

Ten-Year Cleft Surgery in Nepal: Achievements and Lessons Learned for Better Cleft Care Abroad

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Background: Cleft lip and palate surgery abroad is devoid of global consensus regarding standards of therapy, follow-up, and outcome. Cleft surgery in Nepal during a 10-year sustained program provided the opportunity to inform on the need for such standards.

Methods: Medical records were evaluated from the cleft clinic at Sushma Koirala Memorial Hospital, Sankhu, Kathmandu, Nepal, from 1997 to 2007. Four groups were identified for analysis: total cohort, total surgical cohort (TSC), primary program patients (PPP; patients had not been operated on before), and nonprimary program patients (non-PPP; patients operated on elsewhere before). Patient demographics, diagnostic, primary and secondary surgery (corrective surgery), and follow-up were evaluated. **Results:** One thousand forty-five patients were eligible for surgery. Three hundred twenty-three of 1,045 patients (30.9%) did not seek treatment, although scheduled for surgery. One thousand two hundred one procedures were performed in 722 patients [TSC; 845 PPP (70.4%); 356 non-PPP (29.64%)]. Corrective procedures were performed in 257 of 1,201 [3.5% (30 of 845 procedures in 509 patients) PPP vs 63.7% (227 of 356 procedures in 213 patients) non-PPP]. One hundred six lips were completely reoperated on (1 PPP vs 105 non-PPP), and 42 palates underwent a total revision (5 PPP vs 37 non-PPP). The surgical outcome of the TSC group in terms of complication rate was similar to the one in developed countries. **Conclusions:** The high rate of corrective surgery reveals the need for global regulatory mechanisms and the need for nongovernmental organizations to introduce strategies for delivering sustained cleft care until achieving full rehabilitation. The World Health Organization should establish standards for cleft care delivered in less developed countries. (Plast Reconstr Surg Glob Open 2016;4:e711; doi: 10.1097/GOX.000000000000702; Published online 20 May 2016.)

he reported prevalence of orofacial clefts in large municipalities of India¹ and Nepal² corresponds to the average in the world, which is 1.2 of 1,000.³ Epidemiologically, the number of

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Copyright © 2016 The Authors. Published by Wolters Kluwer Health, Inc. on behalf of The American Society of Plastic Surgeons. All rights reserved. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially. DOI: 10.1097/GOX.000000000000702 countries every year; in developed countries, 17,000 children are born with a cleft every year.⁴

Cleft surgery abroad was ranked as the most important missionary activity in low- and middleincome countries in a review from 1987 to 2009.5 Since the late 60s, nongovernmental organizations (NGOs) started cleft surgery programs in developing countries⁶⁻⁸; detailed information on the number of patients treated every year is available.9-11 But almost no data are published on follow-up and corrective surgery from overseas activities, independently of the organizational model. The Global Burden of Disease introduced by the World Health Organization (WHO) in 1990 aims to quantify global and regional effects of diseases, injuries, and risk factors on the health of the population. Cleft lip and cleft palate are considered as a noncommunicable disease.¹² The caused disability ends with the primary surgery; consequently, the corrective surgery is not considered.¹⁰ This conceptual approach limits the evaluation of cleft programs in developing countries, which are mostly driven by NGOs. In fact, the major criticisms against NGOs delivering cleft care abroad is the poor or inexistent follow-up.^{13,14} The aim of this study was to analyze the evolution of a full-range cleft program at an institution lead by foreign cleft surgeons in Nepal over 10 years.

PATIENTS AND METHODS

Study Design

This is a retrospective cohort study. Source data were medical records from the archive of the cleft lip palate clinic at the Sushma Koirala Memorial (SKM) Hospital for Plastic and Reconstructive Surgery from 1997 till 2007. Because the archive exclusively consisted in medical records of patients with cleft lip and palate, no further eligibility criteria needed to be specified. The study size was determined by the number of complete medical records.

An initial analysis of the data suggested a high number of patients operated on elsewhere who then sought mainly for secondary surgery (corrective surgery) or to a lesser extent to continue the therapy at our institution. The unexpected high number of corrective surgery in those patients motivated us to evaluate this patient group independently. Two subcohorts were added to the total cohort (TC): primary program patients (PPP) means patients who received a primary

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operation at our institution and nonprimary program patients (non-PPP) means patients operated on at another institution before presenting at our institution.

The Area of Care and the Structure of the Cleft Program

The study was conducted at the SKM Hospital for Plastic and Reconstructive Surgery (SKM) Hospital in Sankhu, a small village situated 20 km northwest of the Kathmandu Valley in Nepal (Fig. 1). The hospital was founded in 1997 by Interplast Germany, an NGO, which provides fee-free plastic and reconstructive surgery in developing countries. The hospital is financed by donations collected in Germany for Interplast Germany, Nepal Project. Travel costs for German surgical teams are mainly financed by Pro-Interplast, an NGO, which supports Interplast for the financing of logistic costs. The director of the cleft program (H-.D.P., senior cleft surgeon) spent one and a half years in the hospital as a founding surgeon (1998–1999).¹⁵ Since the establishment of the program, cleft surgery is offered by 2 German teams for a period of 4 weeks in spring and 4 to 8 weeks in fall. The teams consist of 2 qualified cleft surgeons and an anesthesiologist. The local Nepali staff consisting of surgeons, nurses, and administrative staff supports the visiting team. Nepalese surgeons join the cleft team for training and are enabled to perform surgery under supervision.

Therapeutic Approach, Operative Techniques, and Follow-Up

In the first 2 years, the senior cleft surgeon (H-.D.P.) based permanently in Nepal created a network with hospitals throughout the country offering cleft care. In the following 4 to 5 years, cleft surgery missions were announced through radio until the program was considered established.

The clinical evaluation consisted of an oral examination with mirror and lamp lighting; palate fistulae were evaluated using a probe. An anesthesiologist evaluated all candidates for surgery. In patients with unrepaired clefts older than 2 years, a 1-stage procedure (lip, alveolus, and palate closure) was preferred, if the general medical condition allowed for it. Speech therapy and orthodontics were not evaluated, and both were generally not available, save in a few cases where therapeutic infrastructure existed. Patients were recalled every 6 to 12 months according to the surgical schedule until full rehabilitation was achieved.

The preferred treatment protocol for cleft lip and palate was with multiple-stage surgery, starting with the lip repair (according to the study by Randall¹⁶) combined with a gingivoperiosteoplasty at the age of 5 to 6 months (closure of the maxillary cleft according to the study by Axhausen¹⁷) and finalizing with the palate



Fig. 1. Map of Nepal showing main cities and main roads (marked in red) in the country. The Sushma Koirala Memorial Hospital for Plastic and Reconstructive Surgery is located in Sankhu (red dot), a small village situated 20 km northeast of the Kathmandu Valley. The distance to the hospital is not as relevant for the patients as living close to a main road and thus a means of transportation. For patients living in far rural areas in the Himalaya mountain range, our hospital is almost inaccessible.

repair (2-flap palatoplasty)¹⁸ at the age of 12 months. Double lip clefts were treated according to the study by Veau.¹⁹ For broad double lip clefts, a lip adhesion (lip approximation without extensive mobilization) was preferred, followed by a Veau's procedure 1 year later. For corrective speech deficiency (velopharyngeal insufficiency), a lengthening of the soft palate, using a pharyngeal cranial-based flap of the posterior pharynx wall (velopharyngoplasty according to the study by Sanvenero-Rosselli²⁰), was performed.

Data Collection

The data collection covered the period from 1997 to 2007, and all medical records were accessible. Data were extracted from the original medical records on a specifically designed Case Report Form (CRF). All documentation was done in a uniform manner by the same cleft surgeon (J.C.R.) with assistance of experienced nursery staff of the institution. The CRF included the following variables: (1) demographic information, (2) history of clefts in the family, (3) diagnosis [cleft lip, alveolus (maxilla), and palate (soft and hard palate)], extension of the cleft lip (complete and incomplete), affected side of the cleft lip (right, left, and both sides), (4) surgical procedures according to the anatomical area, (5) corrective surgery, and (6) complications. The completeness of the archive and the consistent and uniform manner of CRF documentation addressed 2 major sources of bias in this kind of study.

Statistical Analysis

Statistical analyses used descriptive methods within the TC and a number of defined subgroups. Results were reported as counts, percentages, and graphical displays. Differences between proportions were calculated with the chi-square test. All analyses were performed by using the SPSS for Windows (IBM Corp., Armonk, NY).

RESULTS

Patient Cohort

One thousand one hundred sixty-one patients were registered in the cleft clinic at the SKM Hospital. One hundred sixteen had to be excluded from the analysis because of incomplete records. Thus, data of n = 1,045 patients could be analyzed; these patients constituted the TC.

PPPs are those who had not been operated on before in our institution or any other institution (735 of 1,045, 70.3%), and non-PPP received surgical treatment somewhere else before presenting in our



Fig. 2. Flowchart shows the TC (1,045). Three hundred twenty-three patients did not receive surgery. The TSC represents 722 patients. Because of a high number of corrective surgical procedures in patients previously operated on elsewhere, 2 more subgroups were considered: Primary Program Patient (PPP) and Nonprimary Program Patient (non-PPP).

institution (310 of 1,045, 29.7%). Total surgical cohort (TSC) includes all patients who underwent any kind of surgery (722 of 1,045, 69.1%). Figures 2 and 3 show only the number of patients from each group who underwent surgery (PPP = 509; non-PPP = 213).

Median age at admission was 5 years, and the range was 1 month to 73 years. Fifty-nine percent of the patients were male. Family history of clefts was recorded in 1.5% of the patients.

Consideration of the individual anatomical cleft regions yielded the following data: complete cleft lip, 630; soft palate, 564; hard palate, 511; alveolus cleft, 382; and submucous palate cleft, 9 (any combinations of these conditions were seen, but are not shown here).

Demographic information of 910 patients indicated arduous transportation for patients living far away from a main road, taking up to 5 days to reach the hospital (Fig. 1). Three hundred twenty-eight patients



Fig. 3. Treated patients during a period of 10 years on PPP* (n = 509) and non-PPP** (n = 213). The highest volume of treated patients per year was reached in the first 2 years of the program, when the senior and founder cleft surgeon (D.P.) was permanently based in the hospital (Fig. 2). From the third year onward, the volume of treated patients decreased and remained almost unchanged. *PPP, Primary Program Patient; **non-PPP, Nonprimary Program Patient.

	TSC Group	PPP Group	Non-PPP
Lip repair	552	422	130
Alveoloplasty	231	168	63
Palate repair	327	215	112
Setback premaxilla	15	13	2
Columella lengthening	21	9	12
Velopharyngoplasty	7	0	7
Septorhinoplastic/alar	23	7	16
wing correction	2	2	
Facial cleft closure	5	5	0
Others (z-plasty, tooth extraction)	20	6	14
No. surgical procedures	1.201	845	356
each group	(100%)	(70.4%)	(29.6%)

Table 1. Surgical Procedures According to theDifferent Patient Groups

(36%) were considered to come from the Kathmandu area, as they took up to 3 hours to get to the hospital.

Patients Who Received or Did Not Receive Surgery

One thousand forty-five patients presented for surgery, but only 722 (69.1%) patients received surgical treatment. Three hundred twenty-three patients (30.9%) did not undergo surgical treatment: in 298 of 323 (92.26%), reasons for not undergoing surgical treatment are not known; in 25 of those 323, patients were not scheduled for surgery for reasons including low weight (18/5.57%), orthodontic conditions (4/1.23%), or poor health status (3/0.92%; Fig. 2).

Two main reasons to change to the SKM Hospital were found in 214 of 310 patients operated on elsewhere: first, to continue the treatment in 26.6% (57 of 214) and second for corrective surgery in 73.4%

(157 of 214). The most frequent complaints were an unpleasant lip scar (134 of 310, 43.2%), a hole in the alveolus (64 of 310, 20.6%) or in the palate (42 of 310, 1.5%), or speech problems (velopharyngeal insufficiency; 27 of 310, 8.7%).

Surgical Procedures

TSC of 722 patients received 1,201 operations in total (mean = 1.66). The 509 PPP group underwent 845 procedures (mean = 1.66), and the 213 non-PPP group underwent 356 procedures (mean = 1.67; Table 1).

The distribution of surgical procedures for the TSC was as follows: 552 lip repairs and 327 palate repairs. In double cleft cases, a *setback premaxilla* procedure (anterior-posterior repositioning of the premaxilla) was performed in 15 cases, and 5 facial clefts were primary repaired (Table 1 shows more detailed information).

The Need for Corrective Surgery

Of the total number of surgical procedures recorded in the TSC (n = 1,201), 257 (21.4%) constituted corrective surgery. The majority of these procedures were performed in 213 patients of non-PPP group (227 of 257 procedures, 88.3%) and in 509 patients of the PPP group (only 30 of 257 procedures, 11.7%; Fig. 4). Corrective surgery included a variety of procedures including reoperation of the lip, lip scar correction, closure of fistula in the alveolous, closure of hole in the alveolous, vestibuloplasty, closure of fistula in the palate, reoperation of whole palate, secondary rhinoplasty, and alar wing correction (Table 2).



Fig. 4. Corrective procedures on PPP* (n = 509) and non-PPP** (n = 213) over 10 years. In the last 3 years, no corrective surgery on the PPP group was performed. Corrective surgery on the non-PPP group remained constantly high compared with the PPP group. *PPP, Primary Program Patient; **non-PPP, Nonprimary Program Patient.

Complications after Surgery

In the course of 10 years with a total of 1,201 surgeries performed by Interplast, 49 complications were observed (complication rate, 4.07%; Table 3). Complications included postoperative bleeding (3 cases, 0.24%), wound infections (15/1,201 = 1.2%), and palatal fistulas or holes (26/327 = 7.9%). PPP (3.8%) and non-PPP (4.8%) groups did not differ in their proportion of complications, P = 0.43 (Table 3).

The Evolution of the Program

With the senior and founder cleft surgeon (H-.D.P.) permanently based in the hospital, the greatest patient treatment volume was reached in the first 2 years of the program (Fig. 3). The group of patients of the TC presented for surgery in their first year of life increased from 15.6% in 1997 to 58.8% in 2007. From the third year onward, the volume of treated patients decreased and remained almost stable. The ratio PPP versus non-PPP remained constant. Corrective surgery in the TSC (PPP + non-PPP) diminished from 21% to 12% during the observational period. In the past 3 years of the study, no corrective surgery was reported for the PPP group (Fig. 4). Corrective surgery on patients operated on elsewhere before (non-PPP) also diminished from

20.9% (9 revisions in 43 TSC patients) in the first year to 12% (3 revisions in 25 TSC patients) in the last year. A follow-up of more than 1 year (maximum 9 years) was performed in 258 patients (24.7%), covering patients who needed more than 1 surgical session (15.9%). Nine hundred one patients (86.2%) had a follow-up after more than 2 weeks, and 1,023 (97.8%) patients had a follow-up more than 1 week postoperatively. These data support the assessment of early surgical complications.

Six hundred five patients of the TSC (83.8%) completed their therapy, and no differences between the PPP and non-PPP groups were observed [PPP, 428 of 509 (84.1%); non-PPP, 177 of 213 (83.1%)].

The policies of the surgical treatment did not change during the observed period of 10 years. Three Nepalese surgeons were trained, one after another during a period of 3 to 4 years. All 3 surgeons left the program, 2 choosing private practices and the third appointed at a teaching hospital in Kathmandu.

DISCUSSION

This article reports on a 10-year cleft lip and palate surgery program in Nepal lead by a German NGO. The key observations were as follows: (a) the complication rate (49/1,201) was similar to that observed

Table 2. Distribution of the Corrective Procedures According	ng to Evaluated Patient Groups
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	TSC Group (n = 722)	PPP Group (n = 509)	Non-PPP Group (n = 213)
Surgical procedures each group	1.201	845	356
Reoperation of the lip	106	1	105
Lip scar correction	35	10	25
Closure of fistula in the alveolous	25	3	22
Closure of hole in the alveolous	17	1	16
Vestibuloplasty	2	0	2
Closure of fistula in the palate	9	3	6
Reoperation whole palate	42	5	37
Secondary rhinoplasty	0	0	0
Alar wing correction	21	7	14
Corrective procedures each group	257/1,201 (21.4%)	30/845(3.5%)	227/356 (63.7%)
Corrective surgery PPP vs non-PPP	257 (100%)	30/257 (11.6%)	227/257 (88.3%)

PPP group = 845 procedures on 509 patients; non-PPP = 356 procedures on 213 patients.

Table 3. Complications According to Performed Procedures on the Evaluated Patient Groups

	TSC Group (n = 722)	PPP Group (n = 509)	Non-PPP Group (n = 213)		
Surgical procedures each group	1,201	845	356		
Bleeding	3	3	0		
Palate hole*	13	8	5		
Palate fistula†	13	8	5		
Wound infection	15	11	4		
Other complication [†]	5	2	3		
Total complications each group	49/1,201 (4.07%)	32/845 (3.78%)	17/356 (4.77%)		

TSC group = 1,201 procedures on 722 patients, PPP group = 845 procedures on 509 patients, and non-PPP = 356 procedures on 213 patients. *Palate perforation evident on clinical examination without need of instruments.

†Palate perforation evident on clinical examination by using a probe.

‡Anesthesiologic complication as airway and respiratory distress/no transfusion needed.

in developed countries, and this supports the high standard of care, (b) the high number of patients who had an initial examination but either did not show up for scheduled surgery or could not be operated on for medical reasons (323/1,045), (c) the high number of patients (n = 310) who were not operated on by our NGO but presented for corrective surgery (157/310), and (d) the failure to establish self-sustained patient care through local surgeons.

Equal Complication Rate as in Developed Countries

A complication rate of 4.07% for the TSC group was documented. The surgical outcome is comparable with the one observed in industrialized countries in terms of complication rate,²¹ but the patient characteristics are different. In upper-income countries, the palatal fistula rates of 3% to 10% are comparable.²² Parwaz et al,²³ operating in an independent plastic surgery department of India, reported about a palatal fistula rate of 35% (11 of 31); they provided a correlation between fistula rate and cleft width; this observation is relevant for patients operated on abroad, and the late time of presentation^{24,25} implies often broader palatal clefts because of unrestricted growth as observed by Ortiz Monasterio et al²⁶ in unoperated adult patients. Maine et al compared the fistula rate after palate closure by a US cleft team and local surgeons in Ecuador with that of a US cleft unit. The fistula rate in hands of US cleft surgeons in Ecuador was 54% compared with 57% when performed by local surgeons, whereas the fistula rate in the US cleft unit was 2.6%.22 This was the first study that compared the outcome of cleft surgery in the home country (United States) with the one delivered in a host country (Ecuador). Mulliken et al²⁷ reported a revision rate of 100% on 39 bilateral repaired clefts in internationally adopted children in the United States, observed in the last 25 years. Furthermore, McIntyre and Gosman reported on safety and quality in international surgical trips in a survey of the American Society of Plastic Surgery Members. The primary area of surgery in the United States of missionary-involved surgeons was general reconstructive surgery [44.1% (113)] and cosmetic surgery [29.5% (81)].²⁸ The complexity of the cleft palate surgery abroad underlines the importance of the performance of those operations by highly trained surgeons.^{14,29}

The High Number of Patients Who Showed Up for Initial Examination, but Did Not Show Up for the Scheduled Operation

Despite the continuity of the program, 30.9% (n = 323) of patients from the TC presented at the cleft diagnostic clinic at the SKM Hospital did not receive any treatment from us. The fact that the sur-

gery was offered for free and that the program did not interrupt activities still did not make sure that all patients could be covered. Reporting about nonoperated patients is unusual because nonoperated patients usually "do not exist" in a study about surgical outcome. This finding shows that the impact of humanitarian aid is limited. One limiting factor may be patients who (for whatever reason) are unable or unwilling to accept help.

The High Number of Patients Who Had Been Treated at Another Institution and Requested Additional or Corrective Procedures from Our Site

Two hundred twenty-seven corrective surgical procedures from a total of 1,201 procedures were performed in 213 patients operated on elsewhere (non-PPP). One hundred five total reoperations of the lip and 37 reoperations of the whole palate denote the extension and complexity of this cohort. Rai et al¹¹ informed about 8,804 primary cleft procedures performed in Nepal from 1999 to 2010. The authors did not report corrective surgery in this cohort, which is fundamental when evaluating a full-range program. Do NGOs focus on patients not operated on before (primary surgery)? The most important characteristic of patients affected by a cleft deformity is in fact the need for many operations until full rehabilitation occurs to achieve normal speech, hearing, and a normal psychosocial development. Thus, cleft surgery is a complex surgery not limited to 1 surgical event. Singh et al reported about a prevalence rate of cleft deformities (1.64/1,000 live births per year) in a tertiary hospital in eastern Nepal. The calculated burden of cleft in Nepal was around 42,640.30 Assuming an incidence of corrective procedures as reported in this study of 20%, it is expected that 8,528 corrective procedures are necessary to achieve full cleft rehabilitation of the Nepali population. This corresponds to almost the same number of procedures reported by Rai et al,¹¹ based in Kathmandu, on primary cases (n = 8,804).

The Problem to Establish a Self-Sustaining Patient Care Centre under the Direction of or with Permanent Support from Local Surgeons: A Perspective for NGOs and the Need for Rules and Regulations

In the program described, a 2-surgeon team and an anesthesiologist provided sustained cleft surgery together with local surgeons twice a year for 10 years. The size of the team is unusual for such activities. Hollier et al gave instructions on how to prepare and how to perform surgical missions. They stated that 10 to 15 members would be necessary.³¹ Dupuis¹³ and many others criticized big teams, local human resources should be joined, and financial resources should be rationalized. After 10 years of cleft program, no continuity of cleft surgery in Nepalese hands could be established. Staff surgeons did not receive additional compensation for each operated cleft, because they work as employees for the hospital, which is fully financed by Interplast Germany.

In contrast to this model, international organizations introduced the cleft case-rewarded model, consisting in case-related payment to institutions headed by local surgeons; both models coexist in Nepal.³² The initial intention of international organizations to train and enroll local surgeons and pay them for performing cleft surgery in the last 15 years was to create independence and, on the other hand, to create more acceptance by the local community; a reaction against unhappiness of hosting countries because of the fact that foreign surgeons traveled for training and often left complications in the hands of the local surgeon.^{13,32}

The approach to teach and train local surgeons is basically correct; nevertheless, the cleft caserewarded model creates a strong dependence. Previously, cleft surgeons were "hunting" clefts in poorest countries, training their residents.³³ Are cleft surgeons in poor countries now "hunting" clefts for the reward? It is difficult to answer this question. There is no doubt that the volume of patients operated on per year is increasing in developing countries. Magee,³⁴ founder of Operation Smile, one of the leading organizations delivering cleft surgery worldwide, informed on the growth of the organization from 8 million US dollars in 2002 to 40 million US dollars in 2009. Smile Train, also a giant NGO delivering cleft surgery abroad is rapidly growing in the business, incorporating thousands of surgeons in developing countries worldwide since 1999.9 Despite the high volume of cases treated, almost no information about follow-up and corrective surgery is available. Donors are attracted by yearly records of surgeries; corrective surgery award seems not to be a benchmark to stimulate donors. The high rate of corrective surgery in the present cohort suggests that a cleft program not supported financially according to the number of cases seems to be an alternative to fulfill the universal goal of cleft surgery, which is full-range rehabilitation until adulthood is achieved. There are many initiatives trying to provide guidelines for volunteers involved in cleft care in children in less developed countries as the one proposed by the American Society of Plastic Surgeons.³⁵ Nevertheless, there is a lack of global guidelines from the WHO for sustainable cleft programs. Rethinking sustainability of NGO programs is a challenge and should be the focus for all those who devote time taking care of affected children in less developed countries.

Centralization of health care in developing countries is a well-known limiting factor for the poorest from inaccessible regions.^{11,36} This aspect shows the importance of the role of local surgeons and the need for cooperating with local governmental organizations.¹¹ After analyzing achievements and limitations of the different NGO strategies, the lessons we learned are as follows: local surgeons have to develop and resolve problems according to their own skills. Foreign surgeons committed to a long-lasting support may train local surgeons; they should rationalize technical support and avoid any compensation for each individual case to create a transparent commitment of local surgeons and governmental organizations. From this perspective, the case-rewarded model is an ethically questionable issue, which creates dependence. It hinders growing local structures and sustainability.

CONCLUSIONS

The present cohort reveals a high rate of corrective surgery not reported before. The Global Burden of Disease, introduced by the WHO, does not consider corrective cleft surgery. Because cleft surgery is mainly delivered by NGOs in low-income countries, the WHO should establish standards of sustained cleft care abroad. There is a need for global regulations in terms of cleft care until full rehabilitation is achieved. NGOs should cooperate with local organizations to implement local education. Technical and surgical support provided by NGOs should be rationalized to create transparent commitment of local surgeons and sustainability.

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REFERENCES

- 1. Reddy SG, Reddy RR, Bronkhorst EM, et al. Incidence of cleft lip and palate in the state of Andhra Pradesh, South India. *Indian J Plast Surg*. 2010;43:184–189.
- 2 Byasi KPB. *Prevalence of Orofacial Clefts in Bhaktapur Municipality*. Kathmandu, Nepal: Department of Community Medicine and Family Health Institute of Medicine, Tribhuwan University; 2005.
- 3. Mossey PA, Modell B. Epidemiology of oral clefts 2012: an international perspective. *Front Oral Biol.* 2012;16:1–18.
- 4 Mars M, Sell D, Habel A, eds. *Management of Cleft Lip and Palate in the Developing World*. Chichester: John Wiley & Sons, Ltd.; 2008.
- Martiniuk AL, Manouchehrian M, Negin JA, et al. Brain gains: a literature review of medical missions to low and middle-income countries. *BMC Health Serv Res.* 2012;12:134.
- Ward CM, James I. Surgery of 346 patients with unoperated cleft lip and palate in Sri Lanka. *Cleft Palate J.* 1990;27:11–15; discussion 15.
- Henjyoji EY, Laub DR. Residency participation in out-ofcountry medical service. *Plast Reconstr Surg*. 1974;53:660–662.
- Laub DR. Humanitarianism in plastic surgery. Ann Plast Surg. 1981;7:99–101.
- 9. Hubli EH, Noordhoff MS. Smile train: changing the world one smile at a time. *Ann Plast Surg.* 2013;71:4–5.
- Magee WP Jr, Vander Burg R, Hatcher KW. Cleft lip and palate as a cost-effective health care treatment in the developing world. *World J Surg.* 2010;34:420–427.
- Rai SM, Nakarmi K, Basnet S, et al. Age of individuals undergoing cleft lip and cleft palate surgeries in Nepal. *JNMA J Nepal Med Assoc.* 2013;52:591–595.
- Vos T, Flaxman AD, Naghavi M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet.* 2012;380:2163–2196.
- Dupuis CC. Humanitarian missions in the third world: a polite dissent. *Plast Reconstr Surg.* 2004;113:433–435.
- Mulliken JB. The changing faces of children with cleft lip and palate. NEngl J Med. 2004;351:745–747.
- Hoffmann E, Dück M, Oberthür A, et al. Anaesthesia for repair of cleft lip, maxilla and palate in Nepal. *Eur J Anaesthesiol.* 2003;20:677–678.
- Randall P. A triangular flap operation for the primary repair of unilateral clefts of the lip. *Plast Reconstr Surg Transplant Bull*. 1959;23:331–347.
- 17 Axhausen G. Technik und Ergebnisse der Spaltplastiken. Munich, Germany: Hanser; 1952.
- Salyer KE, Sng KW, Sperry EE. Two-flap palatoplasty: 20year experience and evolution of surgical technique. *Plast Reconstr Surg.* 2006;118:193–204.
- 19. Veau V. Operative treatment of complete double harelip. Ann Surg. 1922;76:143–156.
- 20 Sanvenero-Rosselli G. Die Gaumenplastik unter Verwendung von Pharynxlappen. Arch f klin Chir. 1960;295:895–900.

- 21. Nguyen C, Hernandez-Boussard T, Davies SM, et al. Cleft palate surgery: an evaluation of length of stay, complications, and costs by hospital type. *Cleft Palate Craniofac J.* 2014;51:412–419.
- 22. Maine RG, Hoffman WY, Palacios-Martinez JH, et al. Comparison of fistula rates after palatoplasty for international and local surgeons on surgical missions in Ecuador with rates at a craniofacial center in the United States. *Plast Reconstr Surg.* 2012;129:319e–326e.
- Parwaz MA, Sharma RK, Parashar A, et al. Width of cleft palate and postoperative palatal fistula—do they correlate? *J Plast Reconstr Aesthet Surg.* 2009;62: 1559–1563.
- Schwarz R, Bhai Khadka S. Reasons for late presentation of cleft deformity in Nepal. *Cleft Palate Craniofac J.* 2004;41:199–201.
- 25. Adeyemo WL, Ogunlewe MO, Desalu I, et al. Cleft deformities in adults and children aged over six years in Nigeria: reasons for late presentation and management challenges. *Clin Cosmet Investig Dent.* 2009;1:63–69.
- Ortiz-Monasterio F, Serrano A, Barrera G, et al. A study of untreated adult cleft palate patients. *Plast Reconstr Surg.* 1966;38:36–41.
- Mulliken JB, Zhu DR, Sullivan SR. Outcomes of cleft lip repair for internationally adopted children. *Plast Reconstr* Surg. 2015;135:1439–1447.
- McIntyre JK, Gosman AA. Safety and quality on international surgical trips: results from a comprehensive survey of American Society of Plastic Surgery (ASPS) members. *Plast Reconstr Surg.* 2015;136(4 Suppl):1–2.
- 29 Sommerlad BC. Management of Cleft Lip and Palate in the Developing World. Chichester, UK: John Wiley & Sons Ltd; 2008.
- 30 Singh VP, Sagtani R, Sagtani A. Prevalence of cleft lip and cleft palate in a tertiary hospital in Eastern Nepal. *Mymensingh Med J.* 2012;21:151–154.
- 31 Hollier LH Jr, Sharabi SE, Koshy JC, et al. Surgical mission (not) impossible-now what? J Craniofac Surg. 2010;21:1488–1492.
- 32 Zbar RI, Zbar R, Rai S, et al. Establishing cleft malformation surgery in developing nations: a model for the new millennium. *Plast Reconstr Surg*. 2000;106:886–889.
- Natsume N. Safari surgery. Plast Reconstr Surg. 1998;102:1304–1305.
- 34. Magee WP Jr. Evolution of a sustainable surgical delivery model. *J Craniofac Surg.* 2010;21:1321–1326.
- Schneider WJ, Politis GD, Gosain AK, et al. Volunteers in plastic surgery guidelines for providing surgical care for children in the less developed world. *Plast Reconstr Surg.* 2011;127:2477–2486.
- 36. Farmer PE, Kim JY. Surgery and global health: a view from beyond the OR. *World J Surg.* 2008;32:533–536.