

The Americleft Study: An Inter-Center Study of Treatment Outcomes for Patients With Unilateral Cleft Lip and Palate

Part 2. Dental Arch Relationships

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Objective: To compare maxillomandibular relationships for individuals with nonsyndromic complete unilateral cleft lip and palate using the Goslon Yardstick for dental models.

Design: Retrospective cohort study.

Setting: Five cleft palate centers in North America.

Subjects: A total of 169 subjects with repaired complete unilateral cleft lip and palate who were consecutively treated at the five centers.

Methods: Ethics approval was obtained. A total of 169 dental models of patients between 6 and 12 years old with complete unilateral cleft lip and palate were assessed using the Goslon Yardstick. Weighted kappa statistics were used to assess intrarater and interrater reliabilities; whereas, analysis of variance and Tukey-Kramer analysis was used to compare the Goslon scores. Significance levels were set at $p < .05$.

Results: Intrarater and interrater reliabilities were very good for model ratings. One center that incorporated primary alveolar bone grafting showed especially poor Goslon scores that were significantly poorer than the remaining centers. The surgery protocols used by the other four centers did not include primary alveolar bone grafting but involved a number of different lip and palate closure techniques. Using the Goslon Yardstick assumptions, the center with the best scores would be expected to require end-stage maxillary advancement orthognathic surgery in 20% of its patients; whereas, the center with the worst scores would be likely to require this surgery in 66% of its patients.

Conclusions: The Goslon Yardstick proved capable of discriminating among the centers' dental arch relationships. Possible explanations for the differences are discussed.

KEY WORDS: *alveolar bone graft, Americleft, cleft lip and palate, dental arch relationship, dental cast (model), Goslon Yardstick, intercenter study, treatment outcome measures*

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There is a demonstrated need to assess the treatment outcomes of patients with cleft lip and palate, with one major goal: to continually improve the treatment options and outcomes we can offer our patients. Cleft centers in Europe have demonstrated this well with the Eurocleft study and the subsequent changes that were made to the delivery of cleft care in the U.K. Although this has been well implemented in Europe, to date it has not been the case in North America. Thus, the goal of the present study was to use a simple, readily available method to assess treatment outcomes for patients with repaired cleft lip and palate and to make an overall comparative judgment of the level of care being provided in a group of well-established cleft centers.

Given the potential impact of primary surgical protocols on dentofacial growth and development, one of the most noteworthy findings of the original Eurocleft study was the ability to detect differences in dental arch relationships among centers, using a simple yet robust outcome measure, the Goslon (Great Ormond Street London and Oslo) Yardstick. Numerous studies using the Goslon Yardstick for intercenter comparison studies have been reported in this journal (Mars et al., 1987; Mars and Houston, 1990; Mars et al., 1992). They all have found this instrument to be a ‘reliable, robust, and rapid means’ for the assessment of dental arch relationships for patients with unilateral cleft lip and palate and further capable of discriminating among outcomes of various general treatment protocols. Its central premise is the simplification and intuitiveness of measuring clinical features that reflect treatment outcomes and can be related to the burden of care of treatment.

The present study used the Goslon Yardstick to evaluate outcomes of various cleft treatment protocols for patients with complete unilateral cleft lip and palate (CUCLP) from five North American centers.

METHODS

Ethics approval was obtained from each center’s ethics review board. The five centers reported in part 1 of this series participated in this dental arch relationship study. From the five centers, 169 dental models (A = 18, B = 40, C = 38, D = 38, and E = 35) were acceptable for rating. The characteristics of the samples and treatment protocols have been described in Table 1 in part 1 of this series: “The Americleft Study: An Intercenter Study of Treatment Outcomes for Patients With Unilateral Cleft Lip and Palate, Part 1: Principles and Study Design.” The criteria for inclusion in the study, also reported in part 1, required treatment histories to confirm that patients in the samples had nonsyndromic CUCLP and were consecutively treated, with all primary procedures performed at the participating center. All patients were between the ages of 6 and 12 years and had not received any active orthodontic treatment. Passive space maintainers may have been placed, but no patients had undergone any type of active orthodontic tooth movement.

All dental models were duplicated and prepared identically to ensure raters were blinded to the origin of the models during the rating sessions and to minimize analysis bias. The standards for preparation of the models followed those set forth in the original Goslon study (Mars et al., 1992). The entire set of models from all the centers was rated twice, on separate days, by six experienced and calibrated raters. The models were numbered and randomized in their order of presentation. Thus, each set of models received 12 total scores that were averaged to give a mean score for each patient. For the second rating, the models were renumbered and again randomized in order of presentation. Each rater had the opportunity to compare any set of models to be rated with the displayed reference models of the Yardstick. The reference Yardstick consists of a set of calibrated plaster models that were established in the original Goslon study to indicate discrete examples of each of the 5 points of the scale (Fig. 1). No conferring between raters was permitted during the rating procedure. This study used the original plaster Goslon Yardstick mainly to allow for comparisons with the results of the Eurocleft study, which also used the plaster Yardstick, and in this way the methodology was consistent between the two studies. Furthermore, the photographs available from the centers were not standardized, and the use of the plaster Yardstick was thought to be more reliable for use across the centers. A photographic representation of the Goslon categories is shown in Figure 1, but it is important to note that this was not used with these rating sessions. It is, however, acknowledged through the work of Nollet et al. in 2004 and recent studies yet unpublished by this group that photographic representations can be used as valid representations of the Goslon Yardstick models for model ratings. What remains to be assessed is whether both models and photographs can be used in the same study. Of importance in these studies using the Goslon Yardstick, as stated by Sinko et al. (2008, p. 81), is that “standardization of ratings of different centers throughout the world and training the investigators in scoring well-documented Goslon models appear to be beneficial.” They also reported that “Personal training on the original Goslon models appears to improve the accuracy of rating” (Sinko et al., 2008).

The application of the Yardstick has three determinants that influence the score of each model (1 = *excellent* to 5 = *very poor*). The greatest influence on the Goslon score is from the anteroposterior assessment or overjet. If there are dental compensations present such as proclination/retroclination of maxillary incisors or mandibular incisors, the score may shift to the next higher or lower score, depending on the magnitude of the compensation. The second determinant is the vertical assessment. A deep overbite is preferable to an open bite. Only in a borderline case can a deep overbite influence the score to the next lower whole number, indicating a better score. However, an open bite would likely raise the score to the next higher whole number, indicating a poorer score. Finally, the third

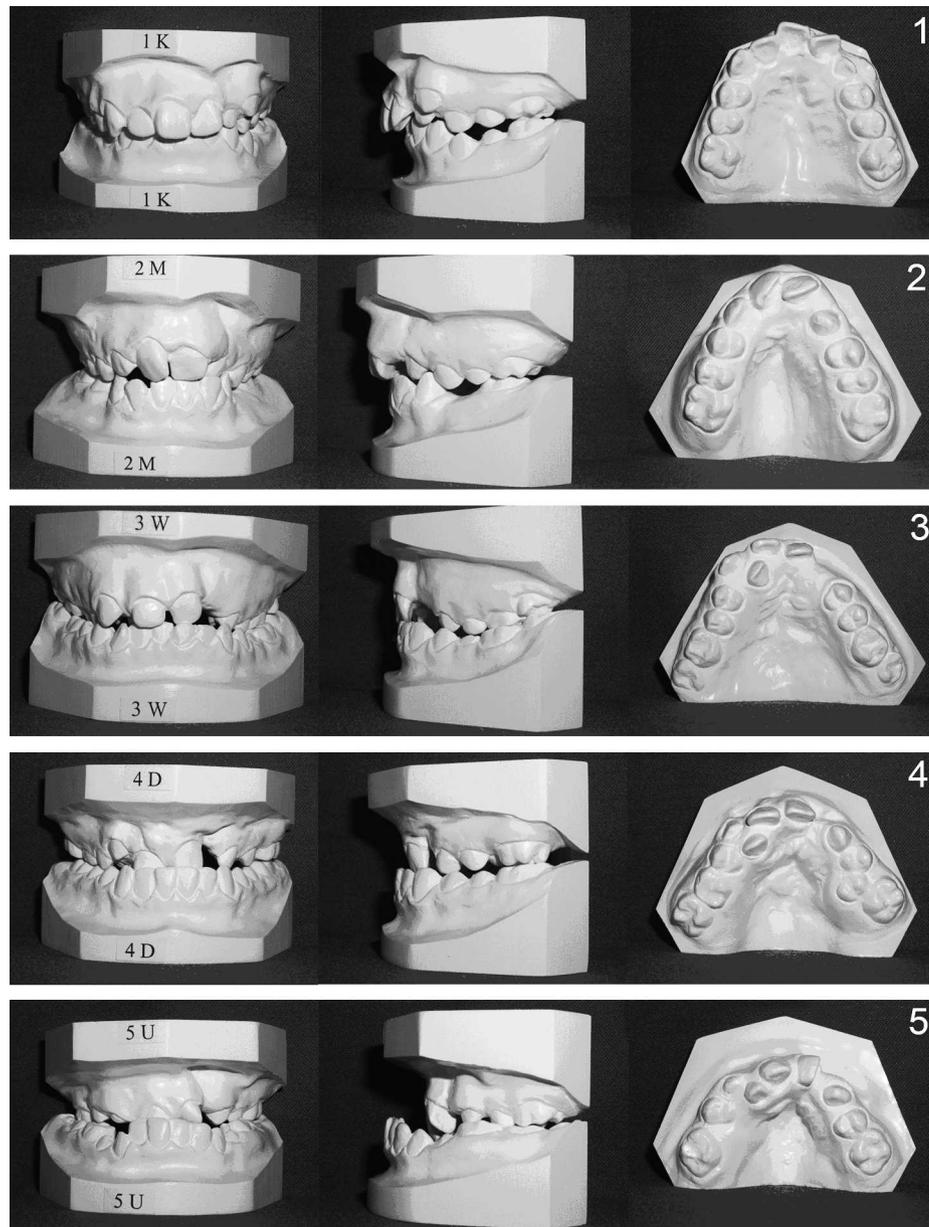


FIGURE 1 Photographs of the five Goslon Yardstick models used for reference by raters.

determinant is the transverse assessment of dental arch relationships. This determinant infrequently influences the Goslon score and is weighted less, based on the assumption that many transverse relationships may be treated with orthodontic therapy alone. Severe narrowing of the arch, however, may increase the score. The weighting of these three determinants emphasizes the need to use the reference yardstick models during rating sessions.

Statistical Methods

Intrarater and interrater reliability testing was done with weighted kappa statistics. Twelve (six raters, two sessions) individual ratings were made for each model using the 5-point scale, and then the mean scores for each model were used for the analyses. All scores for all patients within each

center were averaged to give a mean score for each center. Analysis of variance (ANOVA) was used to evaluate the differences in mean scores between centers. Tukey-Kramer post hoc pairwise analysis was used to examine all pairwise differences. Although individual scores were recorded on a 5-point scale, the summary score was used for analysis. This was considered to estimate values on an underlying continuum, similar to the approach used in the original Eurocleft study as well as the follow-up report in 2005 (Mølsted et al., 2005). The statistically significant level was set at $p < .05$.

RESULTS

The mean intrarater reliability was .91, with a range of .87 to .93 indicating very good reliability for all raters. The

TABLE 1 Agreement Categories From Kappa Calculations (Landis and Koch, 1977)

Value of Kappa	Strength of Agreement
<.20	Poor
.21-.40	Fair
.41-.60	Moderate
.61-.80	Good
.81-1.00	Very good
1.00	Perfect agreement

mean interrater reliability was .86, also indicating very good reliability among the different raters (Table 1). These reliabilities were considered very satisfactory for use with the Goslon Yardstick.

Goslon mean scores for Centers A through E were 3.4, 3.7, 2.6, 3.3, and 3.2, respectively (Table 2). Using ANOVA comparisons of the Goslon scores of the five centers demonstrated that significant differences existed among the centers ($p < .05$) (Fig. 2). The highest Goslon score of 3.7 for Center B indicated a poorer outcome and higher risk for needing maxillary orthognathic surgery than was found in the other centers. The mean score of 2.6 for Center C was lower than the other four centers, indicating a better outcome and a most favorable relationship between the maxilla and mandible. The distributions of the Goslon scores for each center are shown in Figure 3, from best to worst.

Further statistical analysis was done using the Tukey-Kramer post hoc pairwise analysis, using a higher confidence interval for statistical significance to account for multiple pairwise testing. Four significant differences were noted. Center C's mean score was significantly better than those of the four other centers. None of the other pairwise comparisons between centers were significantly different. Although Center B's mean score was worse than all other centers, the Tukey-Kramer test did not find the differences to be significant except between Centers B and C.

DISCUSSION

The intrarater and interrater reliabilities in this study are comparable to others reported in the literature (Nollet et al., 2005; Sinko et al., 2008; Fudalej et al., 2009). Our Goslon results, both ratings and distribution, were also similar to recent outcome studies indicating that many different treatment protocols used by cleft centers around the world achieve similar results (Nollet et al., 2005; Sinko et al., 2008; Fudalej et al., 2009). There have been studies, though, that have identified aspects of treatment as well as the populations being studied that could account for lower ratings. Studies by Susami et al. (2006) reported a higher proportion of Goslon ratings of 4 or 5 compared with the Eurocleft and now the Americleft studies. This has been attributed to a population with a higher predisposition

TABLE 2 Sample Sizes for the Dental Model Analysis and the Mean Goslon Dental Model Scores, With Standard Deviations, for the Five Centers (Analysis of Variance, $p < .0001$)

Center	Sample Size	Mean Goslon Rating	Standard Deviation
A	18	3.38* versus C	0.86
B	40	3.66* versus C	0.61
C	38	2.63	0.81
D	38	3.32* versus C	0.88
E	35	3.18* versus C	0.66

* $p < .05$ using Tukey 95% simultaneous confidence intervals (individual confidence level = 99.35%).

toward a class III skeletal malocclusion, which when combined with a repaired cleft lip and palate would increase the risk for lower Goslon ratings. Both the European and American population samples have a greater predisposition toward class II skeletal malocclusions. This highlights the need to account for the underlying skeletal morphology that may be associated with a specific population. Other studies such as Lilja and colleagues' in 2006 showed a larger proportion of better Goslon ratings that they attribute either to a population with a class II skeletal pattern and/or possible benefits from delayed hard palate closure. In our study, as with the Eurocleft Study and that reported by Nollet et al. in 2005, the use of primary bone grafting has been suspected of contributing to lower Goslon ratings.

The meta-analysis conducted by Nollet et al. (2005) identified two characteristics that were associated with better Goslon ratings: delayed palatal closure after 3 years of age and the presence of Simonart bands, which was thought to reduce original cleft width. The authors did identify limitations with the meta-analysis including identification of race, presence of Simonart bands, alveolar bone grafting, and the number of surgeons. In both the Eurocleft and the Americleft studies, the treatment with primary alveolar bone grafting and a larger number of surgeons performing fewer surgeries were associated with lower Goslon ratings (Mølsted, 2005).

Center A had a less than optimal sample size, based on the results of the power study that recommended a minimum sample size between 30 and 40. The results of this center were included in the analysis. However, the relative outcomes and any conclusions regarding the impact of the treatment protocol on interarch relationship must be treated with caution. Although the results of the Goslon scores for Center A were not different from those of the three other centers, it is unknown whether the scores for this sample accurately represent the treatment outcomes or whether the limited sample is biased toward better or worse outcome results.

Predictions of those patients with repaired CUCLP who might require orthognathic surgery were made from the results of the Eurocleft study using the Goslon Yardstick. It was predicted that individuals with Goslon scores of 3.5 and higher (poorer scores) were considered likely candi-

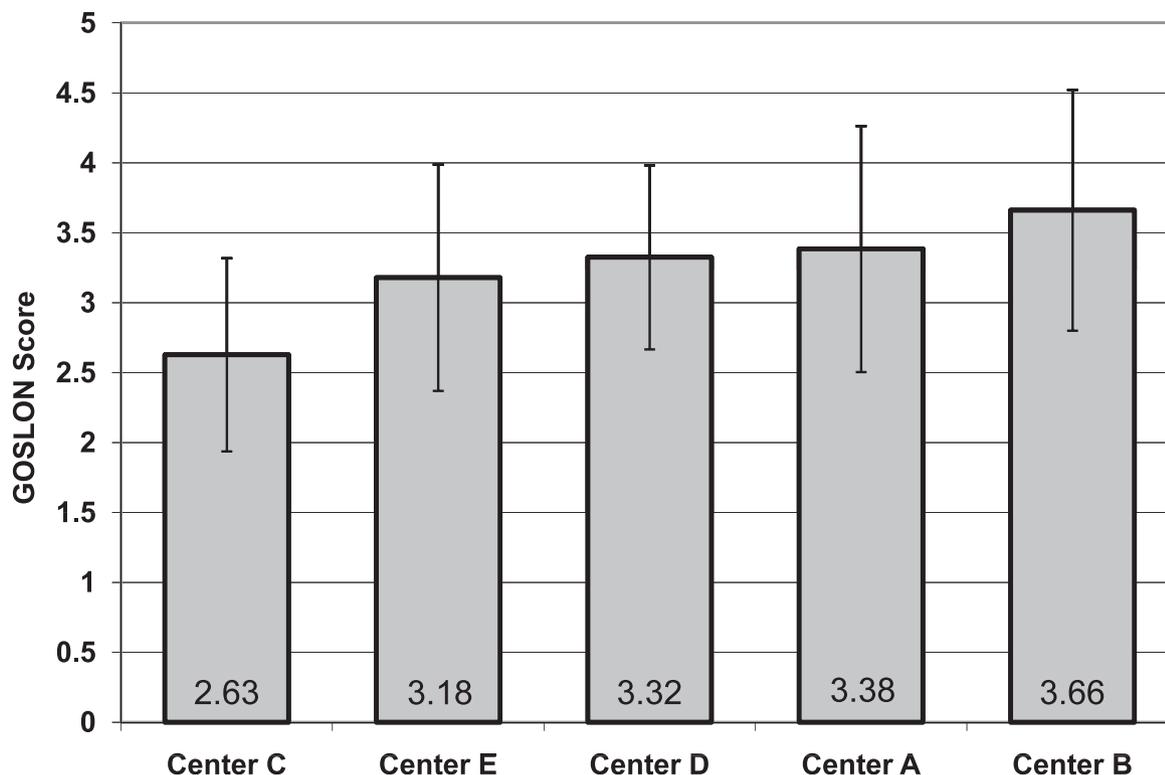


FIGURE 2 Mean Goslon scores for the five centers in the intercenter dental arch study are identified within each bar. Error bars are shown for each center, $p < .05$. Center C has a significantly lower (better) Goslon score than Centers A, B, D, E ($p < .05$). There were no differences identified in pairwise comparisons between Centers A, B, D, and E.

dates to require maxillary osteotomy to advance the maxilla at the completion of growth (Shaw et al., 2008). In a similar manner, the distribution of cases with Goslon scores of 4 and 5 for the Americleft centers (Fig. 3) would predict that approximately three of every five patients from Center B would require a maxillary osteotomy; whereas, only one of every five patients from Center C would require this surgery.

Whereas ANOVA indicated the existence of significant differences among centers, the pairwise comparison confirmed that Center C had a significantly better mean Goslon score than the other four centers. This would predict better maxillomandibular relationships and a less likely need for orthognathic surgery in end-stage treatment. Although Center B did have worse scores than the other four centers, when the analysis accounted for multiple comparisons, the scores for Center B were significantly worse than Center C, but not Centers A, D, and E. When multiple comparisons are part of intercenter studies, the statistical analyses must account for these multiple comparisons and any conclusions drawn with scrutiny. Although the overall treatment protocol for Center B did produce outcome results with poorer Goslon scores, attributing the poor Goslon scores attached to Center B to any one part of its treatment protocol was not strongly supported by either the statistical results or the nature of intercenter comparison studies.

However, multiple possible explanations for the poor Goslon scores for Center B can be made. Over the past number of years, most cleft teams in North America have adopted secondary alveolar bone grafting as part of their treatment protocols due to the evidence supporting better dental and periodontal health, as well as skeletal growth, compared with primary bone grafting. In the past, claims for acceptable long-term results from primary bone grafting had been presented (Rosenstein et al., 1982; Rosenstein et al., 1991). Center B, the only center to use primary bone grafting, was also the only center with a majority of Goslon scores of 4 and 5 and a significantly higher (worse) mean Goslon score than the other centers. These results suggest that some aspect of the treatment protocol or characteristic of Center B had a negative impact on dental arch relationships. With the evidence in the literature showing a negative impact of primary bone grafting on maxillary growth and Center B as the only center in this study using primary bone grafting, it could be suggested that primary bone grafting is an aspect of treatment causing this poor interarch relationship. Although, as explained above, it is not possible to completely assign weight or a causal effect to specific aspects of treatment, it is noted that the Eurocleft study also found the poorest quality of outcomes for centers that used primary alveolar bone grafting. When compared with the Eurocleft center mean scores, Center B had an even higher

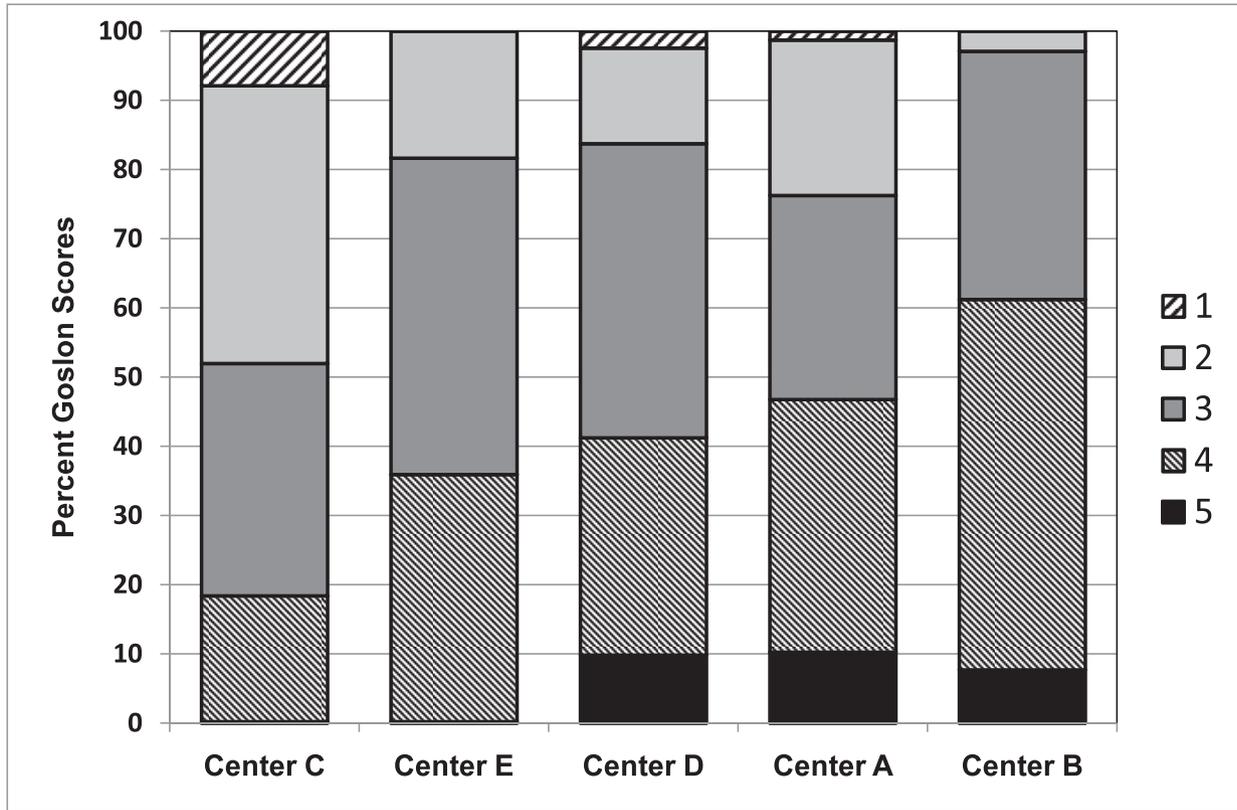


FIGURE 3 Distributions of Goslon scores between 1 (*excellent*) and 5 (*very poor*) within each center are shown.

mean score (poorer result) than all centers in the Americleft as well as in the Eurocleft studies (Fig. 4).

Although the statistical results from the Eurocleft study and the Americleft study cannot be directly compared statistically because the raw data are not available, descriptive comparisons can be made given that the same methodology was intentionally used in the present study. A similar range of Goslon scores was seen in the present study as compared with the Eurocleft study as well as the significantly worse scores for the centers that used primary bone grafting.

It also may be possible that the palatoplasty technique used for patients from Center B contributed to attenuated maxillary growth because this technique was unique to this center. Studies have shown that the Wardill-Kilner push-back palatal surgical procedure, the procedure used at Center B, has produced poorer maxillary development (Palmer et al., 1969; Friede and Lilja, 1994). Although this was not seen in the Eurocleft study for the centers using this palatal surgery, it may be a contributing factor to the overall poorer Goslon scores for Center B, possibly in combination with primary alveolar bone grafting. This emphasizes the combined effect of all aspects of the treatment protocol and cautions one against assigning causation to certain specific aspects of treatment.

General agreement exists regarding the use of midfacial growth as an indicator of beneficial or harmful surgical outcomes. Previous reports that indicated satisfactory

results from primary alveolar bone grafting were limited to cephalometric comparison studies such as those of Rosenstein and from a dental arch dimension study (Hathaway et al., 1999). When outcomes of primary surgical cleft treatment are evaluated with respect to dentoskeletal characteristics, it is important to consider not only the occlusion but also the maxillomandibular skeletal relationships relative to the rest of the facial skeleton. Looking at the positions of the teeth in isolation does not provide the necessary information on the positions of the skeletal bases, and neither do dental arch dimensions using absolute linear distances within a single jaw contribute to an understanding of maxillomandibular relationships. Any assessment of maxillomandibular skeletal relationships and the effect of treatment on midfacial growth must include assessment of the maxilla, the mandible, dental arch relationships, and, to a lesser degree, dental relationships. In this way, the Goslon Yardstick is a very effective method to assess treatment outcomes. This issue is further addressed in depth in the following paper, part 3, where comparisons between the Goslon dental arch relationships are compared with cephalometric measures.

Although Center C had significantly better Goslon scores compared with the other four centers, there were no unique aspects to the treatment protocol that would lead to a hypothesis explaining the better result. The Eurocleft study, however, did conclude that the centers with fewer surgeons and a limited amount of treatment intervention

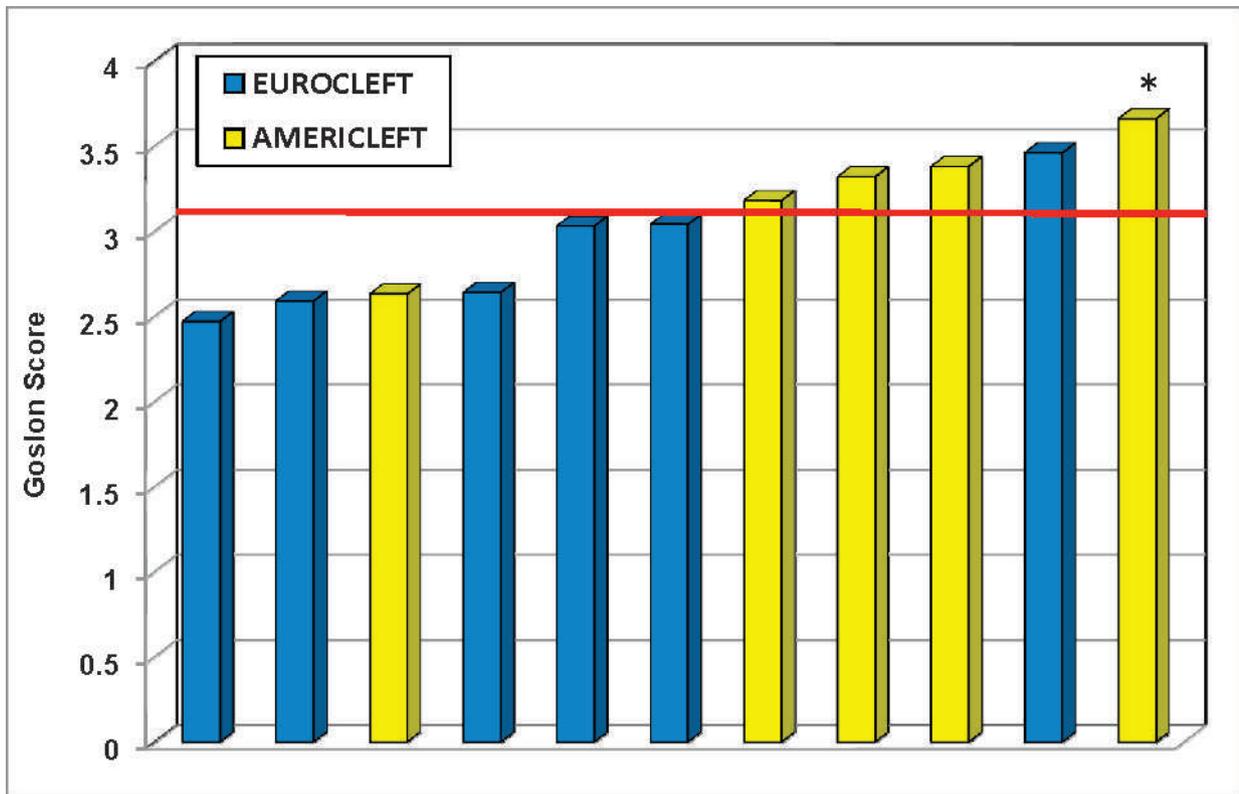


FIGURE 4 Comparison Goslon scores for the Americleft and Eurocleft Centers. Center B from the Americleft Study is shown as the center with the highest (worst) Goslon score. * Americleft Center B.

did tend to have better outcomes. Center C did indeed have only one surgeon performing all of the surgeries; as well, any surgical revisions were performed after 14 years of age, closer to the end of maxillary growth compared with other centers. Thus, our results were again generally consistent with those seen in the Eurocleft study.

The lack of unanimity in the quality of the results among the other four Americleft centers is observed and shown in Figure 3, even though no statistical significances were determined among them. The protocols of Centers A, B, D, and E varied and there were no prominent, overriding aspects of the treatment protocols that could be linked with maxillary growth restriction and poor interarch relationships other than those mentioned previously. Thus, it is not possible to ascribe a reason to the differences in the quality of outcomes suggested by the Goslon scores of these four centers. The number of surgeons, experience and skill of the surgeons, use or nonuse of a standardized protocol, and the surgical timing and sequence of procedures can all be suggested as factors that influenced the final outcomes.

CONCLUSIONS

In the absence of prospective studies, intercenter retrospective studies using analyses such as the Goslon Yardstick can differentiate among dental arch relationships and further constitute a basis to evaluate favorable or unfavorable maxillary growth related to various treatment

protocols for patients with CUCLP. The Goslon Yardstick has been shown to be a reliable and efficacious method to identify differences in treatment outcomes based on interarch relationships. In this study, the Goslon Yardstick identified one center of five with significantly better and another with significantly poorer dental arch relationships; this poorer center's treatment protocol was unique from all others in that it was the only center that used primary bone grafting. In light of these results, the center conducted a review of its treatment protocol, specifically the future use of primary bone grafting for patients with CUCLP.

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