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RESEARCH PROTOCOL

1) Title of the Project: "In-Vivo Comparison of Different Impression Methods in Complete Edentulous Upper Jaw"

2)Importance of the Project:

Complete edentulism is a dental problem that involves the loss of all natural teeth due to iatrogenic, therapeutic or traumatic causes followed by alveolar bone resorption. The quality of life of edentulous patients is negatively affected due to functional disorders such as phonation and mastication, and their social life is negatively affected due to aesthetic deficiency (1). Today, when the socio-economic status of edentulous patients and their tolerance to treatment are evaluated, complete dentures are frequently preferred (2, 3). The large supportive tissue area in the upper jaw and the ability to provide more retention allow the problem-free use of upper complete dentures. Due to the lack of retention and mobility in lower complete dentures, patients have difficulty in using lower complete dentures, especially while eating. Recent studies have shown that mandibular two implant-supported complete dentures may be the first treatment alternative to conventional complete dentures, but implant support is generally not required for upper complete dentures (4). Complete dentures are often produced with the traditional method starting with conventional impression taking, but in recent years, digital workflow has been used following impressions taken with intraoral scanners.

The borders of the complete prosthesis and the tissues supporting the prosthesis can be recorded with different impression methods. The technique and material used during impression determines the contact of the prosthesis with the supporting tissue during rest and function, and thus the retention of the prosthesis. In dental schools, impressions of edentulous arches are usually taken using the two-stage impression method, which involves more complex clinical and laboratory steps, with the assumption of providing a better treatment (5). In this method, the initial impression is taken with metal 'stock' trays and irreversible hydrocolloid (alginate) impression material. An individual tray is produced from the plaster model obtained from the initial impression. The final impression is taken using zinc-oxide eugenol or elastomeric impression materials after border moulding with impression compound using the individual tray (6). As an alternative to the traditional two-stage impression method, a one-stage impression method with fewer clinical and laboratory steps has emerged. The one-step method uses metal-stock trays and irreversible hydrocolloid impression material. This method has been shown to produce clinically acceptable complete dentures at a lower cost (7). Among the many techniques

and materials, physicians choose the most appropriate, comfortable and cost-effective alternative for the patient's clinical situation, taking into account the case situation, impression making stages and material properties.

In a randomized controlled trial comparing single and two-stage impression methods, it was shown that patients' satisfaction with prostheses produced with the two-stage method was higher (8). In addition, when different studies comparing single and two-stage impression methods were examined in the literature, there was no conclusive evidence of the superiority of the two-stage impression method, which is accepted as the gold standard in dental textbooks (7, 9, 10).

Computer-aided design / Computer-aided manufacturing (CAD/CAM) techniques have emerged with advances in technology. With current approaches, the tissues supporting the prosthesis can be recorded with digital methods and more compatible dental prostheses can be produced with CAD/CAM techniques (11). For this purpose, the indirect digital impression method, in which the measurements taken with the conventional method or the models obtained are scanned with a laboratory scanner and digitized, is frequently used. However, the distortion that conventional impression materials undergo when they are removed from the patient's mouth and the dimensional change they undergo during the time until they are digitized can negatively affect the accuracy of the impression.(12) At the same time, inadequacies in patient comfort, the necessity of renewing the entire procedure in case of an inaccurate impression, and cost have played a role in the emergence of direct digital impressions. In the direct digital impression method, the supporting tissues are recorded simultaneously with the intraoral scanner. Initially, direct digitalization was limited to the digital impression of teeth and the production of tooth-supported prostheses. However, today, digital impressions of implants and complete edentulous arches can be taken (13, 14). However, intraoral scanners have difficulty in matching the soft tissue image in edentulous areas due to the lack of reference points and there is insufficient data in the literature regarding the success of direct digital impressions of edentulous arches.

There are few clinical studies in the literature comparing conventional and digital impression methods of edentulous arches. Lo Russo et al. compared conventional and digital impressions of edentulous jaws in a clinical study. Digital impressions were first taken from the patients with an intraoral scanner. The impression was transferred to a design program in "STL" format and a individual tray was prepared based on the model obtained from this impression. A conventional impression was taken with the individual tray and polysulfide impression material and then the impression was scanned with the same intraoral scanner. The impressions taken from the patients were compared and no

statistical difference was found. It has been shown that edentulous jaws can be recorded with direct digital impressions similar to conventional impression methods and that these impressions can be used clinically in the production of tissue-supported removable prostheses (15).

Chebib et al. compared the accuracy of different impression techniques in patients with maxillary complete edentulism in a clinical study. Twelve patients participated in the study and a total of five impressions were taken from each patient. In the ALG group, impressions were taken with a stock-tray and irreversible hydrocolloid impression material. In the ZOE group, individual tray borders were shaped with impression compound and impressions were taken with ZOE material. This group was also considered as the control group. In the PVS group, individual tray and medium-viscosity polyvinylsiloxane impression material were used. In the PVSM group, the inner surface of the impression taken in the PVS group was modified with ZOE impression material. All analog measurements were digitized with the same laboratory scanner. In the TRI group, scanning was performed with an intraoral scanner after the reference points created with composite on the maxillary soft tissue. Then, with the help of a software, the scan data were matched in a best-fit manner. As a result of the study, PVS, PVSM and TRI groups showed similar deviations and were found clinically acceptable. Irreversible hydrocolloid impression material was shown to be contraindicated for the final impression of the complete edentulous maxilla (16).

There is limited information on the comparison of the direct digitalization method used in the impression of edentulous arches with traditional impression methods and there is a need for improvement. Given this situation, the aim of this study was to expand the existing knowledge for direct digitalization in the edentulous maxilla by comparing six different edentulous arch impressions.

3)Materials and Methods:

In this study, it was planned to compare a total of six different permanent impressions obtained from patients with complete edentulous maxilla using three different conventional impression methods and three different digital impression techniques. Patient grouping was not planned in the study, and it was decided to take impressions from each patient who met the inclusion criteria under conventional and digital groups.

Physical Record (fK)=

- fK-I (ALG) (Metal stock tray and irreversible hydrocolloid impression material ("simplified tech.") (7)
- fK-II (ZOE) (Individual tray, border-moulding and zinc-oxide ojenol impression material)
- fK-III (E) (Individual tray, border-moulding and elastomeric impression material)

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Direct Digitalization (dD) =

- dD-I (AI-OFF) (Direct impression with intraoral scanner and A.I off)
- dD-II (AI-ON) (Direct impression with intraoral scanner and A.I on)
- dD-III (MOD) (Intraoral scanner and scanning with OR (17) and A.I off)

All measurements will be completed in two sessions and will be performed by a single operator. The first session will last 40 minutes and the fK-I (ALG), dD-I (AI-OFF) and dD-II (AI-ON) group impressions will be completed. First, the lip and cheek will be excluded with an intraoral retractor (OptiView™ Standard Kit) and the dD-I (AI-OFF) impression will be completed by direct scanning with the intraoral scanner (TRIOS4; 3Shape A/S, Kopenhagen, Denmark) with the A.I closed. Then, with the same intraoral scanner, the A.I. will be turned on and the impression will be taken again and the dD-II (AI-ON) impression will be completed. Direct scan data will be exported in "STL" format. For fK-I (ALG), the most suitable metal stock tray will be selected and irreversible impression material (TROPICALGIN; Zhermack SpA Badia Polesine (RO), Italy) will be used. Within 10 minutes of impression taking, the impression will be scanned with the same intraoral scanner. A negative of the scan data will be obtained and exported in "STL" format. The individual tray will be designed using a design program (Exocad DentalCAD 2.4 Plovdiv; Emerald Dental Works, Hamilton) and produced with a 3D printer (Photon Mono; Anycubic Tsim SHA TSUI, Kowloon)

The second session will last 60 minutes, and the fK-II (ZOE), fK-III (E) and dD-III (MOD) group impressions will be completed. For fK-II (ZOE), the individual tray will be checked in the mouth and necessary adjustments will be made. Border moulding will be done using impression compound (Kemco Tracing Sticks; Kemdent, Purton, UK) to ensure peripheral closure. The impression will be completed with zinc-oxide ojenol impression material (Impression Paste; SS White Lakewood, New Jersey). The impression will be digitized with an intraoral scanner within one hour after completion. For fK-III (E), the individual tray will be checked in the mouth and necessary adjustments will be made. Border moulding will be done with impression compound. The impression will be completed with elastomeric impression material. In the same way, it will be digitized with an intraoral scanner. dD-III (MOD), the base and wax template prepared for the patient will be arranged in accordance with the patient's occlusal vertical dimension, horizontal and vertical relationship between the jaws and aesthetic parameters. The base and wax template will be fixed in the mouth with a prosthetic adhesive. A tooth will then be selected on the upper jaw to allow for pre-scaning. The upper jaw will be scanned together with the base and wax template. The opposing jaw will then be scanned and the bite recorded. For the main scan of the upper jaw wax template from the pre-scan will be cut manually and the whole jaw scan will be completed, starting from the palate (17).

After all measurements are completed, the data obtained will be transferred to a computer software (Geomagic design X version 2016.1.0, 3D Systems Inc. Rock Hill, SC) and the comparison of different impression methods used for the edentulous upper jaw will be performed with this program. When the literature is examined, studies comparing

different impression methods taken from the upper edentulous jaw were evaluated with a similar method (15, 16).

Within the scope of this study, individuals who have completed upper jaw complete denture treatment at Hacettepe University Faculty of Dentistry, Department of Prosthodontics, have completed the controls, have been using the delivered prosthesis for 3 months and have healthy tissues supporting the prosthesis will be included in the study.

Inclusion Criteria;

1) Accepting voluntary participation in the study after reading the informed and voluntary consent form

2) Individuals with no risk factors in terms of general health status

3) Individuals whose complete upper jaw prosthesis has been made and delivered with known methods, whose controls have been completed, who have been using the delivered prosthesis for 3 months and whose tissues supporting the prosthesis are healthy

Exclusion Criteria;

1) Not accepting to participate in the study voluntarily after reading the voluntary consent form

2) Individuals with allergic reactions to the measurement materials planned to be used

3) People with systemic disorders or excessive weight loss that may occur for different reasons or dimensional changes that may occur in the tissues supporting the prosthesis due to other reasons

Sample Size and Power Analysis

PS Version 3.0 package program was used in this study. Δ=0.50, α=0.05, power of the test 1-β=0.80, correlation between repetitions ρ=0.20 were assumed and the minimum sample size was accepted as 15. However, since working with a larger sample reduces the level of bias, it is desirable to work with as many patients as possible.

Randomization

The study was planned as a clinical study. The six different impressions planned for the edentulous upper jaw will be completed in two sessions, and the groups of impressions taken in the first and second sessions will not change. Three different groups of impressions to be taken in each session will not be subjected to randomization.

Blinding

Double blinding will be applied in the study.

1. Blinding of the evaluating researcher: The researcher will not learn which group the obtained data belongs to until the end of the evaluations.

2. Blinding of the researcher performing statistical analysis: The researcher will not learn which group the obtained data belong to until the end of the evaluations.

Data Collection (Primary Data - Secondary Data)

Primary Data:

Primary data will be collected for each case in the form of "STL" format obtained by exporting all maxillary complete edentulous jaw impressions of that case. These data will be overlaid with the help of a computer software (Geomagic design X version 2016.1.0, 3D Systems Inc. Rock Hill,SC), the fK and dD groups will be compared with each other and the differences between the groups will be recorded quantitatively.

Secondary Data:

Secondary data will be determined by an evaluation scale asked to the patient to assess patient comfort, taste, nausea, burning sensation after the completion of each measurement. By analyzing the questionnaires and evaluation scales, the opinions of the patients about different measurement methods will be compared.

Statistical Evaluation

In the study, SPSS 20 package program will be used for data analysis. In the analysis of the study, first of all, Kolmogorov Smirnov adaptation test and Shapiro-Wilk test will be used to check whether the data have normal distribution. Afterwards, parametric or non-parametric statistical methods will be used to evaluate whether there is a difference (it is foreseen that independent and dependent group tests, chi-square test, Anova test, and graphs will be given if appropriate). When evaluating the results of the tests, the significance level will be taken as $\alpha=0.05$ and the results will be interpreted according to this critical value.

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"Tam Dişsiz Üst Çenede Farklı Ölçü Yöntemlerinin In-Vivo Olarak Karşılaştırılması"

-VAS SKALASI-

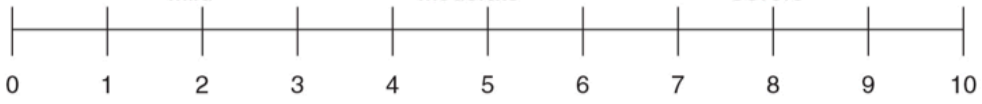
Aşağıdaki parametreleri alınan ölçü sırasındaki değerlendirmenize göre 1 ile 10 arasında puanlayınız.

- Ölçü sırasındaki **konfor seviyenizi** değerlendiriniz.

- Ölçü materyalinin oluşturduğu **tat hissi**ni değerlendiriniz.

- Ölçü materyalinin oluşturduğu **bulantı hissini** değerlendiriniz.

- Ölçü alımı sırasında ağızdaki **yanma hissi**ni değerlendiriniz.



- Bundan sonraki dental ölçü işlemleriniz sırasında hangi ölçü tipini tercih edersiniz?

☐ Geleneksel ölçü yöntemi

☐ Dijital ölçü yöntemi

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