The Assessment of The Volumetric Occlusal Adjustments Required for Michigan Splints Fabricated Using Various Digital Bite Registrations

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Protocol details.

1.1 **Protocol Title:**

The Assessment of The Volumetric Occlusal Adjustments Required for Michigan Splints Fabricated Using Various Digital Bite Registrations

1.2 Protocol Version Control

Version number: (200524)
Final/draft: final
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1.3 Names (titles), roles and contact details:

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2 CI Signature

The Chief Investigator and the RGO (sponsor office) have discussed this protocol.
The investigators agree to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the study in compliance with the approved protocol, GCP, the UK General Data Protection Regulation and Data Protection Act (2018), the Sponsor's SOPs, and any other local or external regulatory requirements as required.

Chief investigator

Arwa Alhusban

Signature Date

Contents (update page number as appropriate)

3 Summary/Synopsis

Full Title	Assessment Of the Volumetric Occlusal Adjustments Required For Michigan Splints Fabricated Using Various Digital Bite Registrations.
Short Title/Acronym	DIGI-OCCLUDE
Protocol Version number and Date	200524 – 31/5/2024
REMAS Number	43439
REC Name	Kings College London Research Ethics Committee
Study registration details (if applicable)	*N/A*
Chief Investigator	Arwa Alhusban
Sponsor name	King's College London
Funder(s)	The Hashemite University of Jordan
Population under investigation	Healthy Volunteers
Design & Methodology	Type of study/trial: controlled, Interventional
Study Duration	12 months
Primary objective	To evaluate volumetric changes on the biting surface of the occlusal splint following four different fully digital workflows. This will indicate the accuracy of the techniques in capturing the bite registration.
Secondary objective(s)	
Number of Participants	40
Endpoints	Using the digital facebow along with the digital record of occlusion (retruded articular position (RAP) versus intercuspal position (ICP)) will result in less modification at the fit appointment.
Main Inclusion Criteria	Able to provide an informed consent and having no more than one tooth missing per quadrant.
Main Exclusion Criteria	Participants who are Edentulous or wearing partial dentures
Statistical Methodology and Analysis	ANOVA statistical test will be used to compare means across the 4 groups. If the mean values between the comparison values between the groups are statistically significant or not.
Data to be collected & associated storage arrangements.	Baseline data, including intraoral scans, clinical photographs, and digital facebow, will be obtained for each participant. This data will serve as a reference for both digital and semi-digital occlusal assessments. The data will be processed under the terms of UK data protection law (including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018).

4 Introduction

Temporomandibular disorder (TMD) is significant public health condition affecting the movement of the lower jaw and is mainly due to teeth grinding during sleep or sometimes by teeth clenching during the day. It can manifest as pain around the ear, clicking sounds when moving your jaw, wear of dental tissues, headaches, difficulty in mouth opening, and sometimes jaw locking. Those symptoms usually get worse when the patients are under stress. It is not usually serious and generally gets better on its own, however in many cases, it requires further consideration. Management of this disordering, soft diet, painkillers, physical joint exercises., Furthermore, for many cases, dentist may decide to fabricate an occlusal splint (Michigan splints) that fits in the upper teeth, to prevent further damage to the teeth and it may help with pain relief, as it positions the joint in a comfortable position.

Traditionally, these devices are fabricated by taking impressions in the clinic for both jaws and pouring these impressions in the lab, waxing up then fabricating the occlusal splints. Dental treatment can be a lengthy and expensive process for the dental technician, the dentist, and the patient. Therefore, it is important to understand the production accuracy, cost, and reproducibility of newly introduced digital methods. Following the design of the dental prosthesis, the prosthesis must be adjusted manually with use of a mechanical articulator increasing both cost and time. Thanks to the improved advancements in dental technology, dentists can use virtual reality in recording and analysing static and dynamic occlusion as well as jaw relation.

Review of literature

Occlusion: is defined as the static relationship between the incising or masticating surfaces of the maxillary or mandibular teeth or tooth analogues and it's considered a critical component for diagnosing and executing a prosthodontic treatment plan, using either conventional or digital methods.[1]

Clinical treatment often requires modifications to the dental occlusion for restorative or prosthetic practice.[2,3] even though most patients adapt to their new occlusion easily, some can develop discomfort and pain, mostly in the presence of an occlusal interference[4]; Irregular occlusal contacts can lead to congestion of the teeth and the appearance of various clinical symptoms, such as migration of the teeth, cracked enamel, darkening of the teeth, atrophy of periodontal tissue, gingival recession, defects in filling or crowns, osteoarthritis of implants, diseases of the TMJ, migraine, and orofacial pain.[5,6,7].Therefore, occlusion analysis systems should meet minimal accuracy standards to detect, quantify, and locate occlusal contacts.

A common way to record the occlusal contacts is the articulating paper which is rapid ,affordable and available in different thicknesses.[8,9] Another way is the silicone occlusal registration, scanned with a light source and analysed by using an image software program, has reported to offer the highest reliability and validity for determining the occlusal contact area (OCA)[10,11] and its claimed to be the ideal and standard method.[12].Recently introduced digital systems, including the T-Scan and digital casts, have also become available for occlusal assessment.[13]And their application in oral rehabilitation represents a significant advancement in dentistry. This technology leverages digital tools to analyse and plan occlusal relationships, contributing to more precise and personalized oral rehabilitation outcome. The mechanical articulator is a physical instrument that facilitates reproduction of the relationship between the jaws and the skull base, as well as mandibular articulation, in relation to each of the three spatial planes. With improvements in technology, the articulator is shifting from a mechanical device to its digital alternative, the virtual articulator which involves software tools. [14]A virtual articulator is a computer software tool that can reproduce the relationship between the jaws and simulating jaw movement. It has gradually gained research interest in dentistry over the past decade. In prosthodontics, the virtual articulator should be considered as an additional diagnostic and treatment planning tool to the mechanical articulator, especially in complex cases involving alterations to the vertical dimension of occlusion (OVD). To correctly simulate jaw movement, the jaw models must be digitalized and properly mounted on the virtual articulator.[15]

The main indication for the virtual articulator is to overcome the main issues with the mechanical articulator, such as creation of new occlusal contacts, material deformation, errors during orientation and positioning of dental casts, and difficulties simulating patient data in three dimensions. Those articulators may also be used as an educational tool to display treatment options to patients.[16] Mounting casts on an articulator is necessary for the diagnosis of malocclusion and allows an assessment of occlusal alterations during the treatment planning phase. The essential elements common to all available virtual articulator are data acquisition and transfer of the arches to the virtual environment, and subsequent articulation of virtual models which includes (1) digital impression of the arches by the intraoral scanning ; (2) recording of static occlusion and excursive movements of the mandible; (3) transferring the position of the maxilla relative to the skull by the use of facebow ; and (4) mounting the virtual models on the articulator.

Facebows are essential and a key point in dental treatment, for a very important reasons, relating the maxillary arch to the condyles. The use of virtual facebows is a critical aspect of assembling digital models in a virtual articulator. During virtual articulator mounting, it is essential to orient the arches

with respect to a reference plane from the patient's head; using a virtual facebow is used. As the mechanical facebows, virtual facebows can be categorized using average values or by kinematics. Prior

toits use the clinician needs to identify a reference plane. Any such reference plane passes through three points: two at the posterior, and one at the anterior. The two posterior landmarks (arbitrary or anatomical) determine a terminal transverse hinge axis. Kinematic facebows involve the identification of the rotational hinge axis using cutaneous landmarks to pinpoint anatomical condylar projections and can therefore be more precise.[17]

When using a kinematic facebow, the possible inclination of the bow in the frontal plane should be considered. In the literature, different methods have been reported for transferring the position of the arches and carrying out assembly in a virtual articulator These different approaches are based on: cephalometric images,[18] scanning the position of a marker in six positions with reference to the head using a 3D optical scanner,[19,20] a series of photographs converted into a 3D face scan,[20] digital axiography,[21] stereophotogrammetry,[22] standardized extraoral photographs,[23] and calculated cone-beam computed tomography (CBCT).[24] The advantages of using a facebow are controversial, but it has been shown that more precise occlusal contacts can be reproduced in centric jaw relation and eccentric movements with a facebow record. In the present trial, we will be using a straightforward and clinically applied scanned digital facebow data, to aid in the manufacture of occlusal devices, alongside with two different bite registrations such as intercuspal position (ICP) and retruded contact position (RCP). Since a little literature is available on the digital aspect of facebows, it is fundamental to understand its implementation in the digital workflow in prosthodontics.

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5 Study/Trial objectives and purpose.

5.1 Research hypothesis.

Null hypothesis: There is no significant difference in the volumetric changes after adjustments between different Michigan splints made by different digital bite registration methods.

5.2 Primary objectives

To evaluate the volumetric changes on the occlusal surface of the splints after the adjustment done and compare these changes before and after in each group.

5.3 Secondary objectives N/A

6 Study/Trial design & Flowchart.

6.1 Study/Trial Design

This clinical trial will be conducted on 40 participants, each will receive an occlusal devices according to the grouping below. Group

Group	Group A	Group B	Group C	Group D
Criteria	Without digital facebow at ICP	With digital facebow at ICP	Without digital facebow at RAP	With digital facebow at RAP

The clinical and the lab steps:

This clinical trial will need 2 clinical visits:

VISIT ONE:

1-Participant information and informed consent.

Before participation, all participants will be provided with a detailed informed consent form outlining the purpose of the study, the procedures involved, potential benefits, and risks. Participants will be given the opportunity to ask questions before providing written consent.

2-**Dental photography** including Frontal, Right buccal, Left buccal, Upper occlusal, Lower occlusal views.

3- **Digital facebow** using the **AxioSnapMount Facebow-Germany.** It typically consists of adjustable earpieces and a bite fork, which are attached to the patient head, the bite fork is inserted into the patient's mouth, and the patient is guided to bite down into occlusion, Once the bite position is scanned, the AxioSnapMount facebow is removed from the patient's head. And the data are transferred as STL file into the program.

4- **Digital impression** of upper and lower teeth using **Intraoral Scanner (IOS) (Primescan, Sirona).** Clinical conditions at the time of scanning the patient will be IOS calibrated before each scan according to the manufacture's recommendations, operatory temperature is at room temperature, Optra-gate will be used to separate the cheeks and saliva suction at the beginning of each arch scan and operatory light will be turned off. The IOS start on the occlusal of the maxillary right second molar, continues along the occlusal surfaces of the adjacent teeth to the left maxillary second molar, continues toward the buccal side of the same left maxillary second molar to the buccal side of the right second molar, and ends with a scan of the lingual side of the same molar to the left maxillary second molar, continues toward the buccal side of the same left maxillary second molar to the buccal side of the right second molar, and ends with a scan of the lingual side of the same molar to the left maxillary second molar.

5- **Bite registration:** A Lucia gauge will be used to separate the maxillary and mandibular teeth for 5 minutes to deprogram the muscles of mastication. The participant will be guided to occlude on the lucia jig to protrude and perform lateral excursions of the mandible without posterior tooth contacts. The position will be recorded with a polyvinylsiloxane occlusal recording material (O-Bite; DMG). Then the teeth will be dried with an air syringe to minimize the influence of saliva on scanning accuracy. the intraoral scanner will scan the maxillary and mandibular dentition and the maxillomandibular bite relationship in the **retruded articular position (RAP)**. While obtaining the occlusal relationship, the occlusal record will be located on one side to scan the teeth on the other side.

6- Another bite record will be taken where teeth meet normal together, as soon as **Intercuspal position (ICP) and scanned** by the IOS.

LAB PROCEDURE:

1- All groups will be mounted digitally on average value virtual articulator.

Group A. Export the scans for the **CAD design** in Standard Tessellation Language (STL) files and processed for virtual mounting the models on virtual articulator with **average values.** The average digital articulator will use average values (Bennett angle=10 degrees; immediate side shift=0.5 mm; condylar angle=30 degrees; angle incisal table=30 degrees) as its parameters with the use the ICP record.

Group B. The scanned **facebow fork** will be imported and matched to the software for the maxillary mount. And the fabrication of the occlusal splint with the ICP record.

Group C. The models will be mounted using the RAP record only.

Group D. The models will be mounted using the digital facebow and the RAP record.

2- **Design** the occlusal splint based on the patient's specific dental anatomy, considering factors like the bite, occlusion, and any specific requirements for the splint.
3- **Printing:** load the digital file and a 3D printer Sprintray **will be** used to print all the digital occlusal devices based on the digital design. These digital devices are to be printed from.
4- **Polishing:** Apply a biocompatible polish (Sof-Lex™ Finishing and Polishing System by 3M).
5- Scan the splint by using lab scanner (3 shape E3) the splint with optical spray to overcome the translucency issue while scanning (Telescan CAD Spray White).

VISIT 2:

Patient fitting

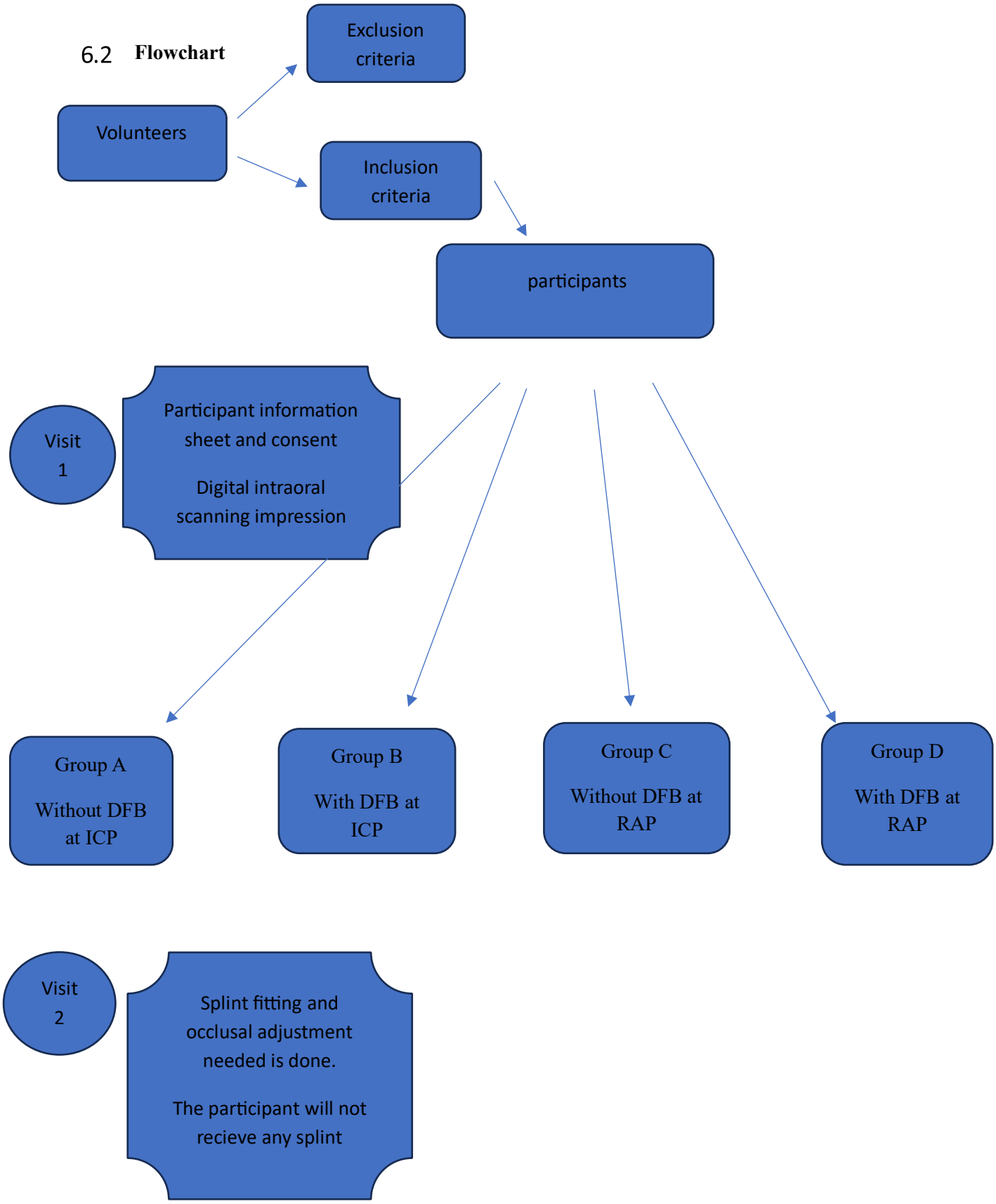
-Try the digital occlusal splint on the patient to ensure a proper fit and make any necessary occlusal adjustment.

-Scan: after the required occlusal adjustments are done, the splints are scanned again.

The next step:

The STL files of both scans of the occlusal device will be imported into a reverse engineering software program (**Geomagic Wrap 2021; 3D Systems),** and the root mean square (RMS) values will be used to represent the volume of occlusal adjustment and will be obtained by the “best fit alignment” and “3D compare” function. the occlusal adjustment positions will be standardized according to the 3D deviation scale diagram in the software program.

6.2 Flowchart



8 Participant selection

A recruitment volunteer sheet will be distributed. The recruitment will only occur through the college advert and this project does not have any incentives. When they show interest in this project, I will send them the consent form. Then they will be given 48 hours to decide if they want to take part before being asked to give their consent. Volunteers themselves will need to sign the form. There is no professional Word in this project. So, there is no potential language problem.

8.1 Participant inclusion criteria

- Aged between 18 and 65.
- Able to provide informed consent.
- Have no more than one tooth missing per quadrant.
- Not diagnosed with any TMD disorder.
- Not undergoing any active dental treatment.
- Regular attendee to the dentist and have stable dentition and oral health.

8.2 Participant exclusion criteria

- Patients with removable dentures.
- Patients receiving medication for psychological disorders.
- Patients diagnosed with systemic joint disorders.
- Pregnant or lactating women
- Patients who have received TMD treatment in the last 6 months.

9 Study/Trial procedures.

9.1 Participant recruitment

- Recruitment research sheets to advertise about the project and will be distributed and advertised. Clinical records will be examined by the to assess eligibility prior to the clinic. Eligible participants or those for whom clarification is required will be approached by their contacts to discuss study participation. Interested participant will have the study explained to them and be provided with an information sheet and given the opportunity to ask questions. Those who agree to take part will then have their eligibility confirmed and informed consent taken prior to participation in the trial. Following consent, baseline clinical assessments will be performed, and the volunteers randomised. We will keep a record of the number approached and the number of participants who are eligible and agree to participate in the trial. Reasons for excluding participants and reasons for nonparticipation will be recorded.

- Participant will be gifted with amazon vouchers of 50 pounds.

9.2 Screening Procedures

10 All participants that accept to volunteer will be logged into a screening log associated with the trial. I will confirm the volunteers' health conditions through basic communication. If they cannot meet the criteria, they will be excluded from this project.

10.1 Randomization Procedures (if applicable)

There is no randomisation in this study as all participants will undergo the same process of scanning and recording.

10.2 Blinding & other measures taken to avoid bias (if applicable)

8.4.1 Blinding.

The trial cannot be blinded.

10.2.2 Other measures taken to minimise/avoid bias.

The scanning will be done by an experienced single operator to all participants with the help of a prosthodontic consultant and if needed it will be repeated.

10.3 Intervention Procedures

Intraoral scanning and using the facebow to record the maxillary jaw mount.

Insertion of occlusal splints, fitting them, and doing the occlusal adjustment needed.

10.4 End of Study/Trial Definition

The end of trial is when all data has been collected and the database locked.

8.7 Approvals

The study protocol and other documentation will be submitted to the King's College London Research Ethics Committee and REMAS before the start of the study.

All correspondence with the REC will be retained.

Any amendments to the study will be submitted to the King's College London Research Ethics Committee as a modification request through REMAS. Amendments will not be implemented until a favourable opinion is issued.

11 Compliance and withdrawal

11.1 Participant compliance

The participant will be provided by an information sheet explaining the trial procedure and will be asked to sign an informed consent.

11.2 Withdrawal / dropout of participants.

The participantes are free withdraw at any point of the project, without having to give a reason.
Withdrawing from the project will not affect you in any way. If so, their data Will be deleted.

11.1 protocol compliance.

Arwa will record non-compliance with the protocol if any happened and will email it to supervisors (Dr Sherif Elsharkawy and Prof. Owen Addison)

12 Data

12.1 Data to be collected.

Baseline data, including intraoral scans, clinical photographs, and digital facebow, will be obtained for each participant. This data will serve as a reference for both digital and semi-digital occlusal assessments.

12.2 Data handling and record keeping.

The data will be processed under the terms of UK data protection law (including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

- we are not collecting any personal information besides the name on the consent form.
- the participants and their personal information will not be identified during or after the study.
- The data will be achieved for future records as long as the PhD course.
- The data will only be shared within the research team.

Specialist teams within King's College London continually assess and ensure that data is held in the most appropriate and secure way.

12.3 Access to the data set

The data will be accessed by the research team and the dental lab which will design and prepare the occlusal splints.

13 Statistical considerations.

The sample size should be 30 per each group but because of limited finance and time we decided to do 10 per each group.

13.1 Sample size calculation.

The participant number will be 40 and 40 splints will be fabricated scanned before and after the adjustment for each group.

For the best statistics result the sample size should be 30 but because of the limited time as a PhD student, limited finance, and recourses. Since the literature had studies on digital facebow as clinical reports without comparisons we decided to use 10*4 as the sample size.

- References Some studies about the volumetric changes using the geomatic software as

Alvaro et al did the trial with 31 participant each received 2 splints.

Blasi Á, Henarejos-Domingo V, Palacios-Bañuelos R, Aparicio C, Roig M. Comparison accuracy of digital and analog method using milled occlusal splints. J Esthet Restor Dent. 2023 Oct;35(7):1103-1112. doi: 10.1111/jerd.13039. Epub 2023 Mar 21. PMID: 36942721.

Tiwu et al recruited 30 patients and divided them in two groups; each 15 received a different splint (α=.05) (P>.05)

Tiwu Peng, Zhikang Yang, Teng Ma, Mindi Zhang, Guanghui Ren,Comparative evaluation of the volume of occlusal adjustment of repositioning occlusal devices designed by using an average value digital articulator and the jaw movement analyser Journal of Prosthetic Dentistry,2023.

13.2 Statistical analysis

Recruitment and Retention

Information on the patients approached to enter the study will be analysed descriptively (Numbers of: patients approached, patients eligible, patients randomised, and patients retained). Reasons for nonentry into the trial will be assessed. Patient drop-out data will be collected to calculate retention rates and identify reasons for non-completion. The number and proportion of participants who did not complete the trial overall will be reported. Reasons for non-completion will be analysed descriptively.

13.3 Interim analysis and data monitoring

13.3.1 Stopping/ discontinuation rules and breaking of randomisation code

For each volunteer, the complete end point of this project will be the final after fitting the splints and doing the occlusal modification needed. After that clinical session they do not need to do any further experiments. Premature discontinuation is defined as volunteers get COVID or they want to withdraw from the research before the end of the project. They will inform the primary researcher (Arwa Alhusban) or the supervisors (Dr. Sherif Elsharkawy and Prof. Owen Addison) and they will be removed along with their data if the data have not already been pooled together.

13.3.2 control and assurance.

There is no data monitoring or steering committee set up for this project.

14 Ethical considerations

This study will adhere to ethical standards, and ethical approval will be obtained from the REMAS.

15 Risk Management & Safeguarding

15.1 *Risk Management*

No risk to your health or teeth will be applied. Slight discomfort may arise when taking the scans as well as during the fitting of the splint and the participant can choose to stop the procedure at any time.

16 Financing

This trial is funded by the Hashemite university of Jordan.

17 Insurance

The study is sponsored by King's College London (KCL). The sponsor will, always, maintain adequate insurance in relation to the study: KCL through its own professional indemnity (Clinical Trials) & no-fault compensation, in respect of any claims arising because of negligence by its employees, brought by or on behalf of a trial participant.

18 Publication and Dissemination

18.1 Publication

All investigators in the study will have access to raw data and right to publication because the raw data will be fully anonymous after publication.

18.2 Informing participants

When the result of the trial is published whoever interested of the participant in getting the result can get them through their email contacts.

19 Disclosure of Interests

There are no financial and other competing interests of the Chief Investigator except for research purposes.