CHAPTER III

Research Methodology

3.1. Study Design

This study was a Randomized clinical trial.

3.2. Site of the study

This study was conducted in Prachatipat hospital, Pathumthani province, Thailand. The Pathumthani Province is located directly north of Bangkok and is part of the Bangkok metropolis. The Prachatipat hospital is 30 bedded public hospital including Department of Dentistry, Department of Medicine, Department of Obstetrics and Gynecology, and OPDs. In the Department of Dentistry there are five Dental units, and 4 Dental specialists. I am the only one Dental Implantologist and Oral and Maxillofacial Surgeon. The selection of the hospital was due to as follow; enough sample size in the Province, easy assessable to follow-up appointment for participants and researcher has been working in the hospital since 2003.

3.3 Population, sample, sample size and sample selection

3.3.1. Study population

The study population for this study were Thai edentulous people over 65 –year old age attending (King project) during the study period from September 2010 to March 2011.

3.3.2. Sample Size Calculation

The estimated sample size was calculated by following formula: (Comparisons of two means),

$$M = \frac{(Z\alpha + Z\beta)^2(\sigma_1^2 + \sigma_2^2/c)}{(\mu_1 - \mu_2)^2}$$

$$= \frac{(1.96 + 1.28)^2(20.3^2 + 34.7^2)}{(89.19 - 63.75)^2}$$

= 27 plus 6 (20% attrition)

= 33 (To increase the validity of the results)

(μ1 – μ2)= Difference between means of two groups

σ1, σ2 = Standard deviations

C= Ratio of the sample size of the two groups, C=n2/n1 and n1=m

n1, n2, n3, n4 = Sample size of group 1, group 2, group 3 and group 4

Z= critical value for 95% confidence interval

α = 0.05 (Type I error)

β = 10% (Type II error)

1-β (power) = 90%

Zα = 1.96

Zβ = 1.28

μ1= 89.19 (From previous study in 2003, primary outcome patients' satisfaction VAS, visual analogue scale)

μ2= 63.75 (From previous study in 2003, primary outcome patients' satisfaction VAS scale)

σ1= 20.3 (From previous study in 2003, primary outcome patients' satisfaction VAS scale)

σ2= 34.7 (From previous study in 2003, primary outcome patients' satisfaction VAS scale); (Morais J.A et al., 2003), $p < 0.05$

M= n1= n2 = n3 = n4= 33in each group

Sampling method

Random allocation was done by Dental assistance after eligibility assessment with table chart. (Appendix)

3.4. Procedure

During the period from September 2010 to March 2011, all patients in waiting list of "King Project for free dental implant for elderly edentulous people" residing in Pathumthani province, Thailand, were invited to participate in this study. All the patients who agreed the study protocol were screened using the following inclusion criteria:

Inclusion Criteria

1. Male and female
2. Age 65 years and older
3. Being edentulous for a minimum of 1 year
4. Patient wants replacement of existing old complete dentures
5. Ability to understand written and spoken Thai language and respond to the scales used
6. Willing and able to accept the protocol and to give informed consent
7. Absence of soft or hard tissue inflammation in the oral cavity.
8. No general medical risks, including previous or current radiotherapy or chemotherapy,
9. Adequate oral hygiene, assessed by oral examination including gums and tongue

Exclusion criteria:

1. Insufficient bone to place two implants in the anterior mandible
2. Other oral conditions that preclude immediate prosthetic treatment
3. Acute or chronic symptoms of temporo-mandibular disorders
4. Systemic or neurologic disease that contraindicates implant surgery

5. Other health conditions: smoking of > 1 pack of cigarettes/day

6. A BMI less than 20 kg/m^2 or more than 35 kg/m^2

7. Psychological or psychiatric conditions that could influence diet and reaction to treatment

8. List of medical exclusions

a. Poor metabolic control (Hb a 1c glycosylated hemoglobin > 13.0% or creatinine > 1.7 ml/dl) (Kapur et al., 1998).

b. Advanced cardiovascular disease or renal disease

c. Blood dyscrasias

d. Uncontrolled endocrine disorders

e. Liver dysfunction

f. Auto immune deficiency

g. Active tuberculosis

h. Osteoporosis

i. Patients on anticoagulant or anticonvulsant therapy

j. Patients on long-term steroid or immunosuppressive therapy

All the inclusion and exclusion criteria were screened by researcher; history taking, physical examination and review from past and current medical records. In case of excluded if it was treatable such as uncontrolled Diabetes Mellitus and active Tuberculosis, was connected to their physicians and explained the implanted overdenture surgical protocol. After controlling Hb a 1C or finish anti TB treatment, IOD was done and provide "NEED" nutritional empowerment. But in the study there were no case above Hb a1c > 13.0%, no active TB case and no DM with chronic renal failure.

Informed written consent was obtained from all subjects and record in the study list. These patients were randomly allocated and Dental assistant was done assignment to four experimental groups, designated the Implant Group I and II and the Conventional Dentures Group III and IV according to random number tables. Those allocate to the Implant Group were offered an implant-retained prosthesis in the lower jaw and a conventional complete dentures in the upper jaw in the first instance. If they refuse implants, they would be offered conventional dentures in both jaws. Those allocate to the Conventional Dentures Group were offered new conventional complete dentures in both jaws only, as planned.

Before randomization, individuals were invited to participate in the study, at their first visit; they were informed about the four treatment options. Moreover, assessment of old conventional dentures were done and recorded.

* Primary outcome = general satisfaction

* Secondary outcome= Secondary outcomes included patient ratings of their chewing and speaking ability, comfort, esthetics, and OHRQoL, as well as assessments of nutritional state by means of three-day food records, blood parameters, and anthropometric measurements.

Pretreatment and post-treatment were recorded at baseline, then at post 1 month, 3 months and 6 months treatment.

Body weight was measured with patients wearing light clothing and without shoes. Height was measured by means of a stadiometer; waist and hip circumferences were measured with a non-elastic tape. From height and weight, the Body Mass Index

was calculated. Skin fold thicknesses of biceps, triceps, sub scapular, abdominal and suprailiac were measure by Lange caliper.

Ten ml (10 ml) venous blood samples were drawn for blood-cell-counting and measurements of the concentrations of nutritional parameters and nutrients, such as albumin, carotene, plasma cobalamin (B12), serum and erythrocyte folate, and serum Fe at pretest and post 6 months assessments.

3.5 Outcome measurement

1. To compare the satisfaction of edentulous patients who had been rehabilitated with mandibular implant-supported overdentures and conventional dentures.

➔ By VAS scores and/or Denture Satisfaction (General questionnaire)

2. To determine the pretreatment and post-treatment diets of edentulous patients who received new dentures with either a conventional complete mandibular denture (CD) or a mandibular implant-supported overdenture (IOD).

➔ By - Quality of Masticatory Function Questionnaire translated into Thai version

- Past one week food intake records

3. To compare OHRQoL of edentulous patients between the two groups.

➔ By OHIP-20 (Thai version)

4. To assess the impact of these 2 types of replacement dentures on the nutritional improvement of the patients.

➔ By MNA (Mini Nutritional assessment) plus Anthropometric measurement (such as BMI) and several nutritional parameters and nutrients, including albumin, carotene, plasma cobalamin (B12), serum and erythrocyte folate, and serum Fe.

5. This experimental research was to explore the cost effectiveness in all four groups. Implementation of new therapies is usually governed by financial considerations, so efficacy studies should also include cost comparisons. The cost and effectiveness of mandibular conventional dentures (CD, n = 33) and two-implant overdentures (IOD, n = 33) will be compared. Effectiveness (Oral Health Impact Profile, OHIP-20) and cost will be measured up to 6 months post-treatment.

After providing informed consent, patients completed a Thai-version of a questionnaire that measures OHRQoL, the Oral Health Impact Profile (OHIP-G 20; Slade and Spencer, 1994) (Appendix).

For dietary intake:

They were given data sheets and instructed (both verbally and through written materials) to maintain a complete food intake log for 1 week (7 consecutive days) before their treatment was initiated and for 1 week after the 3 months, 6 months. The data sheets was included sections for recording the type and amount of food consumed for breakfast, lunch, dinner, and snacks between the major meals. Participants were asked to make these entries as soon as possible after eating. For certain dishes with multiple food items, they were asked to identify the main ingredients. They mailed the completed forms or submitted them in person to the researcher.

Treatment in a patient was judged to be a failure for one or more of the following reasons:

(1) unable to wear study dentures;

(2) never or occasionally used their study dentures for eating;

(3) experienced moderate-to-great discomfort during chewing with study dentures;

(4) required four or more visits for denture adjustments and/or clip replacements during each 180-days interval after treatment completion;

(5) clinically perceptible implant mobility;

(6) 30% distal vertical bone loss around the implant; and,

(7) implant removal for any reason. Patients could receive any number of denture adjustments during the first 30 days after the insertion of dentures.

3.6. Data analysis

Descriptive by Mean, Percent and analyzed by Paired t-test, one-way ANOVA, General Linear Model, Repeated Measures, and Correlation and Regression.

3.6.1. Data Entry, Editing and analysis

After the data collection process, all data were edited and verified before analysis. All data were entered into the Epidata version 3.1 program and then transfer into SPSS statistical software and analyzed in SPSS Statistical software 17.0. Firstly, general characteristics among four groups were test by chi-square test and ANOVAs for comparability. Then, data analysis was done by applying descriptive and inferential statistics. For descriptive statistics; frequency, percentage, mean and standard deviation was used to describe the general characteristics of interviewees. Means were compared

by one way ANOVA and if there was difference among four groups, will be analyzed by post-hoc test to know exactly between which groups, and for equal variances Bonferoni was used and incase of equal variance was not assume the Dunnett T3 was used.. Comparing among the timing of measurements (pretest, post one month, post three months and post 6 months) and among the four studied groups were analyzed by general Linear Model, repeated measures. If in case of among groups, equal variance was not assumed the Kruskal Wallis Test was used. Cost-effective was analyzed by correlation and regression.

3.7. Ethical consideration

This study was submitted approval for ethic issue by the Ethical Review Committee of the Chulalongkorn University. The study was approved as study protocol number 037.2/53 on 28 August 2010.

3.7.1. Rights of the respondents: Anytime they can stop from the study if they want to.

3.8. Detail procedure

The system of implants was positioned by the same surgeon (researcher) under local anesthesia (4% articaine with adrenalin 1:100.000). The following data were recorded: patient age and sex, maxillary or mandibular location, type of edentulism (free extremes, interdental spaces or totally edentulous), implant location (anterior and posterior to the canine) and type (with or without releasing incisions), incision size (in cm), number of implants, and instrumentation (bone bed preparation with a rotary technique or manually using osteotomes). Maxillary sinus lifts or bone regeneration procedures were also being recorded, along with the duration of each operation.

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.

Antibiotic medication was provided after surgery (amoxicillin 500 mg, every 8 hours for 5 days, or clindamycin 300 mg, every 8 hours for 5 days in the case of allergy to penicillin), together with anti-inflammatory treatment (ibuprofen 600 mg. every 8 hours for 3 days) and analgesics upon demand (paracetamol 500mg).

The patients rated pain intensity based on a visual analog scale (VAS from 1 to 10) and verbal scale (1 = no pain, 2 = mild pain, 3 = moderate pain, 4 = intense pain), and inflammation as follows: 1 = none (absence of inflammation), 2 = mild (intraoral swelling in the surgical zone), 3 = moderate (extraoral swelling in the surgical zone), 4 = intense (extraoral swelling extending beyond the surgical zone). All scores were recorded 2, 4, 6, 12 and 24 hours after the operation, and on day 2, 3, 4, 5, 6 and 7.

Patient characteristics were recorded as follow:

Age

Weight (kg)

Height (cm)

Anthropometric data

- BMI (kg/m2)
- Biceps SFT (mm)
- Triceps SFT (mm)
- Subscap. SFT (mm)
- Abdom. SFT (mm)
- Waist circumference (cm)
- Hip circumference (cm)

Waist/hip ratio

Blood parameters

RBC (x 10^{12})

Hgb (g/L)

Total lymph (x 10^{9})

Albumin (g/L)

B12 (pmol/L)

Ser. folate (nmol/L)

RBC folate (nmol/L)

Serum Fe (mmol/L)