interocclusal records in addition to static occlusal records with various software. (8)

Iwauchi et al. compared the accuracy of digital and conventional interocclusal records in a clinical study. Eight subjects with natural dentition and no missing teeth were included in the study. Two different intraoral scanners and silicone-based impression materials were used to take dental arch impressions and interocclusal records in three groups. The plaster models obtained from silicone-based impressions were transferred to the articulator with the interocclusal records obtained with silicone-based material and the model was scanned with a laboratory scanner to acquire digital interocclusal records. These procedures were repeated four times for each group. The obtained interocclusal records were exported in "stl" format and the accuracy of the interocclusal records was evaluated by overlapping the measurements with each other. At the same time, the precision of the interocclusal recording methods was evaluated by overlapping each of the four repeat measurements. As a result of the study, digital interocclusal recordings were shown to be more accurate than the conventional method. (9)

In a clinical study, Fraile et al. compared the accuracy of digital interocclusal records obtained with three different devices. Twenty-five healthy volunteers were included in the study. In the control group, contact points were determined and photographed with eight μm thick articulating paper, which is considered the gold standard. Interocclusal records were obtained digitally by using an intraoral scanner, transferring the models obtained from conventional measurements to the articulator and scanning them with a laboratory scanner, and using the T-Scan III interocclusal analysis system. As a result of the study, intraoral scanners were shown to be reliable in determining interocclusal contact points compared to the gold standard. (10)

For a correct occlusion assessment, the condyle should be directed to the appropriate position in the TMJ. For this purpose, the spatial position of the maxilla relative to the skull base, intercondylar and condyle pathway

distance, hinge axis, static and dynamic relationship of the mandible should be determined and transferred to the articulator with facebow recording. Nowadays, digital facebow transfer is possible and the records obtained are transferred to the digital articulator, facilitating the workflow. Digital facebow includes a new digital occlusal analysis software that enables the recording of mandibular functional movements. In this method, occlusal contact patterns are captured during the actual movement of the mandible and analyzed for appropriate therapeutic positioning of the mandible or occlusal interferences. For this purpose, the digital scan records of both jaws are combined with the motion records obtained using a special attachment table and visualized as a single image. Since the TMJ motion pathways are also recorded, it is also possible to define the appropriate therapeutic position to relieve the TMJ with this software. This method provides a deeper and more comprehensive understanding of the relationship between the structure and function of the occlusion (11,12).

There are not enough studies in the literature to clinically evaluate the changes in occlusal contact points according to different head positions using digital methods. This study aims to quantitatively evaluate the changes in occlusal contact points with digital interocclusal and facebow recordings taken in three different head positions. The hypothesis of the study is that there is no statistically significant difference in interocclusal contact points in different head postures.

Research will be supported by the Scientific Research Projects Coordination Unit of the University of Hacettepe, and an agreement will be reached with the Faculty of Dental Medicine of the Hacetepe University (Hacettepe University Dental Faculty 06100 Sıhhıye, ANKARA), the research center, in order to reach a positive conclusion about the necessary board decisions. Support address: University of Hacettepe Beytepe Campus Rectorate Building, Beytepe/ANKARA.

Materials And Methods:

The study will include healthy volunteers with natural dentition and no missing teeth. The study is planned to obtain a total of three different interocclusal records for three different head positions according to the appropriate head-neck-spine posture with an intraoral scanner, followed by digital facial arch recording and quantitative evaluation of changes in interocclusal contacts. No patient randomization was planned in the study, and direct digital interocclusal records and oJMA records were planned to be collected from each participant who met the inclusion criteria. Each volunteer who meets the inclusion criteria will be expected to carefully read the "Informed Consent Form" and then make his/her own decision about whether or not to participate in the study without any pressure. In line with the consent of the volunteer, surface scanning and digital dental arch records will be taken.

The intraoral scanner to be used in the study (TRIOS4; 3Shape A/S; Kopenhagen, Denmark) will perform surface scans of the mandibular arches and interocclusal records. TRIOS4 was chosen because all data to be acquired can be obtained without being subjected to laboratory stages that are prone to deformation, it offers a more comfortable and shorter procedure time for volunteers, it is manufactured following the latest technological developments, and it is a reliable and fast device with the support of literature knowledge. The device is manufactured in Denmark (3Sahep Trios A/S Holmens Kanal 7 Copenhagen 1060 Denmanrk, +45 70 27 26 20, info@3shape.com) and its authorized representative in our country is BatıGroup Dental (BatıGroup Dental Dental Products Trade Anonim Şirketi, Kızılırmak Mah. Ufuk University Cad. 1445th Sok. Paragon Tower No:2a Çankaya/Ankara, 0312 434 2000, treasury.tr@straumann.com). The device is in pen form and the tip used in the mouth will be sterilized for each volunteer. Possible risks include a feeling of nausea that may occur during surface scanning in individuals with severe nausea reflex, but this can be seen during all dental procedures for individuals with nausea reflex and does not present a different risk.

Another device to be used in the study is an optic jaw motion analyzer system (zebris JMA Optic; zebris Medical GmbH, Germany) and the software program (zebris WINJAW+; zebris Medical GmbH, Germany). The sensitivity, accuracy and reliability of oJMA is supported by literature information, which has a higher data acquisition speed and can be easily integrated with digital surface scans, and at the same time shortens the procedure time for the clinician, patient and technician. The device is manufactured in Germany (Zebris Medical GMBH, Am Galgenbihl 14 88316 Isny Germany, +49 7562 97260, info@zebris.de). The device consists of an electronic face-bow, mandibular sensor, C-bow positioning tip and pedal. All parts will be cleaned and sterilized under appropriate conditions after each

procedure. Due to the ultrasonic sensor content of the device, its use in individuals with pacemakers or defibrillators is considered risky and these individuals will not be included in the study. Exclusion criteria are clearly stated in it.

Investigational products have been manufactured in accordance with good manufacturing practices determined according to the relevant legislation. These products will be used in accordance with the approved research protocol. The control and calibration procedures of the devices to be used within the scope of the research will be carried out regularly. The data obtained will be stored in the software of the devices and will not be shared with third parties. Personal data will not be shared with anyone and will be kept only by the clinician. Data that do not contain personal data, which are shared with the dental laboratory after being created with the coding method, will be automatically deleted from the software used by the dental laboratory within a maximum of three months from the date of sharing. The records of the devices in the system will be deleted immediately after the completion of the work. Confidentiality assurance of the data will be realized with the form signed by the individuals. A comparative device will not be used in the study. In case of early termination or temporary suspension of the study for any reason, the volunteers included in the study will be immediately informed by the principal investigator. The principal investigator or a researcher to be assigned by the principal investigator will immediately notify the sponsor of all adverse events, serious adverse events, device defects. The volunteer experiencing an adverse event will be followed up at the research center until the effects disappear completely and regain their health, and necessary interventions will be made. Information on patient code, age, gender, inclusion and end date will be recorded on the case report form in order to ensure accurate patient follow-up. In case of any damage that may occur to the volunteers due to the research, the damage will be immediately notified to the sponsor and will be provided within the scope of the research. Digital interocclusal records and oJMA records, which are found to be useful within the scope of the research, can also be used in the future prosthetic dental treatment of the volunteers. The results of the study may be used in dental education or scientific publications without disclosing the personal information of the volunteer. If the volunteer signs the 'Informed Voluntary Consent Form', he/she consents to the right of access to the original medical records by monitors, examiners, the Ethics Committee, the Ministry and other relevant health authorities related to this research, but the information is under the assurance of complete confidentiality.

Digital Interocclusal Record Groups

Group 1 (G1): Digital interocclusal recording taken in the neutral position with the head aligned in the head-neck-spine plane

Group 2 (G2): Digital interocclusal recording taken in the position where the head is positioned at 30° flexion relative to the head-neck-spine plane

Group 3 (G3): Digital interocclusal recording with the head positioned in 45° extension relative to the head-neck-spine plane

oJMA Record

For each participant, the spatial position of the maxilla relative to the skull base, the condyle distance and the static and dynamic recording of the mandible will be taken in accordance with the digital occlusal analysis module in the oJMA.

All records will be completed in two sessions and carried out by a single operator. During the first session, participants will be scanned using the intraoral scanner (TRIOS4; 3Shape A/S; Copenhagen, Denmark) in accordance with the scanning protocol recommended by the manufacturer. Each of the scans will take 1.5 minutes and will be completed in a total of three minutes. A goniometer (Goniometer, 360°; Saehan, Germany) will be used to standardize the head position of participants before taking interocclusal records in the dental unit. (13,14) All participants will be in the dental unit, where the back of the unit will support the person's lumbar and thoracic vertebrae, with their arms freely sitting next to the body and watching directly in front of them. The neutral position of the head (G1, PN), 30° flexion (G2, PF), and 45° extension (G3, PB) will be determined by a goniometer. For each participant, the neutral position will first be determined, with the head, neck, and spine on the same axis, the fixed arm of the gonyometer standing on the ground, the central meatus acusticus externus, and the measuring arm aligned with the Camper plane. Then, for

each head position, the measuring arm shall be fixed to the base of the ala nares, with the head in the position of 30° flexion and 45° extension. Then, in addition to normal clinical procedures, these two head positions will take right and left direct digital interocclusal records. These records will take one minute for each main position, and inter-occlusal records will be completed in a total of three minutes. The closing movement will be repeated to get the participants to an intercuspal jaw position, and the muscles will get used to this position. Subsequently, participants will be asked to close their mandible in a repeated intercuspal position and they will be asked to maintain this position. The intraoral scanner will be placed between the teeth and the cheek with minimum pressure, without disturbing the closure, and will be recorded from the teeth's buccal surfaces with movement from the rear to the front. The TRIOS software will automatically match the same areas in the dental arch scans during the interocclusal record with the scan of the buccal surface of the teeth, closing the scans of the lower and upper jaws. Participants will repeat the same procedure for right and left interocclusal records without disturbing the intercuspal jaw position. The oJMA will be recorded at the second session and last 15 minutes. All recordings will then be integrated into the analytical module of the oJMA software (zebris WINJAW+; zebris Medical GmbH, Germany) in 'stl' format.

Enrollment

The person or legal representative who wishes to volunteer to participate in the research shall, before commencing the research, be informed by the research team in a sufficient and comprehensible manner of the purpose, methodology, expected benefits, predictable risks, difficulties, aspects not appropriate to the health and personal characteristics of the person, and the conditions under which the research will be carried out, to be continued, and of the right to withdraw from the research at the time requested.

The study will involve 36 healthy volunteers who have natural dentition and do not have tooth deficiencies. The volunteers' participation in the study will not exceed a total of 25 minutes for two separate sessions, and no follow-up will be implemented. Volunteers may withdraw from the research during the conduct of the research without giving any reason, but they must inform the researchers in advance that they will be withdrawing from the study so as not to put them in difficulty. Data from volunteers who withdraw from the study during or after the recording session will be deleted and not included in the study. The same number of new volunteers will be included in the post-examination research conducted by relevant researchers. All healthy volunteers have been assured that, in the event of any health problems that may arise, whether directly or indirectly, as a result of the implementation of the research, any kind of medical intervention will be provided, and they will not be subjected to any financial burden related to medical interventions. In the event of severe nausea, anxiety, restlessness, or anxiousness during the surface scan and contact point recording, the investigation will be terminated for the volunteer concerned when it is indicated that the operation will be suspended or cannot be continued until it is decided to voluntarily resume.

Inclusion criteria

- Voluntary acceptance of participation in the study after reading the informed and voluntary approval form
- Individuals over 18 years of age with natural dentition and without tooth deficiency
- Individuals with Angle-Class I skeletal relationships
- Individuals with no interocclusal closure problem for any reason

Exclusion criteria

- Refusal to voluntarily participate in the study after reading the voluntary approval form
- Individuals with dental deficiency or restoration that may affect the closure of the foreheads
- Individuals with skeletal contact in Angle Classes II and III
- Temporomandibular joint dysfunction, pain in the orophatic region, and acute oral disease
- Individuals carrying a cardiac battery and a defibrillator
- Individuals with neck muscle problems, neck vertebrae, or benign paroxysmal positional vertigo disease/headache

Sample size and strength analysis

This study uses the PS Version 3.0 package. =0,50, α=0,05, test strength 1-=080, repetition correlation r=0,20 is the default, and the total sample size is determined to be at least 36. But because working with a larger sample reduces the level of misunderstanding, it is desirable to work with as many patients as possible.

Randomization:

The study was planned as a clinical trial. The planned digital interocclusional recordings for three different head positions will be completed in a single session, and the recording groups will not change. The total of three different records to be taken will not be subject to randomization in itself.

Blinding

No blinding will be applied in the study.

Primary Data

The primary data for each participant will be collected in the 'stl' format obtained by scans of the participant's maxillary and mandibular archs and interocclusal records, obtaining three different head positions. These data will also be matched using software (zebris WINJAW+; zebris Medical GmbH, Germany), and the differences between the interocclusal contacts will be quantified.

Primary Conclusion Point

The comparison of the interocclusal records obtained is a quantitative evaluation of differences in interoclusal contacts in different head positions according to the appropriate head-bone-spine position.

Statistical Evaluation

Data from all volunteers participating in the study will be included in the statistical analysis. First, the Kolmogorov Smirnov adaptation test and the Shapiro-Wilk test are considered to be used to see if the data has a normal distribution. Subsequently, the differences between groups will be assessed using parametric or non-parametric statistical methods, depending on the case. Previous studies will be studied in detail, and comparisons will be evaluated using appropriate tests. Taking into account previous studies, it is envisaged that independent and dependent group tests, Kruskal Wallis, or one-way variance analysis, will be used.

Any possible change in the clinical research plan or process will be promptly notified to the research center, relevant institutions, boards, and healthy volunteers. Derogations from the clinical research plan are monitored and managed by the research center, and inconsistencies with the plan are expressly prohibited.

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