

Original Article

Masticatory Ability for A Single Implant Mandibular Overdenture Retained by Two Different Attachments: A Randomized Controlled Trial

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Abstract

Statement of the problem: due to economic and bone related problems some edentulous patients receive one implant to support their complete denture which decrease their masticatory ability compared to two implant supported denture. In this study two different attachments are used to find which one will provide the best masticatory ability for the patient.

Objective: The aim of this randomized clinical trial was to compare subjective masticatory ability scores between ball and CM-LOC attachment (cm-loc attachment is similar to locator attachment but with PEEK cap instead of nylon) for a single implant retained mandibular over-denture at base line (complete denture), after 2 weeks of loading, 3, 6, 9 and 12 month follow up period, and also, the change in masticatory ability from baseline to 6 month follow up, and from baseline to 12 month follow up for both attachments used.

Subjects and methods: Eighty completely edentulous patients were recruited from the out-patient clinic of Prosthodontic –Cairo University. All patients received new complete dentures, after 6 weeks of adaptation period, masticatory ability was recorded using a questionnaire. All patients then, received a single symphyseal implant. After 3 months healing period, patients were randomized using sealed envelopes into two groups: ball or CM-LOC attachment. Masticatory ability questionnaire was again used to record masticatory ability for both groups 2 weeks after loading, 3, 6, 9 and 12 months follow up.

Results: At the end of the healing period 6 patients had reported failure and 3 have been considered as dropouts. Seventy- one patients were then randomized using sealed envelopes into two attachments; 34 patients belonged to the ball attachment group and 37 to the CMLOC group. At the end of the 12 months follow up a total of 65 patients were present after dropouts: 30 patients in the ball group and 35 in the CMLOC.

There was no statistically significant difference in the mean masticatory ability scores between the patients in both groups throughout the follow up period. Patients with complete denture had the highest masticatory ability scores (reduced masticatory ability). After implant installation the mean masticatory scores have improved when compared to base line values for both attachments, but patients with CMLOC attachment have shown an improved masticatory ability when compared to ball throughout the 12 months follow up although it was statistically insignificant. Both attachments have shown an improvement in the mean masticatory ability from baseline to 6 month and from baseline to 12 months, although the CM LOC attachment have shown a slight better non-significant improvement when compared to the ball attachment

Conclusion: Single implant retained mandibular overdenture seems to have improved masticatory ability when compared to complete denture. Both the ball and CM LOC attachments have improved the masticatory ability when compared to complete denture, but the CMLOC attachment has slightly shown a greater non-significant improvement in masticatory ability.

Keywords: single implant, masticatory ability, overdenture, ball attachment, CM LOC attachment.

I. INTRODUCTION

Edentulism should be handled with due care and surveillance, not only to overcome medical illness that could result from improper chewing and swallowing, or influence patient's diet and might end up with malnutrition, but also due to its association with depression and mild cognitive impairment. (Kim et al. 2020)

Socioeconomic factors and improper oral hygiene measures together with chronic disease which affects periodontal health often the reason beyond edentulism. (Hosseini et al. 2015) Complete denture might offer a simple solution for such patients, yet discomfort and retention of mandibular complete denture were considered a major complain. (Koul et al. 2018)

Implant overdenture have solved such problems, providing more retention and increasing patient comfort, which is reflected on the overall quality of life, yet it represents an affordability obstacle to many patients specially in the developing countries. (Koul et al. 2018) (Naguib et al. 2019) The Single mandibular implant overdenture (SMIOD) was introduced to obtain an affordable satisfactory treatment modality that claims to meet patients demands and be superior to complete denture. (Schwind ling et al. 2018)

Patients judge the success of their implant prosthesis from being aesthetically acceptable, masticatory efficient, without jeopardizing comfort or speech. (Papaspnyridakos et al. 2012) Mastication is considered an important pillar for the success of overdenture prosthesis, several studies had been reported addressing means of assessment to chewing efficiency, masticatory performance, or masticatory ability, a debate was set whether the usage of objective assessment tools (e.g. sieve test, chewing colouring gum ...etc.) would be more precise than subjective questionnaire.

Some researchers believe objective assessment gave accurate results about the masticatory performance of a given prosthesis, others believe that due to inevitable variables and confounders that exists among patients, objective methods couldn't be standardized as assessment tools regarding mastication. (Methods for Evaluation of Masticatory Efficiency in Conventional Complete Denture Wearers: A Systematized Review [no date]) Moreover, patient perception towards a certain prosthesis is not necessarily in consensus with clinician assessment, as patients might show high satisfaction from their old dentures despite being in acceptable from a

clinical point of view. And since the served dental prosthesis aimed to please and satisfy the patient, his opinion about a given treatment modality should be met with due care. (Salami et al. 2020; Kumar et al. 2022)

CM-LOC attachment have the same design of the locator attachment but the difference is in the material of the cap. The most common material for the cap is nylon which is used for most of the attachments as it is resilient material. On the other hand the CM-LOC attachment is made of PEEK (polyether-ether ketone) which is less resilient material than nylon and more hard which is supposed to decrease the denture movement and improve masticatory ability. Polyaryletherketones have the advantage of high chemical and mechanical resistance to wear and high tensile, fatigue and flexural strengths.

II. SUBJECTS AND METHODS

Eighty fully edentulous patients were recruited from the outpatient clinic –Prosthodontics Department-Cairo University. All Patients were seeking to improve retention of their mandibular dentures and willing to install a single midline implant for that purpose.

All included patients were recruited following strict inclusion criteria; only patients within the age between 50-69 years were included, Glycosylated hemoglobin level < 8, patient with only class II and III according to Thomas Mc Garry 1999 were included, minimum of 5mm bone width had to be present in the anterior area of the mandible directly or after minimum plateauing. Patients with any condition that would contra-indicate implant placement were excluded. An informed consent had to be signed by all patients before implant installation.

All patients had newly constructed maxillary and mandibular complete dentures. Patients were allowed to adapt to their newly constructed dentures for a 6 weeks period. A Masticatory ability questionnaire was used to record patient satisfaction for all patients after denture adaptation (Figure 5). The masticatory ability chart used in this study consisted of 9 questions, scores from 0 to 4 each, where

(0=never (no problem), 4=always (with problems), a score for each question was recorded and then a total score for the 9 questions were added. The lower the score the higher the masticatory ability (Figure 5).

Following denture adaptation, all dentures were then duplicated to fabricate a transparent radiographic stent with radio-opaque acrylic resin placed in the anterior incisor area. A CBCT was done for all patients wearing those stents. The CBCT was also used for accurate implant installation planning, as the buccal and lingual bone thickness was properly evaluated with the help of radio-opaque marker.

Implant installation

The radiographic stent was then modified into a surgical stent by making a wide hole at the central incisor area in the place corresponding to implant installation. All patients were instructed to take 1gm of amoxicillin 1 hour prior to the surgery. A small crestal incision was made in the central incisor area. All implants installed in this study was of diameter 3.7mm and length 10mm, Zimmer dental implants¹. Drilling was carried out according to the manufacturer instructions, using the Zimmer kit. All installed implants were left to heal for a 3 months period, the patient's denture was properly relieved using soft liner GC Soft-Liner².

At the end of the healing phase 6 patients reported implant failure, and 3 patients were considered as dropouts. A total of 71 patients were then ready to receive the attachment.

Attachment installation and pick up

Two attachments were being used in this study. Ball attachment with a nylon matrix (Zimmer dental implants), and the CMLOC attachment with a PEKK matrix (Cendres

&Meteaux). After the 3 months healing period, patients were randomized using sealed envelopes to receive either ball or CM LOC attachment. Seventy - one patients were randomized into those two groups as the sealed envelopes were prepared at the beginning of the study before drop outs; 34 patients in the ball group, and 37 patients in the CM LOC group.

Both attachments were screwed to the implant with a torque of 30 N, and the corresponding matrix on top of it (Figure 1, 2). The mandibular denture was then modified to receive the housing by drilling a small hole in the area corresponding to the attachment, a red die was placed on the fitting surface of the modified denture to ensure that there was no interference between the acrylic resin and the attachment matrix. The mandibular denture was checked for proper seating, and the occlusion with the maxillary denture was properly checked.

A small piece of rubber dam was used to block the undercuts present in both attachments. The denture was then properly seated in place then a soft mix of self-cure acrylic resin was then added to the hole of the modified denture, the patient was then asked to bite gently in centric relation.

After complete setting of acrylic resin, the denture was removed and pick up of the matrix was checked (Figure 3, 4). All excess acrylic resin was removed and then polished. Patients were recalled 3 days after pick up to check if there are any premature contacts or areas that required relief. This procedure was carried out for both attachments used in this study.

¹ Implants ZDI, Tapered screw vent Indiana America

² GC Corporation, Tokyo, Japan



Figure (1): CMLOC attachment



Figure (2): Ball attachment



Figure (3): PEEK matrix after pick up



Figure (4): Nylon Matrix after pick up

The same Masticatory ability questionnaire was used to record patient satisfaction for both groups of patients at the following intervals; 2 weeks after pick up, 3, 6, 9 and 12 month follow up (Figure 5).

Questions		score
1- Have you ever had to interrupt meals because of problems with your dentures?	0=never , 4 =always	
2- Have you found it difficult to chew any foods because of problems with your dentures?	0=never , 4 =always	
3-Do you need any special food preparation to enable chewing (such as cooking, cutting into small parts)?	0=never , 4 =always	
4- How stable are your dentures when eating foods of a certain consistency?	0=never , 4 =always	
5- Do you need force to swallow foods after chewing?	0=never , 4 =always	
6- Do you think that you are swallowing large pieces of food due to the lack of proper fragmentation?	0=never , 4 =always	
7- Have you found it uncomfortable to chew any foods with your dentures?	0=never , 4 =always	
8- In comparison with other people, do you perceive that you take longer to chew the foods during meals?	0=never , 4 =always	
9- Do you feel uneasy during meals due to the lack of denture security and instability?	0=never , 4 =always	
Total score		

Figure (5): Masticatory ability [], consists of 9 questions, and each question each has options with the best score =0 and worst score =4, a total score was calculated for each patient.

Two patients were considered as dropouts, as they refused to attend the follow ups immediately after randomization; 1 patient belonged to the ball group, and the other patient belonged to the CMLOC group. 1 patient died immediately after randomization and belonged to the Ball attachment group. Two patients died at 9 months follow up; 1 patient was from the ball attachment group, and the other was from the CMLOC attachment group. 1 patient from the ball attachment was considered as drop out at 6 months follow up (Table 1).

	Ball group	CM LOC group	Total
Number (beginning of randomization)	34	37	71
Patients who did not attend the follow ups after randomization	1 (drop out) 1 (died)	1 (drop out)	3

Patients who did not attend 6 months follow up	1 (drop outs)		1
Patients who did not attend the 9 months follow up	1 (died)	1 (died)	2
Total number at the end of the 12 months follow up	30	35	65

Table (1): Distribution of patients after randomization

Data were statistically described in terms of mean \pm standard deviation (\pm SD). Numerical data were tested for the normal assumption using Kolmogorov Smirnov test. Comparison between the study groups was done using Mann Whitney U test for independent samples. Two -sided p values less than 0.05 was considered statistically significant. All statistical calculations were done using computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows.

III. RESULTS:

There seems to be no statistically significant difference in the mean scores for masticatory ability throughout the 1 year follow up period between the ball and CMLOC attachment. At base line period (complete denture) has recorded the highest masticatory ability score which indicates reduced masticatory ability. After the installation of a single implant in the midline, the masticatory ability of patients seems to have improved for both the ball and CMLOC group of patients. Patients with CMLOC attachment have shown better mean masticatory ability score when compared to the ball attachment group from baseline to 6 month interval follow up although this improvement was not statistically significant (Table 2, Figure 6). At 9 month follow up both the mean masticatory ability scores for both groups were nearly equal (mean masticatory score was 7.38 ± 9.034 for the ball attachment group, and 6.96 ± 10.017 for the CMLOC attachment group) and then at 12 month follow up the mean masticatory scores for the CMLOC group have shown a slight non-significant improvement when compared to the ball attachment group (mean masticatory score for the ball attachment group 6.32 ± 8.749 , and 5.13 ± 7.566 for the CMLOC attachment group, $p=0.628$) (Table 2, figure 6).

		Masticatory ability at Base line (complete denture)	Masticatory ability at 2 weeks	Masticatory ability at 3month	Masticatory ability at 6 months	Masticatory ability at 9 month	Masticatory ability at 12 month
Ball	Mean	17.43	9.33	9.46	8.30	7.38	6.32
	SD	11.488	8.360	10.9	11.7	9.034	8.743
CM LOC	Mean	17.15	7.95	5.88	5.52	6.96	5.13
	SD	10.581	8.936	6.058	6.674	10.017	7.566
	p value	0.962	0.764	0.631	0.835	0.813	0.628

Table (2): mean scores and standard deviation of Masticatory ability at base line, 2 weeks from loading, 3, 6, 9 and 12 months follow up, for patients with Ball and CMLOC attachment group. SD: standard deviation, $P \leq 0.05$ is considered statistically significant.

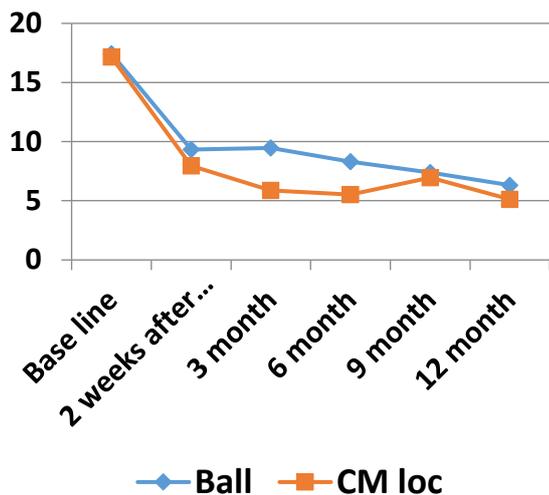


Figure (6): mean scores for masticatory ability for the two attachments used; Ball and CMLOC attachment throughout the different follow up intervals.

Attachment		Base line-6 month	Base line -12 month
	Ball	Mean	-9.42
	SD	12.426	14.625
CMLOC	Mean	-10.86	-12.47
	SD	9.775	12.006
	p value	0.774	0.826

Table (3): Mean scores and standard deviation of change in Masticatory ability from baseline to 6 month, and from baseline to 12 month for patients with Ball and CMLOC attachment group. SD: standard deviation, $P \leq 0.05$ is considered statistically significant.

When comparing the change in the mean masticatory ability score from base line to 6 month and from baseline to 12 month, both attachment have shown an improvement in masticatory ability as the negative value indicates a decrease in masticatory ability scores which signifies better masticatory ability. The CMLOC attachment have shown a slightly better improvement change in masticatory ability when compared to the ball attachment, this improvement was statistically

non-significant (Table 3, Figure 7)

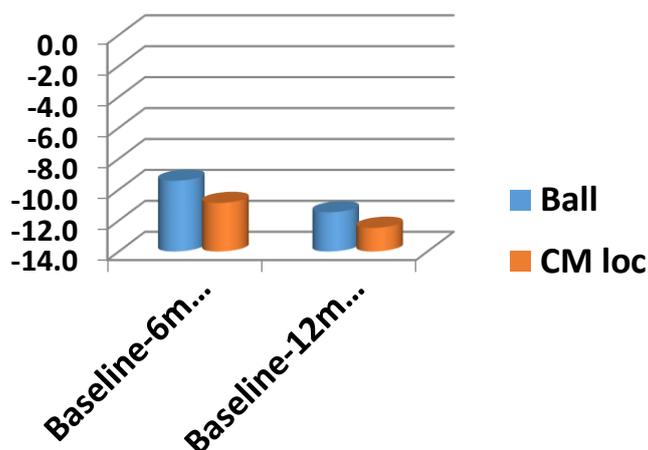


Figure (7): The absolute mean change from base line to 6 month and from baseline to 12 month for ball and CMLOC attachment

IV. DISCUSSION

Several terms of mastication had been used interchangeably in literature, masticatory ability, masticatory performance, and efficiency have been used to refer to masticatory function. Masticatory ability express individual assessment to his masticatory function, it represents the subjective assessment of mastication .(Carlsson 1984)

In literature ,subjective assessment of mastication has been reported as part of other questionnaires as patient satisfaction and quality of life ,the results of which targeted different scope that is more generic rather than specific masticatory assessment ,this inspired researchers to develop their own masticatory based questions to be focused whether the restored prosthesis affected dietary habits, needed special food preparation ,delayed the patient during eating in gatherings or was instable with certain food consistency.(Naguib et al. 2022)

On the other hand, chewing efficiency is the ability to grind a tested food portion at a given period of time. Loss of teeth diminish chewing efficiency and had bad impact on the dietary choice, the quality for the denture is among the factors affecting masticatory efficiency, well-

constructed dentures that is in harmony with lips, cheek and tongue become more stable which encourage the patients to improve his diet and start introducing hard food which in return activate muscle activity and enhance chewing efficiency, thus improve patient satisfaction and masticatory ability. This was clear in the present study that the baseline mean masticatory ability scores were nearly equal for both group of patients, which is considered a strong point for further comparison of the effect of implant and attachment installation through-out the different follow up intervals. All included patients in the following trial received new dentures and were allowed a 6 week adaptation period which resolved their discomfort, together with operator's trust which increased their motivation. (Abdel Aal et al. 2021)

A single symphyseal implant were installed to all included patient in the present randomized trial, and were allowed a three months healing period to ensure osseointegration before receiving one of the assigned attachments. Patients with ACP class I and IV were excluded as patients with ACP class I the posterior bone height of the mandible range would be greater than 21mm, so those patients will be satisfied with retention of their complete dentures and would not need implant installation to improve retention of their mandibular complete denture. Also patients with class IV ACP classification were excluded because their posterior bone will offer little horizontal stability so would require installation of two or more implants to improve retention of their mandibular denture. Only patients with ACP Class II and III were included. (AbdelAal et al. 2019)

It was reported that the biting force of completely edentulous patients with complete denture have increased after implant installation, completely edentulous patient with complete dentures recorded biting force readings ranging from 60-80N while for implant retained overdenture it increased to 150-170N which is very similar to those of natural dentition 200 N. [8] This explains the initial noticeable clinical improvement of masticatory ability from baseline to 2 weeks after loading for both groups, with the slight continuous improvement in masticatory ability scores that was recorded for both attachment throughout the 12 month follow up interval.

When comparing the masticatory ability scores between the two attachments used in this study, it was found that the CM LOC attachment have shown a better non-significant improvement for masticatory ability from 2 weeks to the 6 month follow up period than the ball attachment. The CMLOC is a newly introduced attachment made from polyetherketoneketone (PEKK) which is a member of the polyaryletherketones (PAEKs). Polyaryletherketones have the advantage of high chemical and mechanical resistance to wear and high tensile, fatigue and flexural strengths. There are very few articles that have reported the performance of the CMLOC attachment, so the reason for the very slight insignificant changes in the subjective masticatory ability will mainly be due to the patient perception and might not be related to the mode of action of the attachment. The PEEK could not be used with ball attachment as a cap instead of nylon as the ball attachment have a larger undercut which will induce large forces on implant with the hard PEEK during insertion and removal. (Naguib et al. 2022)

The Masticatory ability for the CMLOC group continued to improve till 6 month follow up then began to decline till 9 months and was nearly equal to the mean masticatory ability scores of the ball attachment group. An explanation for this result that at 9 month follow up was the time of changing of the PEKK cap for some of the patients that complained from loss of retention of their dentures, so the activation of the PEKK cap was among the factors that aided in the slight improvement in the masticatory ability compared to ball attachment. While contrary for the ball attachment group patients changed their nylon caps at the end of the 12 month follow up, which will probably reflect the improvement in masticatory ability at the 24 month follow up. Those results are clearly noticed when it came to the change in masticatory ability where CMLOC group showed slightly better change in masticatory ability both in 6 and 12 months but again the results were statistically insignificant.

The idea that both attachments showed lack of significant difference in their results might be due to the fact that both attachments had been proved to be good options for overdenture attachment, or due to the short term follow up

period that didn't allow for much maintenance ,loss of retention ,fracture...etc to identify the superior attachment. Results had also shown the lack of significant difference of both attachments from the complete denture phase despite the clinically noticeable improvement ,this might be due to the fact that being a subjective assessment it was influenced by patient motivation towards the new prosthesis from the initial phase of denture construction ,another paper had reported that during one year follow up the results of masticatory ability resulted from the full adaptation to complete denture and the full confidence gained by the patient regardless of the implant installed and that the impact of implant installation might be more clear when measuring either biting force of chewing efficiency ,thus a recommendation for a parallel complete denture group should be done to assess the masticatory ability one year from testing a well -constructed denture from those receiving single symphyseal implants, and correlate the results with a chewing efficiency test over a longer follow up to detect the role of the attachment used.(AbdelAal et al. 2019)

V. CONCLUSION

It was clear through out this study the great benefit of adding a single implant to the mandible in increasing Masticatory ability of our patients , regardless of the attachment choice. The choice of the attachment may be affected by other factors as maintenance , cost and prosthodontist preference rather than masticatory ability.

Conflict of Interest:

The authors declare no conflict of interest.

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Ethics:

This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo university on: 13/6/2016, approval number:...16 6 10

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