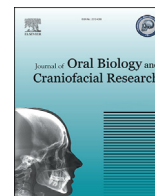




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Cleft surgery in India - Past, present and future and a model for global knowledge transfer

Srinivas Gosla Reddy^{a,*}, Avani Pandey^a, Adity Bansal^b^a GSR Institute of Cranio-Maxillofacial and Facial Plastic Surgery, Vinay Nagar Colony, I S Sadan, Saidabad, Hyderabad, Telangana, 500059, India^b Department of Dentistry (Cranio-maxillofacial Surgery), All India Institute of Medical Sciences (AIIMS), Rishikesh, Uttarakhand, 249203, India

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ABSTRACT

This article represents the point of view and philosophy of GSR Institute of Cranio-maxillofacial and Facial Plastic Surgery (GSRIFCS) in the management of craniofacial and cleft patients. GSRIFCS is a 50 bedded state of art high volume cleft centre in Hyderabad which has accomplished greater than 30000 cleft surgeries. Cleft surgery in India has improved greatly over the last 70 years since the innovations of the Colombo plan to now, resulting in better healthcare facilities, research and transfer of knowledge globally. In this period, the deprivations of the past, due to lack of available, accessible or affordable care or awareness of outpatients and their parentage, of the possibilities, some of cultural origin such as various superstitions leading to isolation and social stigma, have been largely but not completely overcome.

There were minimal centres in the past, which provided care, and this was partly due to scarcity of funding, lack of training and non-sustainability of skilled human resources. Surgery for cleft requires not only a sophisticated infrastructure, but instrumentation, specialized anesthetists and high-end post-operative care along with a multidisciplinary team involving surgeons, anesthetists, paediatricians, psychologists, orthodontists and specialized nurses for optimal outcomes. The article elaborates the vision, mission and plan in establishing the GSRIFCS and how it might form a model for the future of cleft care in LMICs.

1. Introduction

The modern era of cleft surgery in India has evolved over the course of last 75 years.¹ The Hyderabad Cleft Society was formed in the year 2000, with the foresight for state-of-art surgeries for craniofacial and cleft patients, with either no or minimal cost, and to provide them with complete rehabilitation. India being a developing country, has greater than 70 % of population inhabiting rural areas, with minimum access to equitable, high-quality healthcare. Cleft patients are frequently deserted and left secluded due to dearth of awareness and treatment among the general population. Cleft surgery in India has seen a significant change and re-organization in these years due to better healthcare facilities, awareness and understanding of the problem and research. Prior to these advances, though to some extent still problematic now, the situation was far worse with the patients being excluded from society, the family being blamed for the condition, superstitions abounding and, due to the social stigma, a failure to merge into society. Skilled cleft surgeons were few and far between, and the patients were clueless about the treatability of clefts. Moreover, funding was the biggest problem during those times.

Cleft surgery requires sophisticated infrastructure, instrumentation, specialized anesthetists and high end post-operative care along with a teamwork involving surgeons, anesthetists, pediatricians, psychologists, orthodontists and specialist nurses for optimum outcomes. Procurement of all these facilities was a remote possibility until the developments of the 1950s. This resulted in long waiting lists, often with poor results in those centres performing clefts during those times in India.

2. History

The history of modern management services for cleft and craniofacial deformities patients in India started in the 1950s, the era of the Colombo plan providing aid for South East Asia, with Sir Benjamin Rank of the University of Melbourne being invited to India in 1955 to develop an extended training programme for surgeons in plastic surgery. Dr. C. Balakrishnan established a major plastic surgical department at the Postgraduate Institute at Chandigarh in the 1950s, followed by Dr. Behman Davar, Dr. Charles Pinto, Dr. Arthur De Sa, and Dr. Rustom Irani who developed eight cleft centres in the 1960s. Since then, other

* Corresponding author.

E-mail addresses: goslareddy@gmail.com (S.G. Reddy), avnipandey11@gmail.com (A. Pandey), aditybansal@rediffmail.com (A. Bansal).<https://doi.org/10.1016/j.jobcr.2021.08.003>

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dedicated surgeons such as Dr. Hirji Adenwalla in Trichur, Kerala, Drs. K. S. Goleria, Dr Suresh Tambwekar, and Dr Ravin Thatte in Mumbai developed major centres to serve patients with cleft deformities, followed over the years by many others around the nation.¹

Prior to these developments, cleft and craniofacial deformities were often seen in India as cosmetic deformities rather than functional deformities. Thus, the focus had been on the soft tissue defect surgery alone, that is, cleft lip and nose. Patients complete rehabilitation involves patient's education, genetic counselling, and speech management; secondary revisions were not considered by most cleft centres because of the high load and expense, even less, was the patients psychological aspects consideration. Those surgeons did not create multidisciplinary teams to provide comprehensive management, largely due to the potentially high volume of patients, few well-trained personnel, and lack of financial resources.

With the arrival of Smile Train in 2000, a well-endowed US NGO focusing entirely on funding cleft surgery, significant changes occurred. The availability of funds for approved centres and surgeons made it possible to provide free or affordable patient management, resulting in many surgeons collaborating to treat these patients and becoming specialized in this field. Despite this, initially both the hospitals and surgeons did not have proper facilities for optimal utilization of the funding which then disheartened many of them who either completely stopped or only became minimally involved in providing cleft services.

3. Recent development of cleft services in India

During the senior author's early training in the initial 1990s, multidisciplinary teams, including surgeons, speech pathologists and orthodontists from the UK visited Mangalore, India, for teaching and treating cleft patients. On further interaction with them, he learned that the team treated large numbers of clefts every year and, importantly, provided comprehensive treatment for the patients. The child is referred at the time of birth to the team, though on many occasions, patients are in contact with the specialists in the perinatal period too. The team conducted twice monthly multidisciplinary meetings discussing every patient, with their possible treatment plans and requirements.

In India, during those times, comprehensive treatment was still unusual, with only surgical treatment being done and, for various reasons, mainly logistic and financial, no follow up. Cleft patients were managed without constraints of time, and in multiple cases not treated at all. This led to a huge backlog of untreated cases all over India. The incidence of clefts was very high, with 1 in every 500 cases of live births, which further compounded the situation.

India spends merely 1 % GDP on healthcare which has resulted in underfunded, understaffed and government hospitals with poor dedicated infrastructure.² The delivery system for health care in India, and Andhra Pradesh in particular, is by two pathways: government-funded hospitals and private or corporate hospitals. Government-funded general hospitals are situated in every district capital. Subunits of general hospitals are usually located in 2 or 3 large towns in the district and are known as area hospitals. Smaller referral primary health centres or community health centres are located on average, 1 for every 3 villages. This system of health care delivery is funded by government, and the care provided is free of cost for the patient. These hospitals see greater than 2 million patients as outpatients and larger than 160,000 patients as inpatients. The allocated budget for the health care by the government of Andhra Pradesh for the financial year 2017–2018 was Indian Rupee 13, 150 million (US \$292 million).³ The per capita funds allocation for the health care is less than US \$4 per person in this state. This means that government hospitals are understaffed and have a poor infrastructure.

The private or corporate hospitals are usually located in larger towns and cities. These hospitals have better facilities and cater to patients who can afford health insurance or can pay directly for health care services. The average cost of each surgery for simple cleft defects at such hospitals will be between Indian Rupee 25,000 (US \$500) and 50,000 (US \$1000).

With an annual per capita income of US \$755, most people in the state cannot afford health insurance. Less than 10 % of the population has health insurance in Andhra Pradesh, India. Hence, access to care at these hospitals is limited to a minority of population. Corporate or private hospitals have better facilities, but high costs made it impossible to provide cleft care services at nominal rates.³

Lack of funds, both by patients and hospitals, has created a vicious cycle leading to an increasing number of untreated cases, along with the one who had not been treated previously, all, not getting the complete rehabilitation to lead a normal life within their communities, adding a great economic burden to both family and state. This leads to shame, humiliation, unemployment and further personal and societal deterioration for cleft patients. The burden cleft child care has the potential to affect entire family units. It is not unusual to see patients with untreated cleft lip remaining untreated for the entirety of their life. Complete rehabilitation of such patients involves orthodontics and speech therapy; secondary revisions are conflicting, best case scenario, and generally often inaccessible.

4. Establishing a cleft centre

A considerable amount of time was spent by the senior author in a variety of hospitals around the country and elsewhere in the world, like for example, in Germany and UK analysing the requirements for provision of a holistic service. The assignment was difficult but with people from the entire world, gathering to help and provide guidance and support, advances were made.

The GSR Cleft and Craniofacial Hospital was started in 2000. The essential goal was to deliver comprehensive care to patients with craniofacial and cleft defects, who could not otherwise gain access to high-quality and affordable services and to set-up a truly multidisciplinary service including patient enlistment, appropriate pre- and post-operative care, sustainable financial self-stability, data storage and research.³ Since most cleft patients come from low socio-economic groups, fund-raising was the only option to achieve this aim. To deliver optimal treatment, it was decided to focus only on facial deformities. The administrative system was outlined with only essential staff so as to use the available financial resources properly and to be transparent to our donors. The desired goal for the facility was to handle 1200 cleft and craniofacial surgeries with 500 cleft speech therapies and 200 cleft orthodontic therapies every year.

The centre focused to provide a service for a population of approximately 100 million people living in an area within a 1000 km radius from Hyderabad, including nearby towns, villages and districts and some inter-state borders patients. We took care to appoint local people who were inclined to work long term with us, as it improved our efficiency and sustainability.

At first, the surgeon was not only the sole operator but also the sole administrator. The vision for the service was vigorously promoted by him and people who shared his ideas. He started the cleft treatment alone, travelling to various districts on rotation, and arranging surgeries as well as creating awareness of the likelihood and life changing potential of surgery. An increasing realisation of the poor infrastructure and less efficient facilities in the rural areas brought about the establishment of this single unit at which patients could be provided with optimal treatment. The logical place to establish the institute was in Hyderabad, which is the capital of the state of Andhra Pradesh in 2000 (Presently in Telanagana). This city is easily accessible for the surrounding states of Tamil Nadu, Karnataka, Maharashtra, Madhya Pradesh, Chhattisgarh and Orissa.

Starting this project in an existing hospital as a stand-alone unit required huge financial input and support from existing management. In November 2000, after the entry of external funding agencies into India, the team shifted its base to a larger but lesser used hospital in June 2001.

However, the senior author faced procedural and administrative hurdles, and the costs for providing similar care increased with no

improvement in delivery of care. As a result, a decision was made, in 2003, to move the entire service and to become totally independent. In this way, it enabled full and optimal use of external funding, which had initially been provided by Smile Train, then by a Swiss NGO, Cleft Children International, and latterly by Smile Train only. Other consultants were recruited, to form a team that included a pediatrician, an otolaryngologist, a neurosurgeon, a speech therapist, an orthodontist, and a general dentist. A core group of nurses were trained in managing infants and children with facial defects. The Hyderabad Cleft Society (HCS), which was established as a non-profit organization in 2000, provided the umbrella organisation for the GSR Institute of Craniofacial Surgery, to deliver comprehensive treatment to patients with craniofacial and cleft defects and as an instrument to raise funds.

Screening and awareness campaigns were launched throughout the state in all districts and beyond within the 1000 km radius of the hospital. During such campaigns, patients with congenital facial defects were, and still are, screened for treatment at the institute. A database, with funding from a NGO and the state, was established and used to send the information to the centre, also it formed the basis for record keeping and future research. Patient education and awareness increased about consanguinity and its effects on birth of children with congenital deficiencies and superstitions like clefts being associated with the solar eclipse and moon dispelled.

Another problem with cleft defects in India was, and still is, malnutrition because of feeding defects and no awareness of feeding programmes for cleft children. In India, 17 % of children younger than 5 years are mild to moderately under-nourished and 6 % of children are severely malnourished. In Andhra Pradesh, the figures are 11.4 % and 3.8 %, respectively.⁴ Feeding advice in the form of audio-visual tools is now provided for all parents of children inflicted with craniofacial and cleft defects who bring their children for consultation. Our camp co-ordinators have also been trained to provide feeding instructions to the parents during campaigns.³

Establishing a centre that cater all patient's needs in terms of treatment and logistics require a huge finance which is certainly difficult for an amateur surgeons in their initial stage of career. This challenge can be overcome by collaborating with non-government organizations and taking help from government schemes. The other challenge that senior author faced was to sustain the skilled staffs due to professional and personal reasons which affects quality of treatment in long run. The senior author believes that if a staff works for a longer period of time in one organisation, it is beneficial for both the worker and the system as both gets aware of sills and pitfalls of each other. This helps to work on pitfalls and enhance the positives for overall growth of both system and individuals in coherent manner.

As an adjunct to the cleft centre, the Cleft School Project was established in 2009, funding by a Swiss NGO, Cleft Kinder Hilfe, in collaboration with Hyderabad Cleft Society. The project arose as a consequence of a 4 year-old orphan who presented to the hospital with a facial cleft (Tessier 0-14). She was brought for care and treatment after being abandoned by her own relatives due to the scare of her deformity. Given that there were likely many children in a similar situation, it was decided to establish a place where children like her could be cared for, not only for their management surgically, but for livelihood. This led to the development of the hostel. Abandoned or orphaned children were admitted and nurtured in the healthy atmosphere of compassionate tutors and peers having similar deformities, so that differences became shared and understood, helping them not only to feel and become socially acceptable but also someone that everyone will aspire to become in future. In 2017, further charitable funding from Sumbing Biber became available. At present, there are 100 children ranging from nursery to conclusion of schooling, who have been provided a nearby English medium establishment, and on to further training opportunities and degrees.

The Institute has now treated more than 30000 patients. All these patients have the provision of transportation to the hospital, surgical care

at appropriate times, and other treatments such as orthodontics along with speech therapy and then returned to their respective communities. Most care and transportation is provided free of cost. The fees paid by a few patients who can afford to do so, are made use for further development of the service. The HCS continues to expand further with external and domestic funding agencies to ensure long-term sustenance. The GSR Institute of Cleft and Craniofacial surgery raises funds under 4 categories: treatment, infrastructure and equipment, human resources, and research. As a result of continued funding over the years, there is a significant amount of high-end, top quality expensive equipment available, but this takes many years to accumulate, much hard fund-raising activity and general hard work to prove that excellent outcomes are achievable given the right direction of the organization. The 50-bed hospital is highly developed with 2 fully functional operating rooms, an intensive care unit with pediatric ventilators, radiographic machines, orthodontic/dental equipment, and speech therapy equipment. The needs of the patient are addressed starting with transporting the patient from their district or village, delivering treatment in the form of surgery, orthodontics and speech therapy, providing free medicines, and transporting the patient back to their districts. Education and awareness of the parents along with patients with cleft and facial deformities, treatment facilities, and options available are by partnering individuals, non-government agencies, and local government bodies.

The charitable arm i.e the Hyderabad Cleft Society, is a non-profitable corporate entity, maximizing the number of patients receiving optimum care, and continues to retain well-trained personnel. Over the past 20 years, the management of cleft and craniofacial deformities has changed. There is increasing importance given to speech therapy and orthodontics and secondary surgical corrections. Much of the fundraising is done by the surgeons on behalf of all the departments involved.

The surgeons, Institute, and other personnel are encouraged to interact and collaborate with organizations for their technical and administrative expertise. The GSR Institute of Craniofacial Surgery continues to forge partnerships with universities and funding organizations in countries such as Belgium, Canada, Germany, Italy, the Netherlands, South Korea, Sweden, Switzerland, United States of America, United Kingdom, and India. This helps in the constant improvement of the work quality at the Institute. In addition, the regular exchange programmes advance fundraising capacities, with strategic alliances with well-established funding agencies.

Financial quality control and management is conducted internally by non-government third party audits and legally by the Ministry of Home, Government of India, under the Foreign Contributions Regulation Act 1976. The health outcomes of the Institute's technical and medical aspects are overseen by an International Medical Advisory Board encompassing health care professionals from all disciplines including surgery, orthodontics, and speech therapy.

5. Research

Research along with training, are the important developmental aspects of the Institute. To start the serious research, appropriate funding was required for all the research phases, along with support from system. Also, there was concern regarding the importance of standardisation for carrying out qualitative research, because of the inexperience of most of our researchers with the methodology.

Sufficiently large and diverse datasets, required for training, is a significant challenge in medicine which indeed became the strength of GSRICFS owing to its high-volume patients. Initially, cooperation with Radboud University (Nijmegen) and Universitatpsital (Basel), where research system are more systematic and organised, was established.

Altogether, it was observed that the projects for research require flexibility to allow researchers to respond to the concerns and the needs, especially of the community. Also, flexibility in design allows for cooperation and input of the community, which can help in addressing ethical issues for conducting research on vulnerable populations. Establishment

of the community advisory board was done for the promotion of more effective communication, and enabling dissemination of goals for research, while also addressing community needs.

Moreover, third party accountability plays a major role in the effective utilization of global policies and frameworks for research procedures. Hence, we established our international medical advisory board, collaborating with surgeons from United Kingdom, USA, The Netherlands, Belgium, Germany, Brussels, Spain and other parts of the world. This changed our perspective and made us more global in our approach. Not only did it add to our research work but improved the quality of our treatment.

Our research programmes are addressed on four major roles: collaboration/partnerships, sustainability/capacity, meeting local needs, and to standardise process specific recommendations. The vast majority of the projects including the novel morphofunctional approaches for cleft lip, palate, nose and cleft orthognathic surgeries, were started on basis for mutually beneficial partnerships involving commitment to collaboration and equitable relationships.

The importance of trusted and respectful professional relationships, strong and sustained leadership, and the requirement to ensure programmes were found favourable to both the institutions as well as the patients. Necessity for a central coordinating body was observed, which was normally the university with which we collaborated, to recognise synergies and establish new relationships along with the addition of core criteria for evaluation of the projects, instead of focusing on short-term output evaluation.

Coordination with the local providers for the acknowledgement of competence, for improving care quality, and for partnership importance with the community was seen to be essential. Also, national impact consideration, along with assessment of mutually established plans helps in developing partnerships with universities of a host country as the treatment plan and general conditions are similar in many contexts. Universities in India, such as Yenapoya Univeristy, KIMSDU, Datta Meghe Institute of Medical Sciences, and many others are working in association with GSR hospital for the same cause.

Evaluation is a recommended way to determine if these goals are being met, and should include considerations of sustainability, partnership building, and capacity. Thus, at GSR Institute, health research programmes details regarding the research process, the context of research, partnerships, and community relationships are always considered.

6. Training

Training for cleft and craniofacial surgery should involve mentorship, pre-departure preparation of students, and elements developed to increase impact. Clinical care programmes should focus on collaboration, sustainability, meeting local needs, and appropriate process considerations.

The importance of institutional commitment and long-term partnerships is important in designing training programmes along with the establishment of networks. The training programme, as well as being beneficial to the trainee, should be mutually beneficial to the previously established and developing networks as well as the organisation involved, rooted in the transfer of knowledge from both sides.

In order to achieve this, the importance of a clear vision cannot be ignored, and this has increasingly become central to the senior author's work. This vision must focus on the application of knowledge and allow for evaluation of intended outcomes. Core values and principles can also be used as background context for competencies when developing a curriculum, such as that devised for the recently established MCh (Master of Surgery) programme in craniofacial surgery at AIIMS in Rishikesh, India.

At the GSR Hospital, strategic field experiences have been developed to increase the impact of didactic teaching provided in the resident training programme with an input of 4 Indian fellows every year. To date,

we have trained nearly 80 fellows. Mentorship was noted as an important aspect in medical training and there must be personal involvement in training of students by senior and experienced surgeons. Moreover, to spread the load of teaching, especially for the students who have come for short fellowships of 3–6 months and from overseas, the other staffs of the hospital can themselves gain worthwhile teaching and leadership experience. Mentorship by the senior author also provides for structured debriefing and facilitates communication among the students and staff, creating an inclusive atmosphere for learning especially for international fellows supported by IAOMS, EACMFS and AO every year. We have trained more than 70 international fellows in the last 10 years, from UK, USA, Brazil, Belgium, The Netherlands, Iraq, Spain, Germany, Italy, Romania, Dominican Republic, Sri Lanka, Indonesia, Nigeria, Kenya, Iraq and more.

A multitude of capacity building activities are also done in GSRICFS such as educational schemes/programmes, on-the-job training, and symposia, pointing out the building capacity importance via development of long-term and productive relationships, and skills transfer, instead of simply organizing workshops. The use of the existing infrastructure, and focus on long-term impact have been observed as encouraging sustainability in all our projects. Periodic evaluation has been suggested to ensure programmes are meeting outcomes and developing interventions appropriately, developing a framework to evaluate sustainability, including considerations of health outcomes, health services, organizational capacity and viability.

7. Future and global transfer

Financially, GSRICFS is a hybrid operational model and works by generating revenues from the collaboration with NGOs and by providing surgery to fee paying patients (if they are able to afford them), using the revenues to provide free or low-cost surgeries to patients from low socioeconomic populations. Each fully paying patient cross subsidizes the care of two others. The underlying idea is to attain cost effectiveness and efficiency through standardisation, and engineering surgeries for high volume production. GSRICFS is therefore an example of an economically healthy entrepreneurship, and healthcare innovation. Its main two revenue sources are the sliding-scale fee payment system and funding by NGOs. Approximately 65 % of its revenue is generated by collaborating with different NGOs working in the field of clefts. A second considerable source of revenue, approximately 45 %, comes from affluent patients, who pay for the surgical procedure, and receive amenities in the form of accommodation, though the high standards of surgery remain the same. These two income sources enable GSRICFS to support its benevolent free cleft surgeries practices to the poor.

To ensure quality, GSRICFS has an excellent system for documentation, a constant review of complications, outcomes and infections. It is equally essential to monitor follow-up rates of postoperative cases. In high volume settings, such quality assurance processes make extensive use of robust IT systems to capture data and help in evidence-based decision-making. Monitoring is a principal aspect of any health organization striving to continuously improve the quality of services rendered. At GSRICFS, performance review meetings are conducted every week in the presence of all the staff concerned. Relevant data for each kind of medical and research activity is collected from the respective staff. The standard hospital management system is used to monitor the performance of the previous week and plan for the forthcoming operation theatres schedules.

Another innovatory feature is GSRICFS's acquisition of Taylorian principles of management of productivity of labour and economic efficiency.⁵ The staff from the clinical side makes the diagnosis; pre- and post-operative care is being handled by fellows; and senior consultants operate and prescribe. Every doctor handles two operating tables; while one patient is being operated, the next patient is prepared by the fellows in the meantime, so that the doctor can operate the second patient on the

other table as soon as he finishes the first. The surgery is performed in a restricted space, without losing time, rotating from one operation theatre to another, to avoid delays and bottlenecks. This logistically increases doctors' productivity. The equipment for surgery is utilized 12 h a day, thus further reducing the cost for surgery per patient. On the other hand, other health institutions of India illustrate the limitations of progression in technology for the promotion of improvements in health-care delivery or public health, except for middle-income and high-income segments.

8. Transformational implications

GSRICFS has proved transformational as it has affected cultural behavioural patterns and social structures in India. It has transformed the bond between the patients and the doctors in varied ways: it encourages patients to engage and involve in the healthcare delivery process. It motivates doctors to intensify their responsibility and commitment. Also, it proposes its services beyond the free surgeries (eg. free transportation for the accompanying person, free accommodation and meals in the city). It also assigns duties to the local people: when setting camps in the rural areas, the materials aspects are taken over by village notables or chiefs. It also creates awareness in the rural areas about the possible reasons for occurrence of clefts and similar deformities, reducing the fear about the deformity among the general uneducated population. Moreover, heightened awareness has made people realise that care is not a top-down process, which is to be given as an aid or as a philanthropic gesture. Neither it is to be seen in regards of attempting to force rural populations to change their habits via educational classes, propaganda or social workers' interventions. These habits do not change instantly, rather only gradually, by establishing a bond of confidence between the patients and the doctors. By showing outcomes of solidarity and cooperation, and by building the foundation of trust, GSRICFS and team encourage responsibility amongst patients – not only for their family and themselves, but also for the community. GSR hospital is also involved in giving job opportunities to cleft patients in their system, and as of now 60 % of ground staff are former GSR patients. We believe that charity is for corporatization and not for pity. The systems involving should also be benefitted in order to sustain the system.

The condition has improved in India but still a lot to be done when compared to west. The future holds bright for us and we are looking to train more and more young surgeons specially from the northern and eastern part of India, as there is dearth of comprehensive cleft centres in those parts. Moreover, we have also collaborated with organizations and NGOs such as Future Faces, Smile Train, International Association of Oral and Maxillofacial Surgeons, European Association of Oral and Maxillofacial Surgeons and many more who are providing us opportunities to teach fellows from other parts of the world specially Eastern and African countries like Malaysia, Indonesia, Kenya, Ethiopia and others so that our

students can ultimately provide high quality, comprehensive treatment in their respective countries.

Although it takes a great effort to establish and develop these services, we can be certain that future will be better if concepts of our Institute are adopted by its trainees, creating a fairer society. Till this is accomplished, let's create, collaborate, and cooperate in the fight against these dreadful deformities which not only cause functional problems but cripple patients psychologically. GSR hospital is adamant that it will provide cleft care to each and every patient and will work tirelessly till even a single patient of cleft is left untreated. We believe in the transfer of knowledge. We trust and believe that our students will go to their respective places and will develop several units in the mould of GSR hospital. This will accomplish our dream of treatment for all the cleft patients in the entire world.

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Declaration of interest statement

There is nothing to declare.

Declaration of competing interest

There is no conflict of interest to declare from any of the authors.

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