



Sustainability and Success of Cleft Surgery in Developing Countries: Satisfaction Outcome of 125 Patients Operated in Myanmar

Milena Pejko¹, Martin Gosau², Khin Marlar Win³, Thiha Wyain⁴, Heinrich Schoeneich⁵, Philipp Kauffmann⁶, Silke Haerteis¹, Lukas Prantl⁷, Paul Immanuel Heidekrueger^{7, †}, Thiha Aung^{1, 7, *, †}

¹Institute for Molecular and Cellular Anatomy, University of Regensburg, Regensburg, Germany

²Department of Oral and Craniomaxillofacial Surgery, Eppendorf University Hospital, University of Hamburg, Hamburg, Germany

³Department of Plastic and Maxillo-Facial and Oral Surgery, University of Medicine, Mandalay, Myanmar

⁴Department of Oral and Maxillofacial Surgery, University of Dental Medicine, Mandalay, Myanmar

⁵Interplast Germany, Section Munich, Munich, Germany

⁶Department of Oral and Maxillofacial Surgery, Georgja Augusta University, Göttingen, Germany

⁷Centre of Plastic, Aesthetic, Hand and Reconstructive Surgery, University of Regensburg, Regensburg, Germany

Email address:

thiha.aung@ukr.de (T. Aung)

*Corresponding author

† Paul Immanuel Heidekrueger and Thiha Aung have equivalent contribution to this paper.

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Abstract: Non-syndromic orofacial clefts are significantly linked to socioeconomic status. Because of limited access to proper medical care in rural areas of developing countries charity missions are highly required to mitigate negative outcome, but there is still a lack of data on humanitarian missions' sustainability and success. A retrospective analysis of 125 patients who underwent cleft surgery during humanitarian missions in Myanmar was performed. Patients' satisfaction with facial features and function was evaluated pre- and post-surgery. Furthermore, postoperative complications and satisfaction with follow-up care have been analyzed. Between 2008 and 2020 125 patients underwent cleft surgery by the Interplast team. The median patient's age was 2,58 years (mean=7 years) with a range of 3 months to 54 years. Group 1 (patients with cleft lip only, n=58) was analyzed on satisfaction with facial aspects and significant improvement was found. All 125 patients were evaluated regarding function features like eating or drinking and their post-surgical satisfaction was significantly higher than before surgery. To analyze if hearing and nasal breathing difficulties in patients with cleft palate can be decreased by primary cleft surgery these parameters were analyzed in group 2 (n=67). Group 2 as well reported significant improvement. Even with limited medical infrastructure and later primary surgery than in developed countries, cleft surgeries can be performed successfully and sustainable by integrating local surgeons in charity missions. Patients benefit greatly by these missions and further investigation on humanitarian cleft missions should be conducted.

Keywords: Orofacial Cleft, Cleft Surgery, Humanitarian Mission, Foundation-Based Medical Care, Interplast, Cleft Follow-up, Myanmar, Sustainability

1. Introduction

Orofacial clefts are common congenital malformations which mainly occur as isolated cleft palate (CP) and cleft lip with or without cleft palate (CL/P). [1] The reasons for developing a cleft are not yet fully understood, but there are environmental risk factors like smoking or malnutrition, as well as genetic factors. [2] There is an international average prevalence of 7.94 per 10 000 live births for CL/P. [3] Nevertheless, a higher prevalence is seen in Asia compared to America and Europe. [3] Studies have shown that non-syndromic orofacial cleft are significantly linked to socioeconomic status. [4] Infants with orofacial clefts have an increased risk of mortality compared to infants without congenital malformations. [5]

Patients with orofacial clefts suffer under several functional difficulties, like feeding problems after birth and during childhood, impaired hearing, facial malformations, poor Eustachian tube function and speech problems. [6] Furthermore, patients experience psychological and social consequences because of their facial appearance and speech. [7]

Clefts must be treated over a very long period of time until adulthood, which can be very straining for patients and their families. [8] In industrialized countries this treatment is covered by a multidisciplinary team, consisting inter alia of plastic and craniofacial surgeons, speech pathologists, dentists, orthodontists, psychologists, social workers and pediatricians. [9] In developing countries this kind of medical infrastructure is non-existent. Only 3,5% of all international surgeries are performed in the poorest countries, even though they have a share of over one third of the global population. [10] Studies show the access to CP surgery is significantly linked to a country's national income and economic factors. [11, 12] Because of these poor medical conditions patients in low-income countries receive surgery later than required and subsequently experience the complications and disadvantages over an extended period. [7, 11] Often surgical care cannot be provided on an adequate level and humanitarian missions by charity organization appear to be necessary. By providing humanitarian missions, the average age of the patients that received cleft operation could be decreased. First surgical repair of the cleft malformation is performed, but furthermore follow up care, as well as additional operations are required by a lot of patients. [13] Therefore, besides treating the facial malformations to mitigate negative outcomes and to improve the patient's quality of life, the main goal of humanitarian missions should be the creation of a locally sustainable long-term treatment for clefts in developing countries.

To provide an improvement for the surgical care of cleft patients in rural areas of Myanmar, Interplast Germany Teams (Non-governmental organization, section Munich and Regensburg) regularly execute humanitarian missions two to three times per year in the whole country. From 1997 to 2020 about 2500 patients with CP or CL/P underwent corrective surgery in more than 70 humanitarian missions. Local surgeons were always integrated in the treatment and trained

during the team's stay. Surgical methods have been adapted to the patients' needs for the achievement of the best possible outcome.

Most research on the outcome of cleft operations is based on clinical parameters. [14] and the number of studies covering post-operation data as well as patient satisfaction are limited, [15] especially in low-income countries. Cleft surgery affects many areas in the patient's life and the main goal is a postoperative improvement of the quality of life. The patients' satisfaction regarding the treatment outcome is an important factor for the measurement of surgery success. Therefore, 133 treated patients in Myanmar or their caregivers have been handed a questionnaire to evaluate the outcome between 2008 to 2020. Pre- and postoperative facial functions and appearance have been compared and postoperative complications and follow-up care was analyzed.

2. Material and Methods

A retrospective analysis of 125 patients who underwent cleft surgery in Myanmar was performed. Data was collected by handing out a questionnaire to the patient or the patient's caregiver during a follow-up care visit. The questionnaire was handed out to 133 patients. Only fully completed datasets were included in the analysis and 8 patients were excluded from the study. 2 due to not answering major parts of the questionnaire and 6 due to not filling in their cleft type (response rate 94%). The follow-up visits took place at the local hospital, with the Interplast Team or at a local clinic. If patients did not show up for follow-up care, the patient or their caregivers were contacted by phone. The questionnaires were available in English and Burmese. Questions regarding the patient's initial situation before surgery were answered, such as the patient's age, cleft type and number of previous cleft operations. To compare patient's quality of life before and after surgery and to evaluate the outcome of the performed surgeries, patients were asked to rate their satisfaction before and after surgery. The patient's satisfaction with the overall appearance and overall functions was evaluated, as well as specific facial features, such as smile, teeth and specific functions like drinking or hearing. Patients could classify their level of satisfaction on a 5-point-scale as "highly satisfied", "satisfied", "intermediate", "not bad" or "not satisfied". Besides these parameters the questionnaire contained questions regarding the follow-up care and possible problems after surgery.

Patients were divided into two groups in order to evaluate the collected data regarding their satisfaction. Patients with cleft lip only (group 1) and patients with cleft palate only or in combination with cleft lip (group 2) were evaluated. Aesthetic facial features are mainly affected in patients with cleft lip, whereas a cleft palate does not appear as aesthetically displeasing. Therefore, the issues covering facial appearance have been analyzed in the patient cohort diagnosed with cleft lip and bilateral cleft lip (n=58). Functional features (chewing, eating, drinking and speaking) affect both patient groups (CL and CP), thus for the analysis of these aspects all patients

(n=125) have been evaluated. Palate malformations can be a cause for hearing problems and difficulties with nasal breathing can also occur. Therefore, the improvement of hearing and nasal breathing has been examined in the patient group with cleft palate (n=67). A paired *t* test was performed, and the mean of each individual group was calculated and plotted in figures.

3. Results

Cleft lip has been diagnosed in 49 patients (39.2%), bilateral cleft lip in 9 (7.2%), cleft palate in 57 (45.6%) and

bilateral cleft palate in 10 (8.0%) (Figure 1a). 73 (58.4%) patients were male and 52 (41.6%) female (Figure 1b). The median patient's age was 2,58 years (mean=7 years) with a range of 3 months to 54 years (Figure 1c). 15 patients (12.0%) were older than 18 years when surgery was performed, which is considered a very late date for initial cleft surgery in developed countries. 69 patients (55.2%) were older than 2 years. The performed surgeries were mostly initial procedures, which pertain to 98 patients (78.4%). The remaining patients underwent primary surgery earlier by the Interplast team or other surgeons and received secondary surgery during the aforementioned period.

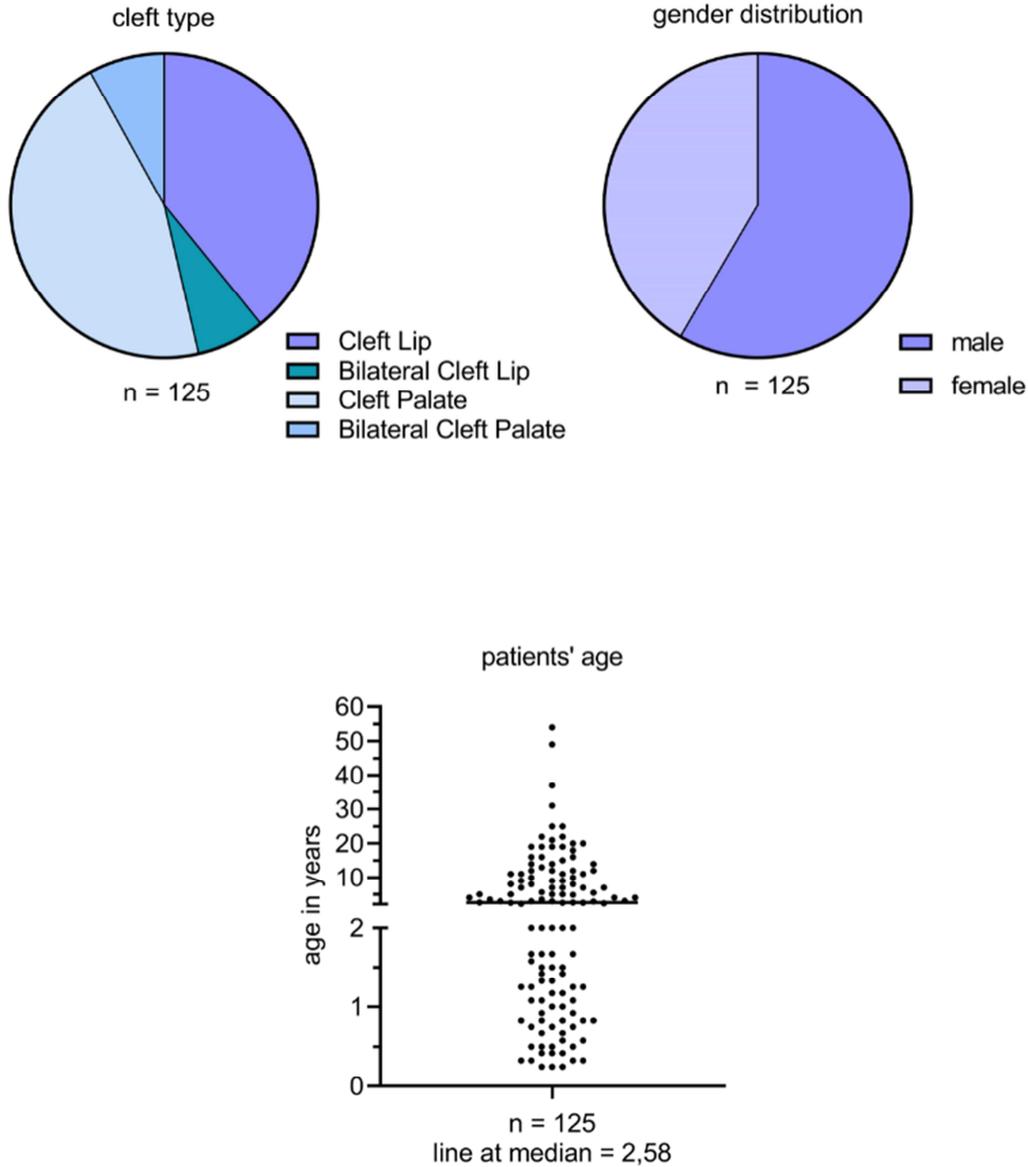


Figure 1. Patient cohort.

1a. Distribution of cleft types in the treated patient cohort

Divided into cleft lip (n=49), bilateral cleft lip (n=9), cleft palate (n=57) and bilateral cleft palate (n=10).

1b. Distribution of gender in the treated patient cohort

Divided into male (n=73) and female (n=52).

1c. Patients' age as a scattered dot plot

Range of age: 3 months to 54 years. The median age is represented as a line at 2.58 years.

3.1. Facial Features in Patients with Cleft Lip (Figure 2)

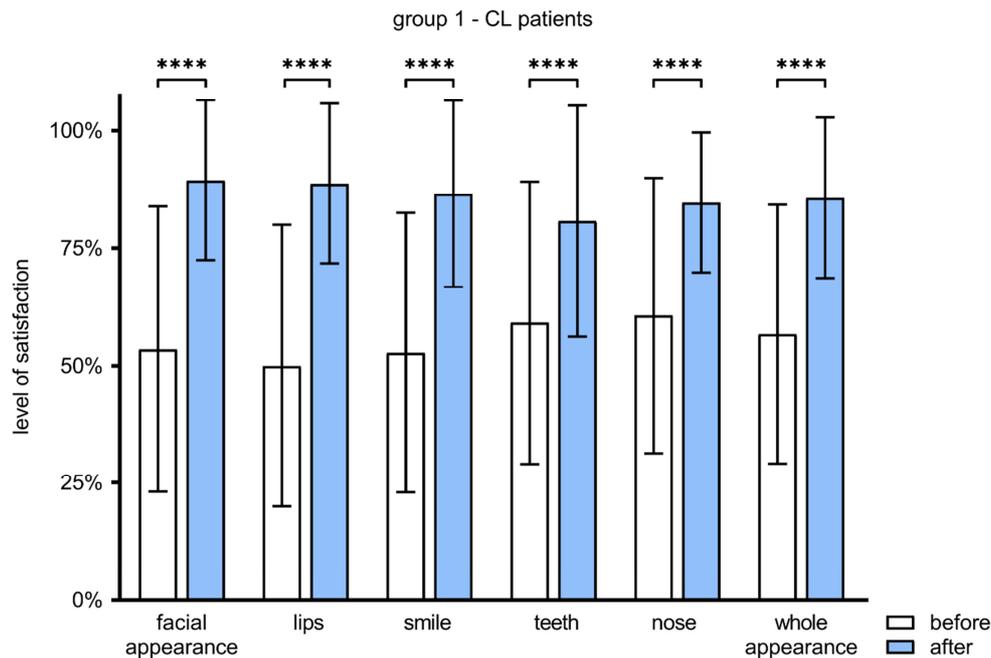


Figure 2. Satisfaction of cleft lip patients (group 1).

Mean pre- and post-operative satisfaction of subjects diagnosed with cleft lip (n=58) rated on a 5-point scale. The rating has been transformed in percentages, resulting in the positive endpoint (“highly satisfied”) being equivalent to 100% and the negative endpoint (“not satisfied”) being equivalent to 0%. Error bars attached to each column represent standard deviation. ****P < .0001, paired *t* test.

Before surgery, most patients (31.0%) reported being satisfied with their facial appearance or rated it as “not bad” (31.0%). Only 13.8% classified their facial appearance as “highly satisfying” and furthermore 6.9% were not satisfied. Post-surgery, this significantly ($p < .0001$) changed to most patients stating a high satisfaction (63.8%) with their facial appearance, in addition to 31.0% of patients being satisfied with it. After surgery, no patients stated being not satisfied with their facial appearance. Therefore, cleft lip surgery provided a highly significant improvement of satisfaction with facial appearance.

Furthermore, patients evaluated single facial features, precisely their lips, smile, teeth and nose. Before surgery most patients declared their level of satisfaction with the appearance of their lips as “satisfied” (29.3%) or “not bad” (29.3%). 10.3% were not satisfied with their lips. The collected post-operative data shows highly significant ($p < .0001$) improvement with patients being mostly highly satisfied (62.1%) and satisfied (34.5%) with their lips. No patients remained not satisfied.

Regarding their smile the largest proportion of patients stated their satisfaction as “not bad” (29.3%) or “intermediate” (24.1%) before surgery. After surgery this significantly ($p < .0001$) changed to most patients being highly satisfied (55.2%) or satisfied (31.0%). Only 5.2% found their post-operative smile to be “not bad” and 1.7% found it to be “intermediate”. Furthermore, no patients were not satisfied with their smile after surgery.

Pre-operative data shows a broad picture regarding the

patient’s satisfaction with their teeth. 36.2% were satisfied, 17.2% state their satisfaction as “intermediate”, 13.8% as “highly satisfied” and 13.8% as “not bad”. Post-operative, this significantly ($p < .0001$) shifted to patients mainly describing their teeth as highly satisfying (43.1%) or satisfying (34.5%). The “intermediate” group decreased to 3.4% and “not bad” to 6.9%.

The last evaluated facial feature was the appearance of the patient’s nose. Most patients declared that they were satisfied (37.9%) or intermediately satisfied (17.2%) with their nose. Pre-surgery, 15.5% stated their level of satisfaction as highly satisfying and 15.5% as “not bad”. 6.9% were not satisfied. After surgery this increased very significantly ($p < .0001$) to 51.7% of patients being satisfied and 39.7% being highly satisfied. No patients rated their level of satisfaction as “intermediate” or “not satisfied” and only 1.7% as “not bad”.

Furthermore, the study analyzed the overall influence of a cleft on the patient’s perception of their bodies. Before surgery, a large proportion of patients were satisfied (43.1%) with their whole appearance and 24.1% found it to be “not bad”. 15.5% stated an “intermediate” level of satisfaction. Post-operatively this improved very significantly ($p < .0001$) to 48.3% being highly satisfied and 44.8% being satisfied with their whole appearance. Only 3.4% rated it as “not bad” after surgery and no patients declared an intermediate level of satisfaction.

The collected data shows a highly significant improvement in all evaluated categories. Patients state a highly improved level of satisfaction with their facial appearance. Furthermore, the analyzed patient cohort shows that clefts do not only affect

the patients' satisfaction with the appearance of their faces, but also their whole appearance and even this can be improved

significantly by cleft surgery.

3.2. Functional Features (Figure 3)

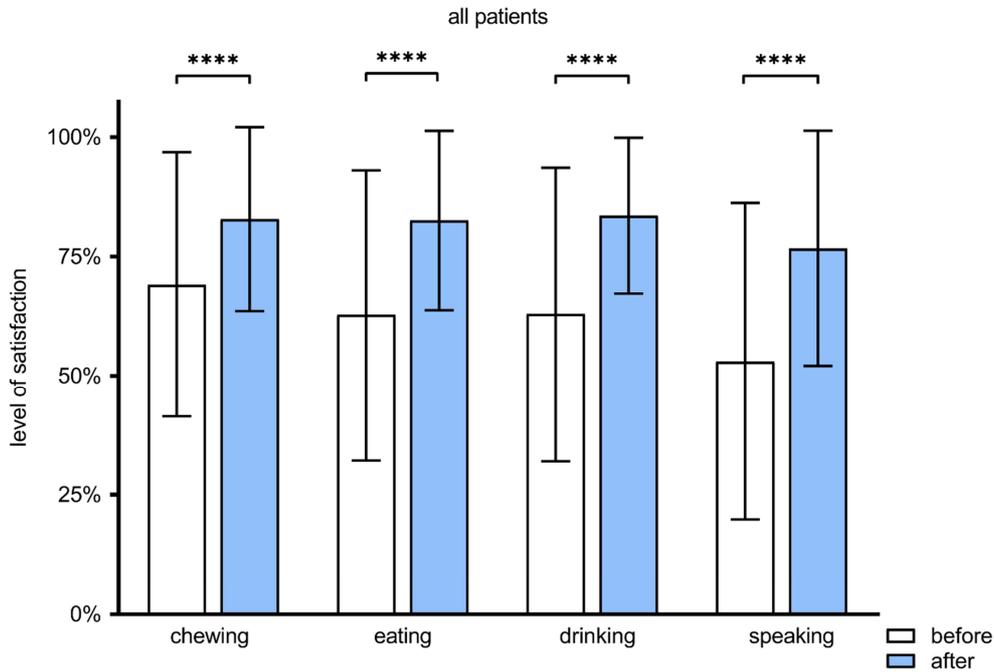


Figure 3. Satisfaction of cleft lip and palate patients (all patients).

Mean pre- and post-operative satisfaction of subjects diagnosed with cleft lip and/or cleft palate (n=125). For y-axis description see figure 2 (group 1). ****P <.0001, paired t test.

Before surgery, most patients were satisfied (44.8%) with their chewing function and 21.6% were highly satisfied. After surgery, a very significant improvement (p=<.0001) was observed, since 44.0% stated to be satisfied and 39.2% were highly satisfied.

With regards to eating 36.0% of patients were satisfied and 21.6% were highly satisfied. 17.6% of patients declared their level of satisfaction as “not bad” and 14.4% as intermediate. Post-operatively this increased significantly (p=<.0001) to 49.6% being satisfied and 40.0% being highly satisfied. Furthermore just 3.2% found the level of satisfaction regarding the eating process “not bad” and 2.4% intermediate.

The changes regarding the process of drinking were similar. Before surgery 36.0% of patients were satisfied and 22.4% highly satisfied. 18.4% described their level of satisfaction as “not bad” and 12.8% as intermediate. Post-operatively the satisfaction regarding the drinking process improved very significantly (p=<.0001) to 51.2% of patients being satisfied and 40.0% being highly satisfied. Only 2.4% stated their level of satisfaction as “not bad” and again 2.4% as intermediate.

In regards of speaking, 25.6% of patients were satisfied, 19.2% described their satisfaction as “not bad” and 18.4% as intermediate before surgery. Only 16.0% were highly satisfied and furthermore 13.6% of patients reported being not satisfied with their speaking function. After surgery a highly significant (p=<.0001) improvement was noticed. Post-operatively 42.4% stated being satisfied and 34.4%

highly satisfied. Patients describing their level of satisfaction as “not bad” decreased to 8.8% and only 5.6% remained with an intermediate level of satisfaction after surgery. The share of patients that were not satisfied was reduced to just 1.6%.

3.3. Hearing and Nasal Breathing in Patients with Cleft Palate (Figure 4)

Before surgery 37.3% of patients were satisfied with their hearing function and 32.8% were highly satisfied. 10.4% stated their level of satisfaction as “intermediate” and 9.0% were not satisfied with it. The post-operative improvement of hearing changed significantly (p=<.001) and resulted in 46.3% of patients stating their hearing function as satisfying and 43.3% as highly satisfying. Just 3.0% remained with intermediate levels of satisfaction and only 1.5% of patients were not satisfied after surgery.

Pre-operatively, 49.3% of patients were satisfied with their nasal breathing and 22.4% highly satisfied. 10.4% rated their level of satisfaction as “intermediate” and 4.5% were not satisfied. After surgery, a very significant (p=<.0001) change could be observed. 50.7% were satisfied and 40.3% were highly satisfied with their nasal breathing function. Furthermore, only 1.5% remained with intermediate levels of satisfaction and none not satisfied.

Besides examining these specific functions, the patients were asked to rate their satisfaction with the overall

function of their orofacial system. Before surgery 41.8% were satisfied with it and 17.9% highly satisfied. 16.4% described their level of satisfaction as “not bad”, 13.4% expressed intermediate satisfaction and 6.0% were not satisfied. Post-operatively this significantly changed ($p < .0001$) to 50.7% of patients being satisfied and 35.8%

being highly satisfied. Only 4.5% rated their level of satisfaction as “not bad” or intermediate and no patients remained not satisfied.

The collected data shows a significant change in patients' satisfaction with specific functional features, as well as overall function of the orofacial system.

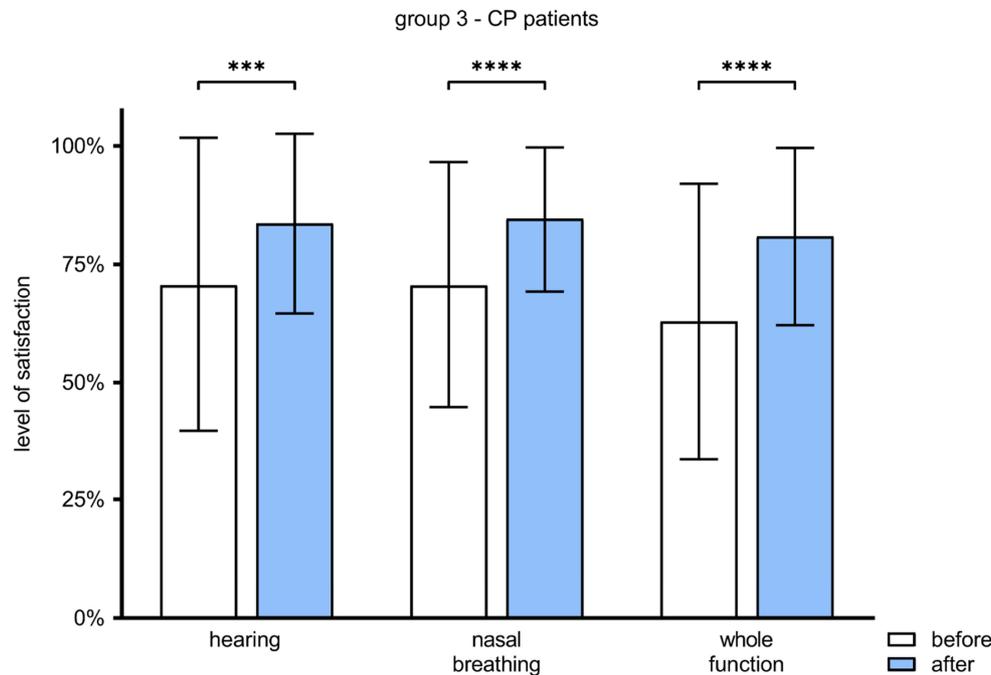


Figure 4. Satisfaction of cleft palate patients (group 2).

Mean pre- and post-operative satisfaction of subjects diagnosed with cleft palate with/without cleft lip ($n=67$). For y-axis description see figure 2 (group 1). *** $P < .001$ **** $P < .0001$, paired t test.

3.4. Follow-up Care and Post-Operative Complications

All patients were asked to state if they were satisfied with the offered follow-up care. The post-operative follow-up was mainly provided by a local hospital (45.6%) or the Interplast team (44.0%). Further 14.4% received follow-up care at a local clinic. Most patients were satisfied with the follow-up care they received (79.2%).

Only a few patients had post-operative complications. 14 (11.2%) reported pain, 6 (4.8%) bleeding, 3 (2.4%) infection and only one patient (0.8%) open stitches. Most patients (83.2%) reported no complications after surgery.

4. Discussion

The prevalence of orofacial clefts and patients' satisfaction with their treatment outcome has been analyzed sufficiently in developed countries, but in developing countries there is still a lack of data examining clefts. [16-19] There are studies examining the prevalence of clefts and postoperative complications in small patient groups in developing countries during humanitarian missions, [20] but there is no data regarding patients' levels of satisfaction with their surgical outcome. Because of the country's infrastructure the collection of data on surgical outcome and even short period

follow-up can be very difficult. [21, 22]

When performing surgery, the primary goal should be improving the patients' quality of life. [7] Cleft lip patients often struggle with their appearance and state lower levels of satisfaction with their facial appearance and facial features than people without craniofacial anomalies. [23] Furthermore, patients with visible cleft malformation have a higher discontent with their facial appearance than less conspicuous clefting. [24] In the analyzed patient group this is reflected by patients pre-operatively stating intermediate levels of satisfaction with their facial features, facial appearance and overall appearance. With cleft surgery their satisfaction improved significantly, which is a positive surgical outcome, since there is a study by Marcusson et al. stating that up to 50% of operated cleft patients were still not satisfied with their appearance. [23] The positive outcome in this study could be based on patients in developing countries not having as high expectations towards surgical procedures. It is more likely that patients in developing countries have a higher regard for improvement of function than for aesthetics. [7]

Even though there are validated scoring systems to evaluate certain cleft surgery outcomes, such as speech, these scoring systems require a good medical infrastructure and an internationally recognized methodology to evaluate facial appearance still does not exist. [25] During humanitarian

missions this often cannot be provided. For an additional evaluation by medical workers a better medical infrastructure is needed. Studies have shown that the patient's own evaluation can be a trusted source for the assessment of cleft surgery outcome. [23, 26] but there is still a lack of validated patient-evaluated measures regarding cleft surgery outcome. We correspond with Eckstein *et al.* that an internationally validated methodology or questionnaire should be developed. [14]

In developed countries the treatment of clefts is much more complex and scheduled according to the patient's age and cleft type. During humanitarian missions patients often receive their first cleft surgery far later than patients in developed countries. This makes surgery more difficult. During humanitarian missions cleft surgery can be provided, but further procedures like speech therapy or orthodontic treatment remain inaccessible. [27] However, humanitarian missions try to improve the patient's life in the best possible way, but often there is no measurement for the success of this goal. This study has been conducted to examine the impact of the offered humanitarian cleft surgeries. Even though patients older than the recommended age for initial surgery have been operated, patients state a high satisfaction with their surgical outcome. With an adequate surgical technique, a good outcome and improvement of the patients' quality of life can be achieved even when the ideal time for surgery had passed.

Only few patients reported severe postoperative complications that needed to be treated, like infections or open stitches. This corresponds to findings from Maki *et al.* that 70% of humanitarian missions have postoperative complications up to 5%. [18] Usual postoperative complications, like bleeding or pain, occurred but required no further treatment.

A frequent criticism of case series from low-income countries is poor follow-up. The fact that most patients are living in remote areas without any established infrastructure makes it very difficult to locate patients and examine them again. After more than 20 years of humanitarian missions in Myanmar, Interplast Germany has developed a well-organized and widespread medical infrastructural network and if patients did not show up for follow up, they could be contacted by phone.

5. Conclusion

In this study the 125 operated cleft patients stated a significant increase in satisfaction with their aesthetic and functional facial features. The overall significant results suggest a high improvement of quality of life by the provided humanitarian mission.

The low complication rate and significant improvements of satisfaction indicate a successful inclusion and training of local surgeons who had an essential role in the performed surgeries.

Overall, these findings show that cleft surgery can be performed successfully and patients benefit greatly even in developing countries with limited surgical possibilities.

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

Conflicts of Interest

The authors declare that they have no conflict of interest.

Authors' Contributions

Milena Pejko \acute{v} ic – writing and review of manuscript, data acquisition
 Martin Gosau – writing and review of manuscript
 Khin Marlar Win – writing and review of manuscript
 Thiha Wyain – writing and review of manuscript
 Heinz Schöneich – writing and review of manuscript
 Philipp Kauffmann – writing, project design and review of manuscript
 Silke Härteis – writing, project design and review of manuscript
 Lukas Prantl – writing and review of manuscript
 Thiha Aung – project design, writing and review of manuscript, development of methodology, data acquisition
 Paul I. Heidekrueger – writing and review of manuscript

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