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Effects of Oral Nutritional Supplement on Postoperative Orthognathic Surgery Patients' Nutritional Status: A Randomised Clinical Trial

Naratorn Prachasartta[1], Kiti Siriwatana[1], Vorapat Trachoo[1], Suwimol Sapwarobol[2], Praew Chantarasinlapin[2]

[1]Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand; [2]The Medical Food Research Unit, Department of Nutrition and Dietetics, Faculty of Allied Health Sciences, Chulalongkorn University, Bangkok, Thailand

Correspondence: Kiti Siriwatana, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chulalongkorn University, Wang Mai, Pathum Wan, Bangkok, 10330, Thailand, Tel +66 933293239, Email kiti.s@chula.ac.th

Purpose: Orthognathic surgery often leads to decreased nutrient intake and increased metabolic demands, potentially resulting in muscle mass loss and delayed recovery. The use of oral nutritional supplements (ONS) alongside nutritional counselling has been proposed to mitigate these effects. This study aimed to investigate the impact of ONS on the postoperative nutritional status of patients undergoing orthognathic surgery.

Patients and methods: A 12-week randomized controlled trial was conducted at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand. The recruitment period was extended from July to December 2022 due to unforeseen delays. Patients aged 18 or older, undergoing orthognathic surgery involving at least one jaw, and without metabolic diseases or allergies were included. The intervention group received nutritional counselling and ONS for one-month post-surgery, while the control group received only nutritional counselling. The primary outcome was nutritional status, assessed through anthropometric, biomarker, and muscle strength measurements at various time points.

Results: A total of 28 participants completed the study (control group: n=12, intervention group: n=16). Both groups experienced postoperative weight and muscle mass loss. While the intervention group showed a significantly lower weight loss at two- and four-weeks post-surgery, no significant differences were found in other nutritional status parameters or oral health-related quality of life between the groups after 12 weeks.

Conclusion: The addition of ONS to nutritional counselling did not significantly improve the overall nutritional status of orthognathic surgery patients in the long term. Further research is needed to explore more personalized and intensive nutritional interventions to enhance postoperative recovery in this population.

Trial Registration: Thai Clinical Trials Registry, TCTR20220624006. Registered 24 June 2022.

Keywords: maxillomandibular fixation, postoperative recovery, malnutrition, muscle mass, biomarkers, quality of life

Introduction

Nutritional therapy is a fundamental aspect of medical care for surgeries.[1] Patients who undergo orthognathic surgery are subject to a maxillomandibular fixation (MMF), a traditional method to immobilise the jaws for the management of maxillofacial fractures. Even though MMF can promote bone healing, it can also pose a significant impact on nutrient intake.[2] This surgical procedure elicits physiological stress and triggers metabolic alterations. Orthognathic surgery may cause several metabolic derangements including metabolic stress. It also increases energy demands while energy intake is limited. These metabolic imbalances, arising from increased energy demands and inadequate nutritional supply, can compromise immunity, impair wound healing, and increase the risk of infection.[3–7] Therefore, it is imperative not to underestimate the importance of ensuring adequate nutrition during postoperative phase, as it plays a crucial role in promoting optimal healing, facilitating recovery, and improving the overall well-being of patients undergoing

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orthognathic surgery.[8] This is highlighted by the observed changes in anthropometric and nutritional biomarkers after orthognathic surgery. Previous study has shown that patients show a 3.9% decrease in body weight at two weeks post-surgery, followed by an additional 8.3% decrease at four weeks.[9,10] The nutritional biomarker data indicates a significant decline at one week after surgery, which persists at the two-week mark, indicating ongoing nutritional changes during this critical period.[9]

In the context of orthognathic surgery, patients experience reduced nutrient intake and increased metabolic demand. A nutritional therapy plan incorporating the use of oral nutritional supplements (ONS) to provide additional energy, and nutrients is recommended.[11] Nonetheless, nutrition therapy has not received much attention in the field of orthognathic surgery, despite its potential benefits.

Therefore, the purpose of this study was to investigate the impact of ONS on the postoperative nutritional status of patients undergoing orthognathic surgery. The investigators hypothesised that subjects receiving ONS after the operation would maintain their overall nutritional status better than those not given ONS. The specific aims of the study were to compare postoperative anthropometric, biomarker, and muscle strength between the two groups, as well as to assess their oral health-related quality of life and dietary intakes.

Methods

Study Design/Sample

The study recruited patients scheduled for orthognathic surgery at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand, between February 1, 2022, and July 31, 2022. However, the recruitment period was extended to December 2022 due to delays in the arrival of the body composition analyser and challenges in patient recruitment, which necessitated an extension to achieve the calculated sample size. Patients were screened for inclusion criteria, which are: being 18 years of age or older; being enrolled in orthognathic surgery for at least one jaw surgery; and having no known metabolic-related diseases, milk or soy allergies, or galactosemia. Patients who underwent segmental procedures or only genioplasty were excluded from the study.

A 12-week randomised controlled trial adhering to CONSORT guidelines was conducted to investigate the effects of ONS on the postoperative nutritional status of subjects undergoing orthognathic surgery. To monitor dietary intake, subjects were asked to record all foods and beverages they consumed over 2 weekdays and 1 weekend.

The sample size calculation was conducted via an online statistical calculator (Statulator, https://statulator.com/) based on a study by Popat, S. P., Rattan, V., Rai, S., Jolly, S. S., and Malhotra, S. (2021).[12] The Calculator for Comparing Two Independent Means was accessed on November 28, 2021, at http://statulator.com/SampleSize/ss2M.html. Assuming a pooled standard deviation of 6 units, the study required a sample size of 14 for each group (total sample size of 28, assuming equal group sizes) to achieve a power of 80% and a level of significance of 5% (two-sided) for detecting a true difference in means between the test and the reference group of 6.63 (ie, 61.33–54.70) units. Accounting for an assumed dropout rate of 20% (The protocol initially assumed a dropout rate of 25%)., the final sample size recruited was 17 patients per group. A total of 41 patients were assessed for eligibility. Thirty-four eligible subjects then were randomly assigned to either the nutritional counselling (NC) group (n = 17) or the nutritional counselling with ONS (NC+) group (n = 17) by block randomisation method via https://www.randomizer.org/. The random allocation sequence was concealed within sealed envelopes. The generation of the random allocation sequence, enrolment of participants, and assignment of participants to interventions were carried out by a single investigator who was not involved in both the surgical procedures and nutritional counselling aspects of the study.

Interventions

The predictor variable was ONS. Subjects were randomly assigned by the block randomisation method into two groups: 1) subjects who received ONS, and 2) subjects who did not receive ONS. All of subjects received nutritional counselling administered by registered dietitians from the Department of Nutrition and Dietetics, Faculty of Allied Health Sciences, Chulalongkorn University, Bangkok, Thailand, according to the nutrition counselling protocol. The counselling sessions were conducted via the tele-nutrition method (a video call) and took place three times over the course of the 12-week study:

the first session was held a day prior to the surgery (baseline, T0), the second session was conducted a day of discharge (discharge day, T1), the third session was conducted before the transition from a liquid diet to a soft diet (2nd week, T2), and the final session was conducted before the transition from a soft diet to a regular diet (4th week, T3).

The nutritional counselling provided to both groups was standardized and delivered by registered dietitians with the same level of expertise, ensuring consistency in the information and guidance provided.

To ensure accuracy and consistency in reporting, subjects were given detailed instructions on how to record their intake, and dietitians reviewed the food diaries at each session. If there were any discrepancies or missing information in the recorded intake, the dietitian would ask the subject for clarification or additional information. Additionally, subjects were encouraged to complete their food diaries on a daily basis. During the nutrition counselling course, subjects were explained the diet regimen (liquid diet, soft diet, and regular diet). During a liquid diet phase, only fluids and foods that are normally liquid and foods that turn to liquid when they are at room temperature were allowed. A daily caloric intake ranging from 700 to 800 kcal was recommended during a phase of a liquid diet. In a soft diet period, subjects were advised to consume soft and easy-to-digest foods. Hard-to-digest foods, as well as those that are tough to chew, should be restricted. A soft diet provided 1000–1200 kcal daily. After week 4, subjects were encouraged to make a transition to a regular diet or more solid foods. During this regular diet, energy and macronutrient content returned closely to their habitual diet. For the postoperative state, a minimum of 25–30 kcal/actual body weight (kg)/day with a protein 1 g/actual body weight (kg)/day were suggested. In the NC+ group, subjects were given nutrition counselling and ONS, which is called Ensure Plus Advance® in vanilla flavour, developed by Abbott Laboratories, Illinois, United States of America. This is to be consumed as one serving daily for one month following the surgery, in addition to their meals. (The protocol initially planned for three months of ONS supplementation, but this was adjusted due to budget constraints). One serving of ONS was 220 mL, containing 330 kcal, 37 grams of carbohydrate, 20 grams of protein, and 7 grams of fat.

Outcomes

The primary outcome variable was body weight changes. The covariates were nutritional status, which was measured using anthropometric, biomarker, and muscle strength assessments, oral health-related quality of life (O-HIP14). the subjects' demographics, and dietary record assessment.

No changes were made to the trial outcomes after the trial commenced.

The study protocol was approved by the Human Research Ethics Committee of the Faculty of Dentistry at Chulalongkorn University (approval number HREC-DCU 2022–008). All subjects provided written informed consent before participating in the study.

Randomization – Implementation

The generation of the random allocation sequence, enrolment of participants, and assignment of participants to interventions were carried out by a single investigator who was not involved in both the surgical procedures and nutritional counselling aspects of the study.

Due to the nature of the interventions, it was not feasible to blind the participants or the investigators administering the nutritional counseling. The participants were aware of whether they were receiving ONS in addition to the counseling, and the investigators providing the counseling needed to know the group assignments to deliver the appropriate interventions.

Data Collection Methods

For the anthropometric assessment, body weight, muscle mass, and fat mass were measured using a bioelectrical impedance analyser (MC-580 MA body composition analyser, TANITA Corporation, Tokyo, Japan) at a day before surgery (T0), a day of discharge (T1), and 2 weeks (T2), 4 weeks (T3), and 12 weeks postoperatively (T4). A blood sample of approximately 15 mL was obtained through vein puncture by either a medical technologist or an anaesthetic nurse. Subsequently, the collected blood samples were divided into four tubes and transferred to a private medical laboratory, National Healthcare Systems Company Limited, Bangkok, Thailand, for the analysis of specific biomarkers of interest. Albumin, BUN, and creatinine were collected at five time points: T0, T1, T2, T3, and T4. Prealbumin and hs-

CRP were collected at four time points: T0, T1, T2, and T3. Random plasma glucose (RPG), HbA1C, and lipid profiles (HDL, LDL, and triglycerides) were collected at two time points: T0 and T4. Muscle strengths were measured at five time points: T0, T1, T2, T3, and T4 by a hand-held Camry digital dynamometer (90 kg/200 lbs, Camry Scale from California, United States of America). Oral health-related quality of life was measured at five time points: T0, T1, T2, T3, and T4 using the Thai Oral Health Impact Profile 14 (Thai OHIP-14) questionnaire.

The study utilized the validated Thai version of the Oral Health Impact Profile-14 (Thai OHIP-14), developed and validated in the study by Suksudaj S. (2010).[13] The Thai OHIP-14 has been tested for reliability and validity in various studies conducted in Thailand.[13] The questionnaire consisted of 7 aspects, with 2 questions allocated to each aspect, resulting in a total of 14 questions. A five-point response format (Likert scale) was employed, ranging from "not at all" (score 0), "hardly ever" (score 1), "occasionally" (score 2), "fairly often" (score 3), and "very often" (score 4). Throughout the 12-week study period, a weekly diet record was collected from each participant, encompassing dietary information from two weekdays and one weekend day. The average energy intake, as well as the intake of macronutrients such as carbohydrate, protein, and fat, were calculated and assessed. Data was reported at the liquid diet period, the soft diet period, and the regular diet period.

Data Analyses

The study employed an intention-to-treat analysis. The normality of the data was tested using the Shapiro–Wilk test. The *T*-test or Mann–Whitney *U*-test was used to compare the mean difference of continuous data, where appropriate. All statistical analyses were carried out using SPSS 23.0 software (SPSS Inc., Illinois, the United States of America). The differences were considered statistically significant when the p-value was less than 0.05.

Results

The flow of participants through the trial is shown in Figure 1.

In a 12-week randomised controlled trial, twenty-eight subjects (NC, n=12 and NC+, n=16) completed the study with a mean age of 26 ± 4 years in NC group and 28 ± 7 in NC+ group. Baseline characteristics were presented in Table 1. In the NC group, there were 8 male and 9 female subjects, while in the NC+ group, there were 5 male and 12 female subjects. Regarding the types of surgery, the NC group comprised 7 subjects who underwent single-jaw surgery, 9 subjects who underwent double-jaw surgery, and 1 subject who underwent double-jaw surgery with genioplasty. In the NC+ group, there were 5 subjects who underwent single-jaw surgery, 10 subjects who underwent double-jaw surgery, and 2 subjects who underwent double-jaw surgery with genioplasty (Table 1). There was no significant different between the two group (NC vs NC+) at baseline.

Anthropometric Parameters

There was a significant difference in weight loss between the two groups at T2 and T3. However, no significant difference was observed in muscle mass loss between the groups at any time point. Both groups exhibited fluctuations in fat mass, although no consistent pattern of change was evident. A significant difference in fat mass was observed between the two groups at T1 and T2 (Table 2).

Biomarker Parameters

There were no statistically significant differences between the groups in terms of changes in the value's nutritional status biomarkers throughout any of the follow-up periods (Table 2). Both groups demonstrated a notable initial increase in hs-CRP levels at T1, but subsequently decreased over time. Furthermore, there were no significant differences observed in the changes of RPG, HbA1c, HDL, LDL, or triglyceride levels at the 12-week postoperative period (Table 2).

Muscle Strength Parameter

The results of the handgrip strength test indicated that there were no significant differences in the changes of handgrip strength between the two groups at any of the postoperative periods. Both groups exhibited a decrease in handgrip

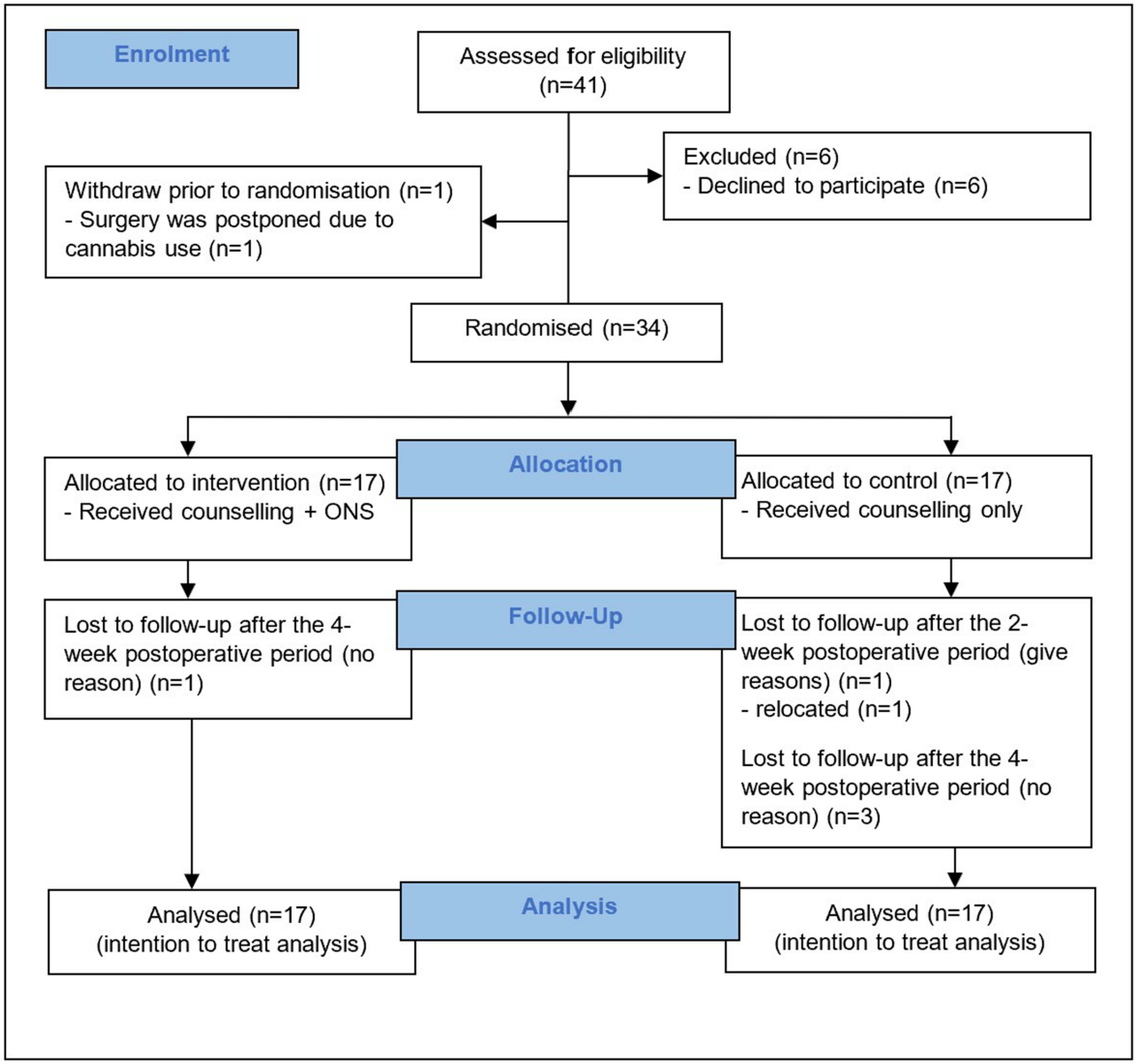

Figure 1 Flowchart showing participant recruitment, allocation, follow-up, and analysis. This figure illustrates the CONSORT flow diagram for the randomized clinical trial, emphasizing the balanced distribution of participants between the two groups and the high completion rate of the study.

strength immediately after surgery (T1), which gradually improved over time. By T4, both groups had regained their handgrip strength and were comparable to their respective preoperative levels (Table 2).

Oral Health-Related Quality of Life Parameter

The Thai OHIP-14 scores gradually improved from T1 to T4 for both groups. However, there were no significant differences observed between the two groups in any of the aspects at any point during the postoperative period (Table 3).

Dietary Record Parameter

The analysis of the diet record provided by the subjects revealed that there were significant differences in total energy, protein and fat consumption between two groups during the liquid diet period while there was no significant different in total energy, carbohydrate, protein and fat consumption between the two groups during soft diet and regular diet periods. (Table 4).

No important harms or unintended effects were observed in either group during the study period.

Table 1 Baseline Characteristics of the Participants, Including Demographic and Preoperative Clinical Parameters. These Data Highlight the Comparability Between the Two Groups Prior to Intervention

	Nutritional Counselling (NC) (N=12)	Nutritional Counselling with ONS (NC+) (N=16)
Age	26 ± 4	28 ± 7
Sex		
Male (n)	8 (47%)	5 (29%)
Female (n)	9 (53%)	12 (71%)
Types of surgery		
Single-jaw surgery (n)	7 (41%)	5 (29%)
Double-jaw surgery (n)	9 (53%)	10 (59%)
Double-jaw surgery with genioplasty (n)	1 (6%)	2 (12%)
Anthropometrics		
Body weight (kg)	64.5 ± 14.8	54.6 ± 9.4
BMI (kg/m^2)	22.7 ± 3.8	20.8 ± 3.6
Muscle mass (kg)	44.2 ± 9.9	37.0 ± 5.3
Fat mass (kg)	18.0 ± 6.8	15.4 ± 7.1
Muscle strength		
Handgrip strength (kg)	32.0 ± 11.5	26.3 ± 7.1
Biomarkers		
Total lymphocyte count (%)	30.4 ± 6.5	25.8 ± 8.9
Albumin (g/L)	4.8 ± 0.2	4.7 ± 0.2
Prealbumin (mg/dL)	28.7 ± 5.1	28.2 ± 3.5
C-reactive protein (mg/L)	2.4 ± 4.3	1.2 ± 1.2
BUN (mg/dL)	11.9 ± 2.1	12.6 ± 3.7
Creatinine (mg/dL)	0.9 ± 0.1	0.8 ± 0.2
Random plasma glucose (mg/dL)	86.7 ± 10.9	87.5 ± 13.6
HbA1c (%)	5.1 ± 0.4	5.2 ± 0.4
HDL (mg/dL)	57.4 ± 11.1	63.6 ± 11.9
LDL (mg/dL)	153.1 ± 37.5	149.8 ± 32.8
Triglyceride (mg/dL)	93.1 ± 48.5	101.2 ± 44.9

Notes: Data are mean ± SD. Significant difference between study groups were determined by t-tests, Mann–Whitney *U*-tests or Chi-square test as appropriate. A P-value<0.05 is considered statistically significant.

Discussion

The primary objective of this study was to examine how ONS affects the postoperative nutritional status of orthognathic surgery patients. The investigators hypothesised that subjects who received ONS following their surgery would exhibit better maintenance of their overall nutritional status compared to those who did not receive ONS. The specific aims of the study included comparing postoperative anthropometric measurements, biomarkers, and muscle strength between the two groups, as well as evaluating their oral health-related quality of life and dietary intake.

Subjects in both group (NC vs NC+) experienced the loss of body weight and muscle mass after 12 week follow up. The difference in weight loss between the two groups was significant at T2 and T3. However, there was no significant difference in muscle mass loss between the groups at any time point. In terms of fat mass changes, the NC group had significantly greater fat mass loss than the NC+ group at T1 and T2. Our findings suggest that current orthognathic patients show weight loss patterns comparable to those observed over four decades ago,[14,15] despite receiving nutrition counselling and ONS, possibly attributed to the prolonged trismus resulting from MMF. According to a hospital's guideline, patients undergoing orthognathic surgery were subjected to a 2-week period of MMF, during which their diets were restricted to a liquid diet. Subsequently, a post-operative dietary regimen advancing from liquid to soft, and regular diets over a span of 4 weeks. Consistent with our study, Worrall's study demonstrated that by the sixth week following surgery, the MMF group experienced a significantly higher degree of weight loss in comparison to the non-MMF

Table 2 Changes in Postoperative Nutritional Status Parameters (Body Weight, Muscle Mass, and Biomarkers) at Different Time Points. Significant Differences in Body Weight and Fat Mass Loss Between Groups are Noted at T2 and T3, Emphasizing the Short-Term Benefits of ONS Supplementation

Parameters	NC(n=12)					NC+(n=16)				
	T0	T1	T2	T3	T4	T0	T1	T2	T3	T4
Anthropometrics										
Body weight (kg)	64.5 ± 14.8	63.3 ± 15.5	61.2 ± 13.2*	61.3 ± 13.9*	60.8 ± 11.8	54.6 ± 9.4	54.8 ± 8.4	51.6 ± 9.1*	52.1 ± 9.8*	51.6 ± 9.4
BMI (kg/m^2)	22.7 ± 3.8	21.9 ± 3.7	21.6 ± 3.3	21.6 ± 3.5	21.8 ± 3.0	20.8 ± 3.6	20.9 ± 3.3	19.7 ± 3.4	19.8 ± 3.4	19.6 ± 3.3
Muscle mass (kg)	44.2 ± 9.9	43.4 ± 11.0	42.3 ± 9.6	42.4 ± 9.5	43.2 ± 9.5	37.0 ± 5.3	36.5 ± 5.1	35.3 ± 5.1	35.5 ± 5.4	35.7 ± 5.5
Fat mass (kg)	18.0 ± 6.8	16.3 ± 6.8*	16.6 ± 2.4*	16.5 ± 6.7	15.0 ± 4.9	15.4 ± 7.1	16.1 ± 7.1*	14.3 ± 6.7*	14.4 ± 6.5	13.5 ± 6.3
Muscle strength										
Handgrip strength (kg)	32.0 ± 11.5	30.1 ± 11.8	30.3 ± 10.9	31.5 ± 12.2	32.3 ± 11.5	26.3 ± 7.1	24.5 ± 7.8	24.7 ± 7.1	25.1 ± 6.8	25.5 ± 7.4
Biomarkers										
TLC (%)	30.4 ± 6.5	25.1 ± 8.8	32.1 ± 9.7	32.5 ± 6.8	33.9 ± 6.5	25.8 ± 8.9	21.8 ± 9.7	26.1 ± 7.2	30.4 ± 7.8	30.4 ± 5.9
Albumin (g/L)	4.8 ± 0.2	4.2 ± 0.3	4.7 ± 0.3	4.8 ± 0.3	4.8 ± 0.3	4.7 ± 0.2	4.2 ± 0.1	4.6 ± 0.2	4.8 ± 0.2	4.8 ± 0.2
Prealbumin (mg/dL)	28.7 ± 5.1	21.7 ± 2.9	23.1 ± 5.3	26.1 ± 5.1	N/A	28.2 ± 3.5	24.6 ± 2.5	23.9 ± 4.2	25.9 ± 4.5	N/A
hs-CRP(mg/L)	2.4 ± 4.3	17.3 ± 19.4	2.4 ± 2.6	1.6 ± 2.4	N/A	1.2 ± 1.2	15.1 ± 10.4	4.2 ± 5.6	2.2 ± 3.0	N/A
BUN (mg/dL)	12.0 ± 2.1	11.3 ± 3.0	9.5 ± 2.4	10.2 ± 3.3	12.8 ±2.5	12.6 ± 3.7	12.2 ± 5.0	9.9 ± 3.7	8.8 ± 2.3	11.0 ± 3.9
Creatinine (mg/dL)	0.9 ± 0.1	0.8 ± 0.1	0.8 ± 0.2	0.8 ± 0.2	0.8 ± 0.1	0.8 ± 0.2	0.7 ± 0.2	0.8 ± 0.2	0.8 ± 0.2	0.8 ± 0.2
RPG (mg/dL)	86.7 ± 10.9	N/A	N/A	N/A	77.4 ± 11.1	87.5 ± 13.6	N/A	N/A	N/A	80.6 ± 7.4
HbA1c (%)	5.1 ± 0.4	N/A	N/A	N/A	5.1 ± 0.3	5.2 ± 0.4	N/A	N/A	N/A	5.3 ± 0.4
HDL (mg/dL)	57.4 ± 11.1	N/A	N/A	N/A	61.6 ± 12.44	63.6 ± 11.9	N/A	N/A	N/A	63.9 ± 10.6
LDL (mg/dL)	153.1 ± 37.5	N/A	N/A	N/A	157.8 ± 59.8	149.8 ± 32.8	N/A	N/A	N/A	137.7 ± 32.2
Triglyceride (mg/dL)	99.1 ± 48.5	N/A	N/A	N/A	117.3 ± 51.0	101.2 ± 44.9	N/A	N/A	N/A	109.1 ± 57.3

Notes: Data are mean ± SD. Significant difference between study groups were determined by *t*-tests or Mann–Whitney *U*-tests as appropriate. *refers to significant differences between study groups (*t*-test). A P-value<0.05 is considered statistically significant.

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Table 3 Comparison of Oral Health-Related Quality of Life (Thai OHIP-14 Scores) Between the Two Groups Over Time. Both Groups Showed Gradual Improvement, with No Significant Differences Observed, Indicating Comparable Recovery Patterns in This Parameter

Aspect	NC (n=12)					NC+ (n=16)				
	T0	T1	T2	T3	T4	T0	T1	T2	T3	T4
Functional limitation	2.1	3.9	2.9	2.6	1.7	2.4	3.4	3.2	2.6	2.2
Physical pain	2.4	3.6	2.3	2.8	2.6	2.7	3.5	3.5	2.6	2.7
Psychological discomfort	3.3	3.0	2.7	2.4	2.0	3.4	3.5	2.9	2.4	2.5
Physical disability	1.9	3.5	3.2	2.6	1.8	2.3	3.7	3.1	2.2	2.3
Psychological disability	2.8	2.8	2.5	2.3	1.9	3.1	3.3	2.6	2.1	2.1
Social disability	2.0	2.8	2.8	2.2	1.8	2.5	3.2	2.7	2.2	1.9
Handicap	2.5	3.5	2.0	2.5	1.8	2.7	3.3	2.9	2.3	2.1
Overall	2.4	3.3	2.7	2.5	2.0	2.7	3.4	3.0	2.4	2.3

Notes: Data are mean. Significant difference between study groups were determined by Mann–Whitney *U*-test. A P-value<0.05 is considered statistically significant.

Table 4 Postoperative Dietary Intake During Different Diet Phases. Significant Differences in Total Energy, Protein, and Fat Consumption Between the Groups are Observed During the Liquid Diet Period, Demonstrating the Impact of ONS Supplementation

Parameters		NC (n=12)	NC+ (n=16)	P-value
Liquid diet period	Total energy (kcal)	748.12 ± 409.15	1,253.94 ± 506.97	0.048
	Carbohydrate (g)	114.19 ± 92.43	173.08 ± 75.00	0.167
	Protein (g)	30.53 ± 20.03	52.05 ± 17.65	0.030
	Fat (g)	18.81 ± 14.7	39.22 ± 18.06	0.006
Soft diet period	Total energy (kcal)	1,082.04 ± 418.46	1,600.37 ± 558.97	0.154
	Carbohydrate (g)	127.61 ± 27.12	186.04 ± 76.43	0.144
	Protein (g)	62.33 ± 35.77	83.11 ± 30.78	0.276
	Fat (g)	35.81 ± 19.87	54.87 ± 23.27	0.175
Regular diet period	Total energy (kcal)	1,207.98 ± 310.27	1,228.49 ± 280.10	0.469
	Carbohydrate (g)	104.67 ± 17.64	162.59 ± 60.35	0.151
	Protein (g)	63.53 ± 33.84	73.97 ± 11.17	0.287
	Fat (g)	42.40 ± 18.33	50.73 ± 21.15	0.018

Notes: Data are mean ± SD. Significant difference between study groups were determined by t-tests. A P-value<0.05 is considered statistically significant.

group.[16] During periods of restricted food intake, the body undergoes adaptations to cope with the lack of food, including the breakdown of liver glycogen and muscle protein to provide glucose for the brain and the gradual depletion of fat stores.[17] Surgical procedures can also trigger metabolic changes mediated by hormone and cytokine release, resulting in catabolic processes. Cortisol secretion further contributes to muscle tissue breakdown, promoting proteolysis and the release of amino acids for tissue repair and synthesis. Inadequate nutrition or high energy demand disrupts metabolic balance, compromising immune function, impairing wound healing, and increasing infection risk,[3–7] especially in individuals with reduced muscle mass who lack essential amino acid sources.[18] Limited research has focused on the loss of muscle mass among orthognathic surgery patients. A recent study investigated acute muscle loss after gastrectomy and found that over 31.82% of patients experienced a loss of more than 10% of their muscle mass within a week post-surgery, leading to decreased quality of life, increased postoperative complications, longer hospital stays, and higher medical costs.[19] Although the muscle loss observed in our orthognathic surgery study may be comparatively lower, it is crucial to recognise the potential adverse effects of such loss.

The addition ONS in our study, along with nutritional counselling, did not result in a significant difference in postoperative nutritional status biomarkers between the groups. Similarly, there was no significant difference observed between the groups in terms of inflammatory biomarkers, specifically TLC and hs-CRP. In addition to the traditional protein nutrition index, Lymphocyte count is often considered a valuable indicator of nutritional status, as undernutrition can cause immunological alterations. Measurement of hs-CRP as an inflammatory marker was also conducted due to the protein consumption associated with inflammation.[20–22] Overall, the addition of ONS did not provide substantial benefits beyond those achieved through nutritional counselling alone. Both groups might have received high-quality nutritional counselling that was equally effective. If the counselling was standardised and provided with the same level of expertise to both groups, this could reduce the differences between them.

In this study, participants were teenagers who were otherwise healthy with a tight control of metabolism. It is believed that a tight control of metabolic homeostasis in young and healthy participants might be the reason for these insignificant changes. In addition, a four-weeks study might be too soon to observe significant changes. Moreover, under-reporting of energy and nutrients intake is prevalent in a healthy dietary pattern study.

Handgrip strength measurement is considered an important indicator of functional status and is commonly included in nutritional assessments,[23,24] with evidence supports the correlation between handgrip strength and markers of nutritional status, muscle mass, and overall health and function. Lower handgrip strength has also been associated with increased mortality rates and longer hospital stays.[25,26] However, we did not observe a significant improvement in handgrip strength recovery with the addition ONS among orthognathic surgery patients. This suggests that handgrip strength recovery after orthognathic surgery is influenced by a complex interplay of multiple factors. While nutrition is undeniably important, its direct impact on handgrip strength recovery may be overshadowed by the intricate nature of the recovery process and individual variability.

The assessment of quality of life is crucial in predicting the benefits of nutritional therapy.[27] However, there is limited past research on the effects of ONS on quality-of-life following orthognathic surgery, highlighting the lack of available data in this area. During the postoperative period, no significant differences were observed in any of the aspects of Thai OHIP-14 scores between the two groups. The lack of significant differences between the groups could be attributed to various factors. The impact of ONS on quality-of-life following orthognathic surgery might be limited to specific unmeasured domains within the Thai OHIP-14 questionnaire. Additionally, the questionnaire's sensitivity might not be adequate to detect subtle changes in oral health-related quality of life. It is noteworthy that the addition of ONS to nutritional counselling did not significantly affect patients' quality of life related to oral health in this study. However, it is important to recognise that nutritional counselling alone may be sufficient to support their quality of life in this aspect following orthognathic surgery.

In general, the subjects' postoperative nutritional status showed signs of improvement at T3, which is 4 weeks after the surgery. Consistent with our findings, Ooi et al observed that biomarker parameters such as total protein, serum albumin, and total cholesterol were decreased at 1 week after surgery and continued to show significant decreases at 2 weeks after surgery.[9] This suggests that it may take several weeks for the nutritional status of patients to recover following orthognathic surgery. This improvement can be attributed to the transition from a liquid to a soft diet, which occurred after the removal of MMF at the 2-week postoperative period. Analysis of the subjects' diet log revealed an increase in macronutrient intake and total energy consumption during this period. It is noteworthy that there were no significant differences in total energy and macronutrient intake between the two groups throughout the postoperative diet phases, as indicated by the diet log.

While our study highlighted the short-term benefits of ONS in reducing postoperative weight loss, especially in the early stages of recovery, the long-term impact on nutritional status, including muscle mass and functional recovery, was not significant. It is possible that the effect of ONS on nutritional status diminished after the supplementation period ended, as patients transitioned back to a regular diet. Extended supplementation beyond the 1-month period may be necessary to observe sustained benefits, especially given the metabolic stress and recovery period after orthognathic surgery. Additionally, other factors such as individual variability in adherence to dietary recommendations, changes in physical activity may have influenced the long-term nutritional status of the patients.

We proposed that nutrition counselling by a registered dietitian could improve patients' dietary intake. During nutrition counselling, patients were advised on how to meet their daily caloric and macronutrients requirements. Recommendations on food choices in liquid or soft diet were introduced. Our participants in this study could eventually maintain their body weight

and others anthropometric indices. Lack of significant differences in nutritional intake between the groups may be a key attribution to insignificant differences found in this study. In addition, it is possible that the ONS in the NC+ group was consumed as a replacement for a main meal rather than as a supplement. This is because all patients in the study were treated with MMF, which made it difficult for them to have a normal diet, forcing them to rely on liquid food at least 2 week post-operatively. The physical disability caused by MMF was reflected in the Thai OHIP-14 score for physical pain (pain and being uncomfortable to eat) and physical disability (diet unsatisfactory and interrupted meals), which showed improvement from T1 to T4 as patients progressed from a liquid diet to a soft diet and eventually a regular diet. A study revealed that 17% of patients had significant concerns about their appearance prior to undergoing orthognathic surgery, and 10% of patients showed positive screening results for body dysmorphic disorder.[28] But our results show that ONS can be used without negatively impacting glucose and lipid metabolism in the postoperative period. At 12 weeks after surgery, there were no significant differences between the two groups in changes to random plasma glucose, HbA1c, HDL, LDL, and triglyceride levels. This emphasises the importance of providing nutritional counselling which helps patients to understand the importance of proper nutrition and guide them in making healthy dietary choices that support postoperative recovery.

Proper nutritional support is essential for postoperative recovery and maintaining homoeostasis in orthognathic surgery patients.[29,30] However, nutrition therapy has been overlooked in this field. Earlier studies conducted in the 1980s indicated that a liquid supplement after surgery can help maintain nutrient intake and preserve body weight.[14,15] More recent research by Hammond et al demonstrated that despite receiving dietary advice and ONS, patients still experienced weight loss and reduced body fat following orthognathic surgery.[10] These findings, along with ours, highlight the need for a tailored nutritional therapy protocol to optimise healing and minimise postoperative complications. It is also important to note that this study's findings do not necessarily suggest that ONS should not be considered as part of nutritional therapy after orthognathic surgery. The decision to use ONS should be based on individual patient needs and may vary depending on the patient's nutritional status and recovery goals. Nevertheless, nutritional counselling remains a crucial element of nutritional therapy, and the study's results emphasise the importance of providing extensive nutritional guidance to patients who have undergone orthognathic surgery. This approach can help ensure that patients are receiving appropriate dietary support tailored to their individual needs, which is essential for promoting optimal healing and a successful recovery process.

Acknowledging the study's limitations, including the small sample size and absence of a control group without nutritional therapy due to ethical reason, caution is needed when interpreting the results. An additional limitation is the potential non-adherence to postoperative instructions, including dietary changes. Patients may not have fully adhered to the prescribed nutritional guidelines, and individual variations in compliance, such as unintended modifications to their diet, could have affected the study outcomes, and introducing bias. Future research should address these limitations by conducting larger-scale, international multicentre studies to improve generalisability and reliability. Inclusion of diverse patient populations and multiple centres would provide a more comprehensive understanding of the role of ONS in nutritional therapy for orthognathic surgery patients. Such studies would offer valuable insights into the potential benefits, optimal dosage, duration of ONS, and variations in response among different patient groups.

Conclusion

In conclusion, this study aimed to evaluate the impact of ONS on the postoperative nutritional status in orthognathic surgery patients. The results indicated that patients who were receiving nutritional counselling alone and those who were receiving nutritional counselling as well as in ONS both experienced postoperative weight and muscle mass loss, with no significant differences observed across all nutritional status parameters at the 12-week postoperative mark. These findings suggested the need for more personalised and intensive nutrition therapy plans to reduce the negative impact of muscle mass loss and associated risk of postoperative infection in orthognathic surgery patients. Future clinical applications of these findings could involve a more tailored approach to nutritional support for orthognathic surgery patients, with regular monitoring of adherence and adjustments to nutritional plans based on individual recovery trajectories. Incorporating more comprehensive nutritional interventions and exploring different supplementation strategies may improve patient outcomes, especially in preventing postoperative complications.

Abbreviations

ONS, Oral Nutritional Supplements; MMF, Maxillomandibular Fixation; NC, Nutritional Counselling; NC+, Nutritional Counselling with ONS; T0, Baseline (a day before surgery); T1, Day of discharge; T2, 2 weeks postoperatively; T3, 4 weeks postoperatively; T4, 12 weeks postoperatively; Thai OHIP-14, Thai Oral Health Impact Profile 14; BMI, Body Mass Index; BMI, Body Mass Index; BMI, Body Mass Index; RPG, Random Plasma Glucose; HbA1c, Glycated Hemoglobin; HDL, High-Density Lipoprotein; HDL, High-Density Lipoprotein; TLC, Total Lymphocyte Count; SD, Standard Deviation; FDA, The United States Food and Drug Administration; ESPEN, The European Society for Clinical Nutrition and Metabolism.

Data Sharing Statement

All data generated or analysed during this study are included in this published article. The full trial protocol is available as supplementary information.

Ethics approval and consent to participate

The study protocol was approved by the Human Research Ethics Committee of the Faculty of Dentistry at Chulalongkorn University with the approval number HREC-DCU 2022–008. The study was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments. All the participants were fully informed about the study's purpose and provided written consent for the use of their clinical data. This study has been registered with the Thai Clinical Trial Registration (https://www.thaiclinicaltrials.org/), with the registration number TCTR20220624006, registered on June 24, 2022.

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Author Statement

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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