STUDY PROTOCOL

Comparative evaluation of condylar guidance obtained by digital panoramic radiographic images with that of obtained during jaw relation and try-in using two different interocclusal record material in completely edentulous patients: an in vivo study [version 1; peer review: awaiting peer review]

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Abstract

Background: In completely edentulous patients, maintaining the patient's TMJ health and intraoral components is very important. This can be achieved by an accurate interocclusal record, which can be taken by various materials and also at various stages. Simulation of the temporomandibular joint anatomy and mandibular movements is possible on a semi adjustable articulator which is use widely in prosthodontics. Transferring the record on articulator is a critical step in fabrication of complete dentures so it should be done precisely to reduce chair side time and also to avoid complications for patients. This study examines which material is more accurate and also records which stage gives more precision, by comparing the Condylar guidance on radiographs. This is because it has consistent bony landmarks and is comparable to clinical methods in terms of standardisation. The objective will be to determine the inter occlusal records created during Jaw Relation stage and Try-in using reinforced wax and Polyvinyl siloxane and compare these values to the condylar guidance obtained by OPG.

Methods: Recording the Condylar Guidance value on OPG, obtained with tracing Glenoid fossa, Articular eminence and the Frankfurt Horizontal Plane. Followed with conventional steps in making complete dentures, at jaw relation and try-in stage. we will record
values of condylar guidance with the two different Interocclusal record materials.

**Expected result:** It will help the clinicians to get knowledge about obtaining precise condylar inclination angle by using right interocclusal record materials.

**Conclusions:** This study will help us to obtain condylar inclination which in turn helps the patients satisfaction as it maintains the patient's TMJ health and intraoral components.

**Keywords**
Condylar guidance, Jaw relation, Try-in, Interocclusal records, Semi adjustable articulator, OPG

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Introduction
Background and rationale
In order to achieve a comfortable prosthesis that will last several years and maintain the patient’s Temporomandibular joint health and intraoral components, proper interocclusal recording should be followed during the procedure. In completely edentulous patients, the slope of articular eminence on a digital panoramic radiographic image will be traced, which will be utilised in the semi-adjustable articulator's programming.

Mandibular movements can be mimicked with the help of a semi-adjustable articulator. Due to their ease of handling and programming, they are frequently used in prosthodontics. Mounting of the master casts on an articulator is very important step in treatment of complete edentulous patient. In articulator programming, the device is modified to mimic the patient's temporomandibular joint structure and movement patterns of the patient. As a result, it acts as a patient when the patient is not present.

Condylar guidance is described as mandibular guidance generated by the condyle and articular disc traversing the contour of the articular eminence-GTP-9. In the event that condylar guidance the mandibular movements are not accurately recorded, the occlusal interference will occur. The time it takes to adjust dentures might go up as a result. Therefore, it is crucial to accurately capture the maxillomandibular relationship.

Condylar inclinations are provided by semi-adjustable articulators in two different ways: horizontally and laterally. Hanau's formula can be used to calculate the lateral condylar inclination from the horizontal condylar inclination (HCI), which determined with protrusive interocclusal records, or it can be done with individual lateral records.

On semiajustable articulators, The condylar guidance has been found to be unreliable when recorded and reproduced. There was a notable variation amongst the condylar guidance angle recorded successively by different practitioner, among multiple record materials, and amongst various articulator. This can be avoided by taking interocclusal records at various points in an edentulous subject, such as after teeth have been arranged or during jaw relation (Arrow point tracing). It is observed that records taken after teeth arrangement is much accurate. The values for the individual's condylar guidance are calculated using these records.

Radiographs can also be used to measure condylar guidance. When compared to clinical methods, it is more reliable because it uses consistent bony landmarks and can be standardised. These pictures offer composite skeleton representations in the sagittal plane. In a semi-adjustable articulators, condylar guidance inclination will be set using outline of the eminence.

Therefore, in the current research comparison of condylar guidance measurements will be made using records introocclusally and digital orthopantomograph image in edentulous subject. Interocclusal recording medium should be capable of reproducing the details of the occlusal surface, as well as preserving the rigidity and accuracy of the materials for re-use more than once. For the purpose of keeping inter-oocclusal records, there are several materials that can be used.

In this study we will also compare the precision and repeatability of two interocclusal recording materials, that is Reinforced wax and Polyvinylsiloxane (Jet bite) in determining the condylar inclination values in semi-adjustable articulators.

Objectives
- To determine condylar guidance values using OPG image.
- To evaluate the condylar guidance values utilize records introocclusally taken during Jaw Relation stage with Reinforced wax and Polyvinyl siloxane (jet bite).
- To evaluate the condylar guidance values utilize records introocclusally taken during Try-in with Reinforced wax and Polyvinyl siloxane (jet bite).
- Comparing the condylar guidance obtained using OPG with that determined during the Jaw Relation and Try-In.

Study design: Analytical observational study.

Study setting
The upcoming research work shall be done in Department of Prosthodontics Crown & Bridge at Sharad Pawar Dental college, Sawangi, Wardha.
Study participants
The study will be conducted on the patient reporting to the Department of Prosthodontics crown & bridge, with the chief
complain of completely edentulous upper and lower archs and who are consider for complete denture prosthesis at Sharad
Pawar dental college and hospital, Sawangi (Meghe), Wardha.

Inclusion criteria
- Participants with no teeth at all and has well-defined ridges

Exclusion criteria
- People who exhibit symptoms of neuromuscular and temporomandibular joint conditions.

Methods
Written informed consent from the patient will be taken, After taking informed consent, the following procedure will be
done.

Evaluation of Condylar Guidance value by OPG
Orthopantomograph will be taken with the normal exposure and tracings will be done, Marking the Glenoid fossa
(Superior curvature), Articular eminence (Inferior curvature) and the Frankfurt Horizontal Plane (FHP). The angle
formed by joining the lines will be the horizontal condylar guidance angle, for that patient. The condylar guidance values
on both right and left sides is recorded. This will be recorded for all the subject.

Conventional steps of complete denture
Preliminary Impressions will be taken with modelling compound and Impressions will be filled with dental plaster,
a positive replica of primary impression known as preliminary cast. On which wax spacer and custom tray will be made.
Using the low fusing impression compound, Border moulding will be done and Final impression will be taken by zinc
oxidized eugenol paste. This impression will also be poured with dental plaster and cast obtained will be the master cast.
Temporary record base will be made on it along with the occlusal rims.

Determination of values of condylar guidance with the Interocclusal record material during Jaw relation
stage
The jaw relation will be recorded using standard techniques. Face bow transfer will be completed and maxillary cast will
be orient on the articulator with the centric relation record mandibular cast will be related to maxillary cast and mount on
the articulator’s mandibular component. Tracers will be affixed to the rims of the maxilla and mandible. Subject will be
seated in upright position and he/she will be trained for mandibular movements. Once the dentist is satisfy with the
patients mandibular movements, tracer plate will be ready to document.

The patient will be asked to retrude the mandible in centric relation once a distinct arrow point tracing with a sharp apex
has been made, and the interocclusal recorded using reinforced wax and polyvinyl siloxane (jet bite) will be taken. The
rims will be held intraorally till interocclusal material is set. When the mandibular jaw is in the centric relation, the head of
the condyle is positioned, anteriorly & superiorly within the mandibular fossa/glennoid fossa as it is possible. And
protrusive interocclusal record will also be made by instructing patient to protrude 6mm of distance from the apex of the
arrow and it will be marked. This will be programmed on hanu-articulator. Articulator programming simulate tmj
anatomy and movements of the subject, thus it serves as subject in the absences of the subject. Horizontal condylar
guidance adjustments will be freed by releasing the locknuts.

Determination of values of condylar guidance with the Interocclusal record material at try-in stage
Teeth arrangement will be done, will proceed for try-in procedure and interocclusal records will be made using two
different interocclusal record material namely, Polyvinay siloxane and Reinforced wax. As it is difficult to maintain jaw
stability at 6mm protrusion position, we will make a Wax indentations prior which will help subject to maintain the
desired protrusive jaw position. The articulator’s lower member will be moved forward by about 6 mm after the try-in
procedure, and it will then be closed in that position. The trial dentures will then be placed on the articulator. The
interaction of the upper and lower midlines, as well as the horizontal relationship between the lower and upper anterior
teeth, will be closely scrutinised. The locknuts will be fixed in that position. After proper training of the patient, we will
register interocclusal record using bite registration paste and reinforced wax, hold the records in the mouth till the material
gets hard.
The programming of the articulator
On the articulator, the trial dentures will be put, and the interocclusal records will be used for programming. The maxillary cast will be constructed in two parts with a horizontal division method to evaluate the condylar guidance angulation. The condylar guidance values will be logged for both the interocclusal material reinforced wax and polyvinylsiloxane for each side, right and left of condyle.

The condylar guidance values succeeded in getting will be subjected to statistical analysis.

Variables and data measurements

**Outcome:** Expected outcome of the study is that it will help the clinicians to get knowledge about obtaining precise condylar inclination angle.

**BIAS:** Bias will be minimized as patients are randomly will be selected from the Outpatient Department of Department Prosthodontics Crown & Bridge, of Sharad Pawar Dental College and Hospital, Wardha.

Sample size calculation

Formula Using Mean difference

\[
 n \geq \frac{Z_{1-\frac{\alpha}{2}}^2 + Z_{1-\beta}^2 \left( \sigma_1^2 + \sigma_2^2 \right)}{(\mu_1 - \mu_2)^2}
\]

Where:

- \( Z_{1-\frac{\alpha}{2}} \) is level of significance at 5% i.e., 95%
- Confidence interval = 1.96
- \( Z_{1-\beta} \) is the power of test = 90% = 1.28

Primary variable:

Mean ± SD. (Articulator Group) = 25.7143 ± 10.15944

Mean ± SD. (OPG Group) = 38.777 ± 2.56.

Pooled std Dev. = \((10.15944 + 2.56)/2 = 6.359\)

As per reference articles.

\[N_1 = 2^+[(1.96 + 1.28) \times 2 (13.0557) 2]/(6.359) 2 = 9\]

Minimum Total samples required = 7 per Group.

Minimum Total sample size is 14.

Statistical analysis

Statistical analysis will be done with the aid of Independent t-test., Analysis of variances (ANOVA) will be applied for analysis. The software that will be used in the analysis will be SPSS 27.0 version.

Dissemination

The scope of this study is to provide the dental practitioners with a method to effectively and precisely record condylar guidance, which won’t lead to maximum intercuspatation interference while doing lower jaw movements. This will contribute to meet needs of the patient in accordance with the operation and durability of the denture in the oral cavity.

**Study status:** Study not yet started.
Discussion
In 2021, S.R. Keerthana studied an article to evaluate the reproducibility of condylar inclination and concluded that HCI values varied with respect to the record material used.5 R. Venkateshwaran in 2014 The relationship amongst the angle of horizontal condylar inclination measured on a semi-adjustable articulator and the angle marked on a TMJ tomogram in patient presenting with no teeth was investigated. He came to the conclusion that the horizontal condylar inclination, which is represented by the articular eminence marked on a TMJ tomogram image, has a mean difference of 5 degrees.2 Another author in 2013 studied the accuracy of articulator programming using radiographs and interocclusal records captured during the Arrow point tracing and Try-in stages. In that they noticed the easonable condylar guidance values determined at Try-in stage was nearer by average condylar guidance values determined on Radiographs.6 Pragya Shreshta in 2012 wanted to evaluate how the horizontal condylar guidance is measured clinically and radiographically. The CT scan and three clinical techniques—the wax protrusive record, Lucia jig record, and intraoral central bearing device were used to assess the condylar guidance. He came to the conclusion that the left and right HCG values were nearly identical. Particularly in comparison to clinical methods, the CT scan revealed higher HCG values, and all of the analytical methodologic values were comparable.5 In 2003, Jose dos Santos Jr(2003) studied this article to differentiate the condylar inclination angles between the protrusive wax record in semi adjustable Hanau articulator and the quick-set recorder for pantographic tracings. He determined that the protrusive wax record did not precisely reproduce the protrusive condylar inclination & that the pantographic tracer technique could do.7

Limitations
• Dentulous patient
• Patient not willing to participate
• Radiographic distortion

Ethical considerations
Ethical approval received by Datta Meghe Institute of Higher Education and Research, Sawangi, Wardha (IEC ref no.-DMIHER (DU)/IEC/2023/849).

Data availability
No data are associated with this article.

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References
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