Original Article

Quality Improvement of Cleft Lip and Palate Treatment

Birte Prahl-Andersen[a]; Qiao Ju[b]

ABSTRACT

Improvement of quality of care for children with clefts requires longitudinal assessments of the outcomes of treatment. The aim of this study was to review the teamwork periodically to evaluate the clinical treatment outcome. In this retrospective study, the outcome of the dental arch relationship was studied using a Goslon yardstick between two cohorts of complete unilateral cleft lip and palate patients. Consecutive series of 9-year-old patients (27 boys, 20 girls) born in 1983–1984 and 1992–1993 from two cleft centers were compared. All the patients were treated according to the same protocol. The results show no statistically significant difference between the cohorts of 1980s and 1990s ($P = .170$). The treatment results of center A as measured in this study are better than those of center R ($P = .003$). A possible explanation for this difference in performance can be the fact that the number of surgeons involved in the care in the center R is higher than that in A. (*Angle Orthod* 2006;76:265–268.)

KEY WORDS: Cleft lip and palate treatment; Quality improvement; Goslon yardstick; Dental arch relationship; Craniofacial malformations

INTRODUCTION

To improve the quality of care for children with facial clefts and other craniofacial malformations, a general acknowledgment of the need for measurement of performance is the real challenge. The measurement of performance should be related not only to outcome but also to the process of care.

Only evidence-based treatment modalities should be adopted. This requirement is difficult to meet at present because hardly any part of the treatment has been tested with proper research designs, such as prospective randomized clinical trials. In a European survey of cleft care in 2001, 194 different surgical protocols were followed for unilateral clefts alone.[1,2]

There is a pressing need to mobilize a critical mass of clinical research expertise and to access sufficiently large samples of patients for adequately powered clinical trial.

To improve the multidisciplinary care for children with clefts, a set of guidelines based on modern management philosophy is needed.[4,5] The total quality management (TQM) concept can be used when striving for better care delivery. TQM is based on three simple rules: work to the patient's satisfaction, measure what you are doing, and seek for continuous improvement. TQM gives a focused approach to professional excellence and the pursuit of high quality. A commitment to quality in cleft care assumes a focus on patient satisfaction, optimal organization, professional development, and adequate financial resources.

At the moment, European health care is scrutinized and the performance measured more precisely than in the past. Two studies initiated by orthodontic professionals should be mentioned in this respect, the Euro-qual project[5,6] and the Euro-cleft project.[1]

During the Euro-qual project, the philosophy of TQM was translated for the orthodontic profession. Mission statements and quality indicators were formulated, and most importantly, consensus was reached among policy makers through a time-consuming process.

The original Euro-cleft study, the six-center study[7–10] launched the methodology of intercenter studies of outcome of treatment of children with cleft lip and palate. Lessons to be learned from these studies are that one should look for simple quality indicators, such as the Goslon yardstick, for the assessment of dental arch relationships, specifically developed for cleft lip and palate patients.[11]

[a] Professor and Chairperson, Orthodontic Department, Academic Centre for Dentistry Amsterdam, Amsterdam, The Netherlands.

[b] Staff member, Orthodontic Department, West China University, Chengdu, Sichuan, People's Republic of China.

Corresponding author: Dr. Birte Prahl-Andersen, Orthodontic Department, Academic Centre for Dentistry Amsterdam, Louwesweg 1, University of Amsterdam, Amsterdam, Noord Holland 1066 EA, The Netherlands (e-mail: b.prahl@acta.nl)

Accepted: April 2005. Submitted: October 2004.

A direct effect of the findings in the six-center study was the installation of the Clinical Standards Advisory Group (CSAG) in Great Britain. The CSAG commissioned an investigation to begin in 1996. One of the conclusions presented in 2001[12] stated: ''A rigorous evaluation of cleft care in the United Kingdom reveals disappointing outcomes.''

In the cleft teams in Amsterdam and Rotterdam, quality improvement projects were started in the 1980s. Protocols regarding the timing of surgery, the timing of record taking, and the visits to the team were implemented. It could be expected that implementation of the procedures would improve the performance and outcome of the treatments. Good cooperation by the patients and strict recording of the development of the children made it possible to do longitudinal research and to monitor the outcome of the cleft care.

The aim of this study was to compare the outcome of the dental arch relationship of two cohorts of unilateral cleft lip and palate patients, consecutive series of 9-year-old patients born in 1983–1984 and 1992–1993. The quality improvement or decrease was demonstrated by the use of the Goslon yardstick and a comparison made between the two centers

MATERIALS AND METHODS

Two cohorts of 47 consecutive treated 9-year-old unilateral cleft lip and palate (UCLP) patients were selected from the files of the Department of Orthodontics, Academic Centre for Dentistry Amsterdam (n = 24) and of the Cleft lip and palate team of the University Hospital in Rotterdam (n = 23). All UCLP patients who were born between 1983 and 1984 and between 1992 and 1993 and referred to the two teams were studied. In Amsterdam, two surgeons operated on the children and, in Rotterdam, eight surgeons operated on the children. The periods 1983/1984 and 1992/1993 were chosen because in these periods, the largest number of patients was referred to the two centers.

The following inclusion criteria were adopted:

- Complete unilateral cleft lip and palate, nonsyndromic, diagnosis being confirmed by neonatal photographs or clearly written hospital notes, or both;
- Cases should be treated by the same surgical protocols;
- Dental study models should be available at the age of 9 years.

Table 1 shows the distribution of study models in the two cohorts according to team. The treatment protocol used was primary lip repair at 4–6 months of age, soft palate closure at 9–12 months of age, and hard palate closure together with bone grafting to the alveolar process at 8–9 years of age.

TABLE 1. Distribution of the Study Models in the Two Cohorts According to the Team

Models	1980s	1990s	Total
Amsterdam	11	13	24
Rotterdam	12	11	23
Total	23	24	47

Some of the patients had presurgical orthopedic treatment (PSOT). According to the results of prospective clinical research performed in the same teams,[13] no difference in dental arch relationship between patients with and without PSOT could be detected after the age of 1½ years. Therefore, no special attention was given to this possible contaminating factor.

The dental study models of the 9-year-olds were assessed twice using the Goslon yardstick.[11]

Because it is essential to eliminate bias, the models were numbered randomly and rearranged after the first assessment. Two assessors ranked the models on two separate occasions after a training session with an expert.

The Goslon yardstick is designed to rank the dental study models of unilateral cleft lip and palate subjects in the early permanent dentition, before the start of definitive orthodontic treatment. It has a scale of five categories of dental arch relationships. Group 1 represents the most favorable, with a positive overjet and overbite that would be treated only by conventional orthodontics. Group 5 would generally require orthognathic surgery because of the severity of a skeletal Class malocclusion.

Interexaminer agreements were evaluated with the kappa calculations. The mean scores of the models from the two centers were analyzed using Mann-Whitney test.

RESULTS

The interexaminer agreement is 0.58. A kappa value above 0.4 suggests moderate agreement, whereas 0.6 and above indicates good to very good agreement.

Figure 1 shows the results of the comparison between children born in the 1980s and the 1990s. There is no statistically significant difference between the two cohorts ($P = .170$). Figure 2 shows that the treatment results of center A as measured in this study are better than the results of center R. This difference is statistically significant ($P = .003$).

From the results of the Amsterdam team (Figure 3), the outcome as measured by the Goslon yardstick is better in the old cohort than in the younger cohort. However, the sample is small, and no statistical difference could be demonstrated.

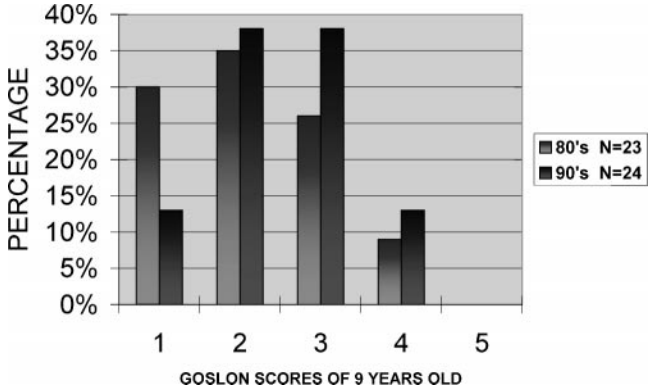

FIGURE 1. Dental arch relationship as measured by the Goslon yardstick. Scores from the two centers are pooled.

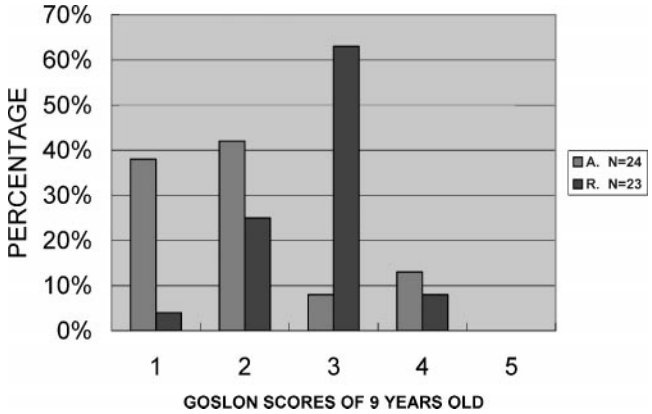

FIGURE 2. Dental arch relationships as measured by the Goslon yardstick. The scores from the cohorts are pooled.

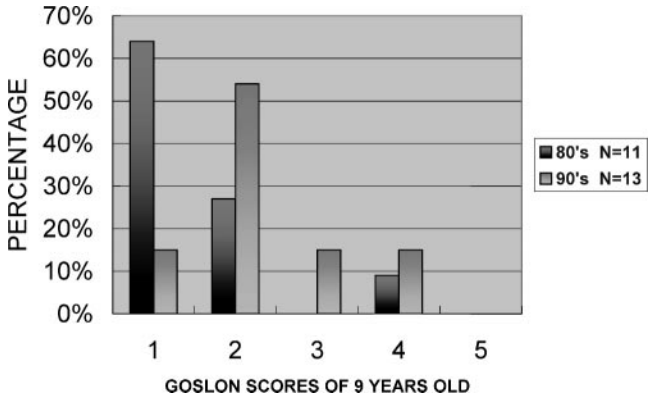

FIGURE 3. Distribution of the Goslon scores of the two cohorts from center A.

DISCUSSION

The Goslon yardstick was applied in the Euro-cleft study[8] and other studies.[12,14–16] It is shown to be highly reliable in cross-center studies, with kappa statistics for interexaminer agreement as high as 0.94 in the national British survey.[12] The kappa statistics of 0.58 calculated in this study may be explained by the lack of experience by one of the assessors.

When the results of this study are compared with results from the literature, the general impression is that the care in the two Dutch centers is better than that in many other countries. In center A 13% of the cases and in center R 8% were in group 4, and no cases were in group 5. Until now, no other centers are known to have no cases in group 5. In the CSAG report,[12] 13% of the cleft children were in group 5; this is a very poor result.

A few study designs are important when trying to improve the team effort. One design is the longitudinal design and the other the time-lag design. Longitudinal designs are adopted in medical technology assessments; measurements are typically taken at selected occasions in an underlying time continuum. Observations of a particular individual at each time will not be independent, and the variance may increase with time. Time-lag studies are used when studying secular trends, and in this study, no improvement in the performance of the two centers over a period of 9–10 years could be demonstrated. Of course, only dental arch relationships have been used as a measure for performance. But a significant difference was found between the two Dutch centers. A possible explanation for this difference in performance can be the fact that the number of surgeons involved in the care in center R is higher than that in center A. The same conclusion was drawn by the authors from the Euro-cleft study[10] and the CSAG report on the situation in Great Britain.[17]

The two teams did not differ in protocol, organization, or number of specialties involved in the multidisciplinary cleft care. The total caseload in center R is higher at 50–60 new cleft cases per year, in contrast to center A, with a yearly intake of 20–30 new cases per year. This should have increased the quality of care in center R because theoretically, more expertise and skills are available. A possible explanation can be that the expertise in center R has been diluted (eight surgeons involved).

The value of all the international comparisons of quality of care that are published more and more often can only at best contribute to the improvement of care of the team with the worst results.[18] Taking quality indicators developed in one country and simply using them in another is inappropriate because professional culture and clinical practice differ, as well as healthcare financing and organization. Straightforward comparisons are difficult, as evidenced in the Euro-cleft study. In some cases, the quality indicators reveal considerable variation in performance between centers, as was demonstrated in the Euro-cleft study. But

only a few patients are aware of this, simply because they do not have the information.

Marshall et al[19] recommended collaboration between countries in the development of quality indicators because the said indicators cannot be transferred between countries. In relation to this study, this would mean that a more discriminatory yardstick should be developed for the Dutch situation. It means that indicators have to be developed through a process of modification. This exercise was carried out for the Euro-qual study.[1] European orthodontic policy makers within the orthodontic healthcare system reached consensus on all the quality indicators. In the Euro-cleft project this was not achieved, but an inventory of services in Europe, mission statements, and recommendations for good practice were formulated and agreed on.

When it comes to implementing procedures that can improve the quality of care, a rather pessimistic view has been brought forward by Sandy.[20] Sandy reported that despite all the evidence put forward in the CSAG report, it is very difficult to change the system in Great Britain, mainly because of politics. It is evident that change management is the key to success, and steps such as coalition building, dealing with resistance, breaking down barriers, making the need for change felt, increasing benefits, and reducing the risk of failure should be part of the management strategy for the improvement of cleft care. In the words of Machiavelli: ''There is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to handle, than to initiate a new order of things,'' and these words explain the frustration felt by many professionals in cleft care.

CONCLUSIONS

- Treatment outcome as a measure for quality development in cleft care can be tested using the Goslon yardstick.
- But consensus on additional quality indicators of cleft care should be reached.

REFERENCES

1. Shaw WC, Semb G, Nelson P, Brattstrom V, Molsted K, Prahl-Andersen B, Gundlach KK. The Euro-cleft project 1996–2000: overview. *J Craniomaxillofac Surg.* 2001;29(3): 131–140.
2. Spriestersbach DC, Dickson DR, Fraser FC, Horowitz SL, McWilliams BJ, Paradise JL, Randall P. Clinical research in cleft lip and palate: the state of the art. *Cleft Palate J.* 1973; 10:113–165.
3. Global strategies to reduce the healthcare burden of craniofacial anomalies. Report of WHO meetings on International Collaborative Research on Craniofacial Anomalies WHO. Geneva, Switzerland: World Health Organization; 2002. ISBN 9241590386.
4. Severens JH, Prahl C, Kuijpers-Jagtman AM, Prahl-Andersen B. Short-term cost-effectiveness analysis of pre-surgical orthopedic treatment in children with complete unilateral cleft lip and palate. *Cleft Palate Craniofac J.* 1998;35:222–226.
5. Prahl-Andersen B. Quality development in orthodontic practice. In: Carels C, Willems G, eds. *The Future of Orthodontics.* Leuven, Belgium: Leuven University Press; 1998:239–248. ISBN 90 6186 9048.
6. Njio BJ, Prahl-Andersen B, Heege G ter, Stenvik A, Ireland RS. *Quality of Orthodontic Care: A Concept for Collaboration and Responsibilities.* Amsterdam, The Netherlands: IOS Press; 2002:43–63. ISSN 0929-6743.
7. Asher-McDade C, Brattstrom V, Dahl E, et al. A six-center international study of treatment outcome in patients with clefts of the lip and palate: part 4. Assessment of nasolabial appearance. *Cleft Palate Craniofac J.* 1992;29(5):409–412.
8. Mars M, Asher-McDade C, Brattstrom V, et al. A six-center international study of treatment outcome in patients with clefts of the lip and palate: part 3. Dental arch relationships. *Cleft Palate Craniofac J.* 1992;29(5):405–408.
9. Molsted K, Asher-McDade C, Brattstrom V, et al. A six-center international study of treatment outcome in patients with clefts of the lip and palate: part 2. Craniofacial form and soft tissue profile. *Cleft Palate Craniofac J.* 1992;29(5):398–404.
10. Shaw WC, Dahl E, Asher-McDade C, et al. A six-center international study of treatment outcome in patients with clefts of the lip and palate: part 5. General discussion and conclusions. *Cleft Palate Craniofac J.* 1992;29(5):413–418.
11. Mars M, Plint DA, Houston WJ, Bergland O, Semb G. The Goslon Yardstick: a new system of assessing dental arch relationships in children with unilateral clefts of the lip and palate. *Cleft Palate J.* 1987;24(4):314–322.
12. Williams AC, Bearn D, Mildinhall S, Murphy T, Sell D, Shaw WC, Murray JJ, Sandy JR. Cleft lip and palate care in the United Kingdom—the clinical standards advisory group (CSAG) study. Part 2: dentofacial outcomes and patient satisfaction. *Cleft Palate Craniofac J.* 2001;38(1):24–29.
13. Prahl C, Kuijpers-Jagtman AM, van't Hof MA, Prahl-Andersen B. A randomised prospective clinical trial into the effect of infant orthopedics on maxillary arch dimensions in unilateral cleft lip and palate (Dutch cleft). *Eur J Oral Sci.* 2001; 109(5):297–305.
14. Hathorn I, Roberts-Harry D, Mars M. The Goslon yardstick applied to a consecutive series of patients with unilateral clefts of the lip and palate. *Cleft Palate Craniofac J.* 1996; 33(6):494–496.
15. Morris DO, Roberts-Harry D, Mars M. Dental arch relationships in Yorkshire children with unilateral cleft lip and palate. *Cleft Palate Craniofac J.* 2000;37(5):453–462.
16. Pigott RW, Albery EH, Hathorn IS, et al. A comparison of three methods of repairing the hard palate. *Cleft Palate Craniofac J.* 2002;39(4):383–391.
17. Bearn D, Mildinhall S, Murphy T, Murray JJ, Sell D, Shaw WC, Williams AC, Sandy JR. Cleft lip and palate care in the United Kingdom—the clinical standards advisory group (CSAG) study. Part 4: outcome comparisons, training, and conclusions. *Cleft Palate Craniofac J.* 2001;38(1):38–43.
18. Donabedian A. *Explorations in Quality Assessment and Monitoring. Vol. 1. Definition of Quality and Approach to its Assessment.* Ann Arbor, Mich: Health Administration Press; 1980.
19. Marshall MN, Shekelle PG, McGlynn EA, Campbell S, Brook RH, Roland MO. Can health care quality indicators be transferred between countries? *Qual Saf Health Care.* 2003;12(1):8–12.
20. Sandy JR. Molecular, clinical and political approaches to the problem of cleft lip and palate. *Surgeon.* 2003;1:9–16.