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*Full Length Research Paper*

# Model development of mandibular two-implant retained overdentures plus nutritional empowerment in elderly with dentures (NEED) (Immediate outcome)

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**It is still unclear whether mandibular two implant-retained overdentures improve the nutritional status of elderly edentulous persons better than conventional dentures. In Thailand, according to age pyramid of 2007, older people above 65 years in men and women are about 4.0 million and 4.4 million respectively. The senior edentulous citizens waiting for dental implants are 107, 366 in Thailand, whereas 2155 in Bangkok and 1038 in Pathumthani province. In this randomized clinical trial, Population was Thai males and females, aged over 65 years and edentulous for at least 1 year, living in Pathumthani Province, Thailand. Intervention was Mandibular two implant-retained Overdentures (IOD) plus NEED (Nutritional Empowerment in Edentulous people with Dentures). Comparison was among IODNEED, IOD only; Conventional dentures (CD) plus NEED and CD only. Outcome: Post-treatment differences in satisfaction, oral heath related quality of life and nutritional status among the groups. The research results found that all general characteristics and pretest mean scores of most of the measured variables were not statistically significant difference among the four groups (p-value >.05). Comparison between pretest and post 1 month intervention within group (paired *t*-test) found that there was highest mean scores difference in IODNEED group than other three groups and mean scores for oral health related quality of life (OHIP), masticatory function (QMF), satisfaction for maxilla and mandibular (VSAMX, VASMD), Mini Nutritional Assessment (MNA), and Body Mass Index (BMI), were statistically significance higher than pretest (p-value <.001). As for comparison among groups after post 1 month assessment, IODNEED group had the best immediate outcomes mean scores in all variables measured and also significant higher mean scores in OHIP, QMF, VASMX and VASMD except MNA and BMI than CDNEED group and CD group (p-value <.05). This revealed that combined effect of surgery and nutritional empowerment have good achievement in not only better masticatory function but also nutritional status. All of all, these results suggest that providing nutritional empowerment and low-cost local made titanium mandibular two implant-retained prosthesis improves their satisfaction, dietary intake and nutritional state.**

**Keywords:** Mandibular two implant-retained overdentures, dental implants, edentulous, elderly, nutrition, dental prosthesis, cost-effectiveness, Funyim.

## INTRODUCTION

Complete loss of all natural teeth (edentulous) can substantially reduce quality of life, self-image, daily masticatory functioning and nutritional status. It was estimated that developing countries will experience a three-fold increase in the proportion of older people in the next 30 years (Barreto et al., 2003). In an epidemiology of complete edendulousness over 65 year-old; in Thailand was 16 percent whereas, in China 11%, in Cambodia 13%, in Singapore 21% and in Indonesia 24% (WHO, 2005).

In Thailand, the senior edentulous citizens waiting for dental implants are 107, 366 persons, whereas, 2155 are residing in Bangkok and 1038 in Pathumthani province (King project MOPH Thailand, 2008).

The fully edentulous condition has negative impacts on oral health related quality of life (OHRQoL) (Szentpetery et al., 2005), including the inability to chew, poor speech, pain, and dissatisfaction with appearance (Walton and MacEntee, 2005).

Conventional dentures "CD" could not chew many types of foods, particularly raw vegetables and other hard and tough foods (Hartsook, 1974; Wayler and Chauncey, 1983; Chauncey *et al*., 1984). Therefore, they consumed significantly less protein and other key nutrients—including fiber, calcium, non-haeme iron, and some vitamins (Sheiham *et al*., 2001). On the other hand, mandibular two implant-retained overdentures "IOD" not only can chew most of the foods (Feine *et al*., 1994; Geertman *et al*., 1999) but also provides significantly greater satisfaction, masticatory function, and oral health-related quality of life (OHRQoL) than CD (Awad *et al*., 2000).

A few studies had reported deficiencies of isolated nutrients in denture wearers, but there was no consistent pattern (Papas et al., 1998; Joshipura et al., 1996; Greksa et al., 1995). Moreover, some studies generally had shown that prosthetic rehabilitation in the absence of dietary counseling does not lead to dietary improvement (Moynihan and Bradbury, 2001; Moynihan et al., 2006; Hildebrandt et al., 1997; Sahyoun et al., 2003; Sheiham et al., 2001). Interestingly, in one study, the differences between "IOD" and "CD" were not significant ($p>0.3$) for the questions arguing on the frequency of consumption of meats, raw fruits or vegetables (Muller K et al., 2008).

In this study, we tested to narrow down the research Gap; it is unclear whether the replacement of conventional mandibular dentures with implant-supported overdentures alters the diet selection and thus improves nutritional status and quality of life of elderly edentulous persons. Thus we empowered one of the factor related to food choice i.e knowledge, attitude and practice concerning about healthy diet by NEED (Nutritional Empowerment in Edentulous people with Dentures) program using participatory learning approach. Our research question was "Can the combine effect of two interventions (IOD+NEED) have better improvement in patient satisfaction and nutritional status than the other compared groups; IOD only, CD+NEED, and CD only". We tested the null-hypothesis that there are no difference in oral health related quality of life, satisfaction and nutritional status among the participants with IODNEED and those with IOD, CDNEED, and CD at 1 month post-treatment.

## MATERIAL AND METHODS

This study was a Randomized clinical trial. This study was conducted in Prachatipat hospital, Pathumthani province, Thailand. The study population for this study were Thai edentulous people over 65 –year old age attending (King project) "Project Dental Implant Honor" during the study period from September 2010 to November 2011. The subjects were recruited from the waiting list of elderly edentulous persons residing in Pathumthani Province. The subjects were invited to participate in this study by telephone conversation. All the patients who agreed the study protocol were screened using the following inclusion criteria and exclusion criteria, see (Table 1). Informed written consent was obtained from all participants.

The estimated sample size was calculated by comparisons of two means formula, according to standard statistical criteria ($\alpha$ =0.05, power of the test = 90%). Difference between means and standard deviation of two groups was used from previous study in 2003, primary outcome patients' satisfaction VAS, visual analogue scale (Morais J.A et al., 2003). The sample size calculated was 27 per each group and we added another 20 percent for estimated attrition. Participants were randomly allocated to each of the four studied groups.

Subjects received either mandibular two implant-retained overdentures (n=66) by "Funyim", provided from King, manufactured in ADTEC (Advanced Dental Technology Center), Thailand or conventional completes dentures (n=66) by new maxillary and mandibular conventional dentures.

For the primary outcome of the study, general satisfaction was measured by visual analogue scales (0 to 100) for maxilla and mandibular. The secondary outcomes were quality of mastication function, oral health related quality of health by OHIP oral health impact profile, mini nutritional assessment, and body mass index. These were gathered at pretest and post 1 month treatment. Data were gathered by a dietitian and a trained public health nurse, who were blind to research protocol.

**Table 1.** Inclusion and Exclusion Criteria for the Study Participants

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| ◙ Male and female<br>◙ Age 65 years and older<br>◙ Being edentulous for a minimum of 1 year<br>◙ Patient wants replacement of existing old complete dentures<br>◙ Ability to understand written and spoken Thai language and respond to the scales used<br>◙ Willing and able to accept the protocol and to give written informed consent<br>◙ Absence of soft or hard tissue inflammation in the oral cavity<br>◙ Adequate oral hygiene, assessed by the plaque index and the sulcus bleeding index | ◙ Insufficient bone to place two implants in the anterior mandible<br>◙ Other oral conditions that preclude immediate prosthetic treatment<br>◙ Acute or chronic symptoms of temporo-mandibular disorders<br>◙ Neurologic disease that contraindicates implant surgery<br>◙ Previous or current radiotherapy or chemotherapy<br>◙ Other health conditions: smoking of > 1 pack of cigarettes/day<br>◙ A BMI less than 20 kg/m2 or more than 35 kg/m2<br>◙ Psychological or psychiatric conditions that could influence diet and reaction to treatment<br>◙ Poor metabolic control (Hb a 1c glycosylated hemoglobin > 13.0% or creatinine > 1.7 ml/dl)<br>◙ Blood dyscrasias and liver failure |

Weight and height was measured by stadiometer (DETECTO, donated by UNICEF), we measured to the nearest 100gm, with light clothing and without shoes. Waist and hip circumferences were measured with non-elastic tape. From height and weight, the Body Mass Index was calculated.

Instruments for data collection: the questionnaires used for data collection were as follows;

(1) For oral health related quality of health by OHIP 20 Thai version already adopted (John et al., 2006), translated and used in King Project “Project Dental Implant Honor”.

(2) Quality of mastication function adopted from original English language was translate to Thai by researcher

(3) Mini Nutritional Assessment (Guigoz Y et al., 1996) was adopted and translated to Thai by researcher

(4) VAS (McDowell I et al., 1996), visual analogue satisfaction score was adopted and translated by researcher.

Regarding the IOD surgery and NEED programme were mentioned in Box 1. To compare demography among the groups was analyzed by chi-square test and univariate ANOVA. For parametric data, pretest and post 1 month among the groups were analyzed by univariate ANOVA. For within-group data, paired *t* tests were performed. The Ethical Review Committee for research involving human research subjects, Health Science group, Chulalongkorn University, Thailand, had approved the study and the title number is 037.2/53.

## RESULTS

According to inclusion criteria, one hundred and thirty two participants (81 female and 51 male) were initially randomized into the study. There were 33 participants in each groups at baseline ie. Experimental group I, two mandibular implant-retained overdentures plus nutritional empowerment in elderly with dentures “IODNEED” group, only two mandibular implant-retained overdentures “IOD” group, conventional dentures plus nutritional empowerment in elderly with dentures “CDNEED” group, and only conventional dentures “CD” group. All of the participants attended post one month follow-up appointment (Figure 1). As for comparing group difference of general characteristic among the four groups, there were no statistical significant difference in gender (p=0.014), age (p=0.261), age at edentulous (p=0.270), current living status (p=0.699), religious (p=0.388), monthly income (p=0.092), associated systemic disease (p=0.350), history of smoking (p=0.927). The research results found that all general characteristics were not statistically significant difference among the four groups; “IODNEED”, “IOD”, “CDNEED”, and “CD" (Table 2).

As for description of mean and standard deviation of sum of scores of oral health impact profile, OHIP (to measure oral health related quality of life) among the four groups were;

***Before the experiment:*** There were 75.1818±19.1449, 75.9394±18.0311, 81.7576 ± 14.2281, and 81.5455±15.3401 in “IODNEED” group, “IOD” group, “CDNEED” group, and “CD control” group respectively. ***After the one month experiment:*** There were 101.3030±12.1591, 98.1515±12.1838, 91.3939±13.9462, and 88.8182±11.1256 in “IODNEED” group, “IOD” group, “CDNEED” group, and “CD control” group respectively.

As for quality of mastication function (QMF) among the

**Box 1. IOD and NEED :**

IOD: All the mandibular two implant-retained overdentures were done by researcher according to the protocol of the King Project (Project Dental Implant Honor), credential by the specialists from Project Dental implant honor, Department of Dental Institute, Ministry of Public Health; clinical professor, Department Dental Surgery , Mahidol University, and Assoc. Prof., Department of Dental Prosthodontics, Thammasart, University, Thailand.

NEED: Nutritional Empowerment in Elderly with Dentures is a nutritional empowerment programme based on the participatory learning process, which is composed of experimental learning and group process, emphasizing developing old experiences and reflecting ideas from discussions until new knowledge is formed.

This program was provided by conjunction with Bangkok Metropolitan Administration (BMA), Bureau of Nutrition Bangkok. The implementation instruments such as NEED nutritional empowerment hand book, power points for teaching and nutritional assessment questionnaires were prepared and validated by experts from BMA. All of the nutritional empowerment sessions were conducted by experts from BMA and assisted by dental team including 1 nutritionist and 1 public health nurse from the Prachatipat Hospital.

NEED detail procedure and contents:

| DAY 1 Objective | Topic | Methodology | Time |
|---|---|---|---|
| To break down the ice | Introduction all participants and organizers | | 15 mins |
| To know overview for NEED | Introduction from workshop organizer<br>To explain Need workshop overview<br>To explain workshop objectives and Outcome | Power Point presentation | 15 mins |
| To know their expectation and fear | Discussion upon their expectation and fear to this workshop | Small group discussion | 30 mins |
| To know how body change for elderly and effect after the change | Participatory learning Body change for elderly and effect after the change | Group empowerment discussion | 45 mins |
| To know good nutrition for healthy eating information | Explain which one can get what nutrient such as Fruits, Grains, Meat, Milk, Vegetable and high fiber foods | Sheets Showing | 1 hour |
| To understand nutrient portion | Nutrients portion | Power point presentation | 45 mins |

| DAY 2 Objective | Topic | Methodology | Time |
|---|---|---|---|
| To know "Pyramid of Food" | Explain pyramid of food and food counting | Power Point presentation | 30 mins |
| To know food count of their daily eating foods | Give information of food counting overview<br>Daily food and food counting | Shopping Card Game<br>- Giving card to buy their suitable food counting on the food stall<br>- On the food stall, organizer arranged food model and photos (Check and Keep their choice) | 1 hour |
| To get skill how to cook | Explain and show cooking under suitable serving | Cooking show and participatory learning | 1 hour |
| To know food for disease | Food for disease | Make small group by disease HT, DM, Gout and discuss what you eat? Is that good enough?<br>Question and answer | 30 mins |

| DAY 3 Objective | Topic | Methodology | Time |
|---|---|---|---|
| To know their usual daily eating food | Discussion | Brainstorming<br>Of their usual daily eating food | 30 mins |
| To give information of daily food intake and food exchange for complete nutrients portion by participatory learning approach | Daily food intake<br>Food exchange | Food Model | 1 hour |
| To give information of good food for overdentures and how to take care overdentures | Good food for overdentures and care for overdentures | dentures model<br>Question and answer | 1 hour |
| To know exercise for elderly | Exercise for elderly (Isometric exercise) | VDO from physical therapy and participant learning show exercise | 1 hour |

four groups were; ***Before the experiment:*** There were 68.3333±20.1117, 67.8182±17.2526, 75.9697±16.7919, and 70.3030±15.4161 in "IODNEED" group, "IOD" group, "CDNEED" group, and "CD control" group respectively. ***After the one month experiment:*** There were 100.606±16.5245, 96.9697±14.7574, 83.0909±14.0809, and 80.6364±11.5402 in "IODNEED" group, "IOD" group, "CDNEED" group, and "CD control" group respectively.

As for visual analogue satisfaction for maxilla (VASMX) among the four groups; ***Before the experiment:*** There were 561.788±125.3179, 550.768±115.732, 605.7576±85.1022, and 553.7879±79.2842 in "IODNEED" group, "IOD" group, "CDNEED" group, and "CD control" group respectively. ***After the one month experiment:*** There were 682.879±63.9339, 651.061±64.563, 635.0000±76.6995, and

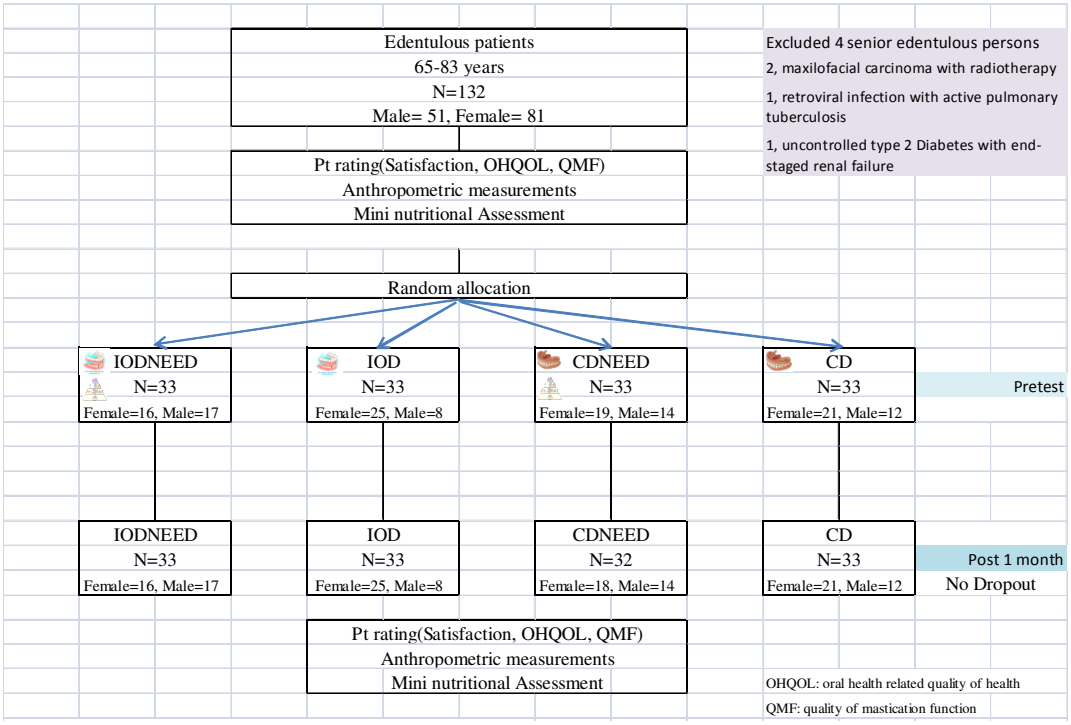


**Figure 1:** Participants flow and follow-up (CONSORT flow chart)

**Table 2.** General characteristics of the participants among the four groups

| General characteristics | | IOD NEED % (n= 33) | IOD % (n= 33) | CD NEED % (n= 33) | CD Control % (n= 33) | Test of group differences |
|---|---|---|---|---|---|---|
| **Gender** | | | | | | |
| Female | | (48.48) 16 | (75.76) 25 | (57.58) 19 | (63.64) 21 | $x^2$=5.464, df=3, p=0.141* |
| Male | | (51.52) 17 | (24.24) 8 | (42.42) 14 | (36.36) 12 | |
| **Age** | Mean±SD | 70.15±5.65 | 68.12±4.71 | 70.03±4.52 | 68.64±5.06 | p= 0.261, df=3 (one way ANOVA) |
| | Mini, Maxi | 65-83 | 65-80 | 65-81 | 65-81 | |
| **Age at Edentulous** | | | | | | |
| | Mean±SD | 62.00±6.15 | 59.42±4.01 | 60.36±6.06 | 60.42±4.80 | p= 0.270, df=3 (one way ANOVA) |
| | Mini, Maxi | 50-80 | 50-73 | 48-73 | 40-72 | |
| **Current living status** | | | | | | |
| | Family | (87.88) 29 | (84.85) 28 | (87.88) 29 | (93.94) 31 | $x^2$=1.429, df=3, p=0.699* |
| | Others | (12.12) 4 | (15.15) 5 | (12.12) 4 | (6.06) 2 | |
| **Religious** | | | | | | |
| | Buddhist | (100) 33 | (100) 33 | 96.97) 32 | (100) 33 | $x^2$=3.023, df=3, p=0.388* |
| | Muslim | | | (3.03) 1 | | |
| **Total monthly income** | | | | | | |
| | Mean±SD | 5569±3210 | 3803±2183 | 4561±3030 | 4136±3329 | p= 0.092, df=3 (one way ANOVA) |
| | Mini:Maxi | 1500-12000 | 1500-10000 | 2000-13000 | 1500-20000 | |
| **BMI (Kg/m$^2$)** | | | | | | |
| | Mean±SD | 24.39±4.12 | 23.77±5.35 | 24.91±4.13 | 25.12±4.09 | p= 0.611, df=3 (one way ANOVA) |
| | Mini:Maxi | 16.41-33.20 | 14.27-38.54 | 15.63-35.55 | 16.40-38.06 | |
| Smoking | | | | | | |
| | No | (72.73) 24 | (78.79) 26 | (75.76) 25 | (78.79) 26 | $x^2$=0.464, df=3, p=0.927* |
| | Yes | (27.27) 9 | (21.21) 7 | (24.24) 8 | (21.21) 7 | |
| Systemic diseases | | | | | | |
| | Have not | (39.39) 13 | (39.39) 13 | (42.42) 14 | (48.48) 16 | $x^2$=3.285, df=3, p=0.350* |
| | Have | (60.61) 20 | (60.61) 20 | (57.58) 19 | (51.52) 17 | |

*Asymp. Sig. (2-sided)

**Table 3:** Descriptive statistics of OHIP, VASMX, VASMD, MNA and BMI

| Variables | IOD NEED | IOD | CD NEED | CD | TIMING |
|---|---|---|---|---|---|
| | Mean ± SD | Mean ± SD | Mean ± SD | Mean ± SD | |
| OHIP | 75.1818±19.1449 | 75.9394±18.0311 | 81.7576±14.2281 | 81.5455±15.3401 | Pretest |
| | 101.3030±12.1591 | 98.1515±12.1838 | 91.3939±13.9462 | 88.8182±11.1256 | Post 1 mo |
| QMF | 68.3333±20.1117 | 67.8182±17.2526 | 75.9697±16.7919 | 70.3030±15.4161 | Pretest |
| | 100.606±16.5245 | 96.9697±14.7574 | 83.0909±14.0809 | 80.6364±11.5402 | Post 1 mo |
| VASMX | 561.788±125.3179 | 550.768±115.732 | 605.7576±85.1022 | 553.7879±79.2842 | Pretest |
| | 682.879±63.9339 | 651.061±64.563 | 635.0000±76.6995 | 604.0909±67.5631 | Post 1 mo |
| VASMD | 488.333±117.0781 | 472.727±96.007 | 557.1212±100.078 | 509.6970±85.5948 | Pretest |
| | 684.546±58.1399 | 647.273±78.522 | 596.0606±91.8623 | 569.3939±74.6843 | Post 1 mo |
| MNA | 24.5606±3.5416 | 26.3182±2.9257 | 26.1970±2.3517 | 26.7727±2.5803 | Pretest |
| | 27.9848±1.9704 | 27.6818±2.5459 | 27.7879±1.9962 | 28.0000±2.6428 | Post 1 mo |
| BMI | 24.3864±4.1260 | 23.7688±5.3477 | 24.9100±4.1289 | 25.1242±4.0957 | Pretest |
| | 24.8667±4.2778 | 24.3876±5.2485 | 25.4470±3.7145 | 24.8755±3.8426 | Post 1 mo |
| OHIP: Oral Health Impact Profile | | | QMF: Quality of Mastication Function | | |
| VASMX: Visual Analouge Satisfaction Score for Maxilla | | | VASMD: Visual Analogue Satisfaction Score for Mandibular | | |
| MNA: Mini Nutritional Assessment | | | BMI: Body Mass Index | | |

604.0909±67.5631 in “IODNEED” group, “IOD” group, “CDNEED” group, and “CD control” group respectively.

As for visual analogue satisfaction for mandibular (VASMD) among the four groups; ***Before the experiment:*** There were 488.333±117.0781, 472.727±96.007, 557.1212±100.078, and 509.6970±85.5948 in “IODNEED” group, “IOD” group, “CDNEED” group, and “CD control” group respectively. ***After the one month experiment:*** There were 684.546±58.1399, 647.273±78.522, 596.0606±91.8623, and 569.3939±74.6843 in “IODNEED” group, “IOD” group, “CDNEED” group, and “CD control” group respectively.

As for Mini nutritional assessment (MNA) among the four groups; ***Before the experiment:*** There were 24.5606±3.5416, 26.3182±2.9257, 26.1970±2.3517, and 26.7727±2.5803 in “IODNEED” group, “IOD” group, “CDNEED” group, and “CD control” group respectively. ***After the one month experiment:*** There were 27.9848±1.9704, 27.6818±2.5459, 27.7879±1.9962, and 28.0000±2.6428 in “IODNEED” group, “IOD” group, “CDNEED” group, and “CD control” group respectively.

As for body mass index (BMI) among the four groups; ***Before the experiment:*** There were 24.3864±4.1260, 23.7688±5.3477, 24.9100±4.1289, and 25.1242±4.0957 in “IODNEED” group, “IOD” group, “CDNEED” group, and “CD control” group respectively. ***After the one month experiment*** There were 24.8667±4.2778, 24.3876±5.2485, 25.4470±3.7145, and 24.8755±3.8426 in “IODNEED” group, “IOD” group, “CDNEED” group, and “CD control” group respectively (Table 3).

Before the beginning of the intervention, sum of scores of pretest OHIP, QMF, VASMX and BMI, among the four groups, were not significant different (p-value >0.05). On the other hand, regarding the mean score of VASMD, the “CDNEED” group had a significant higher mean score than “IODNEED” group and “IOD’ group, with p-value 0.037 and 0.005, respectively. Moreover, as for the mean score of pretest MNA was significantly higher in “CD control” group than “IODNEED” group. Comparison of the mean scores categorized by oral health impact profile, quality of mastication, satisfaction for maxilla, satisfaction for mandibular, mini nutritional assessment and body mass index within the “IOD” group, before and after 1

**Table 4:** Comparison of sum of scores between pretest and post 1 month in IOD group (Paired T-test)

| | | Mean ±SD | N | 95%CI [a] | | t | df | p-value[b] |
|---|---|---|---|---|---|---|---|---|
| | | | | Lower | Upper | | | |
| OHIP | Pretest | 75.9394±18.0311 | 33 | -27.8800 | -16.5389 | -7.975 | 32 | ***< .001*** |
| | Post 1 mo | 98.1515±12.1838 | 33 | | | | | |
| QMF | Pretest | 67.8182±17.2526 | 33 | -36.1630 | -22.1399 | -8.468 | 32 | ***< .001*** |
| | Post 1 mo | 96.9697±14.7574 | 33 | | | | | |
| VASMX | Pretest | 550.768±115.732 | 33 | -141.0110 | -59.5959 | -5.019 | 32 | ***< .001*** |
| | Post 1 mo | 651.061±64.563 | 33 | | | | | |
| VASMD | Pretest | 472.727±96.007 | 33 | -213.9316 | -135.1593 | -9.027 | 32 | ***< .001*** |
| | Post 1 mo | 647.273±78.522 | 33 | | | | | |
| MNA | Pretest | 26.3182±2.9257 | 33 | -2.4764 | -0.2509 | -2.496 | 32 | ***.018*** |
| | Post 1 mo | 27.6818±2.5459 | 33 | | | | | |
| BMI | Pretest | 23.7688±5.3477 | 33 | -1.0455 | -0.1921 | -2.954 | 32 | ***.006*** |
| | Post 1 mo | 24.3876±5.2485 | 33 | | | | | |

a 95% Confidence Interval of the Difference b Sig (2-tailed)
OHIP: Oral Health Impact Profile, QMF: Quality of Mastication Function
VASMX: Visual Analogue Satisfaction Score for Maxilla
VASMD: Visual Analogue Satisfaction Score for Mandibular
MNA: Mini Nutritional Assessment, BMI: Body Mass Index
IOD: mandibular two implant-retained overdentures

**Table 5:** Comparison of sum of scores between pretest and post 1 month in IODNEED group

| | | **Mean ±SD** | **N** | **95%CI [a]** | | **t** | **df** | **p-value[b]** |
|---|---|---|---|---|---|---|---|---|
| | | | | **Lower** | **Upper** | | | |
| OHIP | Pretest | 75.1818±19.1449 | 33 | -33.1393 | -19.1032 | -7.581 | 32 | ***< .001*** |
| | Post 1 mo | 101.3030±12.1591 | 33 | | | | | |
| QMF | Pretest | 68.3333±20.1117 | 33 | -39.5208 | -25.0247 | -9.070 | 32 | ***< .001*** |
| | Post 1 mo | 100.606±16.5245 | 33 | | | | | |
| VASMX | Pretest | 561.788±125.3179 | 33 | -158.8440 | -83.3378 | -6.533 | 32 | ***< .001*** |
| | Post 1 mo | 682.879±63.9339 | 33 | | | | | |
| VASMD | Pretest | 488.333±117.0781 | 33 | -241.1908 | -151.2330 | -8.886 | 32 | ***< .001*** |
| | Post 1 mo | 684.546±58.1399 | 33 | | | | | |
| MNA | Pretest | 24.5606±3.5416 | 33 | -4.5819 | -2.6664 | -6.025 | 32 | ***< .001*** |
| | Post 1 mo | 27.9848±1.9704 | 33 | | | | | |
| BMI | Pretest | 24.3864±4.1260 | 33 | -0.8476 | -0.1129 | -2.664 | 32 | ***.012*** |
| | Post 1 mo | 24.8667±4.2778 | 33 | | | | | |

a 95% Confidence Interval of the Difference b Sig (2-tailed), Paired T-test
NEED: Nutritional Empowerment in Edentulous people with Dentures

month intervention, found: there had higher mean scores than pretest, with p-value ***< .001, < .001, < .001, < .001, .018, and .006,*** respectively (Table 4).

Within the "IODNEED" group, comparison of the mean scores categorized by oral health impact profile, quality of mastication, satisfaction for maxilla, satisfaction for mandibular, mini nutritional assessment and body mass index, before and after 1 month intervention, found: there had significantly higher mean scores than pretest, with p-value ***< .001, < .001, < .001, < .001, < .001, and .012,*** respectively (Table 5).

Regarding in "CDNEED" group, post 1 month mean score for OHIP, QMF, VASMX, VASMD, and MNA significant higher than pretest, with p-value ***< .001, .002, .002, < .001, and < .001,*** respectively. On the other hand, there had a higher mean score for BMI compared with pretest, which was also not statistically significance (p-value .164).

**Table 6:** Comparison of sum of scores between pretest and post 1 mo within group (Paired T-test)

| | | IODNEED | IOD | CDNEED | CD |
|---|---|---|---|---|---|
| OHIP | M diff[a] | -26.1212 | -22.2121 | -9.63636 | -7.27273 |
| | p-value[b] | < .001 | < .001 | < .001 | < .001 |
| QMF | M diff[a] | -32.2727 | -29.1515 | -7.12121 | -10.33333 |
| | p-value[b] | < .001 | < .001 | .002 | < .001 |
| VASMX | M diff[a] | -121.0909 | -100.3030 | -29.24242 | -50.30303 |
| | p-value[b] | < .001 | < .001 | .002 | < .001 |
| VASMD | M diff[a] | -196.2121 | -174.5455 | -38.93939 | -59.69697 |
| | p-value[b] | < .001 | < .001 | < .001 | < .001 |
| MNA | M diff[a] | -3.4242 | -1.3636 | -1.59091 | -1.22727 |
| | p-value[b] | 0.018 | 0.018 | < .001 | < .001 |
| BMI | M diff[a] | -.4803 | -0.6188 | -.53697 | .24879 |
| | p-value[b] | < .001 | .006 | .164 | .404 |

a Mean differences b Sig (2-tailed)
OHIP: Oral Health Impact Profile, QMF: Quality of Mastication Function
VASMX, VASMD: Visual Analogue Satisfaction Score for Maxilla, Mandibular
MNA: Mini Nutritional Assessment, BMI: Body Mass Index
IOD: mandibular two implant-retained overdentures CD: Conventional dentures
NEED: Nutritional Empowerment in Edentulous people with Dentures

**Table 7:** Pairwise comparisons among 4 groups for Post 1 month (Summary)

| Groups | IOD | CDNEED | CD |
|---|---|---|---|
| IODNEED | ◙ | OHIP[a] | OHIP[a] |
| | ◙ | QMF[a] | QMF[a] |
| | ◙ | VASMX[a] | VASMX[a] |
| | ◙ | VASMD[a] | VASMD[a] |
| IOD | | ◙ | OHIP[a] |
| | | QMF[a] | QMF[a] |
| | | ◙ | VASMX[a] |
| | | VASMD[a] | VASMD[a] |

MNA and BMI were not significant difference among the groups
a . Adjusted for multiple comparisons: Bonferoni (p <0.05)
◙ : No significant different

In “CD control” group, It also found that post 1 month mean score for OHIP, QMF, VASMX, VASMD, and MNA significant higher than pretest, with p-value < ***.001, < .001, < .001, < .001, and < .001,*** respectively. On the other hand, there had a higher mean score for BMI compared with pretest, which was also not statistically significance (p-value .404).

In summary, in the table 6**,** it was found that mean scores differences between pretest and post 1 month were higher in “IODNEED” group than “IOD” group, “CDNEED” group, and “CD” group.

Regarding the comparison among groups after post 1 month intervention, it was found that as follows: (Table 7) (Figure 2, 3, 4 and 5)

(i) Comparison between “IODNEED” group and “IOD” group, there had no significant mean score different in OHIP, QMF, VASMX, VASMD, MNA, and BMI. (ii) Comparison between “IODNEED” group and “CDNEED” group, “IODNEED” group had significant higher mean score in OHIP, QMF, VASMX, and VASMD than “CDNEED” group. (iii) Comparison between “IODNEED” group and “CD control group”, “IODNEED” group had significant higher mean score in OHIP, QMF, VASMX, and VASMD than “CD control group”.

(iv) Comparison between “IOD” group and “CDNEED group”, “IOD” group had significant higher mean score in QMF, and VASMD than “CDNEED group”.

(v) Comparison between “IOD” group and “CD control

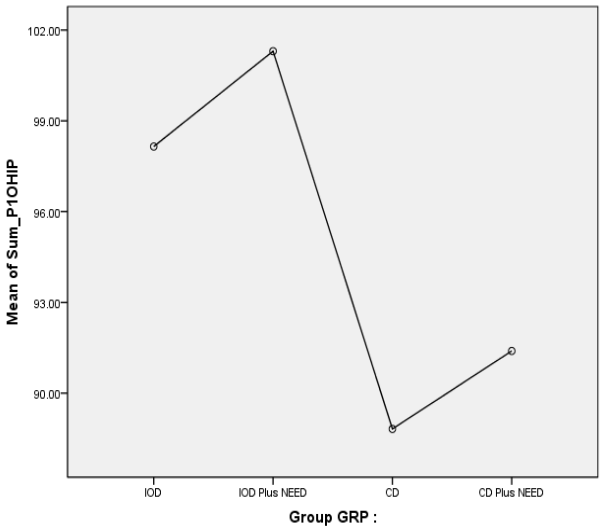


**Figure 2**: Pairwise comparisons among 4 groups for Post 1 month (OHIP)

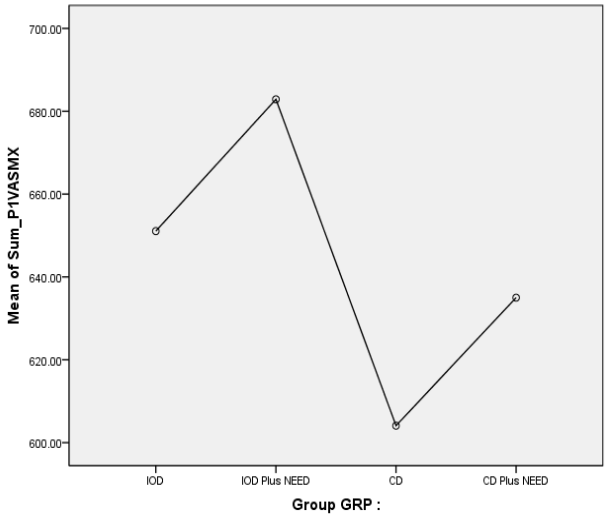


**Figure 4:** Pairwise comparisons among 4 groups for Post 1 month (VASMX)

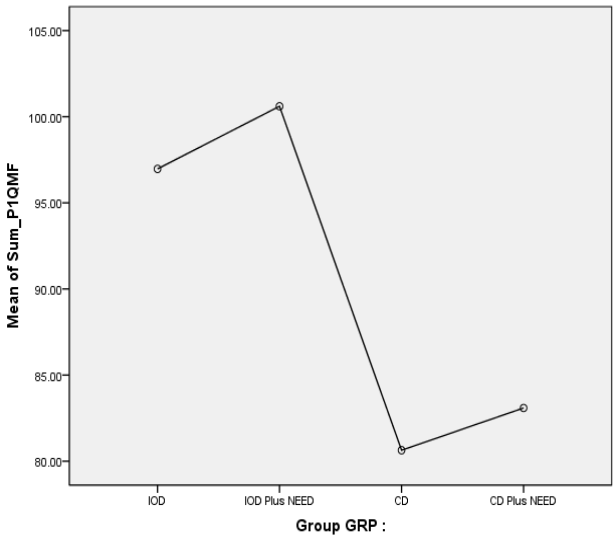


**Figure 3:** Pairwise comparisons among 4 groups for Post 1 month (QMF)

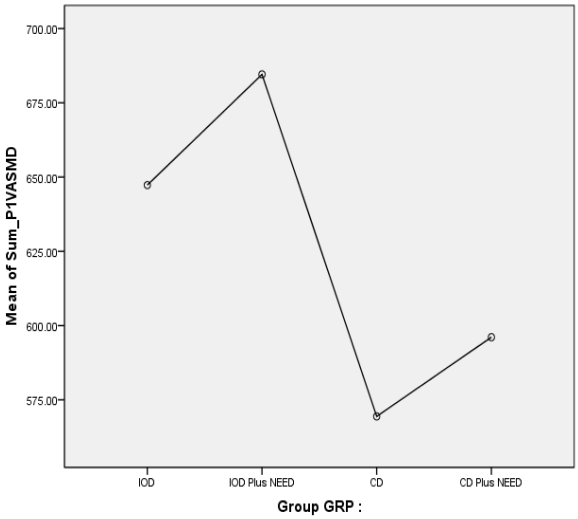


**Figure 5:** Pairwise comparisons among 4 groups for Post 1 month (VASMD)

group", "IOD" group had significant higher mean score in OHIP, QMF, VASMX, and VASMD than "CD control group".

(vi) Mean scores in MNA, BMI, were not significant different among the groups after post 1 month intervention.

## DISCUSSION

The sample size obtained was appropriate for this research. Calculation of sample size that could explain and conclude the results, the appropriate size was at least 27 in each group. In this study, there were 33 participants in each group and there was no attrition at post 1 month appointment. Furthermore, nutritional programs were provided separately between IOD and CD groups in different days. So, it can be concluded that there did not have contamination of information among the groups. The statistic used was appropriate, p-value at 0.05, with responses according with the objectives and hypothesis of the research.

The research results found that all general characteristics were not statistically significant difference among the four groups; (IODNEED), (IOD), (CDNEED), and (CD). It was the same results of other study in Canada (Morais J.A et al., 2003).

Before the beginning of the intervention, mean of scores of pretest (OHIP), (QMF), (VASMX), (BMI) (kg/m$^2$), among the four groups were not significant different. On the other side of coin, it is obvious that pretest satisfaction scores for mandibular (VASMD) were significant lower in lower in IODNEED group and IOD. group, than CD and CDNEED groups. Similarly, Regarding the Mini nutritional assessment (MNA), the mean score was lowest in "IODNEED" group than others; meanwhile the "IODNEED" group had a significant lower mean score than "CD" group. But after post 1 month data, there had significant highest mean scores different in those two variables in "IODNEED".

Thus, from these finding it would be concluded that there were no different between "Before program scores" of the most of the variables among the four groups, that accepted the hypothesis. When, comparison of mean scores between pretest and after 1 month intervention in "IODNEED" group (paired *t*-test), found: mean scores for OHIP, QMF, VAS for Maxilla, VAS for mandibular, MNA, BMI, were statistically significance higher than pretest. This revealed that combined effect of IOD and nutritional empowerment have good achievement in not only better mastication function but also simultaneous increase in body mass index. It can be concluded that the senior persons can chew meat, fruits and vegetables in order to choice healthy diet.

Moreover, in IOD group, even though improved mean differences were lower than IODNEED group, there were clearly seen that mean scores for OHIP, QMF, VAS for Maxilla, VAS for mandibular, MNA, BMI, were statistically significance higher than pretest. It can only be concluded that the senior persons can chew meat, fruits, nuts and vegetables. Our finding is similar to other studies; they reported that a significant number of those who received the implant overdentures reported that they had increased their intake of cheese, raw carrot, raw apple, nuts, and bacon (Allen and McMillan, 2002). Morais (Morais et al., 2003) confirmed that the provision of mandibular dentures supported by 2 implants increases food choice for individuals accustomed to wearing conventional dentures.

On the other hand, in CDNEED and CD group, there had also slight significant higher mean scores for OHIP, QMF, VAS for Maxilla, VAS for mandibular, MNA, than pretest. In this study, the participants in waiting list for IOD had old CD more than 2 years and maximum duration was 5 years. It can be concluded that replacement by new CD prosthesis have also better effectiveness in oral health related quality of life, mastication function, satisfaction and nutritional improvement. But there have no improvement in BMI. This finding is different from the study (Allen and McMillan, 2002), in a nonrandomized prospective study, edentulous patients were provided with conventional and two implant overdentures for the mandible. There was no change in the group receiving the conventional dentures.

To compare after program among the four groups, it can be clearly seen that IODNEED group had the best immediate outcomes mean scores in all variables measured and also significant higher mean scores than CDNEED group. Here in this study when we provided one factor that related to quality of life and nutritional status by nutritional empowerment, it could be concluded that IOD is better than CD to improve nutritional status in elderly edentulous people. This finding is different from the one (Morais et al., 2003), "no significant between-group differences were found". This is highlighting that nutritional empowerment might improved better nutritional status in conjunction with mandibular two implant-retained overdentures.

Whereas, we did not find significant higher mean scores of BMI among groups in immediate outcome analysis, it might need the time for improvement.

All of all, these results suggest that providing nutritional empowerment and low-cost local made titanium mandibular two implant-retained prosthesis improves their satisfaction, dietary intake and nutritional state. However, these finding must be confirmed.

## RECOMMENDATION

Regarding the finding in our research, regular participatory nutritional empowerment and isometric exercise should be provided in conjunction with mandibular two implant-retained overdentures in elderly edentulous persons.

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