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ORIGINAL RESEARCH

Oral health-related quality of life among patients utilizing single or two implants for Mandibular overdentures with immediate loading protocols

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Abstract

Denture replacement options for edentulous individuals might include a single implant-retained mandibular overdenture (1IMO) as an alternative to two implant-retained mandibular overdentures (2IMO). On the other hand, there is a dearth of research about the quality of life (QoL) of these patients after they have been treated with rapid loading regimens. This research aimed to assess the quality of life (OHRQoL) of patients utilizing 1IMO or 2 IMO with instantaneous loading procedures at 1 month and 1 year. The comparison was to be made at both time points.

Materials and the Methods:

52 edentulous subjects were treated with mandibular overdentures by a single operator. Either a single implant (n = 26) or two implants (n = 26) were used for the treatment, and an instantaneous loading technique was used for both groups. Following the insertion of the implants, the low-profile stud attachments (LOCATOR; Zest Anchors) were secured to the implants, and female attachments were removed anywhere from 0 to 7 days later. Before therapy, one month after treatment, and one year after treatment, the Oral Health Related Quality of Life (OHRQoL) was recorded using the Oral Health Impact Profile-14 (OHIP-14) questionnaire in English.

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Methods of Statistical Analysis Employed:

Both the Kruskal Wallis test and the Mann-Whitney-U test were utilized in order to determine whether or not there was a statistically significant difference between the three timepoints and the seven OHIP-14 domains.

Results:

When compared to their scores on the OHIP-14 at the time of baseline, individuals in both the 1IMO and 2IMO groups showed a statistically significant decrease in total OHIP-14 at both the 1 month and the 1 year following treatment time periods (P 0.05). The difference in total and subscale ratings between one month and one year following therapy was determined to be statistically significant (P 0.05), according to the findings of the study. The overall quality of life (QoL) improvement was significantly greater in the 2IMO group as compared to the 1IMO group. Within seven of the OHIP-14 domains, there was a statistically significant difference in the scores (P 0.05). At the beginning of the study, the difference in total scores between the 1IMO and 2IMO groups was found to be statistically significant (P 0.05), however after one month and one year, this difference was no longer significant (P > 0.05).

Conclusions:

Both mandibular single and 2IMO were shown to increase quality of life in edentulous senior individuals after one month of immediate loading and after one year of recalling the study. 1IMO may offer older patients with a quality of life that is equivalent to that of those receiving 2 implants.

Keywords: Single implant overdenture, patient-reported results, and quality of life.

INTRODUCTION

Edentulism is a physical handicap that occurs as a result of a diminished capacity to conduct vital living skills such as speaking and eating.[1,2,3] One of the therapy strategies that is utilized the vast majority of the time is the conventional full denture. Denture wearers, on the other hand, have a reduced capacity for chewing since their dentures lack retention and stability. [4] The clinical stability of the patient's mandibular denture is the single most critical factor in determining the level of pleasure a patient experiences. [5] Dental implants have made it possible to restore totally edentulous arches using a wide variety of attachment techniques that can be either fixed or removable. [6,7,8]

Using 2-implants retained mandibular overdentures was shown in a number of clinical trials to result in a considerable increase in the patient's quality of life (QoL), according to the reports of those research (2IMO).[9,10] However, the idea of a single implant-retained mandibular overdenture, often known as a 1IMO, has been around for quite some time. In comparison to the 2IMO, the 1IMO has lower costs associated with the patient's first treatment, minimizes the risk of postoperative trauma, and requires less money to maintain. Cordioli[11] first presented the 1IMO idea, and then released the 5-year findings, which showed a success rate of one hundred percent for implants. [12] Over the course of the past few years, it has become abundantly clear that 1IMO is, in fact, the clinically feasible alternative choice to 2IMO. [13,14]Extensive study has been conducted on the influence of the timing of the prosthetic loading on the effectiveness of implant overdentures. This loading has been divided into three categories: immediate, early, and delayed (or typical) loading.[15,16,17] The findings of all of the systematic studies [15,16,17] indicated that there was no significant difference between the loading procedures in terms of the outcomes of peri-implant tissue, marginal bone loss, implant

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stability, and quality of life outcomes. The instantaneous loading protocols, on the other hand, have gained popularity since patients may experience immediate esthetics and function. Furthermore, these protocols assist minimize postoperative pain and suffering because they lessen the masticatory load that is placed on the healing tissues. [18]

A large number of doctors have tried and been successful with quick loading methods using 1IMO.[19,20,21,22] The vast majority of these investigations [19,20,21] were either retrospective or prospective clinical studies, and only a very small number [22] were randomized controlled trials (RCTs). On a visual analogue scale, these investigations assessed the marginal bone levels [19,20,21,22], implant stability [19,20,21], complications [19,20], maintenance [19,20], and patient satisfaction [19,20]. [19,20,22] It was determined that a crucial result would be the effect that implant overdentures have on quality of life. [23] However, the research does not provide any information on the patients who used 1IMO with immediate loading procedures about their oral health-related quality of life (OHRQoL). Oral Health Impact Profile (OHIP) is one of the methods that is considered to have the highest level of validity and reliability when it comes to assessing OHRQoL. [24] The efficacy of the 1IMO on patient-reported outcome measures and masticatory performance in edentulous individuals was recently analyzed in a comprehensive review that included 17 research (9 randomized controlled trials and 8 prospective studies). [25] Improved patient satisfaction and OHRQoL were seen when compared with traditional full dentures [9,10], however, inconsistent findings were reported in OHRQoL when compared with 2IMO. [Citation needed] [25]

As a result, the objective of this particular randomized controlled clinical trial was to investigate the OHRQoL of patients who were given either 1IMO or 2IMO restored with quick loading protocols. When both 1IMO and 2IMO were loaded at the same time, the null hypothesis stated that there would be no discernible change in the overall health-related quality of life (OHRQoL) of the patients.

MATERIALS AND METHODS

Study design

The overall health-related quality of life (OHRQoL) of patients who were randomly assigned to receive either 1IMO or 2IMO was the focus of this single-center, prospective, randomized, and controlled clinical investigation. The research was carried out in accordance with the CONSORT 2010 declaration as well as the principles outlined in the Declaration of Helsinki (version, 2008). [13] The approval of the ethical standards of the institution was received from the joint committee on research and ethics.

Participants

A total of 52 participants were given instantly loaded implant overdentures that were attached using low-profile self-aligning attachments. These patients were then monitored for one month and one year after receiving treatment. All of the participants provided their written informed permission, which was collected. The primary endpoint of the trial, which was measuring the improvement in quality of life of 1IMO after 1 year, was a binomial random variable. With the use of the following webtool, the sample size was determined for two proportions that were computed using parallel samples: https://www2.ccrb.cuhk.edu.hk/stat/proportion/tspp sup.htm. In the control group (2IMO), it was expected that the success probability would be 95%, whereas in the experimental group, it would be 85%. (1IMO). If these assumptions are correct, then a power of 80% will demonstrate that the 1IMO is noninferior even if the sample size is just 40 (20 each group) and the allocation ratio is 1:1 in each group. To account for any

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potential dropouts or those who were lost to follow-up, an extra twelve individuals, or thirty percent, brought the total number of participants in the study up to 52.

Standards for admittance.

Patients must be male or female, have a mandible that is completely edentulous, be between the ages of 40 and 80, have worn complete dentures for a minimum of three months, have adequate bone height in the anterior region of the mandible for standard implants, agree to receive treatment, and agree to attend planned recall appointments.

Exclusion conditions

Patients who have medical conditions such as a previous history of therapy with bisphosphonates or anticoagulants, chronic illness, head-and-neck radiation, or any other systemic condition that may contra-indicate implant treatment, as well as patients who have a habit of smoking more than 10 cigarettes[22,26] per day. According to the SAC categorization system, a patient who smoked more than 10 cigarettes per day was regarded to be a heavy smoker and was placed in the high-risk category for receiving implant therapy. [26] After having an expert evaluate the functioning and acceptance of the patients' current full dentures, the dentures were taken into consideration for attachment pick-up. All of the clinical and technical elements of dentures, including denture border extension, occlusion, retention, and stability, were studied. [22] Only the patients who required a new set of dentures were given permission to use their replacements for a period of at least three months before receiving implant therapy. These patients were the only ones for whom a new set of dentures was constructed. In accordance with the predetermined procedures, an intraoral periapical radiograph and bone-sounding technique or a cone-beam computed tomography were utilized in order to determine whether or not the mandibular bone was suitable for the insertion of an implant. [22]

Intervention

The initial screening procedure and the selection of the participants for the study were carried out by both of the authors based on the inclusion and exclusion criteria. The participants were then randomly assigned to either the test group (1IMO) or the control group (2IMO) using the opaque white envelopes that were sealed shut. The allocation ratio for both groups was 1:1. The identity of the patient was concealed by utilizing a unique secret code number that was assigned to each individual patient. In order to reduce the potential for inter-operator skill bias, each and every surgical and prosthetic operation was carried out in accordance with the protocols that had been established by a single experienced implant physician. Based on the amount of accessible bone volume in the anterior mandible, dental implants (Roxsolid SLActive; Straumann) with a diameter of either 3.3 or 4.1 millimeters and a length of either 10 or 12 millimeters were utilized. After administering local anesthetic, the osteotomy site was prepared for implant placement by elevating a full-thickness flap. The implants required primary stability of 35 NCm. In the 2IMO group, both implants were put in the canine area, whereas in the 1IMO group, the implant was placed in the mid-symphyseal region. Both groups received the same number of implants. [9,10,13,14,19,20,21,22] The male LOCATOR attachments, also known as Zest Anchors, were placed immediately after implant placement depending on the tissue thickness, and the female attachment units were picked up in the denture chairside within 0–7 days of implant placement. The height of the male attachments was 2, 3, 4, or 5 millimeters. According to the requirements of the patients, either blue or pink female attachments were inserted into them. All of the subjects were given a prescription for postoperative analgesics to take between three and five days. The statistician and the data

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processor both had their eyes covered. Both the people taking part in the trial and the implant physicians were unable to maintain their anonymity.

Evaluations of one's quality of life

At three distinct time points—baseline (before implant installation), one month, and one year following implant placement—the OHIP-14 was administered in either the English or hindi language, depending on the patient's selection of language and level of comprehension in that language. The OHIP-14 was comprised of 14 items, each of which was divided into one of seven distinct categories or subscales, each of which contained two questions and was referred to as follows: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. Never, seldom, sometimes, frequently, and always were the possible responses to each item in the survey's five answer categories. The items were graded using scales of five points, with "0" representing "never" and "4" representing "always." The OHIP-14 has a possible score range of 0 to 56 out of a total of 14 questions. When presenting the scores, we added up the points received from both questions within each category. Because the OHIP-14 is a questionnaire that measures the frequency of issues that have occurred, and because lower scores represent a lower frequency of difficulties, these results can be read as indicating a greater OHRQoL. [24,28] At baseline, after one month of therapy, and one year following treatment, the OHIP-14 questionnaire was administered to the patients, and their replies were utilized.

A statistical look at the data

IBM Corp., located in New York, United States, was responsible for developing the statistical program known as IBM SPSS Statistics, version 25.0. The Shapiro–Wilk test was used to determine whether or not the data had a normal distribution. The data were not normally distributed, so the Kruskal–Wallis test, which is a nonparametric test, was utilized to determine whether or not there were significant differences between the three time points and the seven OHIP-14 domains. Additionally, the Mann–Whitney–U test was utilized to determine whether or not there were significant differences between the 1IMO and 2IMO groups using a significance level of 0.05 and a 95% confidence interval.

RESULTS

Out of the total of 50 participants, there were 25 men and 25 women, and their ages ranged anywhere from 42 to 80 years [Table 1]. The average age of the participants was 60.1 years. There were 78 implants placed in 50 participants, of which 4 implants failed in the 1IMO group (2 exfoliated in 1 month due to failed osseointegration and 2 removed in 1 year due to peri-implantitis) and 1 implant failed in the 2IMO group due to peri-implantitis. The total number of implants placed was 78. Another three participants failed to show up for their scheduled follow-up sessions. As a result, we evaluated the replies of a total of 44 individuals (20 from 1IMO and 24 from the 2IMO group). At the beginning of the study, the total mean OHIP-14 score for 1IMO was 14.55, while the score for 2IMO was 19.25. It was lowered to 8.65 in the 1IMO group and 9.58 in the 2IMO group after one month of therapy, and after one year of treatment, it was reduced even further to 3.35 in the 1IMO group and 5.25 in the 2IMO group. The lowest scores were obtained with the subscale "social disability" for both the 1IMO and 2IMO groups [Table 2]. The highest baseline scores were found with the subscale "physical pain" in both the 1IMO and 2IMO groups. The only domain that exhibited a bigger change in scores with the 1IMO group was the "psychological discomfort" domain, in comparison to the 2IMO group.

Table 1

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Group-wise details of the participants selected, and the implants used in the study

Category	Patient and treatment details	1IMO	2IMO	Total
Sex	Males	12	13	25
	Females	14	11	25
	Total	26	24	50
Duration of the denture use	Dentures used >1 year	11	7	18
	Dentures used from 3 months to 1 year	15	19	34
Maxillary arch edentulous status	Maxillary arch completely edentulous	23	24	47
	Maxillary arch partially edentulous	3	2	5
Smoking	Smoking >10 cigarettes per day	0	1	1
Implant size	3.3 mm diameter	22	46	68
	4.1 mm diameter	3	6	9
	Total number of implants placed	28	50	78
Implant length	10 mm	14	39	53
	12 mm	12	13	25
	Total number of implants placed	26	52	78

Table 2

Domain wise mean oral health impact profile-14 scores for 1 implants retained mandibular overdenture and 2 implants retained mandibular overdentures groups at three different time points at baseline, 1 month and 1 year

OHIP-14 domains	Domain number	Mean OHIP scores at baseline		Mean OHIP scores 1 month		Mean OHIP scores 1 year	
		1IMO (*n*=25)	2IMO (*n*=25)	1IMO (*n*=25)	2IMO (*n*=25)	1IMO (*n*=25)	2IMO (*n*=25)
Functional limitation	1	2.1	3.6	1.35	2.17	0.65	1.08
Physical pain	2	4.1	4.31	2.6	2.33	1.33	1.08
Psychological discomfort	3	2.25	2.41	1.15	1.04	0.45	0.83
Physical disability	4	3.45	3.61	1.9	1.83	0.75	0.67
Psychological disability	5	1.5	2.53	0.8	0.85	0.15	0.75
Social disability	6	0.45	1.68	0.4	0.54	0	0.42
Handicap	7	0.78	1.8	0.45	0.75	0.10	0.52
Total score		14.75	19.45	8.65	9.58	3.65	5.35

The overall mean as well as the standard deviation of OHIP-14 scores were obtained at each of the three time periods. According to the results of the normality test, the data did not follow a normal distribution (P less than 0.05). When compared to their scores at the beginning of the study, the individuals in both the 1IMO and the 2IMO group showed a statistically significant reduction in total OHIP-14 at the 1 month and the 1 year following

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treatment time points (P 0.05). The difference in total and subscale ratings between one month and one year following therapy was determined to be statistically significant (P 0.05), according to the findings of the study. Both groups showed a steadily lowering tendency on all subscales and in the overall scores after one month, and this pattern continued after one year. The results of the other six subscales and the overall score suggested that the 1IMO group experienced less change than the 2IMO group. The overall quality of life (QoL) improvement was significantly greater in the 2IMO group as compared to the 1IMO group. There was a statistically significant difference between 7 of the OHIP-14 domains' scores (P 0.05). The following statistical differences were found when comparing various domains using the pairwise comparison method: 6-1 (P = 0.000), 6-4 (P = 0.000), 6-2 (P = 0.000); 7-1 (P = 0.002), 7-4 (P = 0.000); 7-2 (P = 0.000); 5-4 (P = 0.007); 5-2 (P = 0.000); 3-2 (P = 0.001). The following pairings all revealed that P was greater than 0.05.

DISCUSSION

The hypothesis was disproved since the findings demonstrated a greater improvement in OHRQoL among patients in the 2IMO group in comparison to those in the 1IMO group (as demonstrated by lower scores on the OHIP-14 scales in all subscales except for the first). The OHIP-14 questionnaire was used in this randomized controlled clinical trial to measure the overall health-related quality of life (OHRQoL). Because a complete 49-item version of OHIP is not always viable in a clinical context, a shorter version developed by Slade[24] was utilized instead. Slade was responsible for the creation of this version. When compared to the minimum standard of care provided by the 2IMO for the edentulous mandible, the utilization of the 1IMO may be seen as being of a lower quality. However, there is a lower cost, minimum surgical stress, and minimal repair or maintenance with the 1IMO, which are only a few of its advantages that are contrasted to assess the OHRQoL. According to the findings of OHIP-14, the 2IMO had higher pretreatment total scores (19.25), whereas the 1IMO had lower scores (14.55). These findings are presented in Table 2. These baseline scores could vary to a certain extent, but they should not be considered relevant in any way because the scoring values are entirely dependent on the characteristics of the patients who are selected for each group. Because of this, the baseline scores should not be considered relevant in any way. All of the participants in this study were chosen at random, and no special criteria—such as age, gender, or ethnicity—were considered in the selection process. From the baseline to the one month and one year points, all of the subscale scores showed a downward trend. The greater drop in scores indicated the increased overall health-related quality of life (OHRQoL). When compared with the 1IMO group, the 2IMO group saw a larger decline in their scores after one month and one year (9.67 after one month and 14 after one year) (5.9 at 1 month, 11.3 at 1 year). Every one of the subscales pointed to a similar pattern, with the exception of the "psychological discomfort" subscale, which shown a higher drop in scores while using the 1IMO in comparison to the 2IMO. This could not be addressed as to why the 1IMO was only successful in alleviating "psychological discomfort" to a greater extent in some patients. This could be an overwhelming response from the participants in the 1IMO group toward their treatment response, and psychologically, they could be feeling more comfortable due to improved retention in comparison to their previous experiences of wearing conventional complete dentures. However, it is also possible that this is just a coincidence.

After conducting a systematic review on 9 randomized controlled trials (RCTs) and 8 prospective studies involving 551 participants, Fu et al. [25] came to the conclusion that the

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1IMO did not show any significant differences when compared to the 2IMO in terms of general satisfaction, satisfaction with speech, comfort, chewing ability, aesthetics, and social life. [Citation needed] However, contradictory findings were found for OHRQoL as well as participants' levels of satisfaction with regard to retention and stability. The majority of these experiments have been carried out using traditional loading techniques. The findings of the current study agreed with those of earlier research, which suggested that participants in the 1IMO and 2IMO groups who underwent immediate loading had equivalent OHRQoL.

There is inconsistency within the body of research in its presentation of the assessment of OHIP scores and, consequently, the QoL outcomes. Brennan et al.[29] used the OHIP-14 to do a comparison of OHRQoL in patients who had been treated with implant overdentures and full implant fixed prosthesis. The scores have been stated in the percentage format. The researchers Berretin-Felix and Felix[30] used the OHIP-14 to study the effects of implant-supported fixed oral rehabilitation on quality of life, and they reported their findings using the median value. The scoring criteria were not used in a consistent manner at any point. The few research that were done employed the range 0–4 for the "never" to "always" 5-point scoring criterion, while even fewer studies used the range 1–5. The literature provides a variety of explanations on how the patient's quality of life might be presented.

Because of the small size of the sample, the researchers in this study did not take into account the demographics and other personal information of the participants. This is one of the limitations of the study. This study was carried out on the population of Indore, Madhya Pradesh, India , and its findings should be regarded with caution when applying them to the care of patients in other parts of the world. The OHRQoL might be affected by the type of food eaten, the frequency of diet, as well as variances in how people perceive the issues, and the scope of the study should be broadened to include the evaluation of such criteria. Comparisons of the effects of different demographics and personal information with other patient-reported outcomes, such as patient satisfaction and masticatory function, might be the focus of research in the future.

CONCLUSIONS

The following inferences and conclusions can be made in light of the constraints imposed by this randomized controlled clinical investigation. The quality of life of senior edentulous patients was improved with the use of mandibular single and two implant-retained overdentures after one month of immediate loading and one year of recall. Patients receiving 1IMO may experience a quality of life that is equivalent to that of patients receiving 2 implants.

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