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# Optimizing Outcomes in Cleft Surgery

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## Abstract

Children born with cleft lip and palate in low- and middle-income countries (LMICs) have limited access to surgical care and suffer substantial morbidity as a result of delayed treatment. Charitable organizations have sought to tackle this problem through high-volume surgical missions, but these efforts have been fraught with high rates of complications and variable esthetic results. Over the past decade, Operation Smile (OS) has placed considerable emphasis on improving the quality of care delivered to patients in LMICs. By establishing an outcome evaluation program among other interventions, OS has achieved measurable improvements in complication rates and post-operative follow-up. The founding of the Guwahati Comprehensive Cleft Care Center in India has been pivotal to the success of OS's work in this field and is the evidence of the impact that an optimized model of care delivery can make. Here we describe OS's efforts to improve the quality of care delivered to patients in LMICs with a focus on the organization's work in India.

**Keywords:** cleft lip and palate, low and middle-income countries, global surgery, models of health care delivery, quality improvement

## 1. Introduction

Clefts of the lip and palate are among the most common congenital deformities, occurring in about 1 in 500 to 1 in 1000 births worldwide [1]. In many areas of the world, the number of patients with clefts far exceeds the capacity of the healthcare system to treat them. Consequently, only a fraction of the affected population receives treatment, resulting in a global backlog of over 600,000 untreated patients, with 72,000 in India alone [2]. Clefts of the lip and palate can have devastating consequences. Children with cleft palate have difficulty with speech and feeding, which can lead to malnourishment and developmental delay [3, 4]. Children with cleft lip face social stigma and often have lower levels of education and greater unemployment compared to their peers, despite having normal intellectual capacity [5–7].

The global response to this problem over the past several decades has been immense. Charitable organizations have provided more than 1 million free cleft repair surgeries and trained local surgeons to perform these procedures [8]. Historically, the success of these outreach efforts has been measured by the number of patients served, and little emphasis has been placed on the quality of care delivered. Research related to surgical missions is needed but seldom performed, often due to limited funding, manpower, and time [9, 10]. The logistical challenges of

locating former patients, varying degrees of patient compliance, and coordinating follow-up with local providers have also been noted as barriers [11, 12].

What little data that exists indicates that cleft mission work in low and middle-income countries (LMICs) has at times been associated with poor outcomes [8]. Complication rates following cleft palate repair in these settings often approach 30% and follow up rates are understandably much lower than at tertiary care centers in developed nations [13, 14]. In order to bridge this gap, thoughtfully designed quality improvement measures must be implemented, and outcomes must be tracked over time to prove the efficacy of these interventions. Recently, various groups have contributed to a growing body of literature related to such efforts, and some substantial improvements have been reported [13, 15, 16].

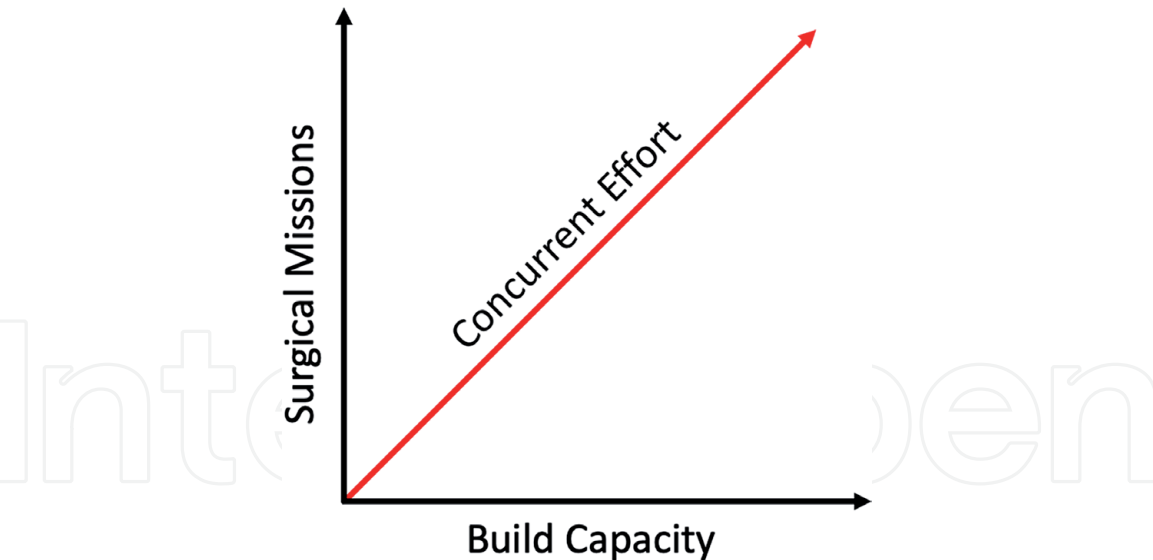
In this chapter, we discuss Operation Smile's quality improvement efforts in global cleft care during the past decade and review their impact on measured outcomes. Operation Smile (OS) is an international not-for-profit organization that has provided hundreds of thousands of free cleft lip and palate surgeries to patients in LMICs since 1982. The organization has placed an emphasis on optimizing patient care through research and maintains electronic medical records and photo documentation for all treated patients. By analyzing data collected from missions and cleft centers, OS has been able to implement standardized protocols and quality control mechanisms that have resulted in decreased complications and increased access to cleft care in LMICs.

## **2. Models of cleft care delivery**

Charitable foundations have supported cleft missions to LMICs since the late 1960s. Early efforts followed a vertical model of care delivery in which teams are sent to underserved regions for short-periods of time to provide surgical care. This model has often been criticized for its emphasis on patient volume over quality, and for its inherently limited provision for post-surgical follow up [8]. Other criticisms include the marginalization of local providers whose welfare may be threatened by foreign aid, and the use of missions as a training ground for surgeons with little experience in cleft lip and palate repair [17]. Despite these criticisms, cleft missions have been an impactful mean to serve a large number of untreated patients and are essential in parts of the world where cleft care is otherwise nonexistent.

A horizontal model of care delivery focuses solely on building local capacity by partnering with area institutions and equipping them to become autonomous centers for comprehensive cleft care. This is accomplished through long-term financial commitments and by providing training to local surgeons, with the goal of ultimately making foundational support obsolete. The horizontal model has been effective in many LMICs, with substantial disability-adjusted life years (DALYs) averted in a cost-effective manner [18, 19]. However, the success of this model hinges on extended periods of investment from charitable organizations, as well as from individual providers, and this limits the scope of this strategy. Additionally, a horizontal program can only be initiated in regions where a care system already exists. Thus, in the most remote areas of the world, surgical missions are still a necessity.

A broadly applicable yet effective strategy for cleft care in LMICs should mobilize surgical missions while simultaneously working to increase the capacity of the local healthcare system, and this has been termed the diagonal model of healthcare delivery (**Figure 1**) [20]. In the state of Assam, India, this model has been utilized to develop a sustainable, high-volume cleft care center that emphasizes empowerment of local providers and continuous quality improvement.



**Figure 1.**  
*In the diagonal model of cleft care delivery, surgical missions are mobilized while simultaneously initiating efforts to increase local capacity. Missions serve as a bridge to the ultimate goal of transitioning care to local surgeons.*

In 2009, OS began missions to Guwahati, a large city in the state of Assam in India. After seeing the outsized burden of untreated clefts in this region, OS partnered with the state government of Assam and with Indian charitable foundations to establish the Guwahati Comprehensive Cleft Care Center (GCCCC) [21]. GCCCC is a surgical specialty hospital dedicated to providing the full spectrum of cleft care to patients who otherwise would not have access to it [22]. Since its opening in 2011, GCCCC has treated over 16,000 patients, while providing a center of operations for follow up and outcomes evaluation [23]. One of the initial goals of GCCCC was to provide training to local providers, and the center is now led entirely by local staff representing plastic surgery, oral surgery, orthodontics, speech pathology, psychology, and nutrition.

Two large missions were held in Guwahati prior to the opening of GCCCC, and this period of transition provides a unique opportunity to compare outcomes between a mission-based model of care delivery and a center-based model. In order to evaluate differences in complications, we performed a retrospective review of 3419 consecutive patients who underwent cleft lip repair and 1728 consecutive patients who underwent cleft palate repair with OS over a 4-year period (2010–2014) [13]. Our results show that early complication rates decreased for both cleft lip and cleft palate repairs with the transition to center-based care at GCCCC ( $p < 0.05$ ) (**Table 1**). For cleft lip repairs, complication rates (infection, wound dehiscence) decreased three-fold from the initial mission, and for cleft palate repairs, complication rates (bleeding, flap necrosis, dehiscence, fistula formation)

	Dec 2010 mission	Jan 2011 mission	GCCCC	<i>p</i>
No. cleft lip repairs	298	356	2765	
Cleft lip complications	13.2%	6.7%	4%	<0.05
No. cleft palate repairs	120	116	1491	
Cleft palate complications	28%	30%	15.8%	<0.05

**Table 1.**  
*Early complication rates after cleft lip and cleft palate repair in Guwahati during the transition from mission-based care to center-based care.*

were halved. These changes are attributable to multiple factors, including the presence of a permanent facility to provide systemized and chronological care, standardized protocols, training of permanent staff in all disciplines, and evolution of techniques over high volumes of cases.

GCCCC was designed from the outset to provide the highest level of care to the people it would serve while integrating the local community into its operations. As the center evolved, various quality metrics began to improve, and this is discussed below. The success in Guwahati highlights the effectiveness of the diagonal model of cleft care delivery, in which surgical missions are initiated with a concomitant effort to build local capacity.

### **3. Patient-centered care**

An effective model of care delivery emphasizes patient-specific needs, and an essential component of such patient-centered care is an intimate understanding of the socioeconomic environment and cultural background of patients' communities. India represents one of the most apparent examples of the growing dichotomy between the rich and the poor. India has the world's 7th largest gross domestic product but ranks 129th in the world with regards to overall standard of living [24, 25]. As of 2018, the per capita income in India was \$2036, and severe disparities exist in terms of income, literacy rates, life expectancy, and living conditions [24]. Access to health care and health care literacy naturally succumb to the same disparities, and this posed a substantial challenge to initial work in Guwahati.

OS conducted two cleft missions to Guwahati in December 2010 and January 2011. During the first mission, it became apparent that there was widespread patient and parent misunderstanding of post-operative instructions. Instructions were given at the discretion of individual surgeons and pediatricians, and patient understanding could not always be confirmed. In response, a standardized, culturally-focused patient education program was initiated during the second mission. Nurses provided individual and group teaching sessions to patients and their parents, going over specific wound care, diet, and hygiene instructions. Additionally, a standardized post-operative instruction sheet was provided to all patients. The instructions were written in Assamese, the local language, and dietary instructions pertained to specific foods that were common in the region. The form also included easy-to-comprehend pictographs for illiterate patients (**Figure 2**).

Of the 220 patients who presented for early follow-up after the first mission, 3.7% had developed lip wound infection and 9.6% developed lip dehiscence. Of the 252 patients who presented for follow up after the second mission, 0.4% had infections and 6.4% developed dehiscence [26]. Logistic regression revealed that patient education was the only covariate that contributed significantly to the decrease in wound infection rates. This demonstrates the powerful impact of addressing disparities in literacy and providing patient-centered care that accounts for community-specific beliefs and practices.

Patient-centered care was also a cornerstone for the design of GCCCC. The center was purpose-built to provide consistent and easy access to multi-disciplinary care for patients with cleft lip and palate. The state-of-the-art facility includes a modern operating suite with an open layout, sophisticated anesthesia and monitoring capabilities, central medical gases, and sterilization facilities (**Figure 3**). Inpatient units were also designed to provide focused pediatric care, education, and rehabilitation. The full breadth of cleft-relevant medical specialties is available



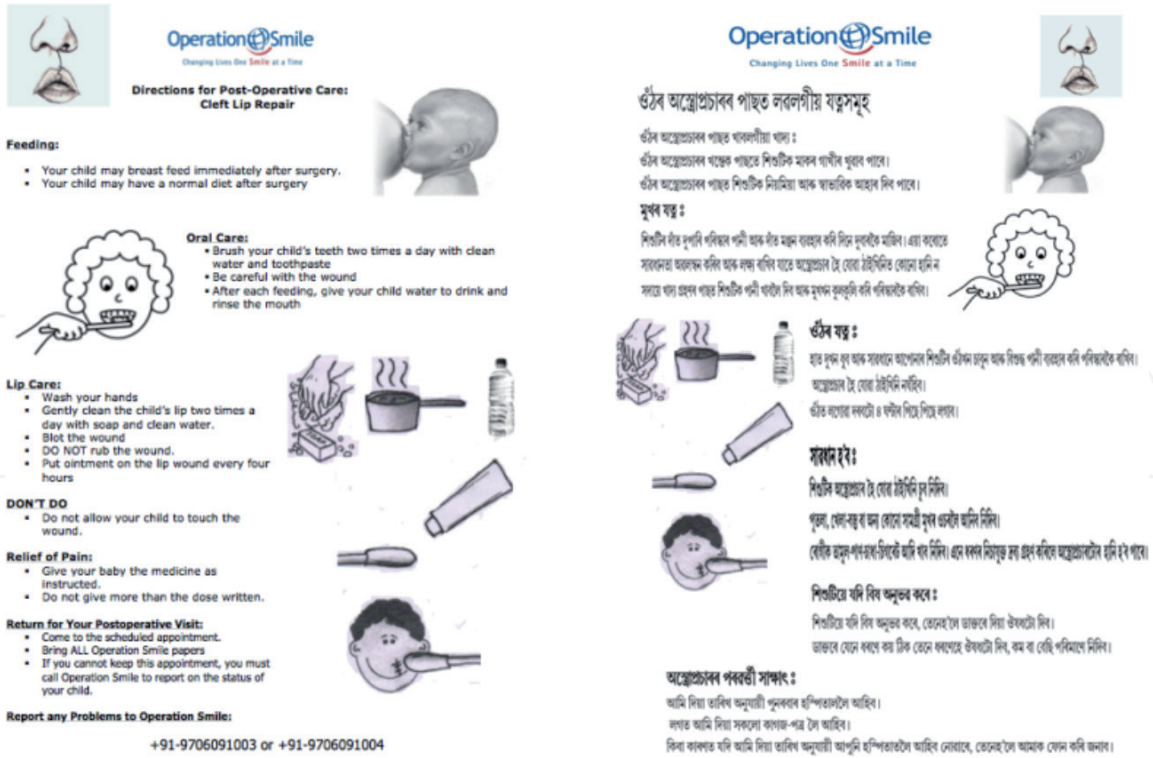


Figure 2.  
Standardized post-operative instructions were printed and provided to patients in the local language, Assamese. Easy-to-understand pictographs were also included for illiterate patients.



Figure 3.  
The Guwahati comprehensive cleft care Center was designed with a modern operating suite with an open layout. This layout facilitates collaboration and teaching among the surgical team.

within the building, facilitating efficient interdisciplinary care for patients. Due to the restraints of providing care in a resource-limited environment, patients undergoing cleft lip repair at GCCCC do not receive preoperative orthodontics. However, post-operative care is provided in all specialties in a longitudinal manner.

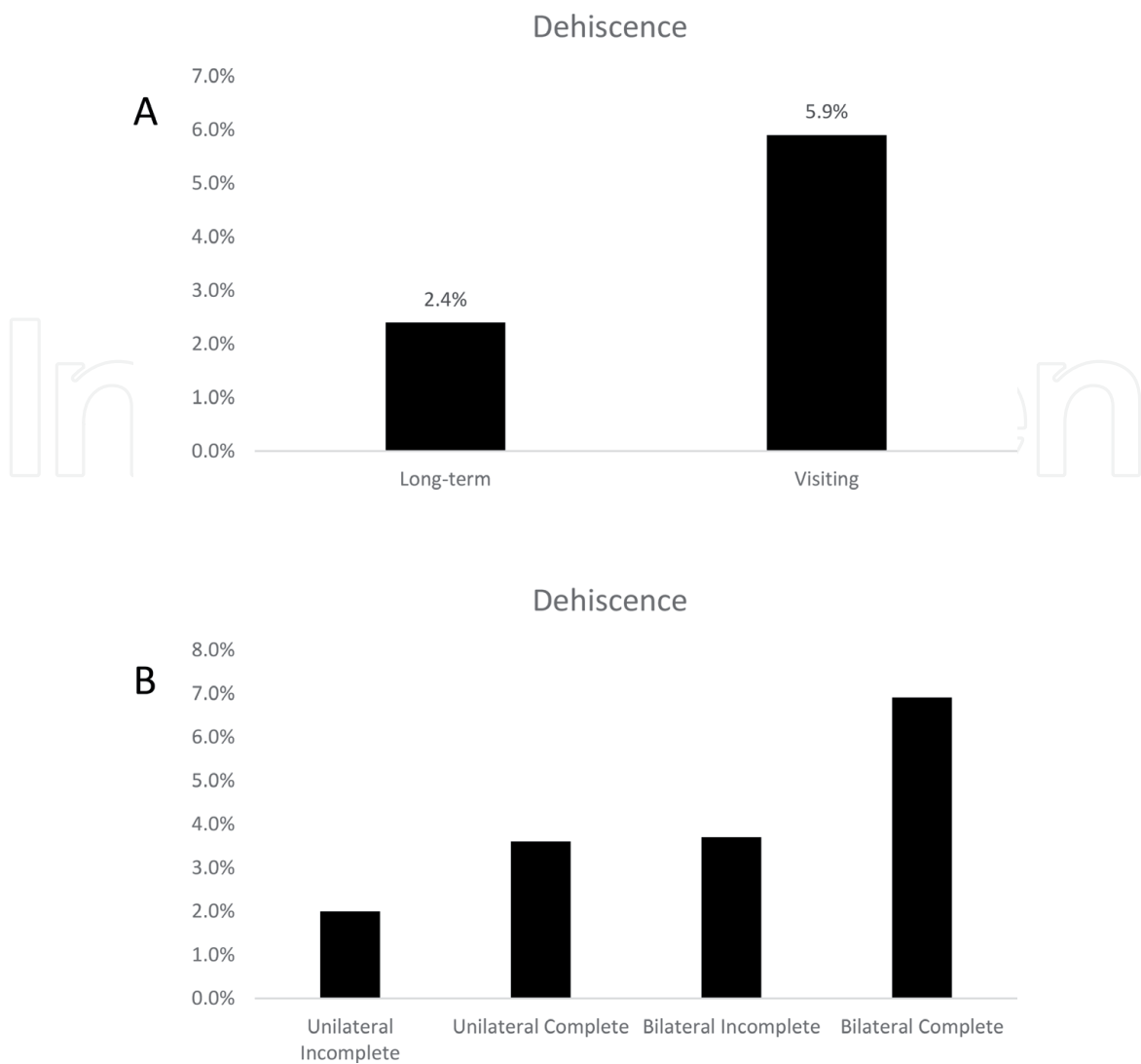
#### 4. Operative and perioperative protocols

In-depth analyses of outcomes from cases completed during the first few years of operation at GCCCC helped establish standardized protocols for the peri-operative and operative care of cleft patients, which is more widely applicable in India and other LMICs. The cumulative effect of these protocols has been to decrease rates of early complications following cleft lip and palate repair as reported in our comparison of mission-based and center-based care. Protocols are supported by a retrospective analysis of outcomes from a consecutive cohort of patients. Our group analyzed rates of early surgical complications from 2062 patients who presented for early follow up after primary cleft lip repair at GCCCC between 2011 and 2013 [27]. All patients received a single pre-operative dose of intravenous cefuroxime, and all patients and families underwent an educational program for post-operative care. Surgical technique was also standardized for the majority of cases (Mohler rotation-advancement technique for unilateral cleft lip and Millard-Mulliken technique for bilateral cleft lip). Malnourished patients were enrolled in a nutrition program and were not operated on until they were considered fit for surgery. Overall, 4.4% of patients developed an early complication (wound dehiscence and/or infection), which represents a three-fold improvement from OS's initial mission to Guwahati. Logistic regression revealed that dehiscence was significantly associated with visiting surgeons (surgeons who were at GCCCC for less than 6 months) (OR 2.64; 95% CI 1.61 to 4.33;  $p < 0.001$ ), complete clefts (OR 1.83; 95% CI 1.07 to 3.11;  $p < 0.05$ ), and bilateral clefts (OR 2.01; 95% CI 1.14 to 3.57;  $p > 0.05$ ) (**Figure 4**). Our results indicate that center-based care and standardized perioperative protocols can improve outcomes in LMIC settings.

A separate analysis of 1408 patients who presented for early follow up after primary cleft palate repair during the same period revealed an early complication rate of 16.9% with a fistula rate of 13.6% [28]. Logistic regression identified cleft type (Veau classification) (OR 1.52; 95% CI 1.27 to 1.81;  $p < 0.001$ ), visiting status of surgeon (OR 1.60; 95% CI 1.15 to 2.21;  $p < 0.01$ ), and increasing patient age (OR 1.03; 95% CI 1.01 to 1.05;  $p < 0.01$ ) as significant contributors to the development of complications (**Table 2**). The results of these analyses collectively indicate that complex cases should only be performed by providers with extensive experience in treating the types of pathology seen in LMICs.

A subsequent study evaluated a subset of 512 patients who underwent cleft palate repair by 6 permanent staff surgeons at GCCCC [29]. The combined fistula rate was 3.9%. Multivariate analysis revealed that Veau IV cleft palates had significantly higher rates of early post-operative complications, but more importantly, that there were no differences in complication rates among the 6 surgeons. The staff surgeons at GCCCC were trained to follow the same foundational principles of cleft palate repair. These includes adequate tissue mobilization for tension-free repair, delicate tissue handling, and multi-layered palatal closure. The outcome of this study validates the training received by the staff surgeons and emphasizes the importance of standardization even in surgeon education.

An additional benefit of center-based care is that it provides the infrastructure necessary for controlled research. Our group performed a prospective, double-blinded, randomized, placebo-controlled study at GCCCC to evaluate the efficacy of extended post-operative antibiotics following cleft palate repair in LMICs [30]. Five hundred eighteen patients were randomized into two cohorts, one receiving 5 days of oral amoxicillin and the other receiving only one pre-operative dose of intravenous cefuroxime. The incidence of early complications was reduced in the treatment group (8.7% vs. 13.8%), highlighting again the importance of tailoring care to the specific communities



**Figure 4.**  
Incidence of wound dehiscence after primary lip repair according to (A) surgeon status (visiting or permanent) and (B) cleft type.

Covariate	OR (95% CI)	p
Cleft Type	1.516 (1.269–1.811)	<0.001
Age	1.028 (1.010–1.045)	<0.01
Surgeon*	1.599 (1.154–2.214)	<0.01

\*Visiting versus long-term (>6 months of service at the center).

**Table 2.**  
Logistic regression analysis of factors related to postoperative complications after primary palate repair.

involved. While patients undergoing cleft palate repair in developed regions uniformly receive only one pre-operative dose of antibiotics, the results of this study show that patients in resource-poor settings with limited access to hygiene benefit from extended antibiotic coverage. This is evidence that rigorous evaluation of outcomes from specific populations helps shape best practices and ultimately improves outcomes.

Based on the data collected from these studies, OS has produced a set of evidence-based recommendations for improving outcomes in cleft surgery (Table 3). These principles continue to direct OS’s efforts to improve outcomes in resource-limited areas all around the world.



1. Implement standardized perioperative protocols for cleft lip and cleft palate.
Standardizing things means all doctors and nurses are doing the same thing and this translates into improved patient understanding and compliance.
Cleft Lip [27]
<ul style="list-style-type: none"><li>• 1 dose pre-operative intravenous antibiotic before incision</li><li>• No post-operative antibiotics</li><li>• No tapes over incisions or other complicated dressings</li><li>• Oral hygiene including washing mouth after eating and brushing teeth twice a day</li><li>• Wash wound two times a day with clean water and blot dry</li><li>• Normal diet with soft foods, breastfeeding okay immediately</li><li>• No chewing tobacco, pan, etc. for older patients</li></ul>
Cleft Palate [28]
<ul style="list-style-type: none"><li>• 1 dose pre-operative intravenous antibiotic before incision</li><li>• 5 days of oral antibiotics post-operatively [30]</li><li>• May breastfeed immediately; liquid diet by syringe / spoon for 1 week; soft diet for three weeks</li><li>• Oral hygiene including washing mouth after eating and brushing teeth twice a day</li><li>• Nothing in mouth</li></ul>
2. Implement standardized patient education program that is taught to nurses then to patients and families [26].
Teaching sessions are held on the ward after surgery before discharge where nurses go through all discharge instructions and provide handouts in the local language with pictographs.
3. Higher risk patients should be done by the most experienced surgeons [28].
Cases to be performed by experienced surgeons
<ul style="list-style-type: none"><li>• Complete unilateral cleft palate</li><li>• Complete bilateral cleft palate</li><li>• Older patients</li></ul>
4. Educate surgeons about optimal techniques for successful outcomes [29].
Complications in cleft palate surgery are very closely linked to technique. Surgeons should be taught to adequately mobilize all tissues for a tension-free repair. Delicate tissue handling is stressed.

**Table 3.**  
*Evidence-based recommendations for improving outcomes in cleft surgery.*

5. Follow up

Post-operative follow-up is an indispensable component of any type of surgical care. It is especially critical in cleft care as speech therapy is a necessary adjunct to realizing the full benefits of palatoplasty. Additionally, longitudinal patient evaluation is important when analyzing outcomes and quality improvement interventions. Unfortunately, follow-up is also one of the most challenging aspects of patient care in LMICs due to the time and financial burden placed on patients, as well as limited access to transportation. In the early stages of operation at GCCCC, significant barriers were noted to follow-up, necessitating a rethinking of the way follow-ups were performed.

The District Outreach Follow-up and Speech Therapy (DOFAST) program was started by GCCCC with the goal of bringing the follow-up to patients instead of having them travel to the center. Small multi-disciplinary teams of providers

were sent to outreach camps near patients living more than 200 km away if there were at least 20 patients to be seen. When patients were evaluated at GCCCC, the direct cost of transportation is covered by the center, but patients must still deal with the indirect costs of travel such as time off from work. These indirect costs are decreased with the DOFAST program, but the costs of staff travel, meals, and lodging had to be covered by the center.

A prospective study was launched to measure changes in follow-up rates and costs after the launch of the DOFAST program [14]. Questionnaires were also completed by 195 patients (122 at GCCCC and 73 at DOFAST camps) to evaluate expenses, time lost, and other patient-related variables. Patients who attended local follow up had fewer accompanying family members, fewer days off work, less lost income (Rs 143 vs. 367;  $p < 0.05$ ) and lower direct costs (Rs 299 vs. 911;  $p < 0.05$ ) compared to patients seen at GCCCC. Post-operative follow-up visits increased from 139 monthly visits (follow-up to surgery ratio of 0.722) to 363 monthly visits (ratio of 1.57). Additionally, the average cost to the center per patient was lower for local follow-up compared to follow-up at the center (Rs. 303 vs. 1100).

## 6. Esthetic outcomes

While complications following cleft lip repairs are widely reported in the literature, esthetic outcomes are rarely assessed. Furthermore, esthetic outcomes after cleft lip repair in LMICs are rarely, if ever, reported. The goals of any quality improvement initiative are not only to reduce complication rates, but also to help patients achieve the best possible esthetic result from their surgery. To that end, OS started the Surgical Outcomes Program (SOP) which aims to critically evaluate post-operative results after cleft lip repair using validated instruments.

The Unilateral Cleft Lip Severity Index was developed as a tool for analyzing and categorizing unilateral cleft lip deformities according to the amount of lip involved and the degree of nasal asymmetry (**Figure 5**) [31]. The severity index was validated in a study measuring the inter-rater reliability of the tool when used by both surgeon and laypersons. Twenty-five participants (10 surgeons and 15 laypeople) evaluated 25 sets of pre-surgical photographs of unilateral cleft lip patients. Inter-rater reliabilities for both groups were categorized as very good ( $ICC > 0.8$ ). The severity index is used in conjunction with the Surgical Outcomes Evaluation Scale, which grades the esthetic outcome of a unilateral cleft lip repair based on the symmetry of the nose, cupid's bow, lateral lip, and free vermilion (**Figure 6**) [32]. A similar validation study was performed for the outcomes evaluation scale in which 20 participants (9 surgeons and 12 laypeople) evaluated 25 sets of post-operative photographs. Inter-rater reliabilities were 0.71 for surgeons and 0.82 for laypeople. The validation of these tools for use by non-medical personnel is important as they were designed to be used in resource-limited settings by mission teams composed of a few surgeons and many non-medical personnel.

The Unilateral Cleft Lip Severity Index and Surgical Outcomes Evaluation Scale are now utilized globally and provide feedback regarding outcomes to volunteer surgeons as well as OS administrators with a relatively short turn-around time. In order to aid in the interpretation of results, a retrospective study was performed applying the severity index and outcomes evaluation scale to 1823 patients who had undergone unilateral cleft lip repair by OS during missions in various countries and at GCCCC [33]. The results of this study established a normative bell curve of outcomes for each severity of unilateral cleft lip deformity (**Figure 7**). Based on these normative values, a surgeon can see where his or her results fall in the range of results for a given severity of cleft. Surgeons who fall on the upper end of the spectrum can

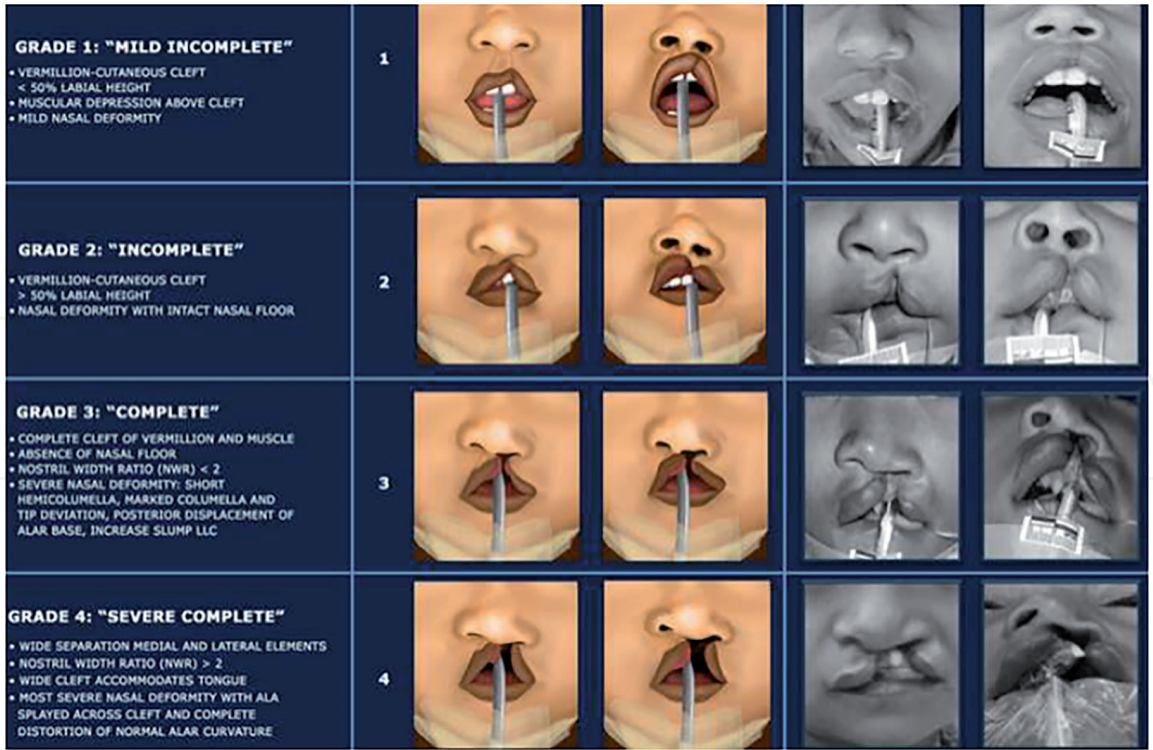


Figure 5.  
Criteria and examples demonstrating each of the 4 grades of the cleft severity index.

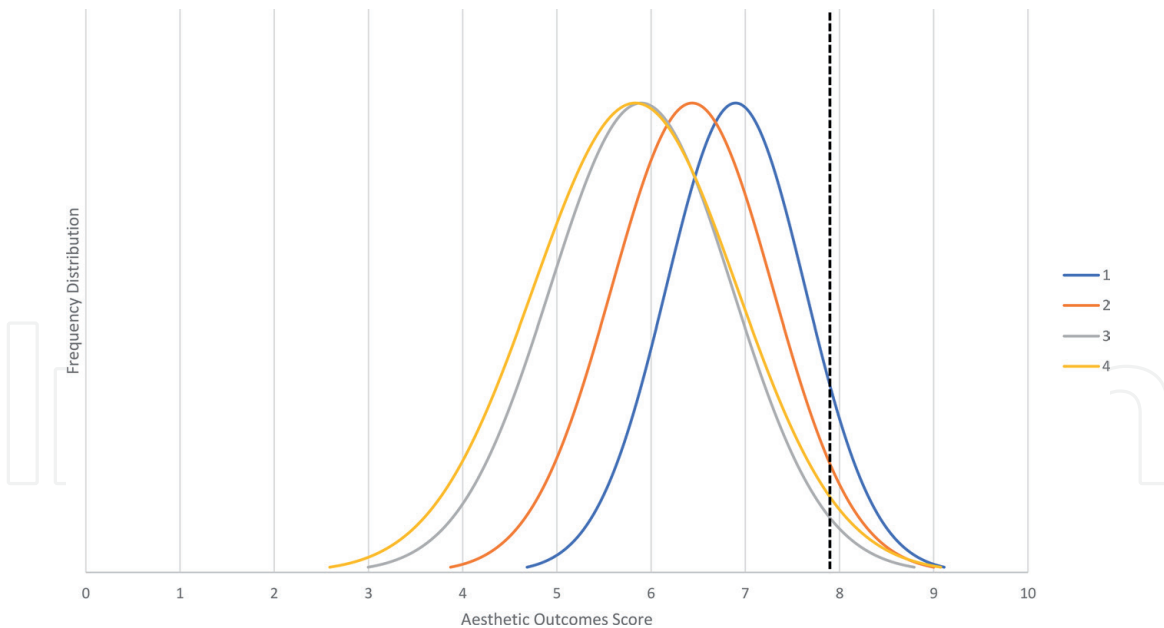


Figure 6.  
Each element is scored on a 3-point scale: 2 (excellent), 1 (mild asymmetry), 0 (unsatisfactory). The scores of the 4 individual components are then summed for a total score of 0 (lowest) to 8 (highest).

provide coaching to less experienced surgeons, and results that fall below a standard deviation of the average can be investigated for root cause analyses.

The next steps in OS's mission to provide the best quality care to cleft patients in LMICs will be to use the cleft severity index and outcomes evaluation scale to study





**Figure 7.**  
*Bell curve of normative surgical outcomes evaluation scores for each of the cleft severities (1 through 4). Dotted line represents the maximum possible score.*

whether certain interventions or models of care delivery improve esthetic outcomes after cleft lip repair. The routine use of these tools in OS’s work around the world provides a means of quality control and ensures that patients in LMICs receive the same high level of care as patients in the developed world.

## 7. Conclusion

Cleft care in LMICs has grown tremendously over the past few decades through the work of charitable organizations and individuals. However, complication rates in this setting have historically been high, and much work is needed to improve the quality of care delivered. Through outcomes analysis and a strong focus on patient-centered care, it is possible to achieve substantial, measurable improvements in the care provided to patients. OS’s work over the past decade is evidence that the diagonal model of care delivery can be effective. If charitable foundations are to improve health care equity around the globe, they must work with the intention of building capacity and transferring responsibilities to the local community. By emphasizing research and continuous quality improvement, these organizations will continue to make great strides toward making top-quality care accessible to every child born with a cleft.



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