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Evolution of Cleft Lip and Palate Surgery and the Pursuit for Consensus on Standardized Algorithms of Care

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Summary: Cleft lip and palate (CLP) surgery has evolved over centuries in an attempt to achieve anatomical closure while optimizing speech and limiting fistulas and midface hypoplasia. Masters of cleft surgery and early pioneers inspired generations of surgical innovators to refine techniques and timing to improve surgical outcomes. Constant modification has resulted in significant diversity of cleft surgical protocols across institutions. Unlike many other surgical conditions, there is no gold-standard algorithm of care for CLP. Several international consortiums, including Eurocleft, Americleft, and Scandcleft, aimed to investigate the ideal cleft care protocol. Despite the inclusion of multiple institutions and attempts at long-term follow-up, these studies were limited by small sample sizes, lack of diversity in patient population, poor long-term follow-up, lack of standardized measurement tools, and inability to control for confounders such as severity. This article aimed to present the findings of these early pioneer consortiums in their pursuit for the optimal CLP surgical protocol and recommend a direction for future research with a global consortium of experts in cleft care. *(Plast Reconstr Surg Glob Open 2025;13:e6643; doi: 10.1097/GOX.0000000000006643; Published online 20 March 2025.)*

INTRODUCTION

Cleft lip and palate (CLP) represents the most common congenital anomaly globally, with low- and middle-income countries (LMICs) shouldering the majority of the burden.[1–4] CLP repair is challenging and has evolved over centuries to achieve functional anatomic closure with optimal speech outcomes while limiting complications such as fistulas and midface hypoplasia (MFH). CLP surgical techniques have historically been taught in a master-apprentice type fashion. Through technique modifications over generations, we have, arguably, moved further from a consensus on CLP repair techniques and timing that will allow for optimal surgical outcomes. Although no 2 clefts are the same, evidence-based practice has long been a cornerstone of surgery and a gold standard of care could improve outcomes, reduce complications and facilitate training. Consortiums, such as Eurocleft, Americleft, and Scandcleft, have been built in an attempt to evaluate a gold standard protocol; however, these studies were met with limitations.[5–10] This article highlights the evolution of cleft surgery and the findings and limitations of previous pioneer cleft consortiums, and recommends a direction for future research.

SURGICAL HISTORY

The first report of cleft lip repair dates back to 390 BC, but innovation in repair techniques rapidly progressed in the 20th century.[11–13] Veau focused on re-approximation of the orbicularis oris, whereas Le Mesurier used a quadrilateral flap to improve definition of Cupid's bow.[11] Tennison, Randall, Millard, and Mohler all advanced these techniques, leading to the straight line and rotation-advancement repairs.[14–16] Their techniques aimed to achieve greater aesthetics by gaining more philtral height.[14–16] Precision increased through the years with greater attention to measurement and detail, evolving from "cut-as-you-go" to the modern-day anatomical subunit approach described by Fisher[17] to

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improve reproducibility through mathematically determined landmarks.

First reports of soft palate repair originated with Le Monnier in 1764, whereas Dieffenbach was the first to report hard palate repair in 1826, followed by von Langenbeck's bipedicle greater palatine artery flap in 1859.[12,13,18] The most significant innovations in soft palate surgery came with the understanding of the aberrant velopharyngeal anatomy of the cleft palate. Veau's and Kriens' contributions to muscular reorientation and recreation of the velopharyngeal sling inspired most techniques used today.[19–21] Bardach expanded on the principle of using greater palatine flaps, first describing his 2-flap technique in 1967.[12,22,23] Furlow further built on these concepts and attempted to gain even more length while reorienting the muscle with a Z-plasty, whereas Sommerlad[21] was the first to introduce a microscope for palatoplasty in the pursuit of precision.[12,19,20]

Over decades, the principal goals of repair also evolved, starting from simple anatomic closure to the addition of muscle repair and achieving maximal length. Additionally, institutions gained awareness of long-term complications such as secondary lip deformities, velopharyngeal insufficiency (VPI), fistulae, and MFH and began varying repair timing in an attempt to limit their occurrence.[8,12,24] In Europe, an early combined lip repair and vomer flap with a delayed soft palatal closure at 18 months or later is commonplace, with the goal of minimizing MFH.[12,25,26] North American centers differ, with some advocating for lip repair as early as the neonatal period and earlier palatoplasty than European institutions to prioritize speech outcomes.[12,27,28]

Significant differences in rates of reported surgical outcomes stem from this substantial variability, not only in technique and timing, but other surgeon and patient factors too. Rates of lip revision are reported between 0% and 100%, and VPI rates are between 2.5% and 25%.[29–32] Rates of orthognathic surgery for MFH are reported between 14% and 75%, and fistula rates are between 0.7% and 60%.[33,34]

THE QUEST FOR CONSENSUS

Variation in protocol as it pertains to technique, timing, and algorithm of care has been a key motivator inciting international collaboration, beginning with the Eurocleft group (Table 1).[9] This group aimed to determine the best cleft protocol by assessing postoperative outcomes between centers using 3 primary measures: (1) the Great Ormond Street, London and Oslo (GOSLON) score for dental arch relationships, (2) cephalometric analysis for skeletal classification, and (3) the Asher-McDade score for nasolabial appearance.[35–37] This study design was replicated by a group of North American centers to allow comparison between the 2 continents, known as the Americleft project (Table 1).[10]

The Scandcleft group took a different approach with a clinical trial of protocols. Their study had 3 arms, each comparing local practice to a single common protocol (Table 1).[38] Their goals were to evaluate (1) acute complications such as postoperative bleeding, infection, and wound dehiscence; (2) nasolabial appearance using a modified Asher-McDade scale; (3) velopharyngeal competence using speech pathology assessment; and (4) maxillary growth with the GOSLON score and cephalometric assessment.[39–43]

Revision surgery rates are considered a proxy for success. Select revision rates were reported by Scandcleft (4.9% underwent lip revision, 1.6% lip and nose, and 0.7% isolated nose revision; VPI surgery at 7.4%) and Americleft (33% underwent secondary lip surgery and 53% underwent secondary rhinoplasty; 19% of children underwent secondary palatal surgery with rates differing significantly between centers).[39,41,42,44] Scandcleft reported rates of secondary surgery at 5 years of age, whereas Americleft patients had a median follow-up of 18 years.[42,44] Understanding of revision rates was limited by lack of long-term follow-up (Scandcleft had a median follow-up of 5 y and Americleft had a median of 18 y). No series specifically reported on MFH rates.

Progress by these international groups was limited by several study design factors: elements of disease natural history, such as cleft severity and intrinsic midface characteristics, not being accounted for; participant selection (phenotype limited by unilateral CLP patients with a complete alveolar cleft and lack of diversity in population); small sample sizes; inability to account for surgeon skill; and limited long-term follow-up.[9,10,38,45,46] Addition of these variables in future work adds significant complexity but is essential for understanding cleft care protocols that can be applied in any setting to optimize outcomes. Table 2 provides a summary of both the key findings and limitations reported by each international group.

THE BARRIERS TO GLOBAL CONSENSUS

Evaluation of surgical outcomes requires long-term follow-up that could span 2 decades to fully evaluate impact on maxillary growth and speech. Long-term follow-up can be difficult to achieve even in high-resource settings.

Takeaways

Question: How has the historical evolution of cleft surgery impacted surgical practice today?

Findings: Despite the innovations of many great surgeons, we are not closer to a "gold-standard" of cleft care. Small sample sizes, limited diversity in phenotype and patient population, limited long-term follow-up, and the lack of standardized assessment protocols were identified as key challenges in previous research. Furthermore, most research on surgical outcomes hails from high-income countries despite the majority of disease burden being shouldered by low- and middle-income countries.

Meaning: A commitment toward global collaboration and collection of high-quality data is required to improve knowledge of surgical outcomes.

Table 1. Description of All Societal Protocols

Center A	Center B	Center C	Center D	Center E	Center F
Eurocleft					
Lip at 3–4 mo (Millard or Skoog) Soft palate at 9–15 mo (von Langenbeck or Perko or Wardill or Kriens) Hard palate at 9 y (alongside ABG)	Lip and hard palate at 3–4 mo (Tennison + vomer flap) Soft palate at 24 mo (Wardill)	Lip at 3–5 mo (variety of techniques) Hard + soft palate at 12–15 mo (variety of techniques)	Lip at 3–5 mo (variety of techniques) Hard + soft palate at 12–15 mo (variety of techniques)	Lip and hard palate at 3–4 mo (Millard + vomer flap) Soft palate at 18 mo (modified von Langenbeck)	Lip and ABG at 3–4 mo (modified Skoog or Tennison-Randall + bone graft) Soft palate at 12–15 mo (Veau-Wardill-Kilner)
Americleft					
Lip at 2–3 mo (Millard), or 5–6 mo (Delaire) Hard + soft palate at 9–12 mo (Bardach), or 5–6 mo (Delaire)	Lip at 2–3 mo (Millard) Hard + soft palate at 11–15 mo (Wardill-Kilner + IVP or Furlow)	Lip at 3 mo (Tennison) Hard palate at 12 mo (Vomer flap) Soft palate at 18 mo (IVP)	Lip at 3 mo (Millard) Hard + soft palate at 12 mo (Wardill + vomer flap)	Lip at 3–4 mo (Millard) Hard + soft palate at 12–14 mo (von Langenback and Vomer flap + Veau pushback)	
Scandcleft					
	Arm A (Common Protocol)	Arm B	Arm C	Arm D	
Surgical protocol	Lip + soft palate repaired at 3–4 mo Hard palate closure at 12 months	Lip + soft palate repaired at 3–4 mo Hard palate closure at 12 mo	Lip repair at 3–4 mo Both soft and hard palate closure at 12 mo	Lip + hard palate repaired at 3–4 mo Soft palate closure at 12 mo	
Trial(s)	Trial 1—A vs B Trial 2—A vs C Trial 3—A vs D	Trial 1—A vs B	Trial 2—A vs C	Trial 3—A vs D	

Specific techniques were not reported for Scandcleft as each trial compared participating centers' standard technical protocol to the common Scandcleft protocol, with a greater focus on timing of repair rather than technique.
ABG, alveolar bone graft; IVP, intravelar veloplasty.

Additional barriers such as transport, infrastructure, and financial cost further complicate long-term follow-up in lower-resource settings.[47–49]

Traditional educational philosophy for cleft surgery may also contribute to the lack of consensus. The "master-apprentice style of teaching has led to regionalization of protocols and substantial variation, making global comparison challenging.

This variation in protocol compounded by the lack of simple standardized evaluation tools further hinders our ability to evaluate surgical outcomes on a global scale. Within the same country or region, surgical outcome assessments and, therefore, criteria for revision may differ, leading to a different criterion for revision.[8] Furthermore, existing evaluation methods examine a singular outcome of interest, such lip appearance, rather than providing a holistic assessment of the patient's appearance, speech, and midface growth in a singular tool. Even within large, coordinated studies such as Americleft or Eurocleft, these barriers have limited robust conclusions.[50–52] Without standardized assessment tools that can be utilized in any setting, comparison of protocols globally will remain elusive.

THE IMPORTANCE OF CONSENSUS IN CLEFT CARE

The described international research groups are all based in high-income countries (HICs). However, 86% of the world's population lives in LMICs, where HIC research may not be easily generalizable.[53,54] According to the Global Burden of Disease data, global prevalence of orofacial clefts is 339,946 in HICs and 4,275,635 in LMICs.[55] Furthermore, a significant amount of cleft care in LMICs is provided by humanitarian organizations such as Operation Smile and Smile Train, among others.[56,57] Participating surgeons from all over the world use their own techniques and protocols on short-term programs. These protocols may not be generalizable to LMIC populations, where patients present later and resources are limited and, therefore, may not lead to reproducible surgical outcomes. However, the myriad techniques from various institutions represents decades of surgical knowledge and an opportunity to draw upon that knowledge to build an armamentarium of surgical protocols to tackle any presentation of cleft. The inclusion of LMIC providers will augment our understanding of surgical outcomes and help to establish improved standards of care.

Table 2. Key Findings and Limitations of Each Societal Research Group

Cleft Society	Finding Category	Finding Description
Eurocleft	Surgical technique	1. The 2 centers employing vomer flaps performed the best on utilized scoring metrics 2. No different in Asher-McDade scores between centers
	Surgical timing	1. No conclusions able to be drawn
	Other significant findings	1. Centers with high-volume surgeons performed better 2. No correlation between use of presurgical orthopedics or Asher-McDade score and patient satisfaction with appearance
	Limitations	1. Sample sizes too small 2. Inability to stratify for surgeon skill 3. No universal speech assessment across different languages 4. Asher-McDade score unable to differentiate between centers
Americleft	Surgical technique	1. The best performing centers also used vomer flaps as with Eurocleft 2. No different in Asher-McDade scores between centers
	Surgical timing	1. No conclusions able to be drawn
	Other significant findings	1. Performance on all evaluation metrics similar to Eurocleft centers 2. Negative correlation between GOSLON and ANB angles, positive correlations between GOSLON, and SNA and SNB angles. Demonstrates predictive value of the GOSLON as well as suggesting that worse dental outcomes are due to worse maxillary growth
	Limitations	1. Sample sizes too small 2. Inability to stratify for surgeon skill 3. Difficulty with long-term follow-up 4. Different postoperative evaluation protocols between centers leading to data loss 5. Asher-McDade score unable to be differentiated between centers
Scandcleft	Surgical technique	1. No difference in dental arch outcomes as measured by GOSLON between different techniques 2. Common arm (A) had significant more airway complications in trials 2 and 3, and significantly more patients with palatal dehiscence in trial 3. Surgeons cited unfamiliarity with the new techniques as a potential reason
	Surgical timing	1. No significant differences between trials or arms of each trial regarding the timing of palatal repair on SNA or ANB angles
	Other significant findings	1. Differences in nasolabial appearance scores between trials. However, no stratification between surgical techniques was reported
	Limitations	1. Commitment/recruitment challenges due to trial length 2. Difficulty in learning the new technique for arm A 3. Inability to stratify for surgeon skill 4. Poor standardization of postoperative images, radiographs leading to significant data loss

In the post-COVID-19 era, the appetite for education in CLP surgery is accelerating as countries aim to increase their local capacity to provide cleft care. As a community, the cleft surgical society has a responsibility to trainees globally, to equip them with evidence-based algorithms for care that can be used in any setting.

Not only are complications and poor surgical outcomes devastating for patients and their families, but they are also costly.[58] Multiple revision procedures can lead to significant morbidity, disability-adjusted life-years, and loss of economic productivity. Conversely, optimizing outcomes of primary CLP repair can have significant economic benefit and be as cost-effective as some childhood vaccinations.[59–62]

RECOMMENDATIONS FOR MOVING TOWARD GLOBAL CONSENSUS

To achieve global consensus on standardized algorithms of care that can be applied to any setting, particularly with respect to technique and timing, we need higher-quality data with greater generalizability to a global population. We recommend that future research include standardized assessments, greater sample sizes, more diverse populations, and the ability to account for confounding factors such as severity. As a critical next step in the progression of CLP research, we propose the following: (1) the development of a standardized assessment tool that can be utilized in any resource setting and (2) the involvement of providers from LMICs in data collection of long-term surgical outcomes. Increased collaboration would encourage larger, more diverse sample sizes and allow advancement of the work already done by cleft societies. We acknowledge that there is substantial variation not only in the presentation of CLP but also in the healthcare resource settings in which they present. As such, there is likely not one standardized protocol for every setting; global collaboration should aim to develop a selection of evidence-based protocols that can be applied to any setting.

CONCLUSIONS

Through centuries, cleft surgical techniques have evolved by innovation from surgeons worldwide. Multiple international societies recognized the importance of evaluating surgical outcomes but were met with limitations. Inadequate sample size, variable long-term follow-up, lack of standardized evaluation tools, and diversity of patient populations have limited these societies' ability to establish conclusions on techniques and timing that would

optimize surgical outcomes. Furthermore, international research has been limited to HICs, despite LMICs shouldering the highest burden of CLP. With the diversity in cleft phenotype and severity, we recognize that there is no single protocol that fits every setting. However, we can build on the work of these international societies and seek to standardize evidence-based recommendations that may reduce secondary deformities of the lip and nose while also improving speech outcomes and limiting MFH and fistulae. Achieving this goal necessitates a drive toward global collaboration to collect higher quality data that will allow us to better understand surgical outcomes in cleft care.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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