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

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Background: International organizations have performed palatoplasties in low- and middle-income countries for decades, often working with local providers. Few studies report long-term outcomes, especially for palatal fistulas. A fistula after palatoplasty may affect speech, socialization, and nutrition. Fistula rates on surgical missions have not been compared with rates at U.S. craniofacial centers nor have the rates of the visiting and local surgeons working on missions been compared.

Methods: Fistula rates for two Ecuadorian cohorts were compared with fistula rates for a craniofacial center in the United States. In Ecuador, North American surgeons repaired one cohort ($n = 46$) and Ecuadorians the other ($n = 82$) during 2000 through 2005. Ecuadorian patients were evaluated during 2007 and 2008. The center's clinical database ($n = 189$) provided U.S. cohort data.

Results: On missions, the fistula rates were 57 percent (95 percent CI, 46 to 68 percent) for Ecuadorian surgeons and 54 percent (95 percent CI, 39 to 69 percent) for North American surgeons. The rate was 2.6 percent (95 percent CI, 0.8 to 6.0 percent) at the U.S. craniofacial center. There was no difference between the two Ecuadorian cohorts' rates ($p = 0.75$), but they were significantly higher than those of the U.S. cohort ($p < 0.001$). Having a cleft lip together with cleft palate was associated with fistula formation, whereas surgeon nationality and older age at surgery were not.

Conclusions: The fistula rate on Ecuadorian missions, regardless of the surgeon's nationality, was significantly higher than in the United States. Further investigation into the causes of this higher fistula rate in this population is needed. (*Plast. Reconstr. Surg.* 129: 319e, 2012.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

Cleft lip and/or palate occurs in one of 500 to one of 700 births,[1–4] with ethnic and geographic variation.[2,3,5] A cleft palate affects a child's ability to communicate, eat, and socialize and can mean lifelong limited educational and economic opportunities for children of low- and middle-income countries.[4,5] Access to reconstructive surgery for these children is limited by economic circumstances and/or the availability of trained medical personnel.[3,5–8] For years, charitable organizations have attempted to fill this void by providing free cleft care for these patients[4–6,9,10] and by supporting and educating local providers to perform these procedures.[3,6,10–15]

Historically, successful missions were defined by the number of patients served or the number

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of providers trained.[4,12,15–18] Although there are data on immediate and short-term outcomes,[4,5,7,10,19] few studies report long-term outcomes.[10,17] The World Health Organization has stressed the importance of research on missions, but the Global Burden of Surgical Disease Working Group and others[1,4,6,10,19] find that research is seldom done, due to limited funding, manpower, and time.[6,10] Many of the patients live in remote areas, and few return for follow-up, making tracking outcomes difficult.[6,10,20]

ReSurge International [formerly Interplast (Mountain View, Calif.)] has provided reconstructive surgeries in many low- and middle-income countries for 40 years and has established outreach programs that enable local surgeons to provide cleft care.[12] One Ecuadorian organization, Rostros Felices (Happy Faces), runs several surgical missions annually with ReSurge International's support. Patients often hear about surgery from local media and travel hours or days to be evaluated by plastic surgeons, anesthesiologists, and pediatricians. Selected patients are scheduled for upcoming mission surgery. Follow-up of treated patients occurs at a postoperative day 2 weeks after each mission. Additional follow-up is done on screening days for other missions. Often, hundreds of patients are evaluated on those days, leaving little time to track long-term outcomes.

The present study sought to locate patients who had undergone palatoplasty and determine the long-term fistula rate. In upper-income countries, palatoplasty usually achieves complete palate closure,[21,22] and fistula rates of 3 to 10 percent are common.[23–32] Similar data are unavailable in low- and middle-income countries and for surgical missions.

PATIENTS AND METHODS

This retrospective cohort study compared three groups of children undergoing primary palatoplasty by two aid organizations in Ecuador during 2000 through 2005. Their outcomes were compared with those of patients treated at an integrated craniofacial center in the United States. All Ecuadorian and U.S. surgeons operating in Ecuador were experienced cleft surgeons. ReSurge International guidelines permit only board-certified plastic surgeons who routinely repair clefts to participate. Potential volunteers are interviewed by ReSurge International's Chief Medical Officer, and they must submit letters of support from plastic surgeons verifying their experience with cleft repairs. All patients in the United States underwent primary palatoplasty by one plastic surgeon (W.Y.H.) at the University of California San Francisco.

In Ecuador, 166 primary palatoplasties were performed by Ecuadorian surgeons and 149 by North American surgeons. Patients were identified from foundation and hospital records (intake forms, operating room registries, medical records, and screening day registries). Additional patients were identified at premission screening days between October of 2007 and June of 2008. Some patients presented for follow-up, others were responding to announcements placed by Rostros Felices in the local media that a follow-up study was being conducted. Patients were not queried as to why they presented at the screening days. Patients who were not initially contacted at screening days were contacted using records from the foundations, hospitals, and local Rotary International (which works closely with the Ecuadorian teams). Forty-two percent of study participants were initially contacted at screening days, 42 percent by telephone, and 16 percent by home visits. All Ecuadorian participants were examined and interviewed to obtain demographic information and medical history. All palates were examined, photographed from an inferior angle, and classified by Veau's schema (Table 1).

For the U.S. cohort, demographic information, surgical history, and presence of a fistula were obtained from records of the 195 eligible patients in the database. These data were collected as part of routine clinical care.

The human subjects committees of the University of California San Francisco and the Universidad Católica de Santiago de Guayaquil approved the study. Informed oral consent was obtained from all patients over 6 years of age and from guardians of participants under 18 years of age.

All Ecuadorian patients underwent a physical examination, a photograph of the palate, documentation of the presence or absence of a fistula, and assessment of nasal escape with speech[33] and the state of the patient's oral health. Patient and caregiver interviews provided demographic information and past medical and surgical history. Preoperative weight and verification of medical and surgical history were obtained from available medical records.

Table 1. Veau Classification of Cleft Types

Class	Extent of Cleft
I	Soft palate only
II	Hard and soft palate
III	Unilateral cleft lip and palate
IV	Bilateral cleft lip and palate

A fistula was defined as a visible oronasal fistula in the hard or soft palate on physical examination or a history of palatal fistula repair. Nasoalveolar fistulas were excluded. For the U.S. cohort, demographics, surgical history, and presence of a fistula were obtained from the clinical database.

Analysis

Data were analyzed using STATA/IC 10.0 software (College Station, Texas). Odds ratios with 95 percent confidence intervals were calculated using logistic regression models. Chi-square, *t*, and Mann-Whitney tests were used to compare demographic and other intergroup characteristics. There were no statistical differences in the fistula rates between the two Ecuadorian cohorts, so they were combined for comparison with the U.S. cohort. Logistic regression comparing the U.S. and Ecuadorian cohorts included age at palate surgery, gender, Veau classification, and country where surgery occurred.

Within the Ecuadorian subgroups, logistic regression modeling, including age at primary palatoplasty (>18 months), gender, place where surgery was performed, oral health, and weight-for-age at palatoplasty, was done to identify potential factors associated with fistula formation. The weight-for-age *z* scores were calculated using a STATA plug-in developed by the World Health Organization.[34]

RESULTS

Despite concerted efforts to locate the 315 patients who had palatoplasties in Ecuador during the study period, only 135 patients were contacted and evaluated. Seven patients were excluded from analysis because their primary palatoplasty occurred outside of the study time period (five patients) or was performed by another organization (two patients). Of the remaining 128 evaluated patients, Ecuadorian surgeons operated on 82 (64 percent) and North American surgeons on 46 (36 percent). This represents a recall rate of 42 percent overall: 49 percent for Ecuadorian surgeons and 31 percent for North American surgeons. All contacted patients agreed to participate in the study; four failed to keep their appointments. Of the 195 U.S. patients, six were excluded because postsurgical follow-up records were unavailable.

Table 2 summarizes demographic and patient information. Ecuadorian patients underwent surgery 8 months later (median age) than U.S. patients ($p < 0.001$). Nearly 40 percent more Ecuadorian than U.S. patients had a unilateral or bilateral cleft lip and palate (Veau class III or IV; $p < 0.001$). Furthermore, the U.S. cohort was significantly younger at palatoplasty than the Ecuadorian cohort (Table 3). Only 10 percent of Ecuadorian patients had primary palatoplasty by 1 year of age versus 75 percent of U.S. patients ($p < 0.001$).

Table 2. Demographic and Outcome Information by Organization*

No. of Palatoplasties	United States	North American Surgeons (Interplast)	Ecuadorian Surgeons (Rostros Felices)	Ecuador Totals (Combined)
Total	195	149	166	315
Evaluated	189 (97%)	46 (31%)	82 (49%)	128 (40%)
Median age at palatoplasty				
Total	10 mo	25 mo	18 mo	21 mo
Evaluated	10 mo†	19 mo	17 mo	18 mo†
Unevaluated	12 mo	31 mo	21 mo	25 mo
Age range for palatoplasty for evaluated patients				
0–12 mo	141 (75%)†	2 (4%)‡	6 (7%)‡	8 (6%)†
12–24 mo	27 (14%)†	28 (61%)‡	51 (62%)‡	79 (62%)†
24–36 mo	1 (0.5%)†	10 (22%)‡	15 (18%)‡	25 (19%)†
36–48 mo	2 (1%)	1 (2%)	3 (4%)	4 (3%)
>48 mo	18 (10%)	5 (11%)	7 (9%)	12 (9%)
Veau classification				
I	33 (17%)	3 (7%)	11 (13%)	14 (11%)
II	52 (28%)	5 (11%)	8 (10%)	13 (10%)
III	76 (40%)	24 (52%)	39 (48%)	63 (49%)
IV	28 (15%)§	14 (30%)	24 (29%)	38 (30%)§
Postoperative fistula	5 (2.6%)†	25 (54%)	47 (57%)	72 (56%)†
On examination	—	20 (43%)	41 (50%)	61 (47%)
Prior repair	—	5 (11%)	6 (7%)	11 (9%)

*There was no statistical difference between the two Ecuadorian cohorts, so they were combined for comparison with the U.S. cohort.
†$p < 0.001$ comparing the U.S. and the combined Ecuadorian cohort.
‡$p < 0.001$ comparing U.S. with individual Ecuadorian cohorts.
§$p = 0.001$ using *t* test comparing the U.S. and the combined Ecuadorian cohort.

Table 3. Multivariate Logistic Regression Modeling of Factors Associated with Fistula Formation in Whole Group and Ecuadorian Subgroups*

	United States Compared with Ecuador Odds Ratio (95% CI)	Ecuadorian Subgroup Odds Ratio (95% CI)
Patient Ecuadorian	40 (15–110)†	—
Older than 18 mo at palatoplasty	1.1 (0.54–2.3)	0.9 (0.4–2.1)
Veau class III or IV	4.9 (2.0–12)†	5.2 (1.7–16)‡
Male gender	1.2 (0.58–2.3)	0.97 (0.44–2.2)
Poor oral health	—	5.6 (1.9–16)§
Indigenous surgeon (Rostros Felices)	—	1.5 (0.49–4.6)
Hospital state		
Cañar	—	—
Guayas	—	4.2 (0.52 to 34)
Imbabura	—	0.8 (0.11 to 5.7)
Loja	—	8.8 (0.69 to 111)
Manabi	—	3.0 (0.56 to 16)

*Using a presurgical *z* score of weight-for-age decreased the sample size to 108 patients. The odds ratio for the *z* score was 0.6 (95 percent CI, 0.2 to 1.7) in the smaller model. When the *z* score was included, Veau class III or IV and poor oral health remained the only significant variables in the model, with an increase in odds ratio to 6 and 6.4, respectively.
†$p < 0.001$.
‡$p = 0.004$.
§$p = 0.002$.

Ecuadorian patients had an odds ratio of 40 (95 percent CI, 15 to 110) of developing a postoperative palatal fistula compared with patients treated at the U.S. craniofacial center (Table 3). The risk of a fistula was equal in Ecuador whether the surgeon was North American or Ecuadorian ($p = 0.75$). The fistula rate in the U.S. cohort was 2.6 percent (95 percent CI, 0.9 to 6.1 percent). In Ecuador, it was 56 percent (95 percent CI, 47 to 65 percent); 54 percent (95 percent CI, 39 to 69 percent) for North American and 57 percent (95 percent CI, 44 to 66 percent) for Ecuadorian surgeons. The fistula rate in Ecuador for each cohort individually and combined was significantly higher than in the U.S. cohort ($p < 0.001$).

By multivariate logistic regression modeling (Table 3), Ecuadorian patients were significantly more likely to develop a fistula (odds ratio, 40; 95 percent CI, 15 to 110). The only additional factor that predicted fistula formation was having both a cleft palate and cleft lip—Veau class III or IV (odds ratio, 4.9; 95 percent CI, 2.0 to 12) (Fig. 1). Age greater than 18 months at palatoplasty was not associated with fistula formation (odds ratio, 1.1; 95 percent CI, 0.54 to 2.3) nor was male gender (odds ratio, 1.2; 95 percent CI, 0.58 to 2.3).

In Ecuadorian patients, fistulas were also associated with clefts that extended into the lip (Veau class III or IV; odds ratio, 5.2; 95 percent CI, 1.7 to 16) and with poor oral health (odds ratio, 5.6; 95 percent CI, 1.9 to 16). Age at palatoplasty, surgeon nationality, presurgical weight-for-age, and hospital region were not associated with fistula formation (Table 3).

Of the 128 patients in Ecuador, 72 had a fistula. Of the 72 patients, 28 (39%), reported frequent symptoms—either nasal regurgitation ($n = 13$), food sticking in the palate ($n = 5$), or both ($n = 10$). Of 67 patients with fistulas whose speech was evaluated,[33] 52 (78 percent) showed nasal escape with "b" and "p" phonemes by fogging mirror test.

It was not possible to analyze the performance of individual surgeons in Ecuador because we could evaluate too few patients for each surgeon. Two Ecuadorian surgeons did 71 percent of surgeries performed by Ecuadorian surgeons. Their fistula rates were similar to those of all Ecuadorian and mission surgeons (Table 4). One of the two surgeons (J.H.P-M) had a fistula rate of 6 percent in his private practice during the same time period (private communication).

DISCUSSION

To our knowledge, this is the first comparison of fistula rates on surgical missions in low- and middle-income countries with those of an integrated craniofacial center. This study also compared the rates of North American surgeons operating in Ecuador with those of local surgeons. Postoperative fistulas developed in over half of evaluated children treated during surgical missions, regardless of surgeon's nationality. This rate was over 20 times that of the integrated craniofacial center at the University of California San Francisco, about 10 times that of private practice patients of the primary Ecuadorian surgeon, and significantly higher than published rates.[23–32]

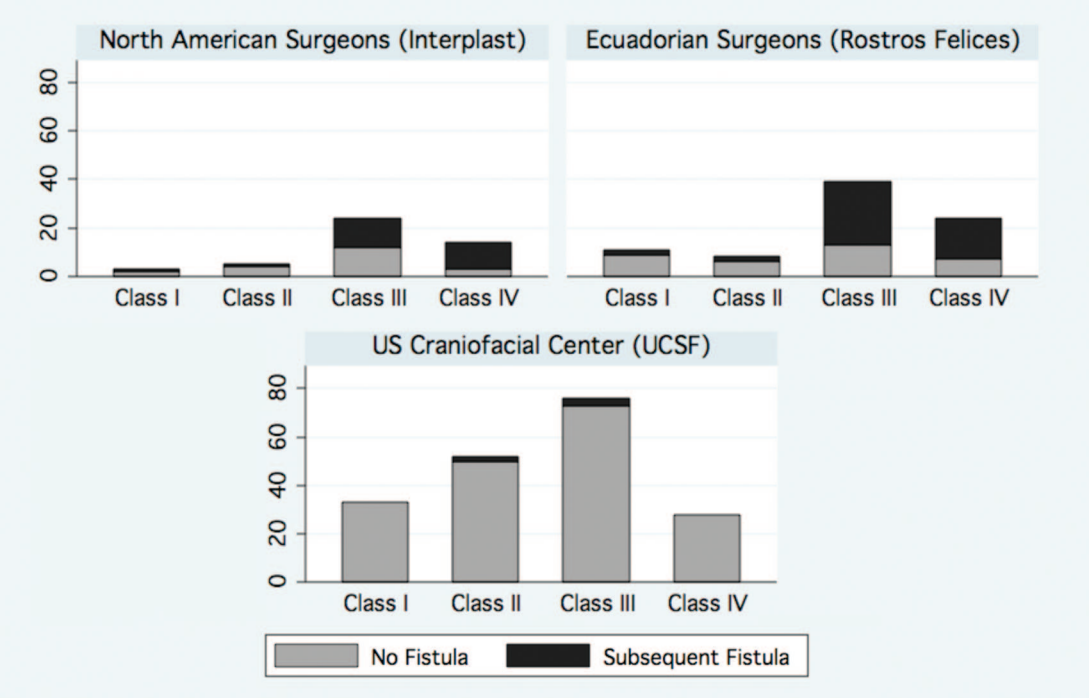

Fig. 1. Veau classification and fistula rate by organization.

Table 4. Outcomes of Highest Volume Surgeons by Organization in Ecuador*

Surgeon	Total Palatoplasties *n* (% of Total)	Evaluated Palates *n* (% of Total)	Fistulas in Evaluated Palates *n* (% of Evaluated)
Rostros Felices			
A	73 (44)	45 (62)	26 (58)
B	40 (24)	13 (36)	7 (53)
C	16 (10)	9 (56)	5 (56)
D	13 (8)	5 (38)	1 (20)
Unknown	2 (1)	2 (100)	1 (50)
Others (7 surgeons)	22 (13)	8 (36)	7 (88)
Totals	166	82 (49)	47 (57)
Interplast			
Unknown	20 (13)	7 (35)	3 (43)
W	15 (10)	5 (33)	4 (80)
X	10 (7)	3 (30)	1 (33)
Y	10 (7)	5 (50)	3 (60)
Z	9 (6)	4 (44)	2 (50)
Others (19 surgeons)	84 (57)	22 (26)	12 (43)
Totals	148	46 (31)	25 (54)

*Disqualified patients were not included in the total number of palates.

These results were both surprising and troubling. Previous studies suggest that older patients are more likely to develop fistulas[25,35] and that outcomes are better when repairs occur between 6 and 24 months.[5–7,9,18,36] This balances detrimental effects of earlier repairs on facial growth with poorer speech outcomes and more fistulas associated with later repairs.[22,25,35] Although early repair has long been recognized as important and has been used as a metric of mission success,[18] palatoplasties are often performed at an older age on missions.[6,9,18] Both the limited access to early treatment[5,6,9] and decreased awareness among health care providers and the public that surgical repair is possible contribute to later palatoplasty. Although the partnership between Rostros Felices and ReSurge International has increased the number of surgery sites, many patients wait 6 to 12 additional months for surgery if they cannot be served on the first mission for which they are evaluated. Although two-thirds of evaluated Ecuadorian patients were repaired by 24 months (Table 3), fewer than 10 percent had palatoplasty by 1 year of age. Because of the large age difference be-

tween Ecuadorian and U.S. cohorts (8 months), the association of older age and fistula in univariate analysis was not seen in multivariate analysis. For Ecuadorian patients, older age was not associated with fistula formation, either in univariate or multivariate analysis. Further investigation into the effect of older age at primary repair in this population and why our results differ from others is needed.

It is unknown if clefts treated on surgical missions differ from those at craniofacial centers in upper-income countries. Larger cleft width is associated with postoperative fistula formation.[22,23,28] Because preoperative cleft measurements were not routinely recorded, we used Veau classification as a proxy for cleft size.[22,25,28] Patients with clefts involving the lip and palate (Veau class III or IV) were significantly more likely to develop a postsurgical fistula ($p < 0.001$) than patients with only palatal clefts. A higher percentage of Ecuadorian patients had clefts extending into the lip, reflecting either an increased prevalence of this type of cleft in Ecuador and/or fewer patients with smaller, less visible clefts presenting for surgery.[7,20] The higher prevalence of cleft lip and palate in Ecuador alone did not account for the large difference in fistula rates between the U.S. and Ecuadorian cohorts. Better prospective documentation of cleft size will allow analysis of its impact on fistula development in this population.[8]

Surgeon's experience and procedure selection impact fistula rates.[22–24,27,28] Experienced surgeons have better outcomes.[3,36,37] In the past, surgical missions were faulted for allowing inexperienced surgeons to operate.[3,6,37,38] This led ReSurge International and others to create guidelines for participation (see above). All surgeons in this study met the requirements for experience and letters of support. The two Ecuadorian surgeons who performed the majority of procedures (Table 4) do more than the recommended number of palatoplasties annually.[3,36] Given the participation guidelines and overall experience of all surgeons operating in Ecuador, it is hard to attribute the increased fistula rates simply to inexperience. The high rate among all surgeons suggests a systemic rather than individual cause.

Procedure selection can affect fistula rate.[23,27,28] Unfortunately, the specific procedure used in Ecuador was often not recorded. The U.S. cohort surgeon used a Z-plasty to close defects of less than 10 mm and a two-flap palatoplasty with radical levator transposition for larger clefts. Future surgical missions should incorporate prospective data collection,[8] including procedure selection, to better understand the impact on fistula rates.

Wound healing depends on good nutrition, yet 20 percent of Ecuadorian children under the age of 5 are malnurished.[39] Unfortunately, the nutritional status of patients served on plastic surgery missions has not been well characterized.[10] ReSurge International requires that the patients meet defined preoperative weight and hemoglobin levels before undergoing surgery, but these data were not recorded for many patients. Weight-for-age was used as a proxy for nutritional status and was available for 108 Ecuadorian patients. There was no relationship between weight-for-age and fistula formation.

Poor oral health has also been associated with higher fistula rates.[40] Our patients were subjectively classified as having poor or good oral health at the time of our evaluation, based on overall oral hygiene and number of cavities. Patients with poor oral health had more fistulas ($p = 0.002$). Given their older age at palatoplasty, Ecuadorian patients had more teeth at the time of surgery, and those with poor oral health may have higher bacterial loads. Access to dental care is limited for this patient population. Developing partnerships with local dental providers and charitable organizations—as Rostros Felices and ReSurge International have recently done—could improve oral health and potentially decrease fistula rates.

Many other differences in perioperative care existed between U.S. and Ecuadorian patients. At the U.S. center, patients and families meet with social workers, nurse specialists, pediatric dentists, orthodontists, geneticists, and speech therapists preoperatively and postoperatively.[41] They learn feeding and other care strategies. In contrast, Ecuadorian families' contact with specialists is usually limited to busy screening days and surgical missions. Although both written and verbal instructions for postoperative care are given to parents, the high volume of operations performed limits the opportunity for individual teaching. Although not specifically addressed, we estimate that only one-third of patients kept their initial follow-up appointment, further limiting opportunities for education and support. Differences in perioperative care and education are targets for future investigation and interventions, including use of perioperative antibiotics, compliance with postoperative instructions, nutritional support programs, presurgical orthodontics, postoperative arm splints, and improved dental care.

The World Health Organization and the Global Burden of Surgical Disease Working Group highlight the role of surgical missions and humanitarian organizations in global surgical care. Incorporating

data collection and follow-up into these organizations is important for accurately estimating the global burden of surgical disease and ensuring that quality care is delivered on missions.[4,6,8,10,12,19] Prior studies focused on short-term perioperative outcomes.[4,6,10] Long-term follow-up is seldom done because organizations direct limited funds to service and educational activities. Some organizations, however, have begun developing databases to track long-term outcomes.[8] ReSurge International has developed programs that track outcomes of surgeries and interventions and identify patients with problems that could benefit from early reintervention. Hopefully, surgical groups can share data to improve quality of care delivered on all missions.

Limitations

Lack of telephone and postal service for many patients treated on missions makes follow-up studies challenging. Although our recall rate was high for mission work,[6,8] only 42 percent of patients were located. This raises concern about selection bias. Whether patients were initially contacted at a screening day, by telephone, or by home visit, the fistula rate was similar—56, 57, and 55 percent, respectively. Records revealed that 16 (8.6 percent) of the 186 Ecuadorian patients not located had subsequent fistula repairs. Assuming that none of the other unevaluated patients had a fistula, the overall fistula rate in Ecuador would be 28 percent (95 percent CI, 23 to 33 percent), 23 percent (95 percent CI, 17 to 31 percent) for North American, and 32 percent (95 percent CI, 25 to 40 percent) for Ecuadorian surgeons. These rates remain significantly higher than those for the U.S. cohort ($p < 0.001$). Because record keeping varied on missions, several other factors such as operative procedure, compliance with postoperative instructions, return for follow-up care, and presurgical care could not be evaluated and should be the focus of future work.

CONCLUSIONS

This study is the first to compare the occurrence rates of palatal fistulas for North American and local surgeons performing palatoplasties on surgical missions. Fistula rates of both groups in Ecuador were high. The retrospective nature of the study limited evaluation of potential causes of fistulas, and no single cause could be identified. The results suggest these patients have unique needs. ReSurge International has initiated similar outcome studies at other mission sites around the world to better understand the population treated on missions. They are also implementing better follow-up care and data tracking for their missions and outreach program in Ecuador. Poor oral health is a potential target for further evaluation and intervention, as are nutritional status, use of preoperative and perioperative antibiotics, and postoperative care. Together with the many other surgical groups working with these populations, strategies to improve long-term surgical outcomes must be developed to ensure that patients served on surgical missions obtain the same excellent results achieved at integrated centers in upper-income countries.

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