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VICTOR LACERDA BARBOSA

Do denture impression techniques impact general oral health related quality of life?

A 6 months follow-up clinical trial

Maringá

2019

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Dissertação apresentada ao Programa de Pós-Graduação em Odontologia Integrada do Departamento de Ciências da Saúde da Universidade Estadual de Maringá, como requisito parcial para obtenção do título de Mestre em Odontologia Integrada.

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Orientador: Prof.Dr. Sérgio Sábio

Coorientador: Prof.ª Dr.ª Mitsue Fujimaki

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Defesa: 13 de dezembro de 2019

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Dedico este trabalho a todos aqueles que contribuíram para a sua realização.

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Nada grande vêm sem sacrifício.

(Adílio Gualberto Barbosa)

A técnica de moldagem para prótese total influencia na qualidade de vida do paciente? ensaio clínico

RESUMO

OBJETIVO: investigar satisfação e qualidade de vida em detrimento da técnica de moldagem convencional vs simplificada para prótese total. METODOLOGIA: pesquisa do tipo ensaio clínico, com 60 pacientes, realizada na clínica de odontológica da Universidade Estadual de Maringá. Pacientes foram divididos em dois grupos de 30, sendo que um grupo recebeu a prótese feita pela moldagem de passo duplo e o segundo moldagem simplificada. A avaliação da eficácia do tratamento foi efetua medindo o grau de satisfação com o questionário OHIP-EDENT19. RESULTADOS: não há diferença de scores de satisfação e qualidade de vida entre as técnicas estudadas, porém a técnica simplificada apresentou maior necessidade de ajustes. CONCLUSÃO: a técnica de moldagem não é um fator determinante de satisfação e qualidade de vida em reabilitação com prótese total.

Palavras-Chaves: prótese total, qualidade de vida, técnica de moldagem odontológica.

Do denture impression techniques impact on general oral health related quality of life? 6 months follow-up clinical

ABSTRACT

OBJECTIVES: this work aims at analyzing by a control and randomized clinical trial satisfaction and oral health quality of life for complete dentures constructed by conventional and simplified impression technique. METHODOLOGY: a clinical trial was conducted with 60 patients from the dental clinic of Universidade Estadual de Maringá. Patients were divided into two groups of 30. One group received dentures from the double-step impression technique and the second via a simplified method. The evaluation of treatment efficacy was performed by measuring the degree of satisfaction with the OHIP-EDENT 19 questionnaire. RESULTS: there is no difference in the scores of satisfaction and oral health quality of life between groups but the simplified impression technique required more adjustments. CONCLUSION: impression techniques do not determine satisfaction and oral health quality of life for denture treatment.

Keywords: complete denture, oral health quality of life, dental impression technique

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INTRODUCTION

Edentulism can lead to an inability to chew, impaired phonetics, reduced self-steem and other oral-health-related quality of life issues that may be overcome with a new pair of dentures. Reports show the prevalence of edentulism has shifted worldwide with a 45% reduction between 1990 and 2010. However, it remains a public health which affects 2.3% of the world population[1].

With the evolution of dental materials, the concept of simplifying denture construction was introduced, utilizing a single impression with alginate instead of the traditional double impression method which is considered time consuming since it required a preliminary and final impression to be taken. Recent studies suggest that using the simplified method not only saves time but financial resources [2], a important consideration seen through the lens of the public service.

The question is therefore whether the rehabilitation of edentulous patients using the simplified approach could reduce their quality of life over the time. While there are studies available aiming to elucidate whether the simplified method can attain a similar result to the conventional technique [3 4 5], the latest systematic review shows it can not due to methodology issues [6]. This gap in the literature requires clarification so that the public health sector can adapt their protocol towards a more cost efficient approach[5].

This study aims at elucidating whether denture impression techniques presents different rates of satisfaction and oral health quality of life. The null hypothesis was that denture impressions techniques affects quality of life and satisfaction over the time.

METHODOLOGY

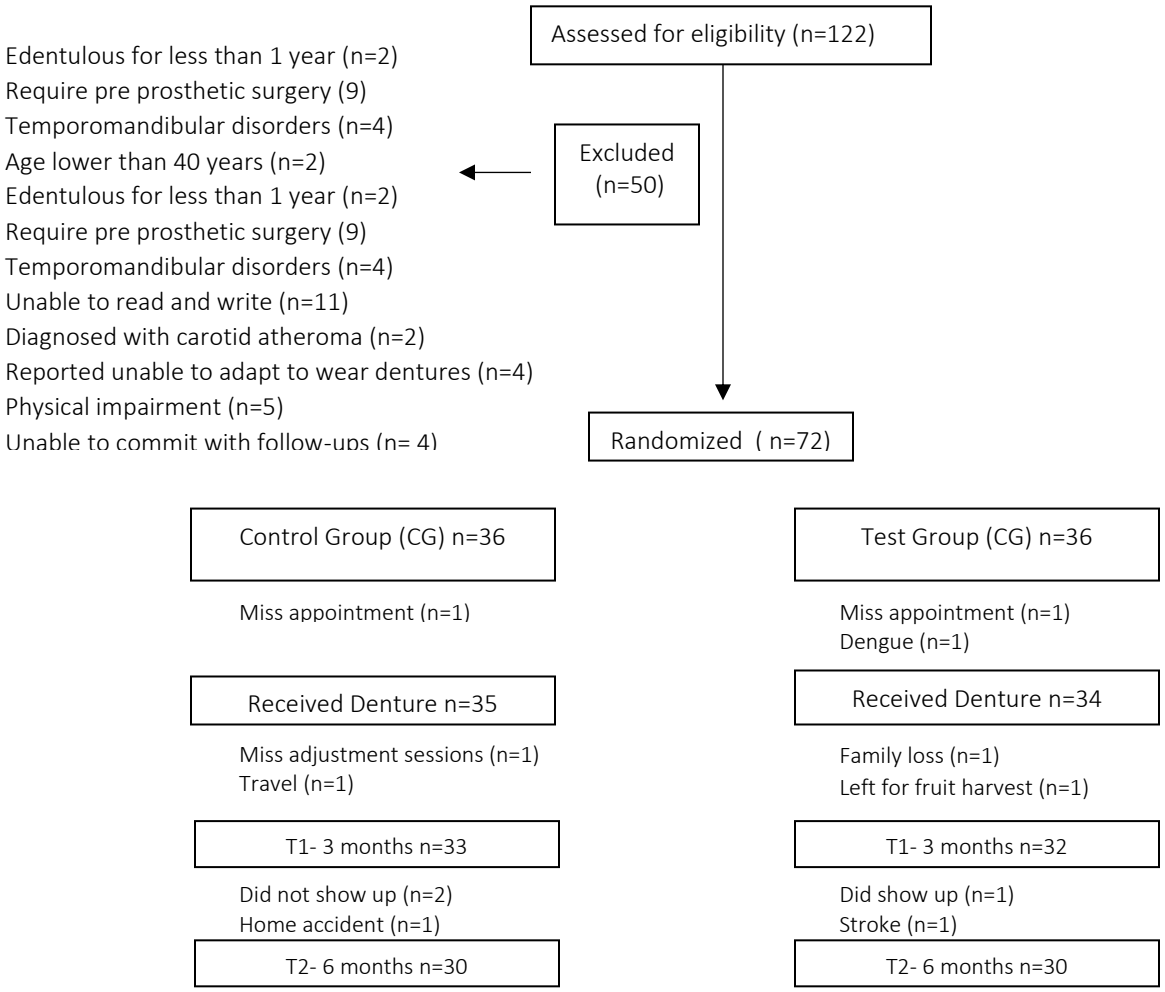
2.1- Research question and Study design

Can a 6 months follow-up clinical trial identify the differences in oral health quality of life when comparing denture impression techniques? This is a 6-month follow-up comprising a parallel randomized controlled clinical trial (RCT) originally carried out from April 2018 to March 2019. The follow up study was carried out from June 2018 to January 2019; including adjustment sessions, OHIP-EDENT 19 and a direct questionnaire. Data was gathered through a face to face interview using Google Forms. Research was approved by the ethic committee on human research of Universidade Estadual de Maringá (92184718.8.0000.0104).

2.2. Subjects

Males and females aged 40 to 79 participated in and completed the 6-month follow-up. As seen in *table 1* a total of 122 patients were assessed for eligibility, 72 remained after initial scanning and 60 at the end of study. Initially the sample was divided into a control group (CG, n:36) who received dentures constructed by the conventional technique and a test group (TG, n:36) by the simplified method. At the end of the study 6 patients were lost by each group. Contact with participants was made over telephone and WhatsApp ®.

Figure 1- study flowchart



2.3 Inclusion and exclusion criteria.

In order to be considered for the study patients had to be aged 40- 80, able to read and write in Portuguese, edentulous in both arches, able to visit the university independently, own a phone and be wearing dentures at the time of the study. Patients were excluded from the study when they were edentulous for less than one year, required pre-prosthetic surgery, reported temporomandibular disorders, were diagnosed with carotid atheroma, reported being unable to adapt to wearing dentures, were unable to commit with follow-ups, were undergoing cancer treatment or reported treating for psychiatric problems.

2.4. Questionnaires

In order to assess oral health quality of life and satisfaction, the questionnaire OHIP-EDENT 19 was used. A direct questionnaire (DQ) was developed to explore patient's characteristics and denture experience over their lifetime.

2.5. Recruitment, interviews and blinding

Patients from this study were recruited through Maringá Public Health Service Office and intermediated by State University of Maringá Dental office. The head of the university dental clinic, who was uninvolved with the study, agreed to refer denture seeking patients to the study team before assigning them to clinical treatment. It was also agreed that those not suitable for the study could be referred back to receive treatment in the same time frame. Patient were then contacted by researchers 1 and 2 for the purpose of inclusion criteria assessment; those selected were accompanied to have a panoramic x-ray taken. A spreadsheet was made categorizing patients in potentially suitable or not suitable for the study. One week later, all patients received a call from researchers 1 and 2 informing them when they would start treatment if selected for the study. Research 3, who was uninvolved with clinical procedures and data collection, created sequences of random numbers on excel® for group assignment. QR codes were then generated from these, printed, cropped, deposited in a sealed bag and delivered to researchers 4 and 5. Selected participants had an appointment with researchers 4 and 5 to clarify study proposal, sign consent paper work, apply DQ and distribute QR codes. When possible, this session was also used to obtain baseline OHIP-EDENT 19 measurements.

2.6.Clinical Procedures

The impressions were taken by researchers 1 and 2, following the university complete denture protocol which is based on a preliminary impression with alginate (Hydrogum, Zhermack®, Italy) in a perforated stock tray (HDR, Giachetti®, São Paulo, Brazil) for edentulous patients. Subsequently, a custom tray was

fabricated with self-curing resin and used for peripheral sealing with high fusion impression compound (Godiva Exata, Nova DFL®, Rio de Janeiro, Brazil) followed by a final impression with zinc oxide eugenol impression material (Lyzanda®, São Paulo, Brazil). In the case of the simplified method, the master cast was the one resulting from the first alginate impression, and the second (final) impression was taken for blinding purposes only. The two methods were similar in terms of procedures used, including recording maxillomandibular relationships as well as fitting on an average value on articulator. After denture delivery, adjustments including denture base seating, elimination of pressure points and occlusal checks were performed at 4 pre-scheduled appointments. After this period, post-delivery analysis was made by researchers 4 and 5 in two occasions for both groups at 3 months and 6 months by applying OHIP-EDENT19. To avoid loss to follow up, patients were asked to attend the clinic every month during the study period.

All the trays used for impressions had peripheral wax applied to them for patient comfort. The impressions were checked by an experienced dentist for quality control. Impressions were considered satisfactory when all the anatomical areas from the images below were captured.

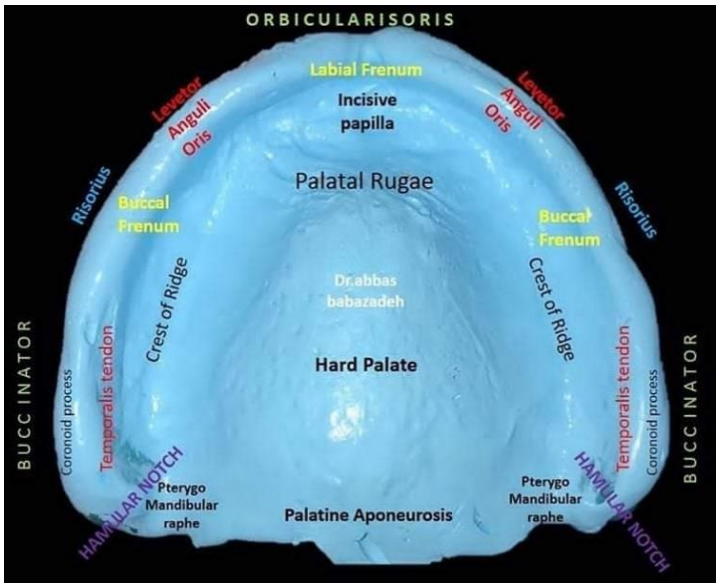


Figure 1- Maxillary anatomic landmarks

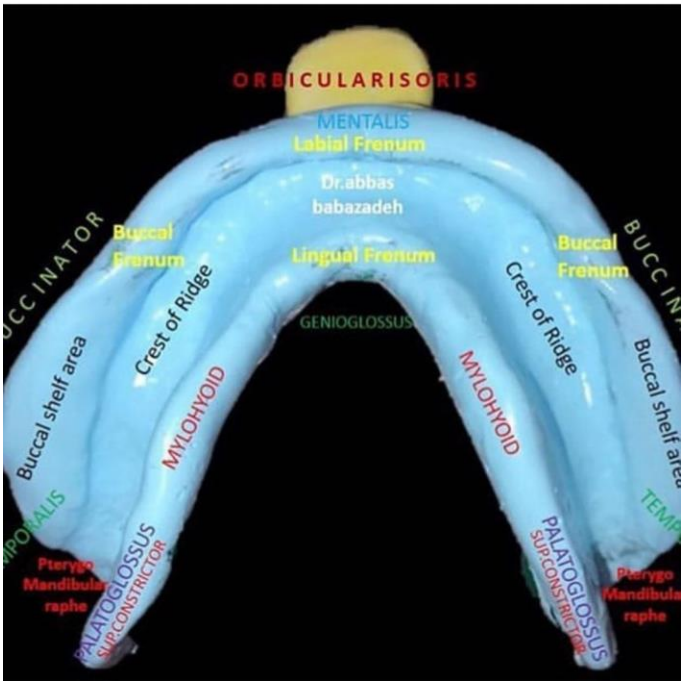


Figure 2- Mandibular anatomic landmarks

All impressions were sprayed with 1% hypochlorite solution and kept in a closed box for 10 minutes for disinfection. Since the dental lab was in the same building of the dental clinic, casting was carried out immediately after disinfection to prevent distortion.

2.7 Sample size and statistic analyses

Sample size was estimated for each of the two treatment groups considering a minimum power of 0.80 (type II error rate) at a two-sided 0.05 significance level (type I error rate). A sample size of 22 in each group was found to be sufficient to reach statistical significance with a minimal detectable difference of 1.5 points in the mean satisfaction scores between groups and a 10% difference in the quality of life scores[7]. This was the smallest difference we proposed would be clinically important in this population. Given the high demand for dentures at the university clinic the research team decided to increase the sample size in order to reduce the impact of loss to follow-up on study power, resulting in an initial sample of 36 participants in each group.

Each question of the OHIP-EDENT 19 was considered an ordinal categorical response variable with five levels: strongly disagree (0), disagree (1), neutral (2), agree (3) and strongly agree (4). Initially, a brief descriptive analysis for each of the responses of time-dependent covariate (T0, T1 and T2) was undertaken. Sphericity was tested with Mauchly's test to check if population variances of all possible difference scores were equal. Multivariate normal distribution assumption was not required as sample size was >= 25. In the inferential part, the logistic model was used for each question of the direct questionnaire and adjusted for all possible 3x3 combinations between the variables present in the study (gender, age group, etc.) and the type of denture as treatment. A model for the analyses was made following the Akaike Information Criterion (AIC) and ran for each question. The first 20 models with lower AIC were analyzed for their predictive capacity, parameters significance and residuals behavior based on the envelope graph. Only a model was chosen. ANOVA was used to check for differences over time and T-test for age. All analyses were done on SPSS 25.

RESULTS

Participant's ages ranged from 40 to 69 years. A T-test showed a mean age of 58 (p:0.5) with 51% identified as female, 62% married or partnered, 40% reported being retired or not working, 60% had elementary schooling, and < 10% reported living alone. The mean net personal annual income was $4.802[1]. The mean age that patients started wearing dentures was 25.1 years (SD= + - 6.9), the same dentures were used for x̄10,4 years (SD= 4.3), denture replacement was x̄2.3 times (SD =1.2) and the main motivation for replacement (67%) was the amount of time wearing the same pair of dentures. Data shows that 57.6 % of patients have the habit of storing dentures in diluted sodium hypochlorite. Over 40 % of patients reported fruit as the hardest food to eat and 68.3 % reported finely chopping them as a means of consumption.

Mauchly's Test of Sphericity indicated that the assumption of sphericity had not been violated, $\chi^2(2) = 46{,}032$ $p = .000$ which means that variances of the differences for T0, T1 and T2) are not equal. In this case (i.e. $p < 0.05$) we rejected the null hypothesis, inferring the results did not occur by chance, but were instead due to the effect of the intervention p:026.

Table 1- Mauchly's Test of Sphericity

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
TIME * OHIP* GROUP	.000	1298.324	665	.000	.418	.583	.028

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept + Grupo
Within Subjects Design: TIME + OHIP + TIME * OHIP

[1] US$1,00 costing BRL$ 4.13 at time of study

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Results of the ANOVA (Table 3) showed that when comparing the conventional impression technique with the simplified method they present the same level of satisfaction across the six month of follow up.

Table 2- Multivariete Tests

Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
TIME * OHIP * Grupo	Pillai's Trace	.766	2.091[b]	36.000	23.000	.033	.766	75.281	.929
	Wilks' Lambda	.234	2.091[b]	36.000	23.000	.033	.766	75.281	.929

a. Design: Intercept + Grupo
Within Subjects Design: TIME + OHIP + TIME * OHIP

b. Exact statistic

c. Computed using alpha = .05

Since Mauchley's had been significant it is by convenience observed the *Greenhouse-Geisse* for the main effect of TIME * OHIP * GRUPO. ($F(36, 2) = 1.95$, $p < .05$, $\eta p^2 = .033$).

Table 3- Tests of Within-Subjects Effects

Tests of Within-Subjects Effects

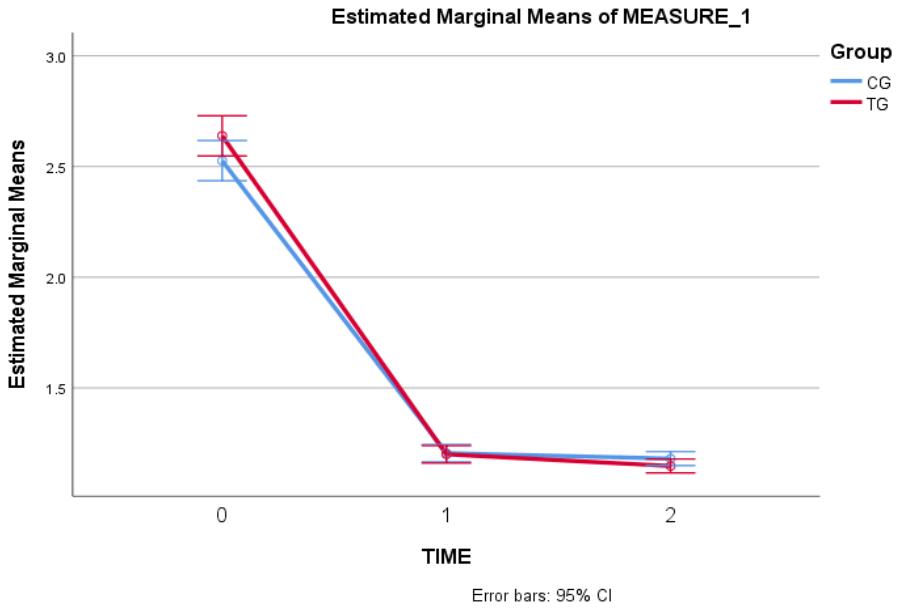
Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
TIME * OHIP * GRUPO	Sphericity Assumed	18.165	36	.505	1.952	.001	.033	70.260	1.000
	Greenhouse-Geisser	18.165	15.060	1.206	1.952	.016	.033	29.391	.959
	Huynh-Feldt	18.165	20.996	.865	1.952	.006	.033	40.977	.989
	Lower-bound	18.165	1.000	18.165	1.952	.168	.033	1.952	.279

Error(TIME*OHIP)	Sphericity Assumed	539.828	2088	.259					
	Greenhouse-Geisser	539.828	873.459	.618					
	Huynh-Feldt	539.828	1217.771	.443					
	Lower-bound	539.828	58.000	9.307					
a. Computed using alpha = .05									

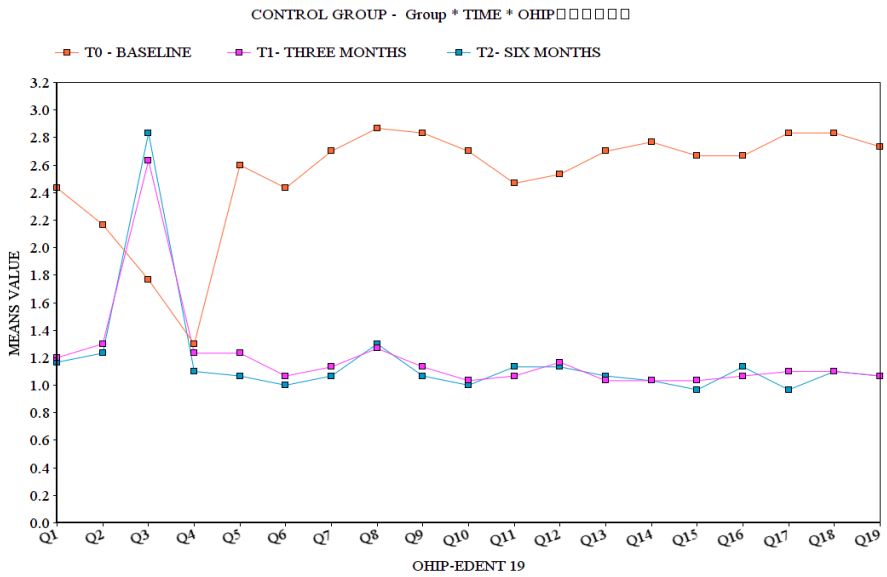
The image below shows a similar pattern across time 1 and 2 for the groups tested

Figure 3-General view of satisfaction across follow up



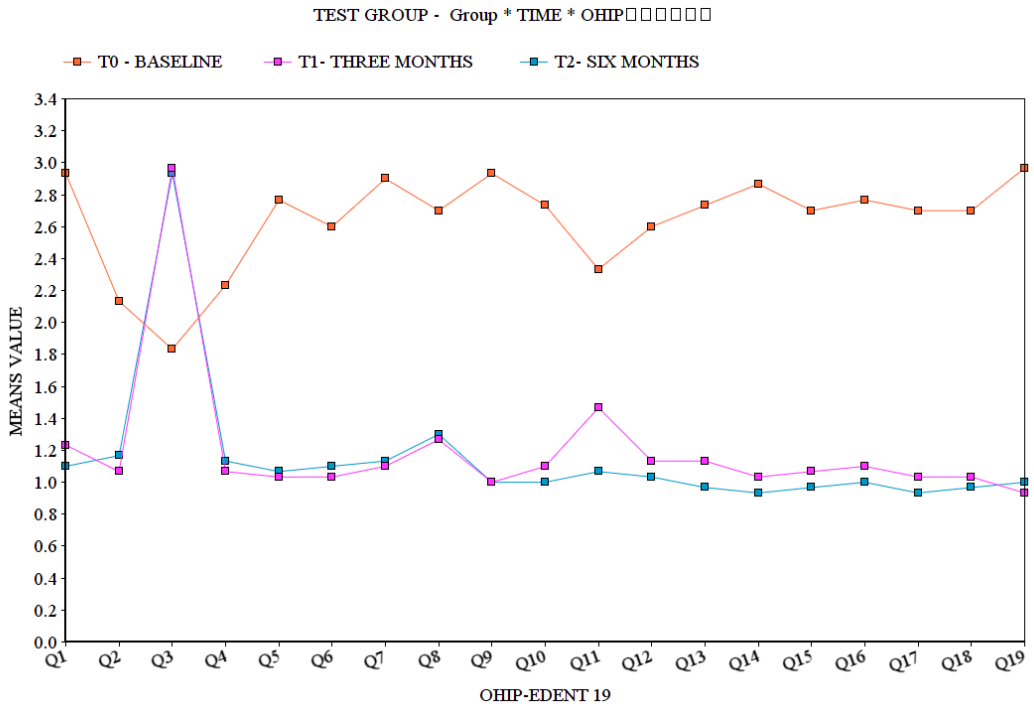
The graph below shows satisfaction for the control group alone at the three stages with a drastic spike for the question *" Have you felt that your dentures have not been fitting properly ?"*.

Figure 4- Control Group over the three observed stages



In TG question 11 brings a distinctive pattern *" Have you been unable to eat with your dentures because of problems with them ?"*.

Figure 5- Test Group over the three observed stages



It can be seen that when CG and TG are put side by side at baseline they score slightly higher for all sections.

Figure 6- Control Group vs Test Group at T0 BASELINE

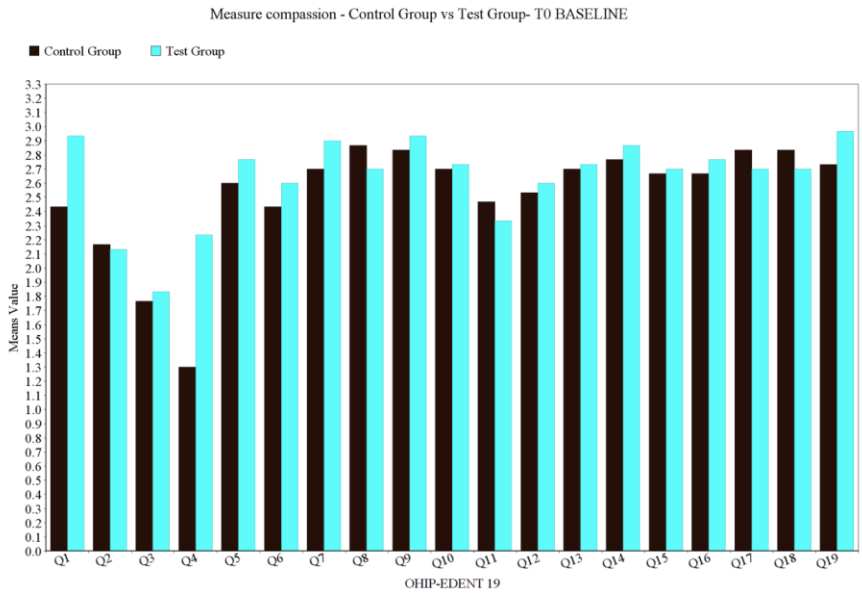
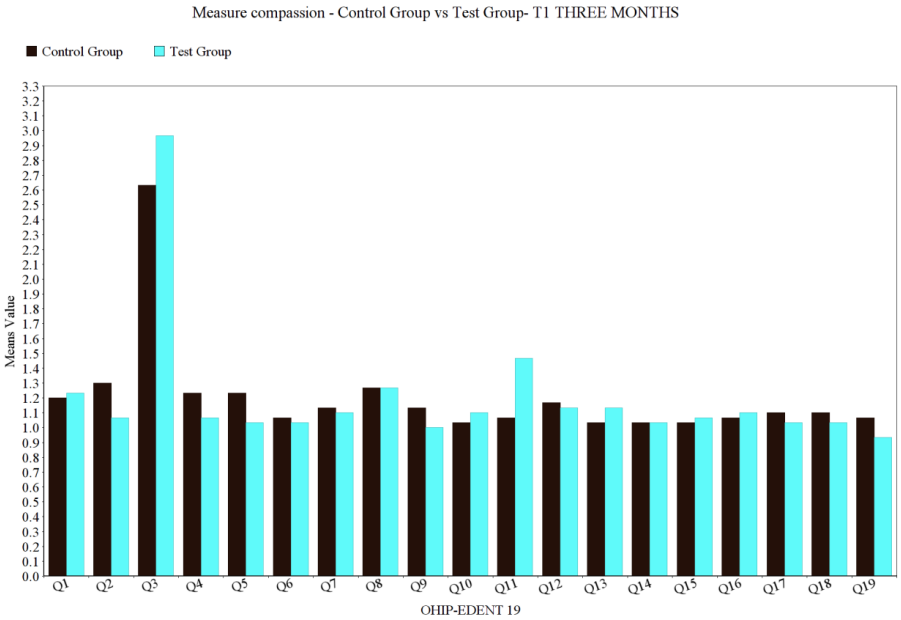


Figure 7- Control Group vs Test Group at T0 BASELINE

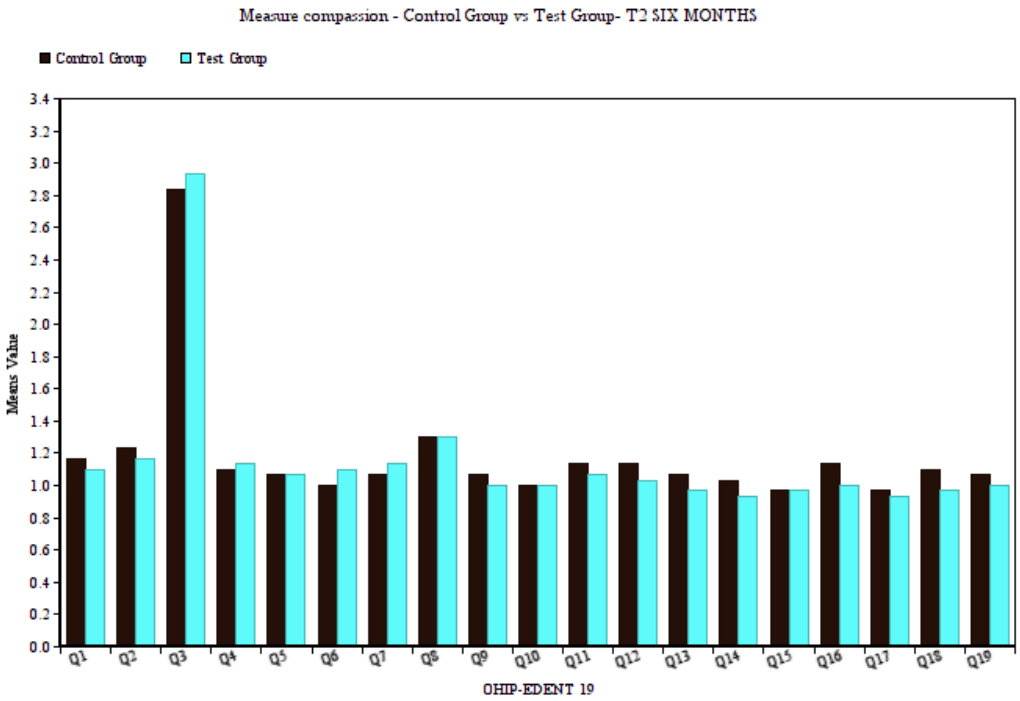
At the first three months of follow up for CG and TG questions 3 and 11 showed a spike with higher scores for TG.

Figure 8- Control Group vs Test Group at T1 – THREE MONTHS



Data presents a steady pattern after six months of follow up

Figure 9- Control Group vs Test Group at T2 – SIX MONTH



Difference of denture adjustments sessions for CG and TG

Table 2- Paired T test for Denture Adjustments

Paired T test for Denture Adjustments		
	Control Group	Test Group
MEAN	1.70	2.87
SD	0.65	0.90
SEM	0.12	0.16
N	30	30
Intermediate values used in calculations: t = 5.4297 df = 29 standard error of difference = 0.215 The mean of Control Group minus Test Group equals -1.17 95% confidence interval of this difference: From -1.61 to -0.73 p-value < 0.0001- this difference is considered statistically significant. *SEM: standard error of the mean		

Figure 10- Denture Ajustaments for CG vs TG

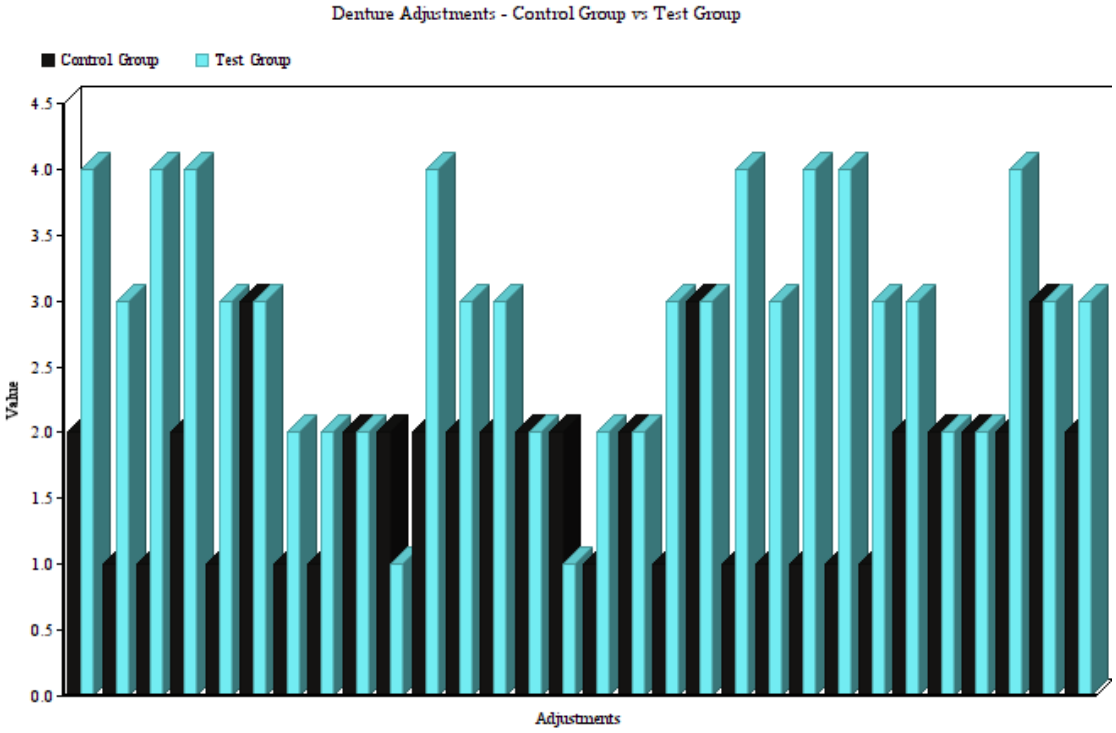


Figure 11- Denture Ajustaments for CG vs TG

Table 5 shows that for T1 and T2 the categories 3 and 4 showed null frequencies and this occurred for nearly all other questions. In practical terms, this means that those patients who reported having issues with their denture before the treatment (T0) did not carry it on after 3 months(T1) and 6 months(T2), which highlight treatment success.

Table 3- Absolute frequency for questions regarding time and type of denrure used

Q_2	T0	T1	T2	Q_2	Conventional	Test
0	1	0	0	0	1	0
1	20	49	48	1	1	65
2	10	11	12	2	52	9
3	27	0	0	3	24	16
4	2	0	0	4	11	0

Table 4- Absolute frequency for questions regarding time and type of denrure used

Individuals who were 31 years or older when they started using mandibular dentures have 63,4% higher chance of suffering denture anxiety than those who were 20 years or younger.

Table 5- Question 8 denture anxiety

	Estimative	sd	Z Value	P(|Z|>z)	OR	5%	95%
(Intercept)	1,15	0,73	1,58	0,11	3,15	0,95	10,40
Test Treatment	-0,96	0,69	-1,38	0,17	0,38	0,12	1,20
Pred41	1,85	0,82	2,26	0,02	6,38	1,65	24,66
Pred42	1,99	0,94	2,12	0,03	7,34	1,56	34,44
Pred151	-0,10	0,88	-0,11	0,91	0,91	0,21	3,87
Pred152	-1,63	0,82	-1,99	0,05	0,20	0,05	0,75

Individuals who have already changed their maxillary dentures three times or more have 84,0% greater chance of feeling embarrassed than those who have never changed their upper dentures.

Table 6-Question 9 embarrassment

	Estimative	sd	Z value	P(|Z|>z)	OR	5%	95%
(Intercept)	1,15	0,73	1,58	0,11	3,15	0,95	10,40
TratamentoTeste	-0,96	0,69	-1,38	0,17	0,38	0,12	1,20
Pred41	1,85	0,82	2,26	0,02	6,38	1,65	24,66
Pred42	1,99	0,94	2,12	0,03	7,34	1,56	34,44
Pred151	-0,10	0,88	-0,11	0,91	0,91	0,21	3,87
Pred152	-1,63	0,82	-1,99	0,05	0,20	0,05	0,75

Individuals who clean their dentures with sodium bicarbonate have 94% less chance of having to interrupt their meals due to denture problems than those who clean with toothpaste.

Table 7- Question 12 interrupt meal

	Estimative	sd	Z Value	P(Z >z)	OR	5%	95%
(Intercept)	2,35	1,05	2,25	0,02	10,53	1,88	58,92
Test Treatment	0,52	0,65	0,79	0,43	1,68	0,57	4,92
Pred11	1,58	1,32	1,20	0,23	4,86	0,55	42,66
Pred12	3,84	1,32	2,91	0,00	46,71	5,30	411,64
Pred21	-4,37	1,55	-2,81	0,00	0,01	0,00	0,16
Pred22	-4,81	1,49	-3,22	0,00	0,01	0,00	0,10
Pred91	-0,99	0,82	-1,20	0,23	0,37	0,10	1,43
Pred92	-2,75	1,02	-2,70	0,01	0,06	0,01	0,34

Individuals from age group 51-61 have 90% less chance of being disturbed by denture problems than those in the 40-51 age group. Individuals who store their denture in a container with water when not in use have 95% less chance of being disturbed by denture problems than those who store the prosthesis in a container without water when not in use.

Table 8-Question 13 disturbed

	Estimative	sd	Z Value	P(Z >z)	OR	5%	95%
(Intercept)	2,77	1,48	1,87	0,06	15,94	1,40	180,99
Test treatment	0,36	0,69	0,53	0,59	1,44	0,02	4,45
Idade51 - 61	-2,34	1,08	-2,17	0,03	0,10	0,02	0,57
Idade61 - 72	-2,34	1,03	-2,26	0.02	0,10	2,99	0,53
Pred41	2,68	0,96	2,78	0,00	14,59	2,99	71,21
Pred42	1,20	0,86	1,38	0,17	3,30	0,80	13,66
Pred71	-2,90	1,41	-2,06	0,04	0,05	0,0	0,56
Pred72	-0,90	1,29	-0,70	0,48	0,41	0,05	3,36

Patients aged 61-72 have 89,1% higher chance of being less tolerant of their spouses or families due to problems with their dentures compared to those from age group 40-51.

Table 9-Question 16 less tolerant with partner/family

	Estimative	sd	Z Value	P(|Z|>z)	OR	5%	95%
(Intercept)	-0,38	0,65	-0,58	0,56	0,69	0,24	2,00
TratamentoTeste	-0,14	0,62	-0,22	0,82	0,87	0,31	2,43
Idade51 - 61	-0,06	0,67	-0,09	0,93	0,94	0,31	2,85
Idade61 - 72	2,29	0,96	2,39	0,02	9,91	2,04	48,17
Pred171	1,04	0,65	1,61	0,11	2,83	0,98	8,22
Pred172	0,22	1,38	0,16	0,87	1,25	0,13	12,02

Individuals in the 51-61 age group have, on average, a 61,3% more chance of feeling that life in general was less than satisfactory due to problems with their dentures compared to those in the 40-61 age group. Individuals who see cooking with heat as an alternative to consuming hard food have 75% less chance of feeling that life in general was less than satisfactory due to denture problems compared to those who insist biting the food to try to eat it.

Table 10-Question 19 satisfactory life

	Estimative	sd	Z value	P(|Z|>z)	OR	5%	95%
Intercept	-0,90	1,02	-0,88	0,38	0,41	0,08	2,19
Treatment Test	1,12	0,70	1,59	0,11	3,06	0,96	9,76
Idade51 - 61	1,97	0,98	2,00	0,05	7,13	1,42	35,88
Idade61 - 72	-0,05	0,82	-0,07	0,95	0,95	0,25	3,63
Pred21	1,57	0,90	1,74	0,08	4,79	1,09	21,04
Pred22	1,80	0,93	1,95	0,05	6,06	1,32	27,80
Pred161	-1,37	0,71	-1,93	0,05	0,25	0,08	0,82

DISCUSSION

This study relied on patients' perceived satisfaction and quality of life as the main evidence to compare the differing interventions studied. Data from the direct questionnaire, number of clinical appointments for adjustments and rebasing were considered as secondary data. Initial power analysis for sample size estimation for non-rejection of the null hypothesis in the between-group comparison was due to the similar effect of treatment using the two protocols and not due to an insufficient number of participants in the study groups.

The null hypothesis was rejected demonstrating that denture impression techniques do not result in different rates of satisfaction over a period of six months. However, graphically the results show slightly different patterns yet not addressed by previous studies. Those are mainly presented in question three and eleven from *figure5* when comparing CG vs TG across the observed stages. The reason for this in question three can be explained due the pattern of responses that tended towards AGREE rather than DISAGREE as observed in the other questions. Denture constructed by the simplified method required more adjustments than control group and since it did not affect satisfaction and quality of life conclusions are directed to cost assessment of multiple dental visits and impact of delay in discharge for the workflow. Results from the directed questionnaire showed correlation between being aware of denture limitations with self-reported increasing frustration and anxiety levels. This can be explained by the habit of some patients to force themselves eat tough food even when aware of their denture limitations [14]**.** Common phrases were "My denture does not stay on and it hurts me every time I eat tough food but I love peanuts. So, I eat it anyways", "My denture drives me crazy! Sometimes I want to throw my dentures away and punch someone".

Different from other reports no participants in this study missed to register their satisfaction with dentures at baseline [7], otherwise it would compromise study analyses and lead to bias. This study is in agreement

with previous reports showing that the traditional protocol for denture construction has no superiority over simplified protocols. For that reason, the simplification of the conventional technique for fabricating complete denture is achievable without a loss of denture quality and patient satisfaction.

This study compared impression made with alginate and Zinc Eugenol paste because these are commonly used by clinicians[8]. However, studies show an increase in use of dental putty especially in the private sector with the argument that it is more practical and less prone to distortion[9]. In terms of public health, it is unlikely that dental putty materials will become the main drive due to limited budget shared by many health centers around the world. From our experience, clinician skill level is more important than the type of material used. Since this study focuses on patient perceived satisfaction, it is important to mention that from patient's perspective, putty material may be better due to taste, texture and comfort.

It is a clinically acknowledged fact that residual ridge classes V and VI, using Cawood classification, affects retention and stability and therefore, care was taken during clinical evaluation and during interviews key phrases were used as an alert signals: " never stays on, falls since delivery, cannot adapt to, frequently sore mouth, it disgusts me or I hate it".

Although studies have been optimistic towards oral health quality of life,[10,6,11,12] the most [13] consolidated idea is that denture impression technique does not supersede one another in terms of final results and it suggests standardized questionnaires provide information which is limited to a reflection of patients' treatment expectations at the outset. Patients' reported satisfaction with their dentures and the impact of that on their quality of life may not be useful measures for determining the most appropriate technique for providing new dentures. Even though implants appear to be a desirable treatment option when compared to denture, assessment of oral health quality of life with questionnaires brings relatively equal results for both treatments [13].

The fact that most patients use their denture for over 10 years and the net personal annual income was $4.802 highlights that dentures are not in fact a choice but perhaps the only option. This can be viewed as a bias for assessing satisfaction. Arguments can be made in regards to nutrition as this study shows an evidence of correlation between denture wear, increased anxiety, food avoidance and cooking method. In addition to that, steam cooking methods oxidizes and washes away valuable micro elements from many food sources, reducing its nutrition value[15 16 17]. Deprivation of those elements can also affect someone's state of mind by interfering on balance of hormones like serotonin, which along with negative denture experience can impact the perception of quality of life[18].

It was observed that individuals who clean their dentures with sodium bicarbonate have a lower chance of needing to interrupt their meals due to denture problems than those who clean with toothpaste. This information somehow goes against common sense. However, the explanation for this phenomenon plays heavily on care as culturally when sodium bicarbonate is used the intention is for a meticulous and deeper cleaning where effort is put into it until desired effect is achieved[19]. Tooth paste, on the other hand is more like an obligation where friction is not executed properly some of the times, leading to plaque buildup which covers up denture cracks and other signs of wear[20]. As a result of this, the ones who use sodium bicarbonate automatically can spot that issues and seek faster for replacement better than their counterparts[21 22].

CONCLUSION

Denture impression techniques had no impact on general oral health related quality of life and satisfaction. The issues around dentures goes beyond a sore mouth and fake teeth. It is rather a complex matter that requires an in-depth understanding of how factors such as age, social status, behavior and education play together. It is not complete dentures that are no longer compatible with our current lifestyle but rather it is being affected by edentulousness.

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T- TEST FOR AGE

T-test for age

	CG (N=30)		TG (N=30)	
	x̄	sd	x̄	sd
Age-years	55.5	8.5	56.9	10.0

Difference	1.400
Standard error	2.396
95% CI	-3.3965 to 6.1965
t-statistic	0.584
DF	58
Significance level	P = 0.5613

Table 11- T test for age

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO-TCL

Comitê de Ética em Pesquisa UEM

Eu VICTOR LACERDA BARBOSA, responsável pela pesquisa **Análise da satisfação geral de pacientes reabilitados com prótese total relacionado a técnica de moldagem empregada.,** estou fazendo um convite para você participar como voluntário deste nosso estudo.
Esta pesquisa pretende avaliar a relação de satisfação de pacientes reabilitados com prótese total construída com a técnica de moldagem de passo simples versus convencional em um estudo do tipo ensaio clínico. Acreditamos que ela seja importante para uma abordagem clínica eficiente e econômica. Para sua realização será feito o seguinte: moldagem para confecção de novas próteses totais. Após 03 meses da entrega da prótese você será solicitado a comparecer na clínica para uma consulta de avaliação onde iremos utilizar um questionário para registro destas informações. Uma última consulta será agendada 06 meses pós entrega para uma última seção de perguntas para equiparação de dados. Sua participação constará de voluntário(a)

Em caso de algum problema relacionado com a pesquisa você terá direito à assistência gratuita que será prestada na clínica odontológica da UEM. Esta pesquisa foi aprovada pelo comitê de ética em pesquisa da Universidade Estadual de Maringá número 92184718.8.0000.0104.

Você tem garantido o seu direito de não aceitar participar ou de retirar sua permissão, a qualquer momento, sem nenhum tipo de prejuízo ou retaliação, pela sua decisão (voluntariedade).

As informações desta pesquisa serão confidencias, e serão divulgadas apenas em eventos ou publicações científicas, não havendo identificação dos voluntários, a não ser entre os responsáveis pelo estudo, sendo assegurado o sigilo sobre sua participação (confidencialialidade). Os gastos necessários para a sua participação na pesquisa serão assumidos pelos pesquisadores do departamento de pesquisa da UEM. Fica também garantida indenização em casos de danos, comprovadamente decorrentes da participação na pesquisa, conforme decisão judicial ou extrajudicial.

Autorização:

Eu, _____, após a leitura (ou a escuta da leitura) deste documento e ter tido a oportunidade de conversar com o pesquisador responsável, para esclarecer todas as minhas dúvidas, acredito estar suficientemente informado, ficando claro para mim que minha participação é voluntária e que posso retirar este consentimento a qualquer momento sem penalidades ou perda de qualquer benefício.

Estou ciente também dos objetivos da pesquisa, dos procedimentos aos quais serei submetido, dos possíveis danos ou riscos deles provenientes e da garantia de confidencialidade e esclarecimentos sempre que desejar. Diante disso, expresso minha concordância de espontânea vontade de participar deste estudo

_____

Assinatura do participante

Declaro que obtive de forma apropriada e voluntária o Consentimento Livre e Esclarecido deste voluntário (ou de seu representante legal) para a participação neste estudo.

_____

Assinatura do aplicador do TCLE

Dados dos pesquisadores:

- **Victor Lacerda Barbosa**- Mestrando em Odontologia Integrada - Universidade Estadual de Maringá

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OHIP-EDENT19

Universidade Estadual de Maringá- Departamento de Pós-Graduação em Odontologia- Mestrado em Odontologia Integrada.

Pesquisa intitulada " Satisfação Geral de pacientes reabilitados com prótese total em relação a técnica de moldagem ".

Equipe de pesquisa: Victor Lacerda, Sérgio Sábio, Youv Finer, Gabriel Castanheira, Isolde Previdelli

Co-orientador (a) Miltsue Fujimaki

Este formulário é o instrumento que esta pesquisa usará para obtenção dos dados para analisar a sua satisfação com a dentadura. Click na alternativa que corresponde a sua resposta para cada enunciado.

SESSÃO A LIMITAÇÃO FUNCIONAL

1- Você sentiu dificuldade para mastigar algum alimento devido a problemas com sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

2- Você percebeu que sua dentadura está retendo alimento? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo muito

3- Você sentiu que sua dentadura está corretamente assentada? *

1. Discordo muito
2. Discordo
3. Neutro
4. Concordo
5. concordo muito

SESSÃO B- DOR FÍSICA

4- Você sentiu sua boca dolorida? *

1. Discordo muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

5- Você sentiu desconforto ao comer devido a problemas com sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

6- Você têm pontos doloridos

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

7- Sua dentadura está desconfortável? *

1. Discordo muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo muito

SESSÃO C- DESCONFORTO PSICOLÓGICO

8- Você se sentiu preocupado (a) devido a problemas com sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

9- Você se sentiu constrangido por causa da dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

SESSÃO D- LIMITAÇÃO FÍSICA

10- Você teve que evitar comer alguma coisa devido a problemas com sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

11- Você se sentiu impossibilitado(a) de comer com sua dentadura devido a problemas com ela? *

1. Discordo Muito

2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

12- Você teve que interromper suas refeições devido a problemas com sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

SESSÃO E- BARREIRA PSICOLÓGICA

13- Você se sentiu perturbado(a) com problemas na sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

14- Você esteve em alguma situação embaraçosa devido a problemas com sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

SESSÃO F- INTERAÇÃO SOCIAL

15- Você evitou sair de casa devido a problemas com sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

16- Você foi menos tolerante com seu cônjuge ou família devido a problemas com sua dentadura ? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

SESSÃO G- DIFICULDADE PESSOAL

17- Você esteve um pouco irritado(a) com outras pessoas devido a problemas com sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

18- Você foi incapaz de aproveitar totalmente a companhia de outras pessoas devido a problemas com sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

19- Você sentiu que a vida em geral foi menos satisfatória devido a problemas com sua dentadura? *

1. Discordo Muito
2. Discordo
3. Neutro
4. Concordo
5. Concordo Muito

QUESTIONÁRIO DIRIGIDO

QR CODE :_____ IDADE:_____

SESSÃO DE AJUSTES

1°- consulta – ( ) sim ( ) não

2° - consulta – ( ) sim ( ) não

3°- consulta – ( ) sim ( ) não

4°-consulta - – ( ) sim ( ) não

Qual seu estado civil ? _____

Quantas pessoas morram com você na mesma casa? _____

Qual é a renda total da família ?_____

Quantos dependentes você têm ? _____

SESSÃO 01- HISTÓRICO DA PERDA DENTÁRIA

1- **O que causou a perda dos deus dentes superiores**
   1. Imprudência do CD
   2. Falta de opções de tratamento
   3. Odontofobia
2- **O que causou a perda dos seus dentes inferiores**
   1. Imprudência do CD
   2. Falta de opções de tratamento
   3. Odontofobia
3- **Quantas anos de idade você tinha quando começou a utilizar a dentadura superior ?**
   1. 20 anos ou menos
   2. 21 a 30 anos
   3. 31 anos ou mais
4- **Quantas anos de idade você tinha quando começou a utilizar a dentadura inferior ?**
   1. 20 anos ou menos
   2. 21 a 30 anos
   3. 31 anos ou mais

SESSÃO 2- UTILIZAÇÃO E HIGIENE

5- **Você precisa aplicar algum adesivo como Corega para a prótese segurar na boca ?**
   1. Sim, superior
   2. Sim, inferior
   3. Não
6- **Você retira sua prótese para dormir ?**

1. Não retiro
2. Apenas uma
3. Retiro as duas próteses

7- Onde você armazena a prótese quando você não esta utilizando-a ?

1- Em recipiente sem água
2- Em recipiente com água
3- solução de água com hipoclorito

8- Momento do dia mais importante para você higienizar sua prótese?

1. antes do café da manhã
2. Após o almoço
3. Antes de ir dormir

9- **Como você higieniza sua prótese ? Associe o instrumento ao produto para responder a pergunta**.

1. Pasta de dente
2. Sabão ou detergente
3. Bicarbonato de sódio

SESSÃO 3- EXPERIÊNCIA COM PRÓTESE TOTAL

10- Quantas vezes você já trocou a dentadura superior ?

1. Nunca
2. Duas vezes ou menos
3. Três vezes ou mais

11- Quantas vezes você já trocou a dentadura inferior

1. Nunca
2. Duas vezes ou mais
3. Três vezes ou mais

12- A quantos anos você está utilizando a dentadura atual superior ?

1. 5 anos ou menos
2. 6-15 anos
3. 16- anos ou mais

13- A quanto tempo você está utilizando a dentadura atual inferior ?

1. 5 anos ou menos
2. 6-15 anos
3. 16 anos ou mais

14- Qual o principal motivo que fez com que você queira trocar a dentadura ?

1. Prótese está quebrada
2. Os dentes da prótese estão escuros e desgastados
3. Tempo utilizando a mesma prótese

SESSÃO 4- LIMITAÇÕES

15- Marque o grupo de alimento que você têm maior dificuldade para comer com a dentadura atual

1. Frutas

2. Hortaliças
3. Carne

16- Do grupo de alimento que você citou acima o que você faz para tentar comê-lo ?

1. Picar o alimento
2. Cozimento

17- A razão principal que te impossibilita fazer implantes é ?

1. Ficanceiro
2. Saúde
3. Medo