CHAPTER III
RESEARCH METHODOLOGY

3.1 Overview and study design

This was a retrospective study to compare the outcome and improvement of treatment in complete cleft lip and palate patients with orthodontic treatment alone and with orthognathic surgery.

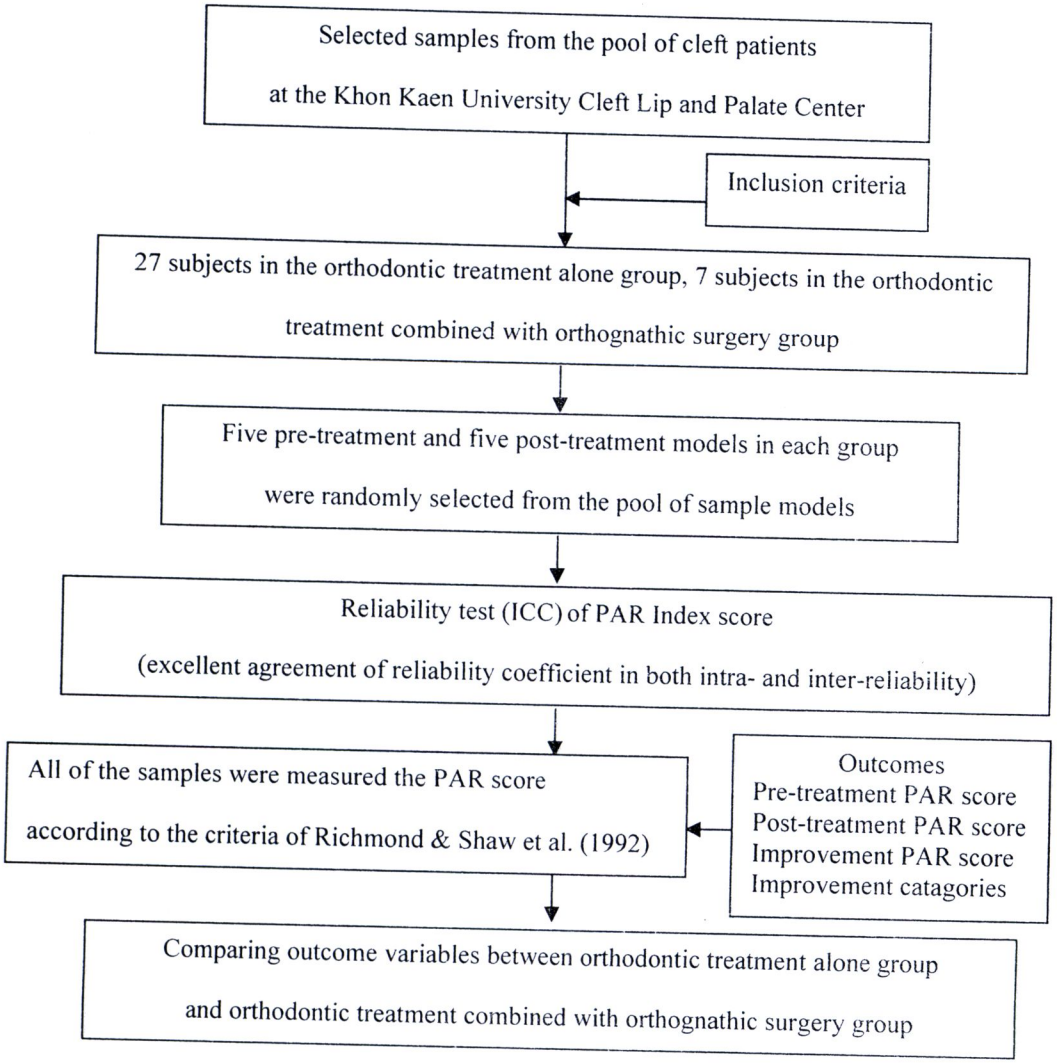

Figure 1 A diagram showing outline of the study

3.2 Study population and selection criteria

3.2.1 Study population

This consisted of cleft lip and palate patients in the Khon Kaen University Cleft Lip and Palate Center who had completed treatment and having complete records.

3.2.2 Inclusion criteria

The subjects in this study were indicated as follows;

3.2.2.1 Cleft lip and palate patients had completed correction of malocclusion (both with and without orthognathic surgery).

3.2.2.2 Permanent dentition was selected.

3.2.2.3 Collected data complete was recorded.

- There were study models at the beginning of corrective treatment (before) and study models in final phase and completed treatment (after).

3.2.3 Exclusion criteria

The subjects had characteristics such as;

3.2.3.1 Cleft-associated syndrome patients were evaluated.

3.2.3.2 Patients had facial cleft.

3.2.3.3 Patients had loss of all upper incisors.

3.2.3.4 Patients had loss of lower central incisors.

3.2.3.5 Patients had permanent teeth loss prior to their final treatment due to excessive dental caries.

3.2.4 Records for comparative study:

3.2.4.1 A set of study models of each subject was taken prior to corrective orthodontic treatment and after complete orthodontic treatment in the orthodontic treatment alone group

3.2.4.2 A set of study models of each subject was taken prior to corrective orthodontic treatment and after complete orthodontic treatment in the orthodontic combined with orthognathic surgery group

3.3 Definitions of words used in this study

Expert orthodontist

- An orthodontist had an experience more than 10 years in both cleft lip and cleft palate care and non-cleft patient care.

- The expert was asked to assess the orthodontic treatment outcome using PAR Index score according to the criteria of Richmond et al.[53] (Appendix A) from study models in each group. This assessment was to be used to test the validity and reliability to confirm the assessments between expert examiner and the other examiner (researcher).

3.4 Sample size

From pilot study to assessed the orthodontic treatment outcome of 5 cleft lip and palate patients in each group using the PAR Index, the standard deviation of post-treatment PAR in orthodontic combined with orthognathic surgery group was 7.96 and orthodontic alone group was 8.53. The mean of post-treatment PAR score in orthodontic combined with orthognathic surgery group was 35.40 and orthodontic alone group was 29.80. The pooled variance for calculating sample size in this study was 68.06. The sample size was calculated at confidence level of 95%, $\alpha = 0.05$ ($Z_{\alpha/2} = Z_{0.025} = 1.96$), 1-$\beta$ (Power of test) = 80%, $Z_{0.2} = 0.84$

$$n = \frac{2(Z_{\alpha/2} + Z_{\beta})^2 S_p^2}{(\mu_c - \mu_t)^2}$$

n = 35 for each group

n	=	sample size
Z	=	Z value
S_p	=	pool variance
$\mu_c - \mu_t$	=	mean difference

In this study, the subjects were found 27 cases in orthodontic treatment alone group and 7 cases in orthodontic treatment combined with orthognathic surgery group that followed by inclusion criteria and completed data record.

3.5 Tools

3.5.1 Divider was used to measure the displacement of contact point.

3.5.2 Ruler was performed the quantity of displacement (mm).

3.5.3 Pencil was used to mark the area of contact point.

3.6 Procedures

3.6.1 Reliability testing

Dental casts were selected according to the two stages of treatment in each group (orthodontic treatment alone and combined with orthognathic surgery) including:

- pre-treatment stage was the time that the treatment started with full fixed orthodontic appliances, either following the OTA treatment approach, or at the start of orthodontic treatment as preparation for the COS approach .
- post-treatment stage was the time that treatment was completed by either OTA or COS.

Five pre-treatment and five post-treatment models in each group was randomly selected from the pool of sample models. To determine intra-examiner reliability, two trained examiners (one was the researcher, another one was an expert orthodontist) used the PAR Index to score 10 sets of models on 2 separate days, 1 week apart, and then to compare the scores. To determine inter-examiner reliability, the examiners used the PAR Index twice to score 10 sets of models from the same lot selected for the intra-examiner reliability test.

3.6.1.1 Statistical analysis was performed using STATA version 10.0 (STATA Corp, LP. College Station, Tx).

3.6.1.2 Intra-class Correlation Coefficient (ICC) was calculated to assess the reliability between two trained examiners.

Reliability of PAR Index score revealed excellent agreement of reliability coefficient in both intra- and inter-reliability. The agreement between first and second examiners ranged from 0.989 to 0.994 whereas the agreement between first and second times of PAR Index score ranged from 0.988 to 0.989 (Appendix B, Table B1).

3.6.2 Use of PAR Index to assess study subjects

Following satisfactory completion of reliability testing of the two examiners in use of the PAR Index, the model records of all the study subjects were assessed.

3.6.3 Malocclusion and outcome measurements

The outcome variables that were measured in this study including:

- The pre-treatment PAR Index score in orthodontic treatment alone group, and orthodontic treatment combined with orthognathic surgery group.
- The post-treatment PAR Index scores in orthodontic treatment alone group, and orthodontic treatment combined with orthognathic surgery group.
- The improvement PAR Index scores in orthodontic treatment alone group, and orthodontic treatment combined with orthognathic surgery group.
- PAR score improvement categories in orthodontic treatment alone group, and orthodontic treatment combined with orthognathic surgery group (category criteria as used by Richmond et al.[53]).

3.6.4 Comparison of outcome measurements

Comparing the outcome variables as follows:

- The post-treatment PAR Index score in orthodontic treatment alone group and orthodontic treatment combined with orthognathic surgery group.
- The degree (percentage) of improvement by PAR Index score in orthodontic treatment alone group and orthodontic treatment combined with orthognathic surgery group.

3.7 Data collection

Each set of study models for all subjects participating in the study was assigned a number in random order by a non-examiner to ensure examiner blinding. This number was placed on the patient's pre-treatment and post-treatment models, and the patient's name was hidden.

The PAR Index score was recorded according to the criteria of Richmond et al.[53] The examiner (the researcher) tabulated pre-treatment and post-treatment PAR scores for each group and degree of improvement (pre-treatment minus post-treatment the PAR scores)(Table 1).

Table 1 Form for recording PAR scores in each patient

Case No..... Examiner.....Date.....

PAR components	Pre-treatment scores	Post-treatment scores	Improvement	
			scores	%
Upper right segment	(6-5)...,(5-4)...,(4-3)...	(6-5)...,(5-4)...,(4-3)...		
Upper anterior segment	(3-2)...,(2-1)...,(1-1)... (1-2)...,(2-3)...	(3-2)...,(2-1)...,(1-1)... (1-2)...,(2-3)...		
Upper left segment	(6-5)...,(5-4)...,(4-3)....	(6-5)...,(5-4)...,(4-3)...		
Lower right segment	(6-5)...,(5-4)...,(4-3)...	(6-5)...,(5-4)...,(4-3)...		
Lower anterior segment	(3-2)...,(2-1)...,(1-1)... (1-2)...,(2-3)...	(3-2)...,(2-1)...,(1-1)... (1-2)...,(2-3)...		
Lower left segment	(6-5)...,(5-4)...,(4-3)...	(6-5)...,(5-4)...,(4-3)...		
Right buccal occlusion	AP ..... V ..... T	AP ..... V ..... T		
Overjet	OJ ..... x-bite	OJ ..... x-bite		
Overbite	openbite ..... OB	openbite ..... OB		
Centerline	.....	.....		
Left buccal occlusion	AP ..... V ..... T	AP ..... V ..... T		
Total				

Notation of teeth in brackets, followed by the PAR score for each contact point.
(AP = anteroposterior, V = vertical, T = transverse, OJ = overjet, OB = overbite)
The PAR scores were filled in the blank of each component, and accumulated to total pre-treatment and post-treatment PAR scores.

3.8 Data analyses

3.8.1 Descriptive statistics

Descriptive statistics were used to determine the general characteristic of subjects which were age and gender in each group (orthodontics alone, and orthodontic treatment combined with orthognathic surgery).

3.8.2 Comparison of pre-treatment, post-treatment, and improvement in PAR scores between orthodontic treatment alone and orthodontic treatment combined with orthognathic surgery group with mean difference and 95% confidence interval were made using Mann-Whitney U Test.

3.8.2.1 Statistical analysis was performed using STATA version 10.0 (STATA Corp, LP. College Station, Tx).

3.8.2.2 All p-values were two-tailed, and p-value < 0.05 was considered to indicate statistical significance.

3.8.3 Comparison of PAR Index score improvement categories between orthodontic treatment alone and orthodontic treatment combined with orthognathic surgery group with mean difference and 95% confidence interval were made using Fisher's exact test.

3.8.3.1 Statistical analysis was performed using STATA version 10.0 (STATA Corp, LP. College Station, Tx).

3.8.3.2 All p-values were two-tailed, and p-value < 0.05 was considered to indicate statistical significance.

3.9 Ethical considerations

According to ethical guidelines stated in the Helsinki's Declaration, the study was granted approval by the Institutional Review Board (IRB) committee at Khon Kaen University (HE 532082). This study ensured the confidentiality of the data obtained by:

3.9.1 Protection of patient data (such as name, address, telephone number)

3.9.2 Identifying models by a number in random order by a non-examiner