

# Oral health-related quality of life of patients using single or two-implant mandibular overdentures with immediate loading protocols: A randomized controlled trial

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## Abstract

**Aim:** Single implant-retained mandibular overdentures (1IMO) is a viable alternative to 2 implant-retained overdentures (2IMO) in edentulous patients. However, literature lacks in the quality of life (QoL) of these patients when treated with immediate loading protocols. The purpose of this study was to compare oral health-related QoL (OHRQoL) of patients using 1IMO or 2 IMO with immediate loading protocols at 1 month and 1 year.

**Settings and Design:** Randomized Controlled Trial.

**Materials and Methods:** Fifty-two edentulous participants treated with mandibular overdentures using either single implant ( $n = 26$ ) or two implants ( $n = 26$ ) with immediate loading protocol by a single operator. The low-profile stud-attachments (LOCATOR; Zest Anchors) were attached to the implants and female attachments were picked up within 0–7 days of implant placement. The OHRQoL was recorded using Oral Health Impact Profile-14 (OHIP-14) questionnaire either in English or in the Malay language before treatment and 1 month and 1 year after treatment.

**Statistical Analysis Used:** Kruskal Wallis test was used to find out significant difference amongst 3 timepoints and 7 OHIP-14 domains and Mann-Whitney-U test to compare 1IMO or 2IMO groups.

**Results:** Compared to baseline OHIP-14 scores, participants had a statistically significant decrease in total OHIP-14 at 1 month and 1 year after-treatment time points in both 1IMO and 2IMO groups ( $P < 0.05$ ). The difference between 1 month and 1 year after-treatment total and subscale scores were also found to be statistically significant ( $P < 0.05$ ). The overall QoL improvement was comparatively higher in 2IMO group than 1IMO group. The OHIP-14 scores were statistically different within seven domains ( $P < 0.05$ ). Overall total scores between 1IMO and 2IMO groups were also found to be statistically significant ( $P < 0.05$ ) at baseline and insignificant ( $P > 0.05$ ) at 1 month and 1 year.

**Conclusions:** Mandibular single and 2IMO improve the QoL of elderly edentulous Malaysian participants at 1 month of immediate loading and 1 year of recall. 1IMO may provide comparable QoL with the elderly patients using 2 implants.

**Keywords:** Mandibular overdenture, patient-reported outcomes, quality of life, single implant overdenture

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## INTRODUCTION

Edentulism is a physical impairment due to compromised ability to perform essential life tasks, such as speaking and eating.<sup>[1-3]</sup> Conventional complete dentures are one of the most widely used treatment modalities. However, lack of retention and stability result in decrease in chewing ability in denture users.<sup>[4]</sup> The clinically stable mandibular denture is the most important determinant of patients' satisfaction.<sup>[5]</sup> Dental implants have provided varieties of fixed and removable attachment systems in restoring completely edentulous arches.<sup>[6-8]</sup>

Numerous clinical studies reported a significant improvement in the quality of life (QoL) of the patient using the 2-implants retained mandibular overdentures (2IMO).<sup>[9,10]</sup> However, the concept of 1 (single) implant-retained mandibular overdenture (1IMO) is not new. The 1IMO reduces the patient's initial treatment cost, minimize postsurgical trauma, and provides lesser maintenance cost as compared with the 2IMO. The 1IMO concept was introduced by Cordioli<sup>[11]</sup> and later published the 5-year results with 100% implant success rate.<sup>[12]</sup> In recent years, 1IMO has been proved to be the clinically viable alternative option to 2IMO.<sup>[13,14]</sup>

Timing of the prosthetic loading on the success of implant overdentures has been researched extensively and categorized as immediate, early, and delayed (or conventional) loading.<sup>[15-17]</sup> Results of all the systematic reviews<sup>[15-17]</sup> revealed no significant difference in peri-implant tissue outcome, marginal bone loss, implant stability, and QoL outcomes among the loading protocols. The immediate loading protocols, however, gained popularity because patients can enjoy immediate esthetics and function and it also helps reduce postoperative pain and discomfort, as the masticatory load on the healing tissues is reduced.<sup>[18]</sup>

Many clinicians have successfully attempted immediate loading protocols with 1IMO.<sup>[19-22]</sup> Most of these studies were retrospective or prospective clinical studies<sup>[19-21]</sup> and very few<sup>[22]</sup> were randomized controlled trials (RCTs). These studies evaluated the marginal bone levels<sup>[19-22]</sup> implant stability,<sup>[19-21]</sup> complications,<sup>[19,20]</sup> maintenance,<sup>[19,20]</sup> and patient satisfaction on visual analogue scale.<sup>[19,20,22]</sup> The impact of implant overdentures on the QoL was identified as an essential outcome.<sup>[23]</sup> However, the literature lacks the information on oral health-related QoL (OHRQoL) of the patients using 1IMO with immediate loading protocols. Oral Health Impact Profile (OHIP) is one of the most valid and reliable tools used to evaluate the OHRQoL.<sup>[24]</sup> A recent systematic review of 17 studies (9 RCTs and 8

prospective studies) evaluated the effect of the 1IMO on patient-reported outcome measures and masticatory function in the edentulous patients.<sup>[25]</sup> Improved patient satisfaction and OHRQoL were evident when compared with conventional complete dentures,<sup>[9,10]</sup> however conflicting results were observed in OHRQoL when compared with 2IMO.<sup>[25]</sup>

Hence, the present randomized controlled clinical study was designed to evaluate the OHRQoL of patients receiving 1IMO or 2IMO restored with immediate loading protocols. The null hypothesis was that no difference would be found in patients' OHRQoL using either 1IMO or 2IMO when loaded immediately.

## MATERIALS AND METHODS

### Study design

This was a single-center, prospective, randomized, controlled, clinical trial that aimed to compare OHRQoL between groups of patients receiving 1IMO or 2IMO. The study was conformed to the CONSORT 2010 statement and in compliance with the Declaration of Helsinki (version, 2008).<sup>[13]</sup> Institutional ethical approval was obtained from the joint committee on research and ethics (No. R148/2014). The trial was prospectively registered with the National Medical Research Register (NMRR-15-19-23859) of the authors' country. This project was supported by a grant from the International Team for Implantology Foundation, Switzerland (Grant Number: 927\_2013). The study site was the oral health center of the authors' university.

### Participants

A total of 52 participants were treated (between August 2015 and October 2020) with immediately loaded implant overdentures using the low-profile self-aligning attachments (LOCATOR; Zest Anchors) and followed up for 1 month and 1 year. Written informed consent were obtained from all the participants. The improvement in QoL of 1IMO after 1 year as the primary endpoint of the study was a binomial random variable. The sample size was calculated for two parallel-sample proportions using following webtool: [https://www2.ccrb.cuhk.edu.hk/stat/proportion/tspp\\_sup.htm](https://www2.ccrb.cuhk.edu.hk/stat/proportion/tspp_sup.htm). The success probability was assumed to be 95% in the control group (2IMO) and 85% in the experimental group (1IMO). Under these assumptions, a power of 80% reveals the noninferiority of the 1IMO if the sample size is 40 (20 per group) with 1:1 allocation ratio in each group. Twelve (30%) additional participants were added to make a total of 52 participants to compensate for possible dropouts or losses to follow-up.

### Inclusion criteria

Male or female with completely edentulous mandible, aged between 40 and 80 years, with 3 months of complete denture wearing experience, adequate bone height in the anterior mandible for standard implants, agree to receive intervention, and agree to attend planned recall appointments.

### Exclusion criteria

Patients having medical conditions including a history of bisphosphonate therapy, anticoagulant therapy, chronic illness, head-and-neck radiation, any systemic condition that may contra-indicate implant treatment or habit of smoking more than 10 cigarettes<sup>[22,26]</sup> per day. A person smoking more than 10 cigarettes was considered a heavy smoker and classified as a high-risk patient for implant treatment according to the SAC classification system.<sup>[26]</sup> Patients' existing complete dentures were considered for attachment pick-up after expert evaluation for its functionality and acceptability. All the denture-related clinical and technical aspects were evaluated including denture border extension, occlusion, retention, and stability.<sup>[22]</sup> A new set of dentures were fabricated only for those patients who need to change their denture and allowed them to use for minimum 3 months before undergoing the implant treatment. The mandibular bone was evaluated for suitability of implant placement with intraoral periapical radiograph and bone-sounding method or with a cone-beam computed tomography as per the set protocols.<sup>[22]</sup>

### Intervention

Both the authors performed initial screening process and selection of the participants based on the inclusion and exclusion criteria. The participants were then randomly allocated to the test (1IMO) and control (2IMO) groups using the sealed opaque white envelopes with an allocation ratio of 1:1 [Figure 1]. The patient's identity was protected using a secret code number given to each patient. All the surgical and prosthetic procedures were performed according to the set protocols, by a single experienced implant clinician (primary author) to minimize the risk of inter-operator skill bias. The dental implants (Roxsolid SLActive; Straumann) with 3.3 mm or 4.1 mm diameter and 10 mm or 12 mm length were used based on the available bone volume in the anterior mandible. The implants were placed under local anesthesia by raising a full-thickness flap at the osteotomy site with primary stability of 35 Ncm. For the 2IMO group, both implants were placed in the canine region and for the 1IMO group, the implant was placed in the mid-symphyseal region.<sup>[9,10,13,14,19-22]</sup> The male LOCATOR attachments (Zest Anchors) (2, 3, 4, or 5 mm height) were placed immediately after implant placement

depending upon the tissue thickness and the female attachment units picked up in the denture chairside within 0–7 days of implant placement [Figure 2a and b]. Either blue or pink female attachments were used in the patients according to the needs [Figure 3a and b]. Postsurgical analgesics were prescribed to all the participants for 3–5 days. The data processor and statistician were blinded. The study participants and the implant clinicians could not be blinded.

### Quality of life measurements

The OHIP-14 was used in English or Malay language based upon patients' language preference and understanding at three different time points: Baseline (before implant placement), 1 month, and 1 year after implant placement. Malay version of the OHIP-14 was validated by Saub *et al.*<sup>[27]</sup> The OHIP-14 consisted of 14 items grouped into 7 domains or subscales containing 2 questions each and named as: Functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. The five response categories for each item were never, seldom, sometimes, often, and always. The items were scored on 5-point scales ranging from "0" = "never" to "4" = "always." Achievable OHIP-14 scores range from 0 to 56 for 14 questions. The scores were presented by adding the scores of both questions of each domain. As the OHIP-14 is the questionnaire of frequency of the problems that occurred and the lower scores depict the lesser frequency of the problems and thus interpreted as higher OHRQoL.<sup>[24,28]</sup> The patients' responses using the OHIP-14 questionnaire were used at baseline, at 1 month, and 1 year after the treatment.

### Statistical analysis

The data were analyzed with statistical software IBM SPSS Statistics, v25.0; IBM Corp., New York, USA. The test of normality of the data was carried out using Shapiro–Wilk. Since the data were not normally distributed, the nonparametric Kruskal–Wallis test was used to find out significant differences among 3 time points and 7 OHIP-14 domains and Mann–Whitney-*U* test to compare 1IMO or 2IMO groups at the significance level of 0.05 and 95% confidence interval.

## RESULTS

Of the 52 participants included, 21 were men and 31 were women with an average age of 63.5 years ranged between 42 and 80 years [Table 1]. Seventy-eight implants were placed in 52 participants, of which 4 implants were failed in 1IMO group (2 exfoliated in 1 month due

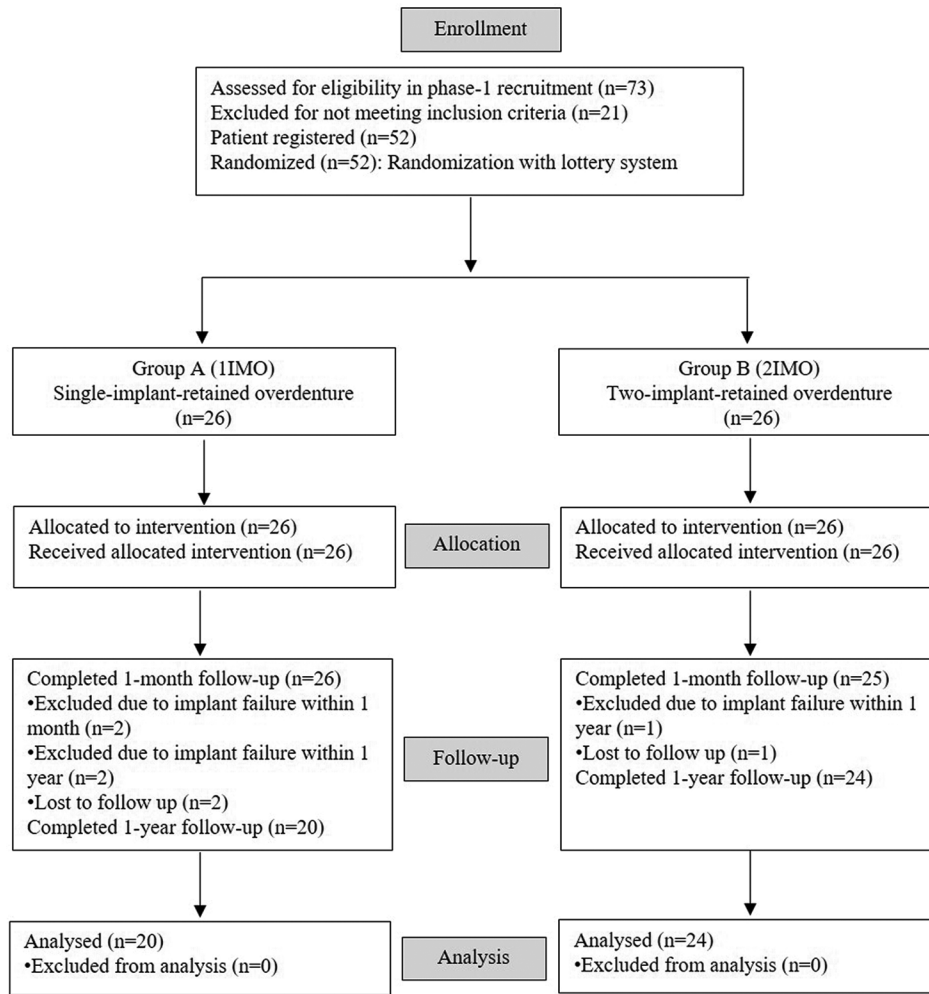


Figure 1: PRISMA flowchart indicating patient dropouts

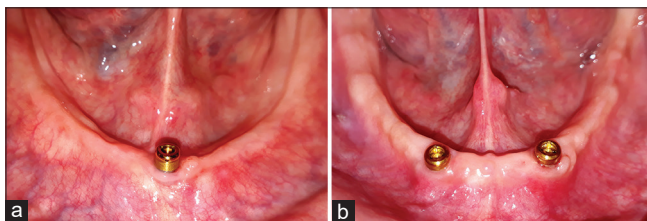


Figure 2: (a) Intraoral view of a participant from single implant-retained mandibular overdentures group at 1 year recall. (b) Intraoral view of a participant from 2 implant-retained overdentures group at 1 year recall

to failed osseointegration, 2 removed in 1 year due to peri-implantitis) and 1 implant failed in 2IMO group due to peri-implantitis [Figure 1]. Another 3 participants lost to follow-up appointments [Figure 1]. Hence, responses of total 44 participants were analyzed (20 from 1IMO and 24 from the 2IMO group). Total mean OHIP-14 score at baseline for 1IMO was 14.55 and for 2IMO was 19.25. At 1 month after treatment, it was reduced to 8.65 in 1IMO and 9.58 for 2IMO group and at 1 year after treatment, it was further reduced to 3.35 in 1IMO and 5.25

in 2IMO group. The highest baseline scores were observed with the subscale “physical pain” in both 1IMO (4) and 2IMO (4.1) groups and the lowest scores were observed with the subscale “social disability” for both 1IMO (0.55) and 2IMO (1.58) groups [Table 2]. Only “psychological discomfort” domain showed higher change in scores with the 1IMO group (1.2 at 1 month, 1.9 at 1 year) compared to 2IMO group (1.17 at 1 month, 1.38 at 1 year).

Overall mean and standard deviation of OHIP-14 scores at three-time points were recorded [Table 3]. The test of normality indicated that the data were not normally distributed ( $P < 0.05$ ) [Table 3]. Compared to baseline scores, the participants had a statistically significant decrease in total OHIP-14 at 1 month and 1 year after-treatment time points in both 1IMO and 2IMO group ( $P < 0.05$ ) [Tables 4, 5 and Figure 4a-d]. The difference between 1 month and 1 year after treatment, the total and subscale scores were also found to be statistically significant ( $P < 0.05$ ) [Table 5 and Figure 4c, d]. All subscale

and total scores indicated consistently decreasing trend in both groups at 1 month and further at 1 year. The remaining all 6 subscales and the total scores indicated lower changes in 1IMO group than 2IMO group. The overall QoL improvement was comparatively higher in 2IMO group than 1IMO group. The OHIP-14 scores were statistically different within 7 domains ( $P < 0.05$ ) [Table 6]. Pairwise comparison among different domains indicated statistical differences between following different pairs of domains 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 remaining all pairs indicated  $P > 0.05$ .

Overall total scores between 1IMO and 2IMO groups were also found to be statistically significant ( $P < 0.05$ ) [Table 7 and Figure 5a]. However, further timeline wise analysis indicated that this difference was only statistically significant at baseline ( $P = 0.011$ ) and insignificant at

1 month ( $P = 0.402$ ) and 1 year ( $P = 0.053$ ) [Table 8 and Figure 5b-d].

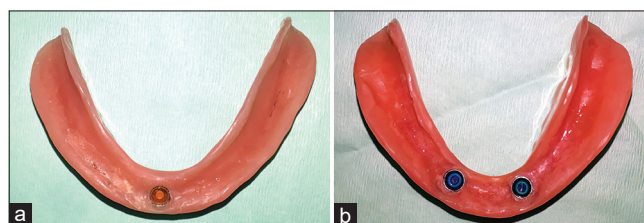
**DISCUSSION**

The hypothesis was rejected as the results indicated higher OHRQoL (as indicated by lower OHIP-14 scores in all subscales except 1) with the 2IMO group compared with the 1IMO group patients. This randomized controlled clinical study evaluated the OHRQoL using the OHIP-14 questionnaire. A full 49-item version of OHIP is not always practical in a clinical setting and hence a shorter version development by Slade<sup>[24]</sup> was used. Use of the 1IMO could be considered inferior as compared with the minimum standard of care of the 2IMO for the edentulous mandible. However less cost, minimal surgical trauma, and minimal repair or maintenance are few of the advantages of the 1IMO and compared to evaluate the OHRQoL. The OHIP-14 results depict that higher pretreatment total scores for the 2IMO (19.25) and lower for the 1IMO (14.55) [Table 2]. These baseline scores could vary up to certain extent and should not be considered of any relevance as the scoring values are completely depending on the characteristics of the patients being selected in each group. The present study randomly selected all the participants with no specific criteria being applied like age, sex, or ethnicity. All the subscale scores shown a decreasing trend from baseline to 1 month and 1 year. Greater reduction in the scores indicated the improved OHRQoL. The reduction of the scores at 1 month and

**Table 1: Group-wise details of the participants selected, and the implants used in the study**

Category	Patient and treatment details	1IMO	2IMO	Total
Sex	Males	6	15	21
	Females	20	11	31
	Total	26	26	52
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	24	45	69
	4.1 mm diameter	2	7	9
	Total number of implants placed	26	52	78
Implant length	10 mm	14	39	53
	12 mm	12	13	25
	Total number of implants placed	26	52	78

IMO: Implants retained mandibular overdentures

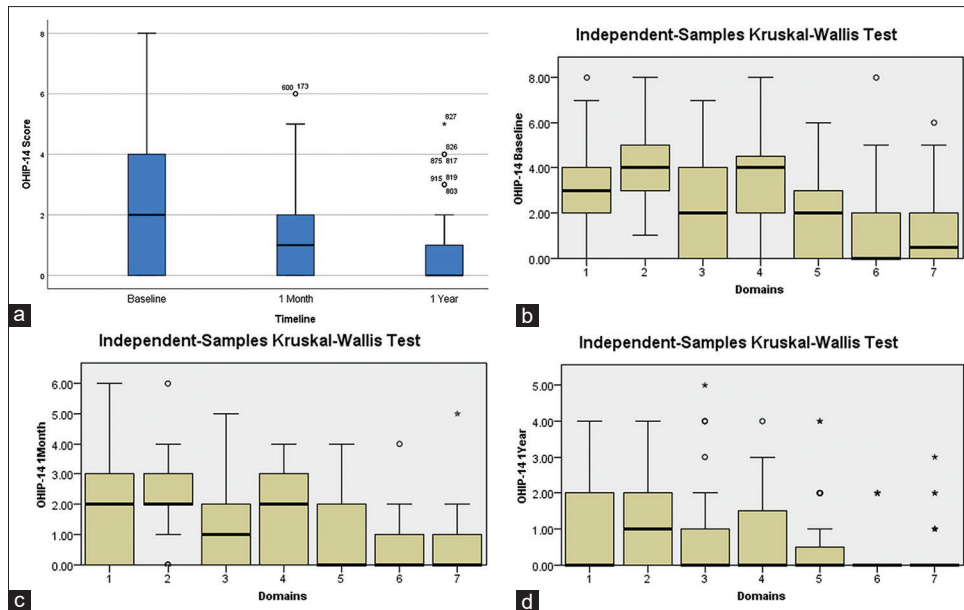


**Figure 3:** (a) Implant overdenture of single implant-retained mandibular overdentures group at 1 year recall. (b) Implant overdenture of 2 implant-retained overdentures group at 1 year recall

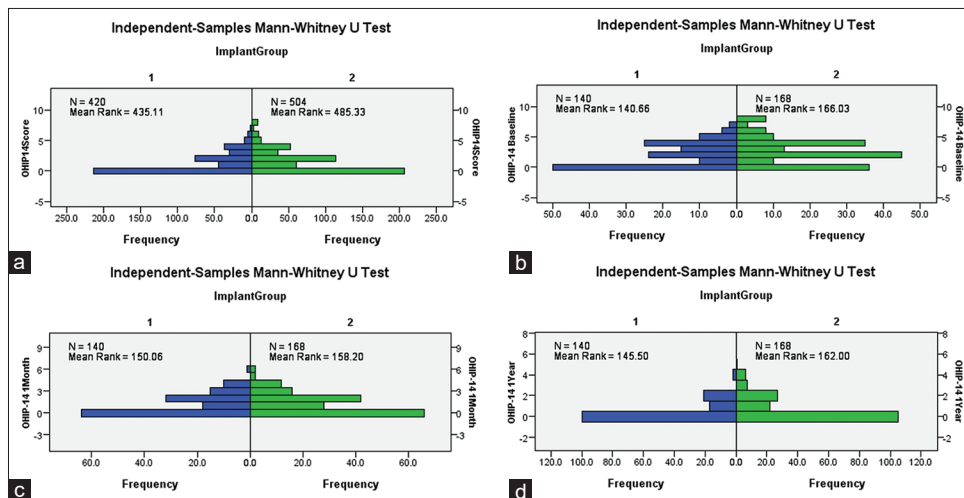
**Table 2: Domain wise mean oral health impact profile-14 scores for 1 implants retained mandibular overdenture and 2 implants retained mandibular overdentures groups at three different time points at baseline, 1 month and 1 year**

OHIP-14 domains	Domain number	Mean OHIP scores at baseline		Mean OHIP scores 1 month		Mean OHIP scores 1 year	
		1IMO (n=20)	2IMO (n=24)	1IMO (n=20)	2IMO (n=24)	1IMO (n=20)	2IMO (n=24)
Functional limitation	1	2.2	3.5	1.35	2.17	0.65	1.08
Physical pain	2	4	4.21	2.6	2.33	1.2	1.08
Psychological discomfort	3	2.35	2.21	1.15	1.04	0.45	0.83
Physical disability	4	3.35	3.71	1.9	1.88	0.85	0.67
Psychological disability	5	1.4	2.33	0.8	0.83	0.15	0.75
Social disability	6	0.55	1.58	0.4	0.58	0	0.42
Handicap	7	0.7	1.71	0.45	0.75	0.05	0.42
Total score		14.55	19.25	8.65	9.58	3.35	5.25

IMO: Implants retained mandibular overdentures, OHIP: Oral health impact profile



**Figure 4:** (a) Independent-Samples Kruskal–Wallis Test with timeline as a grouping variable. (b) Kruskal–Wallis Test with domains as a grouping variable at Baseline. (c) Kruskal–Wallis Test with domains as a grouping variable at 1 Month. (d) Kruskal–Wallis Test with domains as a grouping variable at 1 year



**Figure 5:** (a) Mann–Whitney Test with for overall OHIP-14 score with implant groups as a grouping variable ( $P = 0.003$ ). (b) Mann–Whitney Test with for Baseline OHIP-14 score with implant groups as a grouping variable ( $P = 0.011$ ). (c) Mann–Whitney Test with for 1 month OHIP-14 score with implant groups as a grouping variable ( $P = 0.402$ ). (d) Mann–Whitney test with for 1 year OHIP-14 score with implant groups as a grouping variable ( $P = 0.053$ )

**Table 3: Mean oral health impact profile scores and test of normality of data**

Time points	Overall OHIP-14 scores				Shapiro–Wilk test of normality		Groupwise OHIP-14 scores		
	<i>n</i>	Mean±SD	Minimum	Maximum	Statistic	<i>P</i>	Implant group	<i>n</i>	Mean±SD
Baseline	308	2.44±2.102	0	8	0.903	0.000	1IMO	140	2.08±1.949
							2IMO	168	2.75±2.180
1 month	308	1.31±1.402	0	6	0.835	0.000	1IMO	140	1.24±1.376
							2IMO	168	1.37±1.425
1 year	308	0.63±1.031	0	5	0.656	0.000	1IMO	140	0.48±0.852
							2IMO	168	0.75±1.146

IMO: Implants-retained mandibular overdentures, OHIP: Oral health impact profile, SD: Standard deviation

1 year were greater for 2IMO group (9.67 at 1 month, 14 at 1 year) compared with 1IMO group (5.9 at 1 month,

11.3 at 1 year). All the subscales indicated a similar trend except the “psychological discomfort” which shown a

**Table 4: Kruskal–Wallis test with timeline as a grouping variable**

	Timeline	n	Mean rank	P
OHIP-14 score	Baseline	308	590.10	0.000
	1 month	308	458.56	
	1 year	308	338.84	

OHIP: Oral health impact profile

**Table 5: Pairwise comparison with Kruskal–Wallis test with timeline as a grouping variable**

Timeline pairs	Test statistics	SE	Standard test statistics	P
1 year and 1 month	119.718	20.332	5.898	0.000
1 year and baseline	251.255	20.332	12.358	0.000
1 month and baseline	131.537	20.332	6.470	0.000

SE: Standard error

**Table 6: Kruskal–Wallis test with oral health impact profile-14 domains as a grouping variable**

	Domains	n	Mean rank	P
OHIP-14 score	1	132	532.09	0.000
	2	132	633.00	
	3	132	445.01	
	4	132	550.97	
	5	132	406.06	
	6	132	324.00	
	7	132	346.36	

OHIP: Oral health impact profile

**Table 7: Mann–Whitney test with implant groups as a grouping variable for overall oral health impact profile-14 score**

	Implant group	n	Mean rank	Sum of ranks	P
OHIP-14 score	1IMO	420	435.11	182,745.50	0.003
	2IMO	504	485.33	244,604.50	

1IMO: Implants-retained mandibular overdentures, OHIP: Oral health impact profile

**Table 8: Pairwise comparison with Mann–Whitney test with implant groups as a grouping variable at different time points**

	Implant group	n	Mean rank	Sum of ranks	P
OHIP-14 baseline	1IMO	140	140.66	19,693.00	0.011
	2IMO	168	166.03	27,893.00	
OHIP-14 1 month	1IMO	140	150.06	21,009.00	0.402
	2IMO	168	158.20	26,577.00	
OHIP-14 1 year	1IMO	140	145.50	20,370.50	0.053
	2IMO	168	162.00	27,215.50	

1IMO: Implants-retained mandibular overdentures, OHIP: Oral health impact profile

greater reduction in the scores with the 1IMO compared with the 2IMO. This could not be explained as why only “psychological discomfort” was improved in greater extent with the 1IMO. Probably, this could be just 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 compared with their previous experiences of wearing conventional complete dentures.

Fu *et al.*<sup>[25]</sup> performed a systematic review on 9 RCTs and 8 prospective studies involving 551 participants and observed that the 1IMO showed no significant differences as compared with 2IMO regarding general satisfaction and satisfaction with speech, comfort, chewing ability, aesthetics, and social life. However conflicting results were observed in OHRQoL and satisfaction with retention and stability. Most of these studies have done with conventional loading protocols. The present study results were in accordance with the previous studies indicated comparable OHRQoL between 1IMO and 2IMO groups with immediate loading.

The literature is inconsistent in presenting the measurement of the OHIP scores and subsequently the QoL results. Brennan *et al.*<sup>[29]</sup> compared OHRQoL in patients treated with implant overdentures and complete implant fixed prostheses using OHIP-14 and the scores have been mentioned in the percentage. Berretin-Felix *et al.*<sup>[30]</sup> studied the consequences of implant-supported fixed oral rehabilitation on the QoL using OHIP-14 and the results were presented using median value. There was no consistency in using the scoring criteria. The few studies used 0–4 and few used 1–5 for “never” to “always” 5-point scoring criteria. There are multiple ways explained in the literature to present the patient’s QoL.

This study has not considered individual’s demographics and personal details due to limited sample size and can be considered as a limitation of the study. This research was conducted in the Malaysian population and can be carefully interpreted while treating the patients in other geographical locations. The type of food, frequency of diet, differences in the perception of the problems could affect the OHRQoL and studied can be expanded to evaluate such parameters. Future research can be directed comparing the effect of different demographics and personal details with different patient-reported outcomes including patient satisfaction and masticatory performance.

## CONCLUSIONS

Within the limitations of this randomized controlled clinical study, the following conclusions were drawn. Mandibular single and 2 implant-retained overdentures improve the QoL of elderly edentulous Malaysian patients at 1 month of immediate loading and 1 year of recall. 1IMO may provide comparable QoL with the patients using 2 implants.

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## Conflicts of interest

There are no conflicts of interest.

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