CHAPTER I
INTRODUCTION

1. Rationale and Background

Cleft lip and cleft palate deformities are craniofacial malformations that occur with high frequency throughout the world. Published reports from Thailand indicated incidences per 1000 live births as high as 1.62[1] and even 2.59.[2] Two other reports gave figures of 1.10[3] and 1.59.[4] Disparities among such epidemiological estimates may or may not be attributable in part to variable reporting and sampling differences.[5]

Cleft lip and cleft palate patients normally encounter many problems such as undesirable facial appearance, hearing and speech impairment, early feeding problems, malocclusions, and psycho-emotional problems. A deficient maxilla is one of the most common associated skeletal problems in patients with clefts in which dental development is also impaired causing esthetic problems.[6, 7] This problem is also accentuated during the adolescent growth spurt, producing the characteristic of Class III malocclusion with Skeletal Class III pattern.[8-10]

Many studies had tried to find the causes of maxillary growth deficiency in cleft patients; however, most of them ended in different conclusions. Graber[11] observed that closure of the hard palate and of the alveolar cleft performed too early might cause the immobilization of the vomer which is an important growth center of the midface region. Bardach and Kelly[12] and Ross[13] suggested that any treatment results for clefts should be assessed after completion of the individual's growth. Hence, a long observation period is required which makes the cause of midface deficiency difficult to determine as it may come from the effect of the malformation itself, the surgical operations, or by functional deficiencies, with consequent closing rotation of the mandible, the latter leading to forward position of the chin. The effect of treatment from a particular surgical technique, the expertise of the surgeon, and especially timing of initial surgical closure of the hard palate, have been studied and considered to have a great impact on the nature of continuing growth and development of the craniofacial complex in children with oral clefts.[11, 14, 15] On the

other hand, Shaw et al.[16] found that neither technique nor timing of surgical procedures had a significant influence on the amount of midfacial growth; the most important factors were the number of involved surgeons and their respective skills and experiences.

Generally, it is difficult to judge the effect of one aspect of treatment without considering its influence on other aspects of growth and development since the quality of facial development has a very important role on facial appearance. The pattern of facial growth results from the interaction of genetic and environmental factors. Continued growth may enhance or detract from the treatment results previously obtained during childhood and adolescence. If the skeletal discrepancy is mild and esthetic concerns are minimal, dental compensation with orthodontic treatment alone by changing the axial inclination of the anterior teeth may camouflage the skeletal discrepancy effectively. In other words, slightly inadequate growth may result in a malocclusion that can be treated conventionally by orthodontics, with acceptable results in terms of facial appearance, thus avoiding surgical correction of the minor skeletal base problems.[17] Conversely, for patients who tend to have severe skeletal discrepancy or have unfavorable growth pattern, the orthodontic treatment should be aimed first at decompensation of the malocclusion so that the maxillary and mandibular anterior teeth are placed in their correct relationship to their underlying skeletal bases. After achieving an ideal relationship of the teeth to each jaw, surgical movements will result in the maxilla and mandible and their dentitions being optimally related.

However, facial growth is an uncertainty in orthodontic treatment planning. One should be cautious because orthodontic overcompensation for the skeletal discrepancy when the skeletal surgery is a later possibility produces not only unsatisfactory esthetic results but also increases treatment time. In addition, a reliable and reproducible method is required to evaluate and measure patient conditions which in turn reflects the quality of facial growth and also gives a practical indication of those patients who can be treated by orthodontics alone, or who will require a combination of orthodontics and further surgical correction. Many studies have used the cephalometric analysis and prediction tracings, by collecting the cephalometric values from the cleft lip and/or cleft palate patients at an early age and establishing a

model for prediction, to provide further information for deciding whether a patient can be treated by orthodontics alone or by combined orthodontics and an orthognathic surgical procedure.[18-21] Such predictions, using equations developed from statistical prediction methods such as multiple regression analysis, may not be universally applicable as it is necessary to take account of variation among different populations of patients with clefts and differing treatment protocols. These prediction methods using cephalometrics may be deficient in so far as they are concerned with two dimensions of facial structures, thus missing the use of three dimensions that guide the overall perception of facial esthetics.

In Thailand, Singhawannakul[22] developed the Formula for Orthodontics and Surgery Prediction (FOSP) which was an equation that aimed to predict the need for additional orthognathic surgery or orthodontic treatment alone in patients with cleft lip and palate. It was obtained from 119 patients with cleft lip and/or palate patients who received treatment at the Orthodontic Department, Khon Kaen University in the age range 8 - 24 years. This formula was intended to be applied to all oral cleft patients with no account of age and gender. In Singhawannakul's study, the subjects were placed in one of two groups, orthodontic treatment alone, or requiring additional orthognathic surgery, according to evaluation by an expert in orthodontic care of patients with oral clefts. A discriminant analysis was performed using a collection of the lateral cephalometric measurements to compare with treatment need determined from visual examination of clinical records by the expert. There were 38 measurement variables from three components which were cephalometric skeletal measurements, cephalometric dental measurements, and soft tissue measurements. Only three cephalometric variables, the skeletal type (ANB angle), position of upper anterior teeth (U1 to APog in millimeters) and lower lip profile (L lip to Nperp in millimeters), were found to be significant diagnostic factors that were then incorporated in the FOSP formula for discrimination between cases requiring both surgery and orthodontics and orthodontics alone. The FOSP may help to forecast the definitive treatment planning for clefts, with the prospect of replacing the predictive application of more subjective indexes, such as the Goslon Yardstick[23] and the 5-year olds index.[24] Nevertheless, both of these well-known indexes require a standardized set of dental models, or photographs of models[25] for diagnostic application to two specific

age groups with simply ordinal ranking of severity of malocclusions. The severity of a malocclusion is compared against these standard models by qualitative judgment of a specially trained examiner and the predicted treatment plan is then established, according to the ranking. However, when the judgment from examiner is involved, it should be realized that the more experienced an examiner is in treating the clefts, the less severity he/she tends to score, creating systematic bias.[26]

To reduce the error that may come from qualitative and subjective assessments, this newly developed FOSP formula provides the possibility of more quantitative and objective assessments using measurement data of patients that are normally available in an electronic database of clinical records which also facilitates statistical analysis. This prediction formula is intended to assist in early deciding whether definitive camouflage orthodontic treatment for these patients should proceed, or whether it has to be postponed until orthognathic surgery is carried out at the end of adolescent growth, or later. Although Singhawannakul indicated that 83.2% of the subjects could be correctly classified according to treatment group from this equation[22], for clinical application, this was still questionable since the predictive value of its use needed to be confirmed by comparison with the actual treatment employed for each patient.

2. Research Question

For a group of cleft lip and/or palate patients, how closely does the predicted treatment plan using the Formula for Orthodontics and Surgery Prediction (FOSP) in these patients before they received their concluding treatments, compare with their actual received treatments?

3. Research Objectives

3.1 To evaluate whether the Formula for Orthodontics and Surgery Prediction (FOSP) can be used as a clinical tool in treatment planning process of cleft patients by testing:

3.1.1 The reliability of the predicted treatment plan from the FOSP by comparing agreement and disagreement proportions between the treatment plan

from the prediction equation before they received concluding treatment and the actual treatment plan that they received or were receiving.

3.1.2 The validity of the predicted treatment plan from the FOSP, using the actual treatment plan as a reference.

3.2 To consider the impact of variables such as gender and cleft type on the reliability and validity of the treatment plan when using the FOSP as a prediction tool.

4. Scope and Limitation of the Study

The study sample consisted of cleft patients who had final orthodontic treatment decision at the Orthodontic Department of Khon Kaen University. The clinical usefulness of the FOSP was determined by considering reliability and validity of the predicted treatment plan relative to the actual received treatment, using kappa statistics and diagnostic test, respectively. With the use of the receiver operating characteristic (ROC) curve, an optimal cutoff discriminant (D) score for classification of predictive treatment plan was identified. The role of the age, gender, and cleft type on reliability and validity of the predicted treatment plan from the FOSP were evaluated as well.

5. Expected Benefits and Application

Confirmation of the usefulness of FOSP would reduce the problems of over-compensation in camouflage cases that had to finally turn to orthognathic surgery which usually causes more visits, more cost and patient dissatisfaction in patients with cleft deformities. In addition, it might be applicable to predict the need for additional orthognathic surgery or only orthodontic treatment alone in Skeletal Class III noncleft patients since they usually have the same type of malocclusion.

Moreover, this study is also expected to provide some information about the percentage of cleft patients who received or receiving additional orthognathic surgery at Khon Kaen University cleft care center which generally imply the success or failure of the treatment protocol.