Research

Comparison of patient satisfaction between complete dentures fabricated using "conventional" and "cephalometric angular reconstruction" vertical dimension procedures: A multicenter randomized clinical trial

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Abstract

Aim: In Prosthodontics, during complete denture fabrication, conventional methods employed to determine occlusal vertical dimension require patient co-operation. Hence, the aim of the present study is to evaluate the clinical effectiveness of the 'cephalometric angular reconstruction' procedure in the calculation of these lost dimensions.

Settings and Design: Multicentric randomised clinical trial conducted in four dental hospitals.

Materials and Methods: Fully edentulous people who came to the hospitals for complete denture treatment were recruited into the study. Those who fulfilled the inclusion criteria were randomly assigned to two groups; Group 1: Dentures fabricated using a 'conventional' procedure and Group 2: Dentures fabricated using 'cephalometric angular reconstruction'. The patient's level of satisfaction was assessed on a scale of 1 to 5; 1-dissatisfaction to 5-excellent. The confounding factors that can influence the satisfaction were also recorded.

Statistical Analysis Used: The distribution of patient's satisfaction was assessed using Chi-square test, whereas the difference between the two groups was evaluated using Mann–Whitney test.

Results: There was no significant difference either in the vertical dimension determined ($P = 0.465$) or the patient's level of satisfaction ($P = 0.943$) between the two groups. There was no influence of confounding factors considered in the present study on the satisfaction levels. There was no difference in the distribution of satisfaction levels based on the dentist's quality assessment ($P = 0.243$).

Conclusion: Complete dentures fabricated using cephalometric angular reconstruction procedure of vertical dimension determination were equivalent with respect to patient satisfaction, compared to those made using a conventional method. Hence, the new method can be clinically recommended during denture fabrication.

Keywords: Cephalometrics, complete dentures, occlusion, vertical dimension

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INTRODUCTION

The vertical dimension of occlusion (VDO) refers to the measurement in the vertical plane that establishes the relation between the maxilla and mandible when occluded.[1] It is of great biological importance as it plays a vital role in mastication, speech, appearance, and functioning of surrounding tissues.[2-4] In completely edentulous individuals, VDO is lost, and reconstituting the occlusal support is essential during prosthodontic rehabilitation. As the association between morphology and function is inseparable, an increase in this dimension prevents muscular relaxation, whereas a decrease causes over-relaxed musculature.[5-8] Hence, to avoid the disturbance in neuromuscular tone, precise measurement of VDO is essential. Many methods based on preextraction data, intra-oral measurements, profile tracing, rest position, swallowing, phonetic, neuromuscular perception, and craniometrics values are described in the literature.[5,9-14] Although there are many advances, clinical judgment based on experience alone is considered to play a significant role in the assessment of this important component during the construction of dentures. In routine clinical practice, the conventional technique of determining the vertical dimension at rest and positioning VDO to establish 2–3 mm of interocclusal rest space is employed. Another traditional technique based on anatomical landmarks and facial proportions is also used clinically. All these techniques require patient co-operation, and additionally, are extremely subjective. Hence, attempts were made to implement other standardized methods of calculating the lost facial dimensions.

In recent times, cephalometric analysis has gained much popularity in this field. Information pertinent to the role of cephalometrics in prosthodontic diagnosis, treatment planning, and prognosis is evident in the literature.[15-18] Many software programs are also being developed to calculate VDO using computer-assisted cephalometrics.[19,20] These methods are based on the skeletal landmarks that are not affected by edentulism.[21-29] The accuracy, and the reliability of angular and linear measurements and correlations, led to the development of regression equations.[30,31] In a study, based on multiple regressions, five angular and two linear cephalometric landmarks with weak to moderate positive and negative correlations were observed, yielding satisfactory results.[30] However, complexity is the major barrier to apply this technique clinically because most prosthodontists seldom use cephalometric techniques and analysis. To overcome this, an easy and simple method of cephalometric angular reconstruction that combines both the concepts of facial proportions and cephalometrics has been tested in contemporary dentulous individuals.[31] The positive results led to the framing of simple linear regression formulae. Thus, cephalometrics showed a lot of scope in this arena because of the positive observations in the preliminary studies.

The reconstructed VDO, in people with lost facial dimensions, influences the success of the prosthesis. This is because the tolerance, stability, esthetics, function, and phonetics of any prosthesis change based on the determined maxillomandibular relations. Hence, any deviation of the VDO affects all these aspects, in turn impacting the satisfaction of persons wearing these dentures. As there is no clinical trial that has compared the clinical effectiveness of determining VDO using cephalometric approach, the present multicentre randomised trial has been planned to determine the difference in the overall satisfaction of persons wearing complete dentures fabricated using "conventional" and "cephalometric angular reconstruction procedures."

MATERIALS AND METHODS

Ethical clearance

The present clinical trial is registered at the Clinical Trials Registry, India, with the registration number CTRI/2021/05/033585. A total of four dental institutes participated in the clinical trial. The institutional ethical committees of all the participating institutes approved the study protocol. The ethical approval number of the primary and leading center is IEC/NDCH/2020/P-48. Ethical approval numbers of other centers are PMNMDCH/1968/2020–21; Rc. No. 99/Academic/GDCH/Kadapa/2020; MDC_R_088429. Informed written consent was obtained from all the participants prior to screening for possible inclusion. All the participating investigators took part in an online meeting before the inclusion of the first patient to predefine and standardize the methodology and ensure uniform treatment outcome.

Trial design

This was a multicentre, parallel-group, equivalence, triple-blind trial with restricted randomization and an allocation ratio of 1:1 conducted in India (four centers).

Participants

All the participants attending the outpatient department of the four dental institutes (centers) were recruited based on the following eligibility criteria.

- Completely edentulous persons with Class I skeletal pattern (The Class I skeletal pattern was determined using the YEN angle, [Figure 1], which is based on the

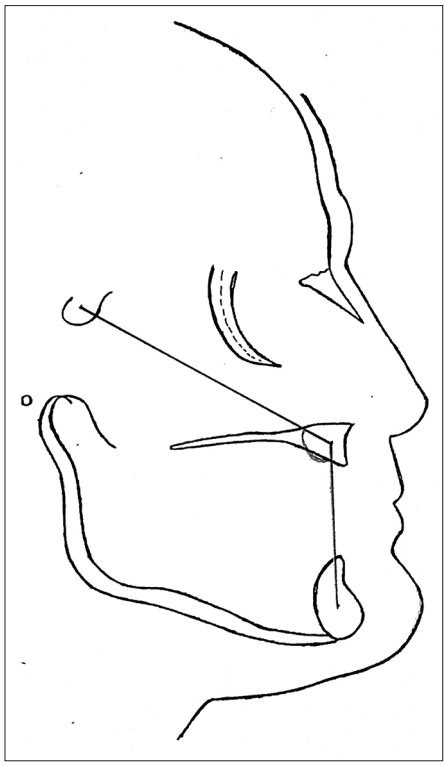

Figure 1: Yenn angle considered in the present study

landmarks midpoint of sella, the midpoint of premaxilla, and center of the largest circle that is tangent to the internal inferior, anterior and posterior surfaces of the mandibular symphysis, measured at the midpoint of the premaxilla. If this angle was between 117 and 123 degrees, it was considered as Class I skeletal pattern)
- Age range of 50–80 years
- Who gave their written informed consent to participate in the study.

Those with craniofacial malformations, facial asymmetries, or cleft palate were excluded from the study.

The study took place in the Departments of Prosthodontics in four dental institutions of India from December 2020 to June 2021.

Interventions

All the standard steps involved in the fabrication of complete dentures were followed for every participant, irrespective of the group. One postgraduate student in each center performed all the clinical procedures. In addition, they were trained and calibrated to determine the vertical dimension using either conventional or angular reconstruction procedures. That trained student recorded the vertical dimensions of all the participants in a centre. The details of the interventions for each group are mentioned below.

Group 1: The anatomical landmarks method was considered for determining the vertical dimension at rest. The Willis guide was used to measure the distance from the pupils of the eye to the rimaoris and the distance from the columella to the lower border of the mandible. When these measurements are equal, the jaws were considered at rest. Then, by establishing 2–3 mm of interocclusal rest space, the VDO was calculated.

Group 2: The cephalogram was obtained and placed on the view box with the patient's image facing the right. The four corners of the radiograph were taped to the view box. The matte acetate film was placed over the radiograph and taped securely to the radiograph and the view box. With a sharp 3H drawing pencil, the required reference landmarks, Nasion (N), Anterior Nasal Spine (ANS), Porion (P), and Gonion (G) were marked, as represented in Figure 2. These points were joined as shown in Figure 3 to form angles; N-ANS-G (by joining the landmarks N, ANS, and G) and P-G-ANS (by joining the landmarks P, G, and ANS). Then, using the formulae "N-ANS-Gnathion (Gn) (in degrees) =1.271 N-ANS-G (in degrees) +24.83" and "P-G-Gn (in degrees) = 0.987 P-G-ANS (in degrees) +35.93," the two angles were determined (where Gn is point Gn) and reconstructed on the tracing[31] [Figure 4]. The intersection of the two angles was marked as Gn [Figure 5]. The distance between ANS and the reconstructed point Gn was considered as the VDO in cephalogram [Figure 6]. The distance between N and ANS ($\dot{x}$); as well as ANS and reconstructed Gn ($\dot{y}$) was measured on the tracing [Figure 7]. The clinical distance between N and columella ($\dot{x}$) of the patient was measured, and using the formula $\dot{x}/\dot{y}$= x/y, the clinical distance between columella and Gn (y) was determined and considered VDO [Figure 7].

Immediately after insertion of fabricated complete dentures, all the participants were evaluated by respective investigators in each center. A questionnaire, which was divided into three parts, was used for assessing the outcome. In the first part, the dentist assessed the quality of the dentures; a rating scale of 1–5 was used, where 1-poor quality and 5-excellent quality. In the second part, the patients answered the questions regarding gender, age, level of education, marital status (married, divorced, single, or widowed), self-supporting lifestyle (1-ability to live by themselves, 2-supported by their families, and 3-able to live alone), smoking habits, period of tooth loss, and the number of previous complete dentures worn. In the third part of the questionnaire, patients rated their complete dentures, depending on the level of satisfaction. The patients rated using a scale ranging from 1 to 5 (where 1 – dissatisfaction and 5 – excellent).

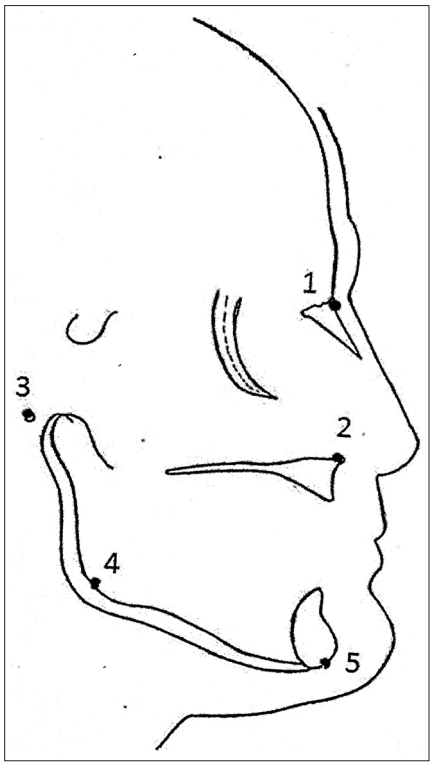

Figure 2: Landmarks considered in the present study; (1) Nasion; (2) Anterior Nasal Spine; (3) Porion; (4) Gonion; (5) Gnathion

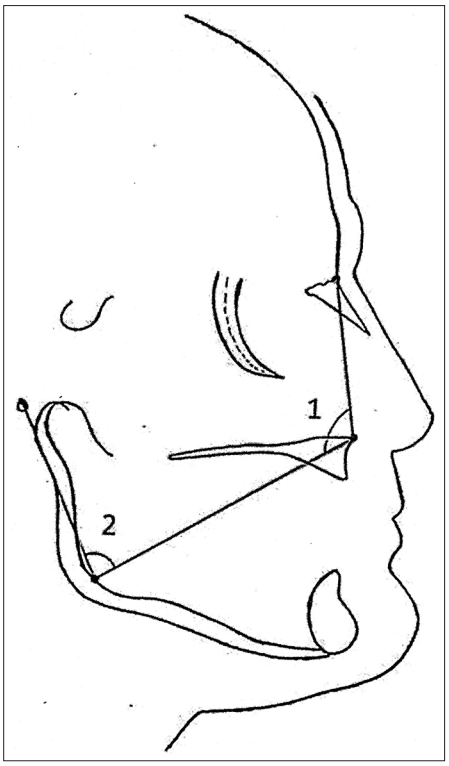

Figure 3: N-ANS-G and P-G-ANS (1) Angle formed between Nasion, Anterior Nasal Spine, Gonion (2) Angle formed between Porion, Gonion, Anterior Nasal Spine

Outcomes

The patient satisfaction on a scale ranging from 1 to 5 (1 – dissatisfaction to 5 – excellent) was considered the primary outcome measure. On the other hand, the dentist rating the denture quality from 1 to 5 (1 – poor quality and 5 – excellent quality) was considered the secondary outcome. There were no changes in the outcomes after the trial commenced.

Sample size

Based on the pilot study findings done on 12 participants (6 for each group), with 5% significance level and a power of 90%, considering patient satisfaction scale as the primary outcome measure, a sample size of 236 (118 in each group) was necessary. So, a final sample of 240 (120 in each group) was determined. To recruit this number of patients, a 6-month inclusion period was anticipated. No interim analysis was performed.

Randomization

The randomization was stratified by centers (four dental institutions) with a 1:1 allocation. Restricted randomization, i.e., block randomization was employed in the present study with multiple block sizes of 4 and 6. The table of random numbers was used to generate the random allocation sequence. Sequentially numbered opaque-sealed envelopes were used as mechanism for the allocation concealment. Determination of whether the participant should be given dentures using the conventional method or angular reconstruction procedure was done after enrolment, and initials steps of primary and secondary impressions, and fabrication of occlusal rims was completed. The appropriate numbered envelope was opened at the main center, and information given to other centers, during the jaw relation procedure. A professor in the main center (unrelated to the study) generated random allocation sequence, and assignment of participants to interventions. The enrollment of participants was done by the four investigators individually in their respective centers. The participants, the outcome assessors, and data analysts were blinded to the allocation.

Statistical analysis

The statistical analysis was carried out using SPSS 17.0 version for Windows (Chicago, III, USA). The level of significance was set at 0.05 level. Descriptive statistics regarding confounding factors like age, gender, level of education, marital status, self-supporting life style, smoking, period of tooth loss, and number of previous dentures worn was represented in number and percentage. The difference in the distribution of patient's satisfaction based on the various confounding factors considered was determined using Chi-square test. The difference in

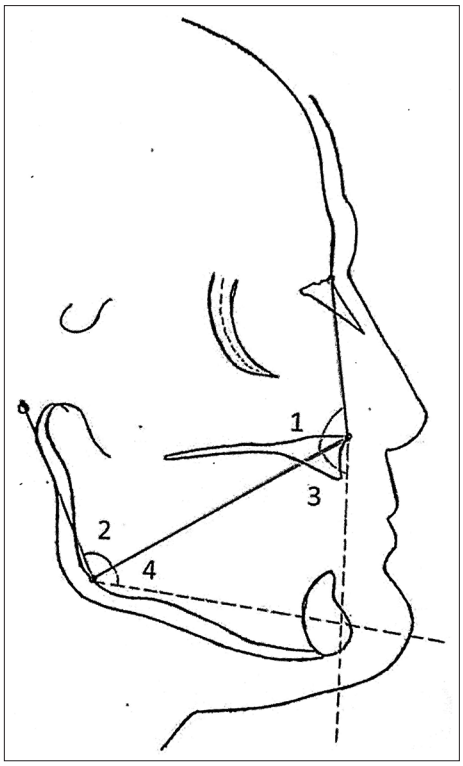

Figure 4: Determined angles N-ANS-Gn and P-G-Gn (1) Angle formed between Nasion, Anterior Nasal Spine, Gonion (2) Angle formed between Porion, Gonion, Anterior Nasal Spine (3) Angle determined between Nasion, Anterior Nasal Spine, Gnathion (4) Angle determined between Porion, Gonion, Gnathion

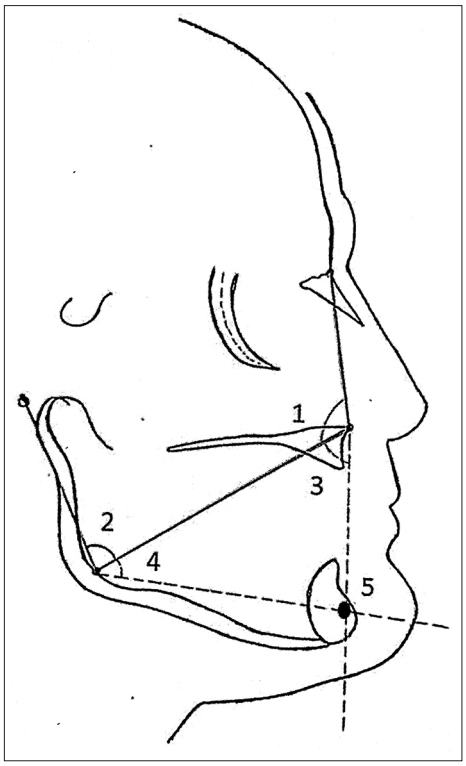

Figure 5: Reconstruction of point Gnathion

the distribution of patient's satisfaction based on center and dentist's assessment was tested using Chi-square test. The difference in the patient satisfaction scale between the two groups was assessed using Mann–Whitney test. The difference in the VDO between the two groups was assessed using unpaired *t*-test.

RESULTS

The details of the enrolment, number of participants who were randomly assigned to two groups, who received the intended treatment, and who were analyzed for the primary outcome is represented as a participant flow diagram [Figure 8]. The required number of participants could be recruited in the specified period of 6 months. The demographic characteristics of the participants are represented in Table 1. The mean age of the participants was 63.87 (range: 50–80), and among them, 136 were male and 104 females. The patient's level of satisfaction ranged from 3 to 5 (median: 4). The mean N-ANS-G obtained in the angular reconstruction group was 92.19 ± 3.54, whereas mean P-G-ANS was 89.53 ± 4.54. There was no significant influence of confounding factors on the level of satisfaction reported by complete denture wears [Table 2]. There was no

Table 1: Demographic characteristics of the participants *n*=240

	n (%)
Age (years)	
≤65	158 (65.83)
>65	82 (34.17)
Gender	
Male	136 (56.67)
Female	104 (43.33)
Level of education	
Illiterate	74 (30.83)
Primary school	61 (25.42)
Middle school	48 (20.00)
High school	27 (11.25)
Intermediate/diploma	22 (9.17)
Graduate	6 (2.50)
Professional degree	2 (0.83)
Marital status	
Married	221 (92.08)
Divorced	2 (0.83)
Single	5 (2.08)
Widowed	12 (5.00)
Self-supporting life style	
Ability to live by themselves	221 (92.08)
Supported by their families	14 (5.83)
Able to live alone	5 (2.08)
Smoking habit	
Yes	92 (38.33)
No	148 (61.67)
Period of tooth loss (months)	
≤12	125 (52.08)
>12	115 (47.92)
Number of previous dentures worn	
0	176 (73.33)
1	64 (26.67)

Represented as number (Percentage)

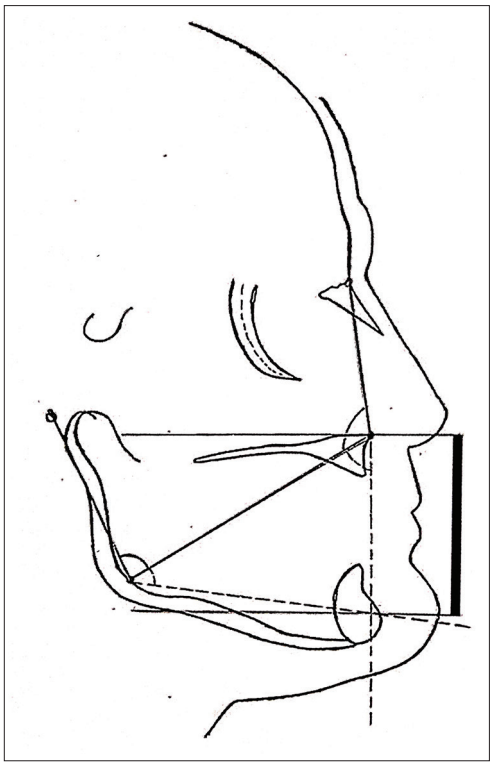

Figure 6: Reconstructed vertical dimension of occlusion in cephalogram

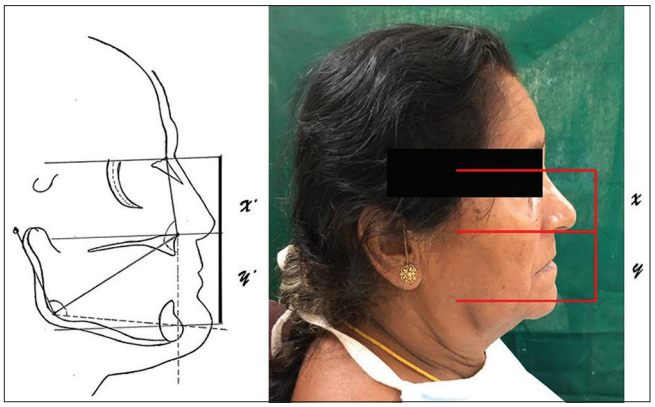

Figure 7: Clinical determination of vertical dimension of occlusion

difference ($P = 0.943$) in the patient's level of satisfaction between the conventional and angular reconstruction groups [Table 3]. Even, there was no influence of center on the difference in the level of satisfaction between the groups [Table 3]. The distribution of satisfaction levels based on dentist assessment also showed no significant difference ($P = 0.243$), which is depicted in Table 4. The VDO determined based on the two considered methods also showed no significant difference ($P = 0.465$), the details of which are represented in Table 5.

DISCUSSION

In recent times, prosthodontics has advancements in techniques and materials, but clinical steps for the determination of VDO could not evolve for preciseness. In edentulous people, because of the absence of posterior teeth, there will be a loss of VDO. The restored dimensions should be the same as probably what existed before the edentulous situation, as correct registration of VDO has biological importance.[2-6] However, the major problem with the existing methods is that the muscles controlling the mandible become tense when the mechanical recording devices are placed in the mouth. In addition, the physiological methods employed show variation in measurements between sittings and within the same sitting. Thus, failure in determining the VDO might cause many kinds of problems such as temporomandibular joint disorders, muscular dysfunction, atrophy, alveolar bone resorption, a trauma of soft tissue, disturbance in phonetics, esthetics, swallowing, and chewing.[6] Specifically, the VDO, if it is greater, causes trauma to supporting tissues, phonetic problems, disturbance in temporomandibular joint and esthetics, whereas low VDO decreases the masticatory efficiency and esthetics. So, proper establishment of VDO is important to improve the function and esthetics, and thus the patient's quality of life.[26] Measures to avoid indiscriminate increase or decrease in this value are important.

Standard measurement established through radiographic techniques and cephalometric analyses, which are easy, accurate, convenient, economical, and individualized, can be a useful additional tool in prosthodontics, if proved to be effective. A study reported maximum correlation between VDO inferior (lower facial angle from the G point to the ANS and the chin point) and the gonial angle.[27] The regression formulae derived in that study were encouraging in the field of Prosthodontics. Still, the major drawback was that the formulae proposed were based on a single cephalometric dimension that can influence the accuracy of the measurement. To surpass this, multiple regression equations derived by considering six angular and four linear cephalometric measurements were proposed.[30] However, for this, the dentist needs to invest more time in completing the analysis. Later, a simple cephalometric angular reconstruction method was tested on dentulous people and proved to be accurate.[31] The reconstruction of the facial dimensions through angles reported statistically significant positive correlations, which can be due to the fact that the human face follows precise dimensions. Hence, the present study was planned to determine the clinical effectiveness of the angular reconstruction method in edentulous people by comparing the satisfaction levels of people wearing complete dentures fabricated using the vertical dimensions predicted by cephalometrics to those with the conventional method. There was no difference

Table 2: Effect of confounding factors on complete denture wearer's level of satisfaction

	Level 3	Level 4	Level 5	*P*
Age (years)				
≤65	30 (19)	61 (38.6)	67 (42.4)	0.349 (NS)
>65	17 (20.7)	38 (46.4)	27 (32.9)	
Gender				
Male	24 (17.6)	57 (41.9)	55 (40.5)	0.682 (NS)
Female	23 (22.1)	42 (40.4)	39 (37.5)	
Educational level				
Illiterate	12 (16.2)	32 (43.2)	30 (40.6)	0.589 (NS)
Primary school	13 (21.3)	23 (37.7)	25 (41.0)	
Middle school	12 (25.0)	21 (43.8)	15 (31.2)	
High school	6 (22.3)	10 (37.0)	11 (40.7)	
Intermediate/diploma	3 (13.6)	11 (50.0)	8 (36.4)	
Graduate	0	1 (16.7)	5 (83.3)	
Professional degree	1 (50.0)	1 (50.0)	0	
Marital status				
Married	41 (18.6)	94 (42.5)	86 (38.9)	0.238 (NS)
Divorced	0	1 (50)	1 (50)	
Single	3 (60.0)	0	2 (40.0)	
Widowed	3 (25.0)	4 (33.3)	5 (41.7)	
Self-supported life style				
Ability to live by themselves	42 (19.0)	92 (41.6)	87 (39.6)	0.148 (NS)
Supported by their families	2 (14.3)	7 (50.0)	5 (35.7)	
Able to live alone	3 (60.0)	0	2 (40.0)	
Smoking habit				
Yes	18 (19.6)	35 (38.0)	39 (42.4)	0.681 (NS)
No	29 (19.6)	64 (43.2)	55 (37.2)	
Period of tooth loss (months)				
≤12	26 (20.8)	46 (36.8)	53 (42.4)	0.342 (NS)
>12	21 (18.3)	53 (46.1)	41 (35.6)	
Number of previous dentures worn				
0	33 (18.8)	72 (40.9)	71 (40.3)	0.785 (NS)
1	14 (21.9)	27 (42.2)	23 (35.9)	

Represented as number (Percentage). NS: Nonsignificant

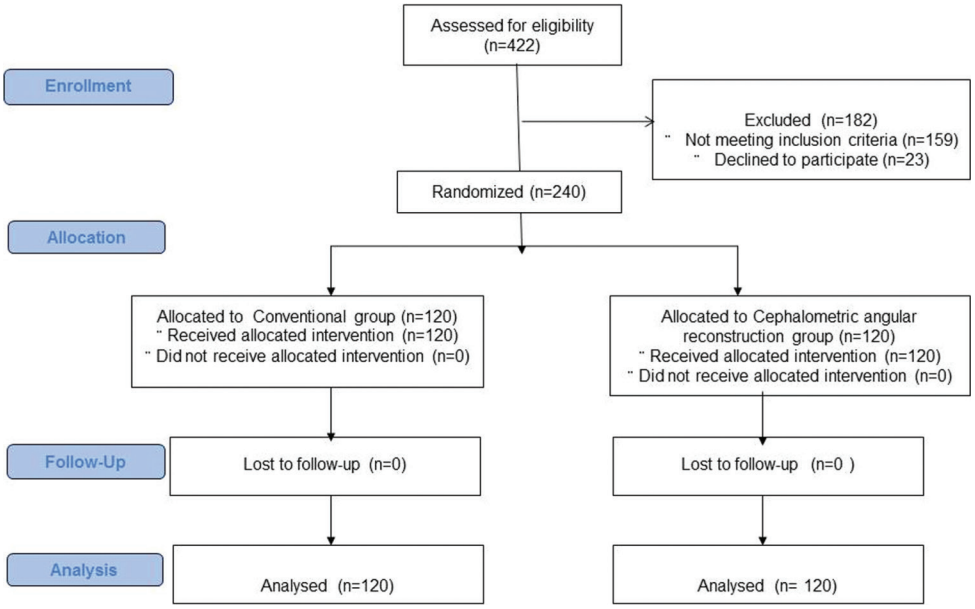

Figure 8: Participant flow diagram

either in the vertical dimension values determined as well as the in the satisfaction levels between the two groups. This shows that the angular reconstruction method can be employed clinically.

The famous artist Leonardo Da Vinci gave simple ratios for drawing the face, which was applied to complete denture construction by Ivy.[32-34] The facial dimensions follow simple proportions, and this concept of harmonic faces

Table 3: Complete denture wearer's satisfaction based on centre

Centre	Level 3	Level 4	Level 5	*P*
1	12 (20.0)	21 (35.0)	27 (45.0)	0.423 (NS)
2	9 (15.0)	23 (38.3)	28 (46.7)	
3	13 (21.7)	25 (41.7)	22 (36.6)	
4	13 (21.7)	30 (50.0)	17 (28.3)	
Group	**Mean±SD**	**Median**	**Range**	***P***
		Centre 1 (*n*=60)		
1	4.23±0.77	4	3-5	0.854 (NS)
2	4.26±0.78	4	3-5	
		Centre 2 (*n*=60)		
1	4.30±0.75	4	3-5	0.904 (NS)
2	4.33±0.71	4	3-5	
		Centre 3 (*n*=60)		
1	4.13±0.78	4	3-5	0.886 (NS)
2	4.17±0.75	4	3-5	
		Centre 4 (n=60)		
1	4.1±0.71	4	3-5	0.723 (NS)
2	4.03±0.72	4	3-5	
		Total sample (*n*=240)		
1	4.19±0.79	4	3-5	0.943 (NS)
2	4.20±0.78	4	3-5	

Represented as Number (Percentage). NS: Nonsignificant, SD: Standard deviation

Table 4: Cross tabulation of dentist assessment and wearer's level of satisfaction

Dentist/wearer	Level 3	Level 4	Level 5	*P*
4	10	31	33	0.243 (NS)
5	37	68	61	

Represented as Number (Percentage). NS: Nonsignificant

Table 5: Outcome measures considered in the present study

	Level		
	Level 3	**Level 4**	**Level 5**
	Group 1		
Weare's satisfaction	24	49	47
Dentist assessment	0	41	79
	Group 2		
Wearer's satisfaction	23	50	47
Dentist assessment	0	33	87
Vertical dimension of occlusion determined			
Groups	**Mean±SD**	**Range**	***P***
1	66.52±4.22	59.1-73.4	0.465 (NS)
2	66.91±4.11	59.1-73.1	

Represented as number. NS: Nonsignificant, SD: Standard deviation

can be utilized for the rehabilitation of lost dimensions. Research and clinical experience have revealed a close interdependence of facial proportions.[35-37] In the early stages of research, it has been observed that nasal height (N to ANS) accounts for 43% of the total facial height (N to Gn). In another study done on harmonious individuals, total facial height has been divided into 45% and 55% of nasal height and dental height, respectively. Later, in another study, the population has been divided into three facial types based on the growth pattern; normal, retrognathic, and prognathic. It has been observed that the upper facial height varied very little between the three facial patterns, whereas on the other hand, lower facial height has been found to be 56%, 59.5%, and 54.1% of total facial height in normal growth pattern, retrognathic and prognathic groups respectively. The proportion of middle and lower third the proportion of middle and lower third was proposed to be 0.8. Thus, the literature has proved a definite correlation between various facial dimensions, which led to the development of an instrument called a golden ruler. In another study, the face has been divided into four proportions and the ratio used for prosthesis construction. In the present study, for the conventional method of denture preparation, Willi's gauge was employed. The Pupil-rima oris distance has been considered to be equal to chin-nose distance, which is also based on facial proportions. That might be the reason for the similar vertical dimensions obtained in both methods. In almost all the cases, the level of patient comfort was satisfactory. This is the "comfort zone concept" that emphasizes VDO to be in a range instead of a fixed point.[38] Because of this adaptive capacity, small dispersions were acceptable and did not influence muscle activity. A study observed that the increase in VDO could change the extent of mandibular trajectory during swallowing only if the increase was more than 3 mm.[39]

The major drawback/limitation of cephalometrics is the need for a radiographic setup, which might not be available in all dental clinics, and additionally, the radiation exposure. Another drawback is the influence of racial differences[40] and the need to frame separate formulae for other populations based on the same theoretical principle. Thus, generalizabilty is a significant issue. However, there are many advantages of the angular reconstruction procedure considered in the present study. The landmarks selected were simple and could be marked easily. Using four cephalometric points, reconstruction of another point, Gn was done efficiently; there was ease in calculation, construction, and application. Angular variables were minimally affected due to problems of magnification and distortion when compared with the linear measurements. The patient's acceptability is another crucial factor in the success of this technique. Further studies on the clinical application of angular reconstruction procedure for partially edentulous people requiring removable partial dentures and dentate individuals undergoing orthodontic treatment are indicated. In addition, usage of radiographic markers for increasing the accuracy of transferring the cephalometric measurements to actual measurements is also indicated.

CONCLUSION

Based on the limitations of the present study, the cephalometric angular reconstruction procedure has been proved to be successful and can be suggested as an equivalent to standard methods of recording the VDO. It can be suggested as an alternative to patients with neuromuscular problems, those unable to co-operate for the conventional methods of recording the vertical dimension and in scenarios, which demand reduction of the time spent in contact with patients.

Registration

The study is registered at the Clinical Trials Registry, India, with the registration number CTRI/2021/05/033585.

Protocol

The full detailed protocol can be downloaded from the Clinical Trial Registry.

Acknowledgment

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Nil.

Conflicts of interest

There are no conflicts of interest.

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