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A Randomised Controlled Study Comparing the Anterior Mandibular Labio-Lingual Neutral Zone Position in Edentulous Subjects With and Without Their Maxillary Denture In-Situ

ABSTRACT:

Opinion is divided as to whether the neutral zone impression to determine the labio-lingual position of mandibular complete dentures requires the maxillary denture to remain in-situ or not.

Two such neutral zone impressions were recorded for each of the 12 participants of this randomised controlled study. The presence of the maxillary denture made no statistically significant mean difference in labio-lingual position of the mandibular neutral zone.

Within the confines of this research protocol there was no evidence that the shift in the labio-lingual position of the anterior mandibular neutral zone was consistently affected by the presence of a maxillary appliance.

INTRODUCTION

According to the latest Adult Dental Health Survey of England and Wales¹ the average age at which people become edentate is continuing to increase. Becoming edentulous at an advanced age adversely influences two prerequisites for successful management of complete dentures: The patient is more likely to have a diminished capacity for successful neuromuscular adaptation² and poor quality denture bearing tissues due to earlier tooth loss or periodontal destruction. Poor tolerance of complete dentures impacts on quality of life and nutrition.³

The neutral zone (NZ) is defined as the potential space between the lips and cheeks on one side and the tongue on the other; that area or position where the forces between the tongue and cheeks or lips are equal.⁴

After tooth loss, the process of mandibular alveolar residual ridge resorption begins.⁵ As it flattens it has a reduced ability to resist the lateral displacing forces exerted by the adjacent oral musculature on complete dentures, particularly in the mandibular arch as this ridge experiences greater atrophic change.⁶ In addition, as the distance from the occlusal surfaces of the teeth to the alveolar ridge increases greater leverage is

applied by functionally generated forces leading to compromised denture stability.⁷ Other patient factors said to contrive against full denture stability include the so called 'lateral spread of the tongue', migration of the mentalis muscle and a loss of facial tonicity. Lateral tongue spread results in its encroachment on the denture tooth space⁸ although this may be avoided if the transition from partial to full edentulousness is managed by the timely provision of partial dentures.⁹ The migration of the origin of the mentalis muscle is a consequence of alveolar bone resorption and it affects denture stability by reducing the NZ.¹⁰ A lack of facial tonicity also impacts on muscular control of dentures.¹¹ In contrast, patients generally tolerate maxillary complete dentures very well.³

Although it is often stated that the preferred minimum treatment option for stabilising mandibular complete dentures is two mandibular implants and an Implant Over Denture (IOD),^{3,12} it should not be forgotten that NZ techniques also have a place within all contemporary treatment options. A number of studies¹³⁻¹⁶ have shown that implant treatment is often not the patients chosen or preferred option. In other patients the surgical considerations^{14,16-18} may contra-indicate implant placement. Clearly for patients that do not receive IODs the NZ remains an important consideration to stabilise the lower complete denture. However, it is also important to state that the NZ remains an important concept in IODs. In IOD cases where the NZ is ignored, destructive lateral forces may be placed on the underlying implants with an increased potential for early implant failure especially for the elderly.

It is predicted that positioning teeth within the NZ, will become increasingly important as the demographics of edentulous patients continues to change. The value of an evidence-based, predictable NZ technique is therefore significant.

There is consensus within the literature that patients prefer mandibular complete dentures manufactured in accordance with the principles of the NZ,¹⁹⁻²¹ although studies that attempt to objectively measure denture performance conflict: some tentatively support the provision of conventional dentures^{20,22} and others support NZ dentures.^{23, 24} Raja and Saleem²⁴ performed a parallel sided study, whereas all similar studies adopted the more methodologically robust cross-over design^{2,19,20,22,23,25,26} with each patient undergoing both procedures. For patients with well-formed ridges, dentures constructed with the aid of NZ impressions may have no advantage over those of conventional construction.¹⁹

The exact mechanism for achieving muscle 'balance' of a complete mandibular NZ denture is not fully understood. Studies suggest that a NZ impression represents the average space available for denture teeth over the time taken for the impression material to set. Many individual functional movements are not balanced at the point in time at which they are being performed or, if they are balanced, the reciprocal force is not at the same location.²⁷ Appropriate shaping of the polished surfaces can provide a 'purchase-point' for 'denture-anchoring' by the tongue and circumoral musculature.²³ Furthermore, it is probable that occlusion of the denture teeth during swallowing stabilises the mandibular denture perhaps rendering the swallowing technique for recording the NZ not appropriate²⁶ or redundant.

These cross-over studies are limited by small,^{2,22,23,26,27} uncalculated sample-sizes,^{2,20-28} lack of blinding,^{2,21-23,25-27} and a lack of randomisations.^{21,22,25-27} Much of the relevant evidence from the literature is of a low level providing only a limited confidence in research findings. To a great extent this reflects its historic nature. The majority was generated at a time when less emphasis was placed on eliminating bias but there existed a greater reverence for respected experts. The lack of quality evidence has resulted in a great variation of techniques described for obtaining NZ records. Regardless, these studies should not be dismissed. Instead they should be appraised to inform future research²⁹ as many research questions still have contemporary validity and deserve the application of improved methodology.

The following quotations offer an insight into the differing opinions that have been expressed within the literature. Some authorities have strong views on the relevance of the maxillary denture to the position of the mandibular NZ, whereas others are apparently indifferent as evidenced by their lack of comment.

Watt:³⁰ "...the lower denture space cannot be properly delineated unless a maxillary appliance holds the lips and cheeks in their correct position."

"It is essential that the upper block is carved to restore the lips and cheeks to their former position before any attempt is made to locate the lower incisors by this functional method"

Gahan and Walmsley:³¹ "It is vitally important that the [maxillary] record rim is correctly trimmed to the full width of the sulcus; otherwise the correct width of the lower arch cannot be developed"

Cagna, Massad and Schiesser:¹¹ "Do not use a maxillary record base during clinical registration of the mandibular neutral zone as eliminating the maxillary record base and rim avoids compressive interferences if occlusal contacts are encountered during this functional recording procedure."

The conflicting opinions expressed in the literature on the importance of the presence of the maxillary denture in recording the mandibular NZ are summarized in Table 1.

The aim of this study is to determine whether the labio-lingual position of the anterior mandibular NZ is affected by the presence of a maxillary appliance during the impression taking procedure.

The objectives are:

1. Take two NZ impressions from each study participant.
2. To use a standardised protocol to measure the labio-lingual position of each impression.
3. To compare measurements for the two NZ impression techniques.

The null hypothesis is: The average labio-lingual position of the anterior mandibular NZ is not affected by the presence of a maxillary appliance during the impression taking procedure.

MATERIAL AND METHODS

This was a single-centre, cross-over randomised controlled study. Ethical approval was granted by the UK National Research Ethics Service on 03/05/2012 (Reference number YH/12/0183). The Trial was registered with ISRCTN before recruitment (registration number, ISRCTN56080673).

See Table 2 for inclusion and exclusion criteria

A sample-size calculation was indicated and data generated by this study is of a continuous response variable from matched pairs of study subjects, no previous studies could be identified to indicate the difference in the response however it was thought that the data would be normally distributed with a standard deviation of 2 mm. If the true difference in the mean response of matched pairs is 2 mm then paired data from 11 subjects would need to be studied in order to reject the null hypothesis that this response difference is zero with probability (power) .85. The type 1 error probability associated with this test of this null hypothesis is .05.³² To allow for drop outs (10%) 12 participants were required.

It was considered that 2 mm would represent a clinically important difference between the two proposed NZ techniques.

Two cold-cure acrylic base plates, as similar as possible, were produced for each patient. They incorporated wire loops and two thin occlusal stops at the previously established occlusal vertical dimension. One tray was arbitrarily labelled "A" and the other "B". Both base plates were tried in the patient's mouth and assessed for comfort, stability and to ensure that the wire loops did not encroach on the estimated location of the NZ. This was achieved by observing the seated trays whilst the patient trialled the oral movements.

A sealed envelope was randomly allocated by trial number to each patient. When opened the randomisation card designated which tray ("A" or "B") was used first and the order of the alternative NZ techniques ("maxillary denture in" or "maxillary denture out"). The impression material, Optisil (Heraeus-Kulzer) was mixed according to the manufacturer's instructions and weighed. The first tray was loaded such that the wire loops were covered; the height of the material was to the acrylic stops and was the same bucco-lingual width as the tray. To determine the mass of material required for the second impression, the excess material was also weighed.

Following a briefing, the loaded base-plate was inserted into the patient's mouth. The patient was then requested to perform, in order, the following oral movements: Brush the tip of their tongue along their lower lip, smile, purse their lips, take a sip of water, say out loud "M", "B", "P", "T", "D", "S".

These movements were repeated until the impression material had set. After a few minutes' rest the procedure was repeated for the second NZ impression. The pre-determined weight of material was applied to the tray and the maxillary denture was removed or inserted as required by the randomisation.

The two NZ records were mounted in turn on the same dental casts on the same articulator (Denar WhipMix Corporation, CO, USA) and a standardised 'profile' photograph was taken of each mounted record. The digital images were opened in Adobe Photoshop 5.0 LE and were rotated until the superior surface of the pin block was horizontal. A fine grid was superimposed on the image (Grid Generator V1.7, 2008 Richard Rosenman Advertising & Design) to ensure that the distance measured between the impression and the pin was the horizontal distance (*Figure 1*). The image was cropped to exclude the peripheral detail before being imported into VXWin Platinum (Gendex PA, USA) where it was initially expanded by one set increment. Calibration was performed within the software by reference to the scale on the image. The image was then expanded by one further set increment (the highest magnification at which all important elements could be viewed simultaneously on-screen). The VXWin Platinum software was used to measure the horizontal distance to an accuracy of 0.1 mm.

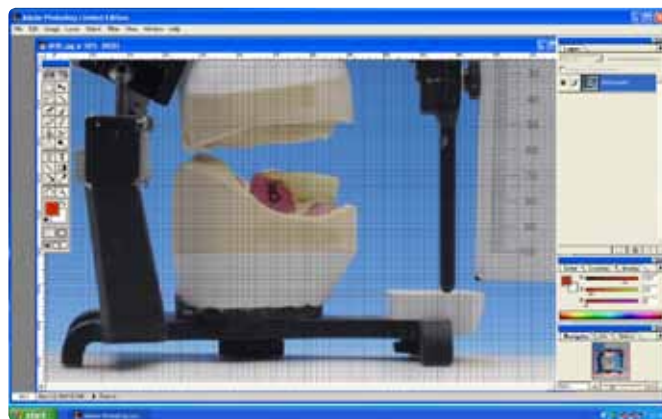


Figure 1: Grid superimposed on image ready for measurement. The image was then cropped to exclude peripheral detail.

For patients with rear-sloping NZ impressions, and therefore no 'most anterior position', an alternative method of measuring a consistent position on the impression was devised as follows: A 10 mm vertical line was 'drawn' from a reference point on the dental cast (the most superior part of the land of the cast). A horizontal line was then 'drawn' from the posterior surface of the pin, to the uppermost point on the vertical line and along until the anterior surface of the impression was met. The length of this line was then recorded for both NZ impressions for that patient.

The measurements of the NZ positions described above were undertaken by two independent and blind examiners. Bland-Altman³³ plots (*Figures 2&3*) were constructed to analyse inter-examiner variability for the measurements undertaken. Intraclass coefficient correlation (ICC) was also calculated.

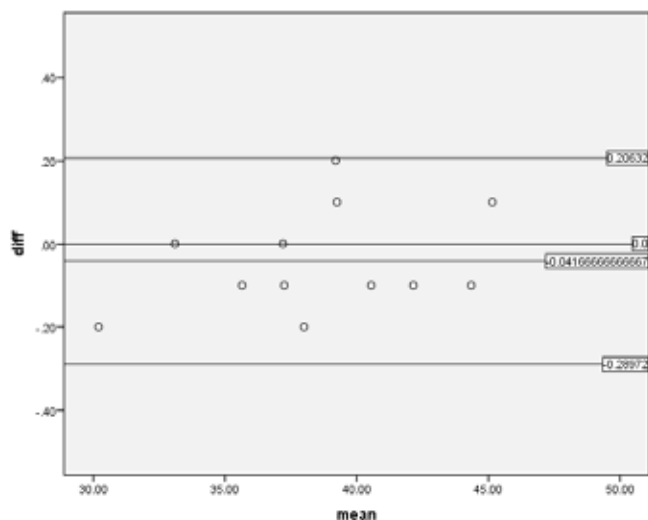


Figure 2: Bland-Altman plot for “denture in” procedure. The horizontal lines show 0 for reference; the mean of the difference and the upper and lower 95% range.

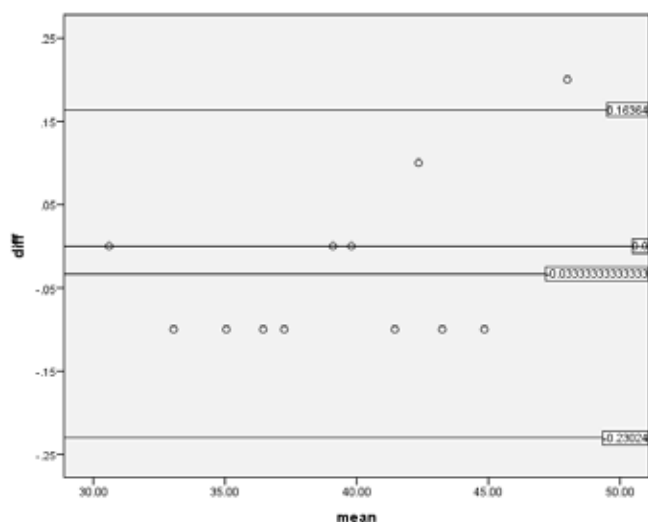


Figure 3: Bland-Altman plot for “denture out” procedure. The horizontal lines show 0 for reference; the mean of the difference and the upper and lower 95% range.

The mean difference in the measurement between the two examiners was analysed against the order in which the alternative procedures were performed (that is whether the “denture out” impression preceded or followed the “denture in” procedure). This cross-over analysis takes into account the period effect (the sequence of “denture in” and “denture out”) while comparing the treatment effect (“denture in” and “denture out”).

The resultant data was explored and then analysed by using an independent samples t-test. All data analysis was performed with IBM SPSS Statistics 20 software.

RESULTS

12 patients were recruited from 18/07/2012 to 08/07/2013; 58% of the patients were women, with a mean age of 71.9 years (SD 8.37). There were no serious unexpected adverse events that were related to trial procedures. 12 patients completed the trial. With the exception of 1 outlier (for “denture-out” procedure) Bland Altman plots demonstrated intra examiner correlation fell within two standard deviations. The ICC between examiners for the measurement of the “maxillary denture in” NZ was 0.999 with a significance of <0.0001 and 0.999 with a significance of <0.0001 for “maxillary denture out”. No significant period effect was observed p value = .190, CI = -0.205 to 0.529. The data was normally distributed (Shapiro-Wilk p = .749)

The difference value was recorded as negative when the position of the NZ became more anterior upon removal of the maxillary denture. Effect size -0.149, CI= -3.78 to 0.80 and p = .177

DISCUSSION

Within the confines of this study, a statistically significant difference could not be detected in the mean position of the NZ between the alternative NZ techniques (p = .177). The null hypothesis could not be dismissed.

Within the published literature, some authors have failed to address the issue of the influence of the maxillary denture on the mandibular NZ. Others assert that the maxillary denture does influence the mandibular NZ but are divided between those who believe that the maxillary denture should be used and those who believe it provides an unfavourable influence (Table 1).

The authors of this study anticipated that the presence of a maxillary denture would have a constant directional influence on the mandibular anterior NZ in all patients or alternatively have no influence. It was not expected that the maxillary denture could move the NZ anteriorly in some patients, posteriorly in others and have negligible influence for others. Intuitively, one might expect that the maxillary denture, in supporting the facial musculature, would reduce pressure on the NZ impression material and effectively allow the mandibular NZ to shift anteriorly. However, for 4 participants the mandibular NZ was observed to move forward in the absence of the maxillary denture (producing a negative mean difference).

Neill and Glaysher²⁶ observed high lingual pressures during swallowing which, under normal function, would be resisted by the denture teeth in occlusion. They therefore caution against the use of swallowing to mould a NZ impression as this may distort the record. Based on the speculation of Neill and Glaysher²⁶ it is possible that, for these 4 patients, the apparent anomaly is due to an adaptive swallowing mechanism to produce the oral seal necessary for swallowing to occur. In doing so the tongue is artificially protruded to a position where the necessary air-tight seal can be achieved. An alternative possibility is that during normal swallowing, the anterior movement of the tongue is restricted by its position in

Table 1: Use or otherwise of a maxillary appliance for obtaining the NZ record and the associated evidence base

Use of maxillary appliance for recording the anterior mandibular neutral zone

Technique	Authors	Level of evidence to justify technique
Maxillary denture / rim in-situ	Lynch and Allen 2006 ⁹	All opinion
	Ikebe et al. 2006 ²	
	Stromberg and Hickey 1965 ²²	
	Gahan and Walmsley 2005 ³¹	
	Neill and Glaysher 1982 ²⁶	
	Lott and Levin 1966 ³⁴	
	Watt 1978 ³⁰	
	Barrenas and Odman 1989 ¹⁹	
	Mersel 1989 ³⁵	
Maxillary denture / rim out	Wee at al. 2000 ⁷	All opinion
	Alfano and Leupold 2001 ³⁶	
	Makzoume 2004 ²⁵	
	Fahmy and Kharat 1990 ²⁰	
	Cagna et al. 2009 ¹¹	
Not clear from article	Beresin and Schiesser 2006 ²⁸	
	Fahmi 1992 ⁶	
	Schiesser 1964 ³⁷	
	Murphy 1966 ³⁸	
	Delvin and Hoad-Reddick 2001 ³⁹	
	Razek and Abdalla 1981 ⁴⁰	
	Walsh and Walsh 1976 ²¹	

the palatal vault of the maxillary denture. This action may, in isolation or combination with the adaptive tongue movement or occlusion of the base-plate against the maxillary denture, contribute the ‘negative’ difference in the two records. Further research is required to clarify this issue (see below).

The rear-sloping records of four patients necessitated the application of an alternative rule for measuring changes to the NZ position. This rule involved two measurements instead of one, and the accuracy of second measure depended on the accuracy of the first. Any error in the first measurement would be compounded in the second, raising the potential for intra and inter examiner error. However, the tests of inter-examiner variability that were used demonstrate good correlation and this potential for error did not materialise in this study.

The aim of this research was to make an objective assessment of two alternative techniques, the outcome of which could inform future clinical guidance. However, further research is required to investigate how various functional movements affect the NZ and which movements result in the optimal NZ position, for example the influence of the tongue on the mandibular NZ during swallowing needs to be defined more precisely. An investigation into a possible relationship between the extent of alveolar resorption and the influence of the maxillary denture on the mandibular NZ in edentulous subjects may explain the current observations.

A further suggestion would be to repeat Ikebe *et al*² trial and define the value of clinical significance in the difference in the anterior denture space when the volume of impression material was varied and explore how impression material volume may influence the mandibular anterior NZ shape and relate this to its 3-dimensional spacial arrangement to the ridge crest. In other words, does the width of the impression increase equally on both labial and lingual aspects?

Finally this research was restricted to the anterior NZ; further research is required to determine whether the presence of the upper denture may affect other regions that impact on the stability of the mandibular prosthesis.

A statistically significant difference in the change of the position of the mandibular NZ could not be detected because the direction in which the mandibular NZ shifted varied. However, it is clear from the results that the maxillary denture changes the position of the mandibular NZ in some individual patients with an effect size that is clinically significant (albeit with an unpredictable direction). In so far as the patient would normally wear both dentures simultaneously it would seem appropriate that the mandibular teeth are placed in a position where they are most stable when the maxillary denture is in place. This would be best achieved by recording the NZ with the maxillary denture in irrespective of whether, for a particular patient, the presence of the maxillary denture moved the mandibular NZ posteriorly or anteriorly.

The relevance of the maxillary denture to record the mandibular NZ is a contentious issue; opinions, not evidence, abound. A robust study design was used to investigate if a consistent relationship between the position of the NZ and the presence of the maxillary denture existed; none was found.

CONCLUSION

This study shows that there is no statistically significant difference between the two sides of the trial (p=.177); the null hypothesis cannot be dismissed. There is insufficient evidence to conclude that the shift in the labio-lingual position of the anterior mandibular NZ was consistently affected by the presence of a maxillary appliance during the impression taking procedure.

MANUFACTURERS’ DETAILS

- Optisil (Heraeus-Kulzer, Hanau, Germany)
- Denar (Whip Mix Corporation, CO, USA)
- Adobe Photoshop 5.0 LE
- Grid Generator V1.7, 2008 Richard Rosenman Advertising and Design
- VX Win Platinum (Gendex PA, USA)
- IBM SPSS Statistics 20 software

Table 2

Inclusion Criteria	Exclusion Criteria
18 years or older	Known allergy to acrylic
Able to attend an additional appointment	Known allergy to Optisil (Heraeus Kulzer, Germany)
Competent to consent	Severe xerostomia
	Diagnosed oral tumour
	Patient uses an obturator

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