COMPARISON OF PREOPERATIVE AND POSTOPERATIVE NASAL AIRFLOW IN PATIENTS UNDERGOING FUNCTIONAL SEPTORHINOPLASTY

THESIS

Submitted to All India Institute of Medical Sciences, Jodhpur

In partial fulfillment of the requirement for the degree of

Master of Surgery (M.S.)

OTORHINOLARYNGOLOGY

July 2020 **Dr. Swathi Krishna M**

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DECLARATION

I, hereby declare that the work reported in the thesis titled - "**Comparison of preoperative and postoperative nasal airflow in patients undergoing functional septorhinoplasty**" embodies the result of an original research work done by me in the Department of Otorhinolaryngology, All India Institute of Medical Sciences, Jodhpur. I further state that no part of the thesis has been submitted, in part or in full, to any other University or Institute for the award of any other degree.

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CERTIFICATE

This is to certify that the thesis titled "**Comparison of preoperative and postoperative nasal airflow in patients undergoing functional septorhinoplasty**" is the bona fide work of Dr. Swathi Krishna M carried out under our guidance and supervision, in the Department of Otorhinolaryngology, All India Institute of Medical Sciences, Jodhpur.

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Dr. Swathi Krishna. M

CONTENTS

LIST OF ABBREVIATIONS

QOL	Quality of life
ULC	Upper lateral cartilage
LLC	Lower lateral cartilage
NIPF	Nasal inspiratory peak flow
NOSE	Nasal obstruction symptom evaluation score
INV	Internal nasal valve
ENV	External nasal valve
DNS	Deviated nasal septum
ROE	Rhinoplasty outcome evaluation
AR	Acoustic rhinometry
RM	Rhinomanometry
OR	Odiosoft Rhino

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INTRODUCTION

Humans have always been enchanted by beauty and the factors that contribute to someone's perceived beauty. The nose plays a crucial part in determining the overall balance and proportion of the face because it is located at the centre of the face (1).

Nose also plays an important role in respiration, humidification, olfaction, warming the inspired air, filtration, phonation and secondary sex organ (2).

Phylogenetically, the original function of the nose was solely olfactory. During the process of evolution the gradual atrophy of this sense organ resulted as olfaction wasn’t essential for survival. It also resulted in an enlarged nasal vault which serves as a respiratory conduit. Therefore, respiration is now the primary function of human nose (3).

Nasal airway obstruction is one of the most common presenting complaints in Otorhinolaryngology and facial plastic surgery clinics and can cause huge impacts on quality of life (QOL) of the patient (4,5). A clinical diagnosis of nasal obstruction is made based on symptoms perceived by the patient and physical examination findings. The anatomical source of obstruction such as a deviated septum, inferior turbinate hypertrophy, or the upper and lower lateral cartilage (LLC) that form the internal and external nasal valve should be addressed as these structural abnormalities are refractory to medical management and can only be treated by surgery. Surgical techniques used to address the nasal septum and nasal valve are together known as functional Septorhinoplasty(4).

The Nasal Obstruction Symptom Evaluation (NOSE) scale is a useful measure in understanding the patient reported quality of life in terms of nasal obstruction symptoms(6). The NOSE scale is made in such a way that it is brief and it can be used in a busy clinic as well. It includes five questions with scores ranging from 0 to 100. This scale is valid in case of both septoplasty and functional septorhinoplasty(4,7,8).

Assessment of nasal airflow is the simplest measure of outcome analysis of functional septorhinoplasty. Acoustic rhinometry, Rhinomanometry have not been very successful in directly quantifying the nasal airflow due to expense, test burden and lack of correlation with patient reported outcome measures (6,9–15). Another alternative is Nasal inspiratory Peak Flow (NIPF) which is an inexpensive, rapid, easy-to-use objective measure that directly measures nasal airflow during maximal inspiration (16).

This study intends to find out the subjective and objective improvement in nasal airflow in patients undergoing septorhinoplasty using NOSE scale and nasal inspiratory peak flowmeter. Study also intends to find out the commonest as well as the area of maximum obstruction in nose by the application of snoring strips at the level of internal and external nasal valve areas. The study also analyses how NIPF meter can help in diagnosing the site of obstruction and planning the accurate surgical technique that is to be used.

REVIEW OF LITERATURE

History of Rhinoplasty

Today when India has been acknowledged as the 'cradle of Rhinoplasty' it necessitates a quick walk through the history of Rhinoplasty and it takes us to an ancient Indian surgeon in 600 B.C - Sushruta, the renowned " Father of Indian Surgery" and ''Father of Indian plastic surgery". His ancient encyclopaedic treatise "Sushrutasamhita" beautifully explains the technique of Rhinoplasty. The need for reconstruction of the external nose emerged from the antique method of castigation in India, the amputation of the nose, for criminals, war prisoners, and anyone who had committed adultery. Sushruta used a pedicled cheek flap to cover the defect of nose after placing two tubes of castor-oil plant in place of the nostrils. (17)

Nichter and his co-authors (1983) highlighted that the first description of mutilation of the nose originated from India with the purposeful amputation of Lady Surpunakha's nose by Prince Lakshamana in 1500 B.C. This infuriated the King Ravana, who then ordered his doctors to reconstruct the lady's nose and thus this became the first documented nasal reconstructive surgery in India. (18)

It took centuries for rhinoplasty concepts and procedures to spread throughout Europe and the rest of the world. The modification of Sushruta's cheek flap to a rotating forehead flap was a traditional Indian form of rhinoplasty that has been practiced for generations in India by the Kanghairas of Kangra (Himachal Pradesh), the Marathas of Kumar near Poona, and certain Nepali families. (19)

For several thousand years the interest in Rhinoplasty remained scattered, including peaks of enthusiasm brought on by the accomplishments of the Brancas and Tagliacozzi. Later in 1794, a letter published in the Gentleman's magazine of London became the terminus for the 200 years of inactive period and led to the revival of the art of Rhinoplasty. (20)

Killian and Freer initiated the submucous resection septoplasty procedure to correct a deviated septum, elevating mucoperichondrial flaps and surgically

removing the cartilaginous and bony septum (including the ethmoid bone's perpendicular plate and vomer), sustaining septal support with a 1.0-cm margin. The open rhinoplasty procedure, by making mid columellar incision to modify the tip of the nose, was proposed by A. Rethi in 1921, popularly known as the “Rethi incision” (21).

When Padovan demonstrated his technological breakthroughs, backing the open rhinoplasty approach, which was backed by Wilfred S. Goodman in the 1970s and Jack P. Gunter in the1990s, endonasal rhinoplasty fell out of favor (22). Goodman paved the way for technological and procedural advancements, as well as popularising the open rhinoplasty method (23). For the treatment of complex nasal abnormalities, external rhinoplasty is a physiologically sound procedure better than endonasal access in several ways (24).

Functional Septorhinoplasty

Septorhinoplasty is not only done for aesthetic purposes but also for functional and a combination of these indications (25). Preservation of nasal airway in attempt to construct an aesthetically pleasing nose is of utmost importance as conventional rhinoplasty procedures were known to cause impairment in nasal airway (26).

In the past, septoplasty, inferior turbinate reduction surgeries, and submucous resection of the quadrangular cartilage were the mainstay treatments for fixed nasal obstruction. A weak lateral nasal wall, pinching of the upper lateral cartilage (ULC), or alar collapse are examples of anatomic obstructions that are not immediately addressed by these surgical modalities, despite the fact that they remain an essential component of nasal airway surgery. Such deformities are termed as “nasal valve insufficiency”. Surgeons have embraced a wider variety of operational procedures to treat these issues, frequently referred to as "functional rhinoplasty."(27)

The Nasal Valves

Nasal valve, the narrowest part of the upper airway, was first described by Mink. It is divided into internal and external nasal valves (28).

The internal nasal valve is the narrowest among these two and is bounded medially by the nasal septum, laterally by the distal (caudal) end of the upper lateral cartilage and inferiorly by the nasal floor (29). The upper lateral cartilage is a paired, triangular cartilage forming the middle vault, the medial border of which fuses with each other and with the dorsal border of septal cartilage, laterally it fuses with the pyriform edge of maxilla (30).

The external nasal valve is bounded laterally by the lateral crura of the lower lateral cartilage whereas medially by its medial crura and the caudal end of the septum (28).

According to Poiseuille's law,

Resistance to flow, $R=8\eta l / \prod r^4$ (η- fluid viscosity, l-length, r- radius)

That is the resistance offered by the airflow tract is inversely proportional to the fourth power of its radius. Small changes in the cross-sectional area of the nasal valve produce exponential effects on airflow and resistance. In other words, when there is further narrowing of the nasal valve area, the resistance offered to the flow of inhaled air increases which manifest as nasal obstruction or difficulty in breathing through the nose (2).

In a study by Seung-Kyu Chung, they have developed a model of nasal cavity based on the data obtained from 1.25mm CT along with a cam driven piston pump to simulate and measure respiration at rest. With this they have interpreted that the maximum velocity of airflow is at the level of nasal valve area on inspiration, and also the main stream occurring in middle and superior airway (31).

Nasal obstruction

Nasal obstruction being one of the most common complaints with which patient presents to an Otorhinolaryngologist or a general physician. Etiology is multifactorial ranging from anatomical, physiological as well as neurological factors (32).

Static and dynamic dysfunction are additional categories for nasal valve blockage. Static dysfunction is brought on by persistent occlusion at the level of the nasal valve due to skeletal and anatomical abnormalities, such as medial displacement of the ULC or inferior turbinate hypertrophy. More intranasal pressure is needed to produce the same quantity of nasal airflow in static dysfunction. Contrarily, dynamic dysfunction is brought on by collapsing lateral wall or insufficient structural support, including the cartilaginous, fibrofatty, and muscular elements, which causes the nasal valve to collapse at low transmural pressures (29).

Treating nasal obstruction is of prime importance as it can cause facial deformity as a result of obligate mouth breathing. It also affects concentration, quality of life by causing poor sleep , recurrent otitis media and malocclusion (33).

Grafts used in Septorhinoplasty

Different types of grafts are used for the aesthetic as well as functional correction of the nasal deformities. This also varies based on the type of Rhinoplasty, that is, whether open (external approach) or closed (34). Most of the grafts used in rhinoplasty are cartilaginous. The sources can be septal, conchal or costal (35). Septal cartilage is the most preferred one in primary septorhinoplasty because of the same site of harvesting and to avoid a second incision in another part of the body(36). The optimal grafting substance should be simple to shape, resilient to injury, infection, and extrusion, inert, and easily accessible (37).

To address the obstruction at the Internal Nasal Valve (INV) area, various techniques of grafting have been developed like spreader grafts and auto-spreader

grafts (by widening the INV area), alar batten grafts or stair step (to support the weak upper lateral cartilage) and butterfly grafts (for both purposes) (11).

In a study of functional rhinoplasty among the pediatric and adolescent population reported internal nasal valve narrowing as the leading cause of airway narrowing followed by external nasal valve, caudal deviation of septum, narrow middle vault and over projected dorsum, among which at least 92.3% patients had graft placed and the most common procedure being septoplasty, spreader graft (84.6%), dorsal hump reduction (41%), columellar strut graft (30.8%) and swinging door technique (23.1%) (33).

Measurement of nasal airflow

Hygrometry is considered as the first method for objective assessment for nasal flow, followed by the Hum test. In Hygrometry, we measure the diameter of the fog that is caused by breathing onto a mirror. This test was developed by Zwaardemaker in 1894. In Hum test, change in the timbre of the sound that is produced while occluding the decongested nasal side when the patient is producing a humming sound is analysed. This test was developed by Spiess in 1902. Computed Tomography volumetry is a recent methodology, but with the risk of radiation exposure. The routine objective assessment tools of nasal airflow at present are -Nasal Inspiratory Peak Flow (NIPF), Acoustic Rhinometry (AR), Rhinomanometry and Odiosoft Rhino (OR)(38).

NIPF (Nasal Inspiratory Peak Flow) – It is an non invasive method, in which the nasal airflow is measured in maximum forced nasal inspiration. It depends on patients co-operation and instruction of examiners for an appropriate assessment. Even though it has the disadvantage of inability to measure without maximal effort (making it difficult in patients with respiratory difficulty), it is considered as reliable and reproducible on comparison with other methods(38).

AR (Acoustic Rhinometry) – It is one of the rapid, non-invasive and in expensive test which measure the cross sectional area of nose, useful in patients with anatomical blockage such as septal deviation and nasal polyps. The main

advantage is that it can be done with minimal patient co-operation, and also can be done during sleep or under anaesthesia also. Here it assesses the change in the sound distortion occurring inside the nasal cavity which varies with size and contour (38–40).

RM (Rhinomanometry) – In this both the trans-nasal pressure and airflow are measure simultaneously. Tachometer and pressure transducer are used here. A decrease in resistance less than 35% before and after decongestion is considered to indicate anatomical obstruction.(38,41,42)

Both Rhinomanometry and Acoustic rhinometry are unable to calculate obstruction due to alar collapse and tip deformity, as the measurements are distal to these sites (38).

OR (Odiosoft Rhino) – in this the sound frequency generated is converted into cross sectional area measurement. This is based on the principle that nasal turbulence creates an higher frequency sound, thus spontaneous generation of sound is calculated with reliable sensitivity and specificity (38,43).

Computational Fluid Dynamics is also found to be useful to measure pressure, velocity and other invisible parameters of nasal airflow, hence can be applied in assessing nasal physiology (44).

Normal nasal airflow

Even in healthy individuals, inter-individual variability was noted in relation to nasal airflow, estimating unilateral airflow to be varying from 60-191ml/s (45).

NIPF studies till now showed wide ranges and variability among the individuals of different part of the world as well. Normal PNIF values were said to be lower in the French population than in earlier published data from other nations. The NIPF value variations seen are likely the result of the respondents' varied ethnic backgrounds (46).

Subjective and Objective measurements

The various validated questionnaires for subjective assessment of nasal obstruction are SNOT-22 (Sino-nasal Outcome Test) and NOSE Test (Nasal Obstruction Symptom Evaluation test)(38). ROE (Rhinoplasty outcome evaluation) score is also an 'easy to assess' tool for quality of life after septorhinoplasty (47).

Eccles et al in his study, mentioned the importance of the fact that, objective measurement of nasal obstruction doesn't always correlate with the subjective measurement (48).

Jones et al found no co-relation between nasal resistance calculated by rhinomanometer and visual analogue scales. Also it has been determined that nasal airflow sensation and resistance to airflow are two distinct modalities that are not directly related (49).

Rhee et al in 2010, stated that patient-reported outcome measures are more significant than objective outcome measurements and that there is poor correlation between objective measures and subjective outcomes in clinical settings (28).

Outcome evaluation

Balikci and Gurdal et al utilised Rhinoplasty Outcome Evaluation score (ROE), which consists of 6 questions covering the Physical, emotional and social factors with 2 questions each for assessing the results of functional septorhinoplasty and found significant improvement postoperatively(50).

Ilhan et al in 2015 said, lateral crural repositioning and strut grafting in patients showed a significant improvement in post operative NOSE scores and ROE scores (51).

Manteghi et al in 2018 found no significant impact of gender, previous nasal surgery, nasal trauma or allergic rhinitis on the post operative NOSE score in patients undergoing septoplasty and functional septorhinoplasty(52) .

Hismi et al assessed sleep quality in patients undergoing functional septorhinoplasty with Functional Outcomes of Sleep Quality (FOSQ-10) and found improvement in the scores postoperatively at 2, 4 and 6^{th} months(53).

Shuaib et al found significant improvement in Apnoea Hypopnoea Index particularly in non obese patients undergoing septorhinoplasty. It is due to the fact that the higher nasal airway resistance resulting in a higher pharyngeal negative pressure (54).

Unadkat et al compelled that, even during COVID 19 pandemic, Functional Septorhinoplasty procedure should not be overlooked since it can affect the quality of life in patients awaiting for surgery (55).

This study is an attempt to find out the change in nasal airflow post functional septorhinoplasty in terms of both subjective and objective measures and their correlation with each other. Since it is a cheap, easy to carry instrument, we used NIPF meter for the measurement of nasal airflow preoperatively as well as post operatively. We have chosen NOSE scale for subjective assessment since we are dealing only with nasal obstruction in our study. We also tried to find out the area of maximum obstruction and the possible corrections that can be done to improve the quality of life of the patient.

AIMS AND OBJECTIVES

AIM:

To compare the preoperative and postoperative nasal airflow in patients undergoing Functional Septorhinoplasty using Nasal inspiratory peak flow meter

OBJECTIVES:

1. To assess preoperative nasal airflow in patients undergoing Functional Septorhinoplasty using nasal inspiratory peak flow meter without applying and with applying snoring strips at the level of internal nasal and external nasal valves separately
2. To assess post operative nasal airflow in the same patients by the same method
3. Compare both these values to find out the change in nasal airflow following Functional septorhinoplasty

RESEARCH QUESTION

Is there any change in nasal airflow postoperatively in patients undergoing Functional Septorhinoplasty in the Department of Otorhinolaryngology, AIIMS Jodhpur

RESEARCH HYPOTHESIS:

Null hypothesis

There is no change in nasal airflow postoperatively in patients undergoing Functional Septorhinoplasty in the Department of Otorhinolaryngology, AIIMS Jodhpur

Alternate hypothesis

There is change in nasal airflow postoperatively in patients undergoing Functional Septorhinoplasty in the Department of Otorhinolaryngology, AIIMS Jodhpur.

MATERIALS AND METHODS

STUDY DESIGN: Prospective observational cohort study**.**

STUDY SETTING: The study has been conducted at the All India Institute of Medical Sciences, Jodhpur in the Department of Otorhinolaryngology.

STUDY DURATION: from December 2020 to May 2022

INCLUSION CRITERIA:

1. Patients undergoing Functional Septorhinoplasty in the Department of Otorhinolaryngology, AIIMS Jodhpur
2. Patients aged more than or equal to 16 years

EXCLUSION CRITERIA:

1. Patients with other causes of nasal obstruction like nasal polyps, allergic rhinitis, nasal mass, ciliary abnormalities
2. Patients who did not give consent for the study
3. Patients with known coexistent pulmonary pathology

SAMPE SIZE: All patients who underwent Functional septorhinoplasty, in the department of Otorhinolaryngology, AIIMS Jodhpur between March 2021 and May 2022 were screened using inclusion and exclusion criteria and a final of 32 patients were included in the study.

PREOPERATIVE WORKUP

1.CLINICAL EXAMINATION

All patients presented to us for septorhinoplasty were assessed by taking history and clinical examination. Examination of the external nose done followed by anterior rhinoscopy. Nasal patency tests were also performed in all these patients. Diagnostic nasal endoscopy also done to rule out other causes of nasal obstruction like nasal mass or polyp. Co-existent pulmonary pathology was also looked for before enrolling the patients for the study.

2.NASAL OBSTRUCTION SYMPTOM EVALUATION SCORE (NOSE)

Patients enrolled in the study were provided with the NOSE questionnaire first. Nasal obstruction in these patients was quantified using this NOSE questionnaire which included scores from zero to 100. The symptoms considered in NOSE score are as follows:

Nasal stuffiness
Nasal blockage or obstruction
Trouble breathing through my nose
Trouble sleeping
Unable to get enough air through my nose during exercise or exertion

These symptoms were analysed within a scale of scores between zero and 4.

0- Not a problem
1- Very mild problem
2- Moderate problem
3- Fairly bad problem
4- Severe problem

The sum of all responses from each symptom was then multiplied by 5 to obtain a final value that ranges from zero to 100 (zero representing the lowest level of satisfaction and 100 representing the highest), and the final NOSE scores can be classified as mild (5–25), moderate (30–50), severe (55–75), or extreme (80–100)(56). NOSE score was assessed pre-operatively and 2,4,6 months post operatively in this study.

3.NASAL INSPIRATORY PEAK FLOW (NIPF) MEASUREMENT

Nasal airflow was measured using portable nasal inspiratory peak flowmeter (*Clement Clarke*
International Ltd., Harlow, UK). Peak nasal inspiratory flowmeter has a tight-fitting mask which does not allow air leak and not compressing the nose as well. The participants were instructed to keep their mouth closed and to inhale as hard and fast as possible through the mask. Patients were allowed to practice with the device prior to formal testing. At formal testing, patients were seated comfortably and performed three trials at maximal effort. The highest flow rate (litres per minute [L/min]) of these three measurements was recorded.

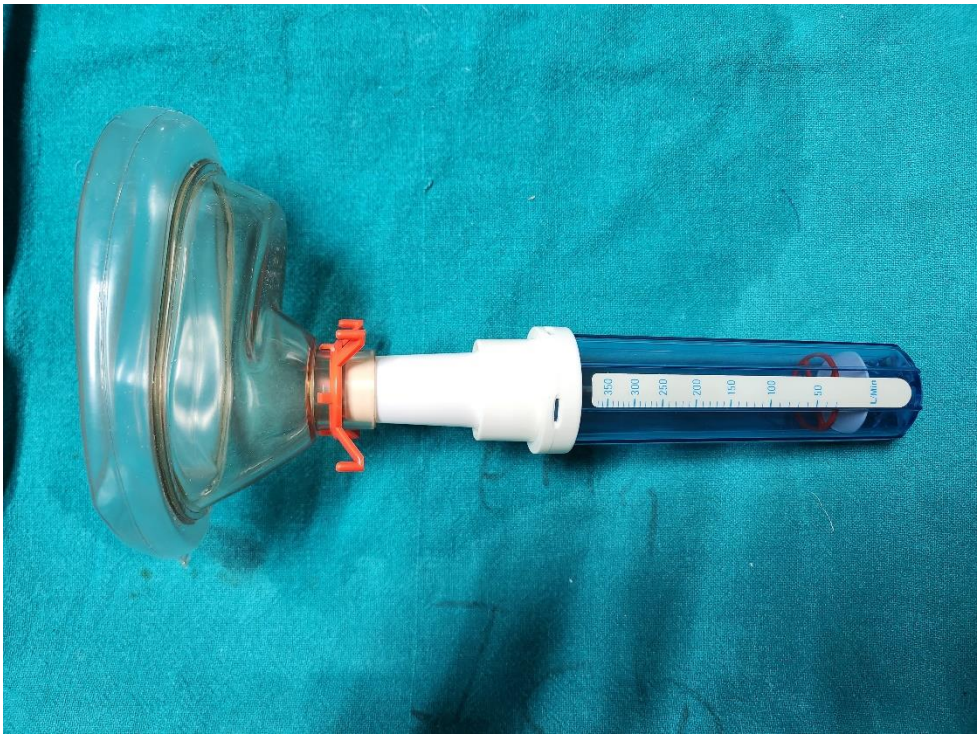


Figure 1. showing Nasal inspiratory peak flowmeter

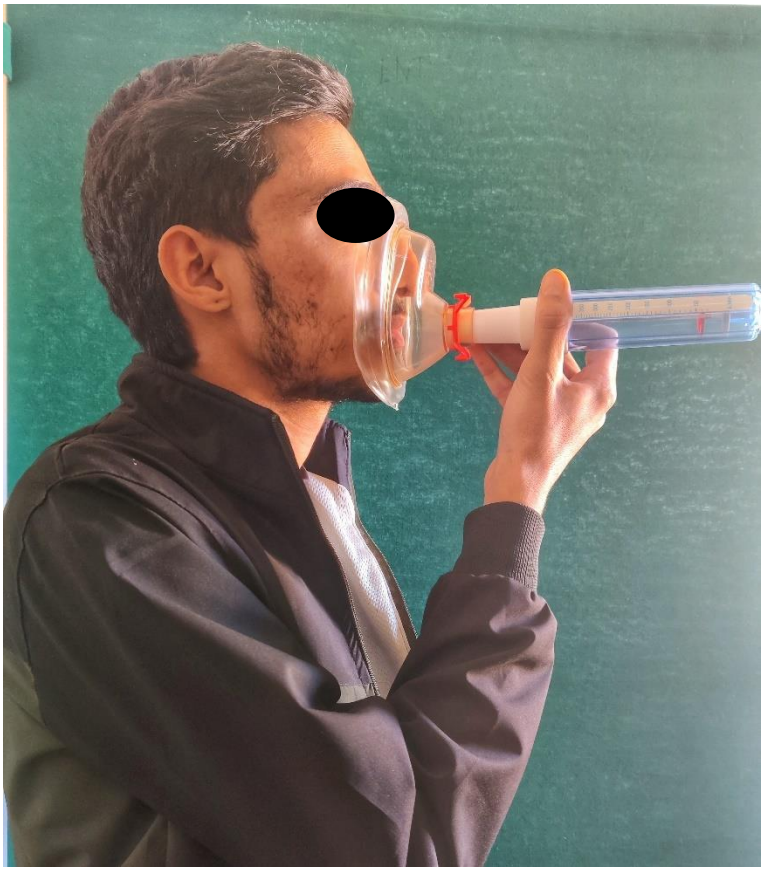
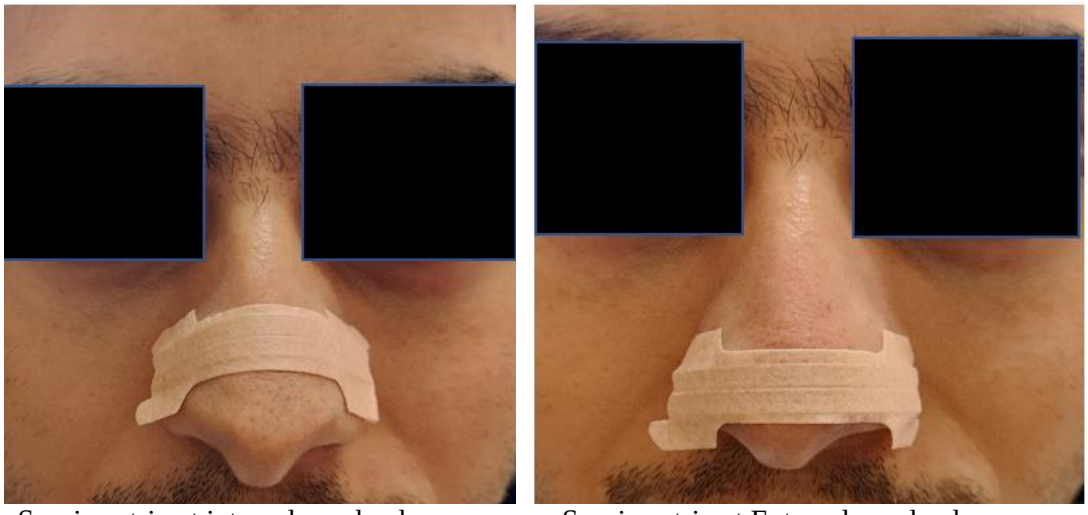


Figure 2. Showing a patient performing the test with NIPF meter

Nasal airflow measurements were taken without applying snoring strips (*Breathe Right nasal strips*) and with snoring strip at the level of internal nasal valve and external nasal valve separately, preoperatively and 2,4,6 months post operatively.



Snoring strip at internal nasal valve area Snoring strip at External nasal valve area

Figure 3. Showing site of application of the snoring strips

4.PRE-OPERATIVE PHOTOGRAPHY

All the patients enrolled in the study were photographed preoperatively for better planning of the surgery and documentation purpose. Photographs were taken in Frontal, right and left lateral, right and left oblique (45 degree) and basal views.

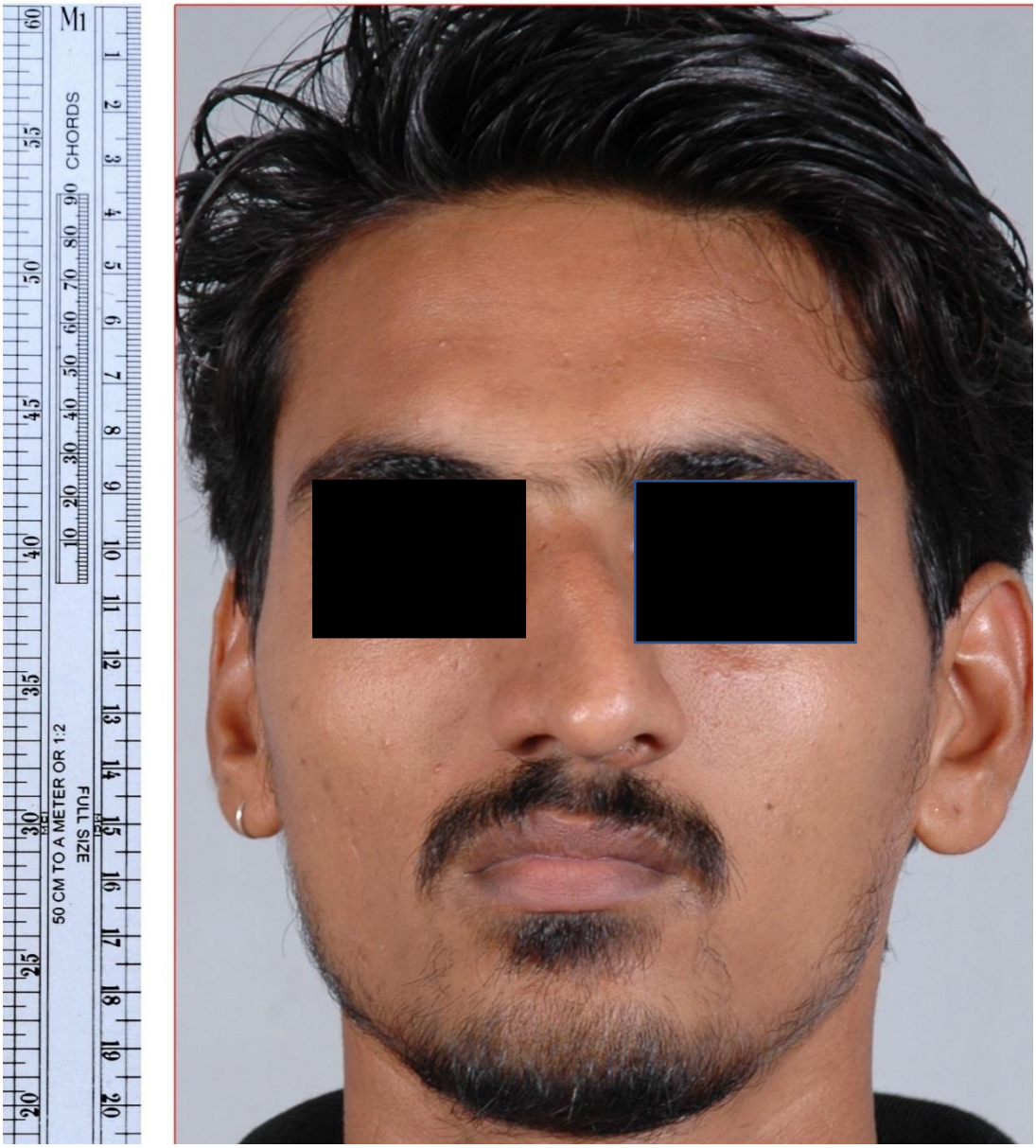


Figure 4. Frontal view of preoperative photography

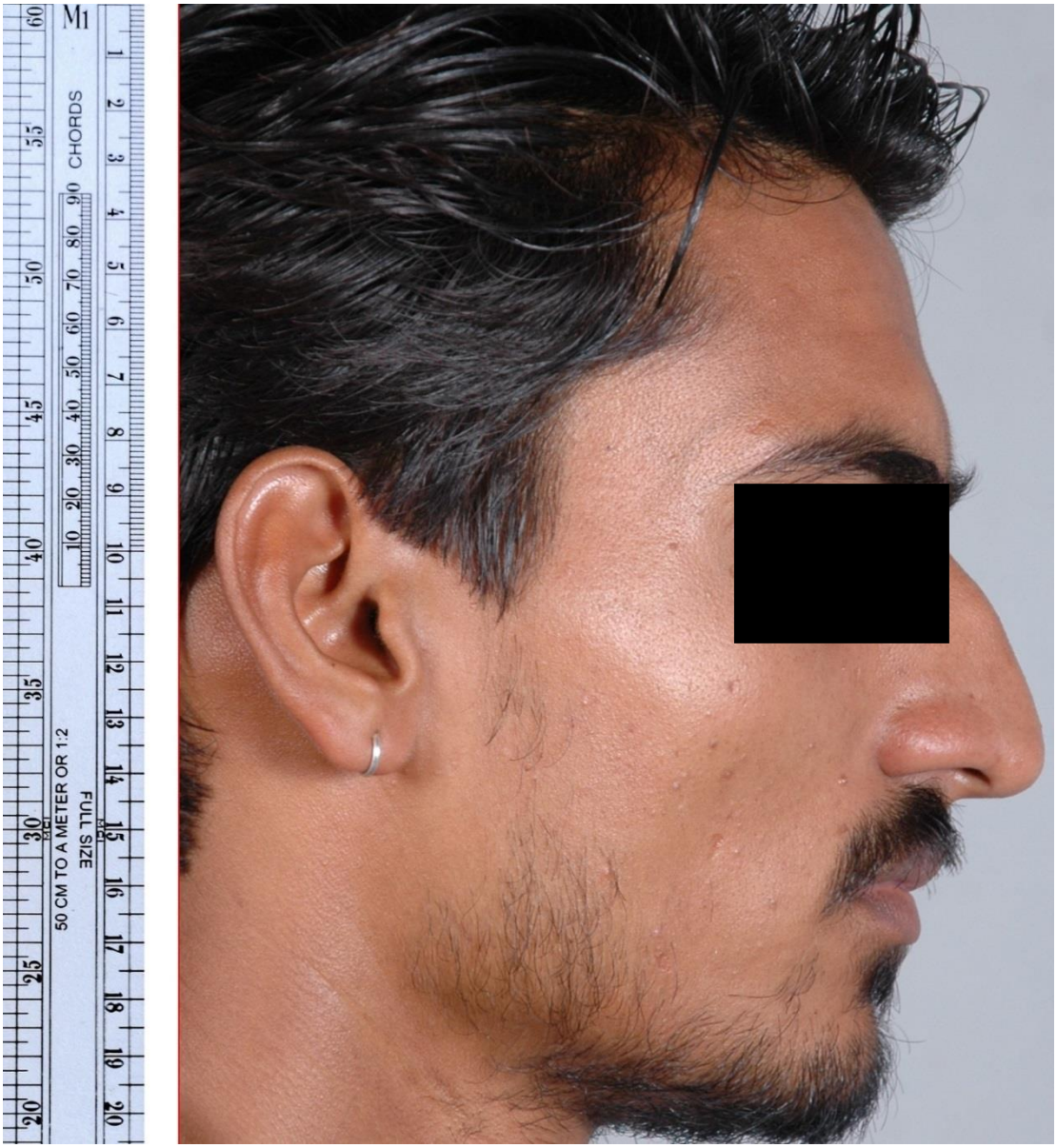


Figure 5. Right lateral view of preoperative photography

Figure 6. Right oblique view (45 degree) of preoperative photography

Figure 7. Left lateral view of preoperative photography

Figure 8. Left oblique view (45 degree) of preoperative photography

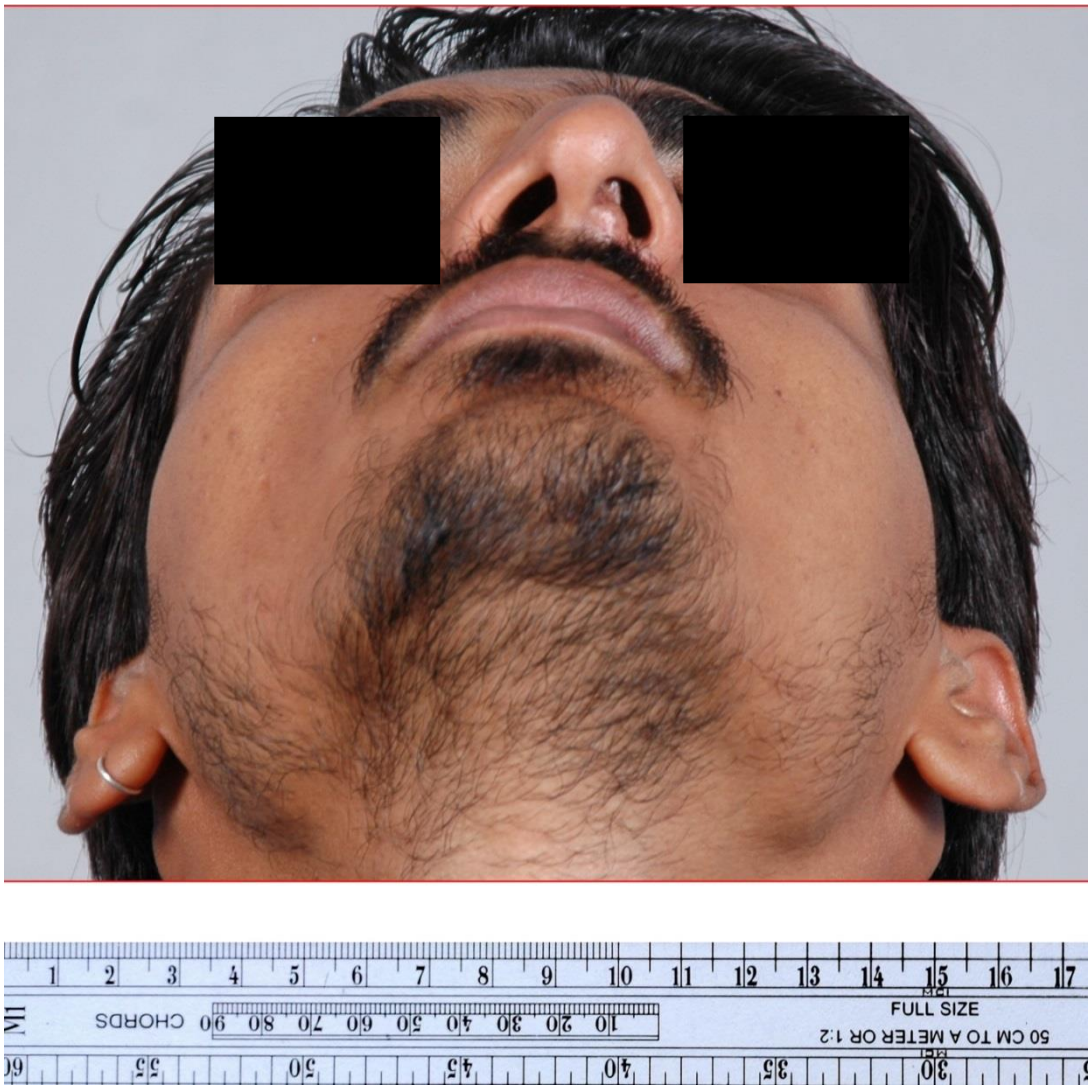


Figure 9. Basal view of preoperative photography

4.OPERATIVE PROCEDURE

- Under general anaesthesia, patient positioned. Under all aseptic precautions parts painted and draped.
- Local infiltration was given with xylocaine (2%) with 1:2 lacs adrenaline.
- Incision: Inverted V-shaped incision was marked and made over the columella and extended laterally as marginal incision.
- Dermocartilaginous ligament (pitanguy's) cut and retracted superiorly, interdomal ligaments cut bilaterally.

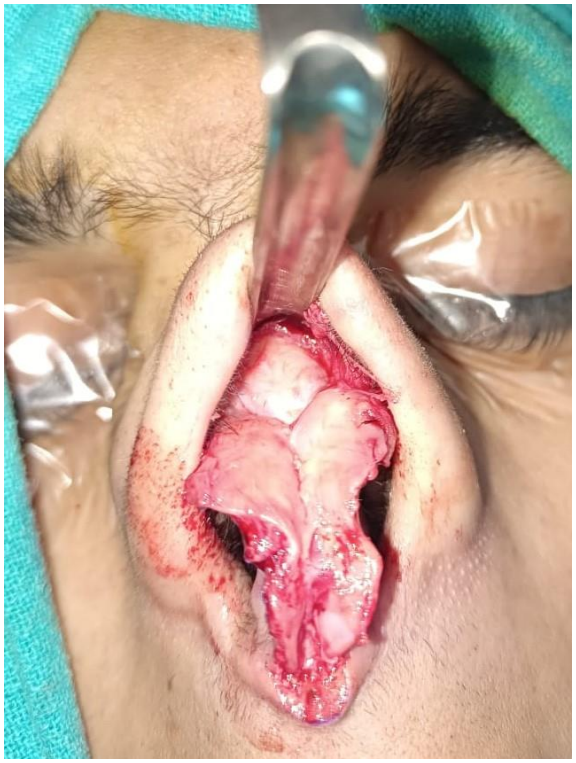


Figure 10. Showing intraoperative picture after exposing the lower lateral and upper lateral cartilages

- Sharp dissection done in supraperichondreal and subperiosteal plane done.
- Mucoperichondrial and mucoperiosteal flap elevated on both sides of septum.

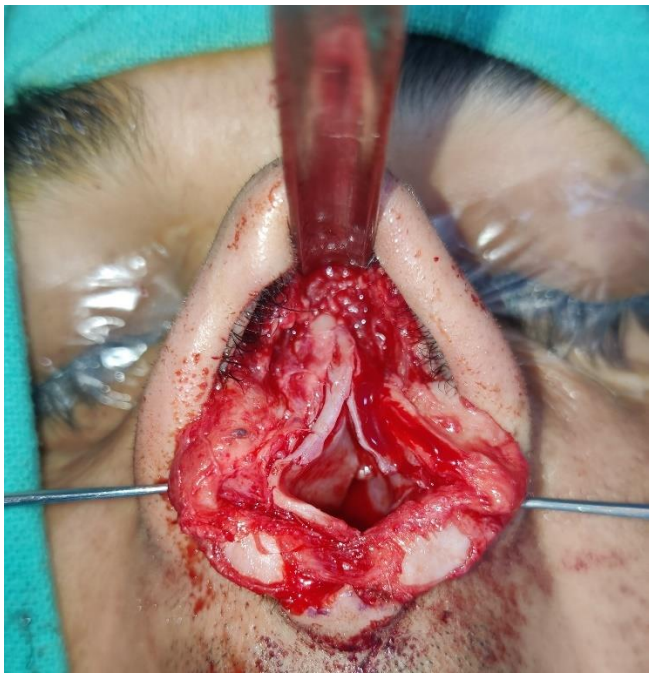


Figure 11. Showing intraoperative picture showing the deviated septum

- Dorsal hump if present, corrected using rasp and shaving off the excess cartilage.
- Septoplasty done – Extracorporeal / open depending upon the need
- Deviated part of the maxillary crest if present, also removed using gouge and hammer.
- Bilateral Median oblique followed by low to high lateral osteotomies and horizontal osteotomy done to reduce the dorsal widening

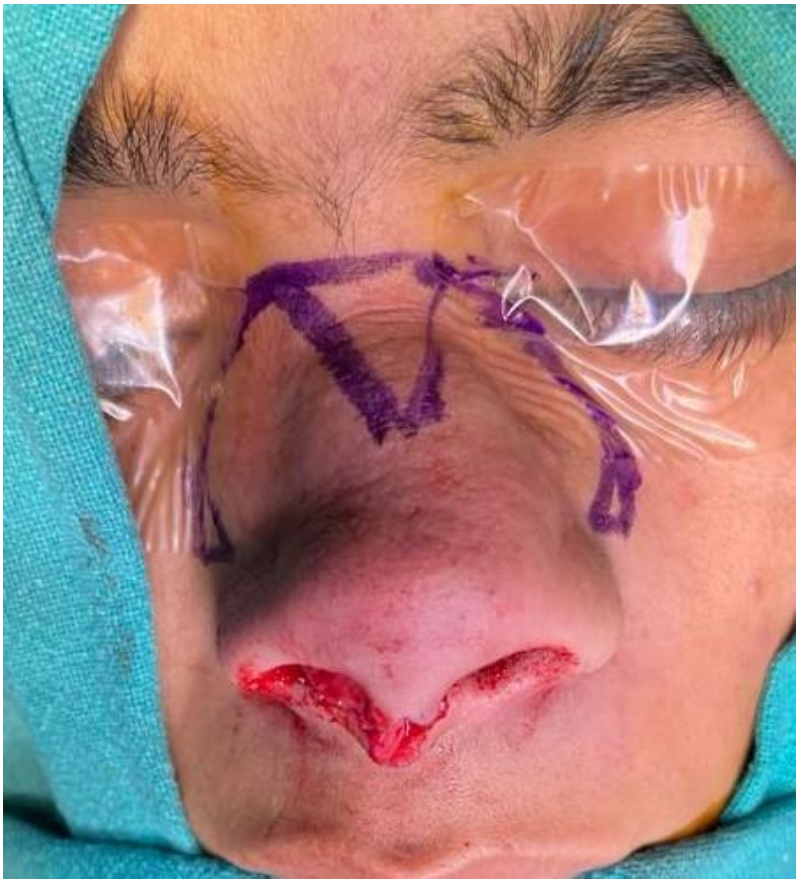


Figure 12. Showing markings for median oblique and lateral osteotomies

- Caudal end of L shaped septal cartilage was sutured with a piece of cartilage as septal extension graft and placed in midline by tongue in groove technique between medial part of lower lateral cartilages and sutured using PDS 5-0 Sutures.

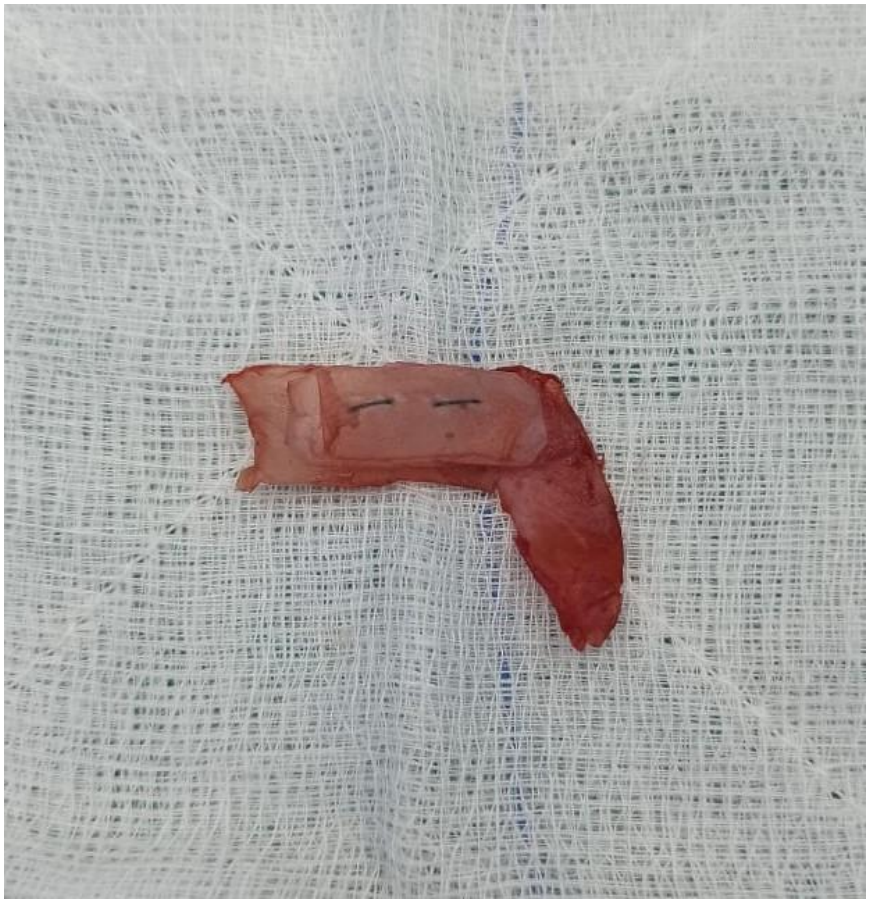


Figure 13. Showing a cartilaginous L strut used as a septal extension graft

- Batten graft is placed to support the weak upper lateral cartilage, spreader graft placed between the ULC and septum to widen the internal nasal valve area, cantilever graft for the correction of INV collapse, columellar strut graft for strengthening the columella or increasing the projection of the tip, septal extension graft is placed after an extracorporeal septoplasty for correction of DNS. Different alar corrections like alar batten graft, alar strut graft, alar turn in graft also placed according to the need.

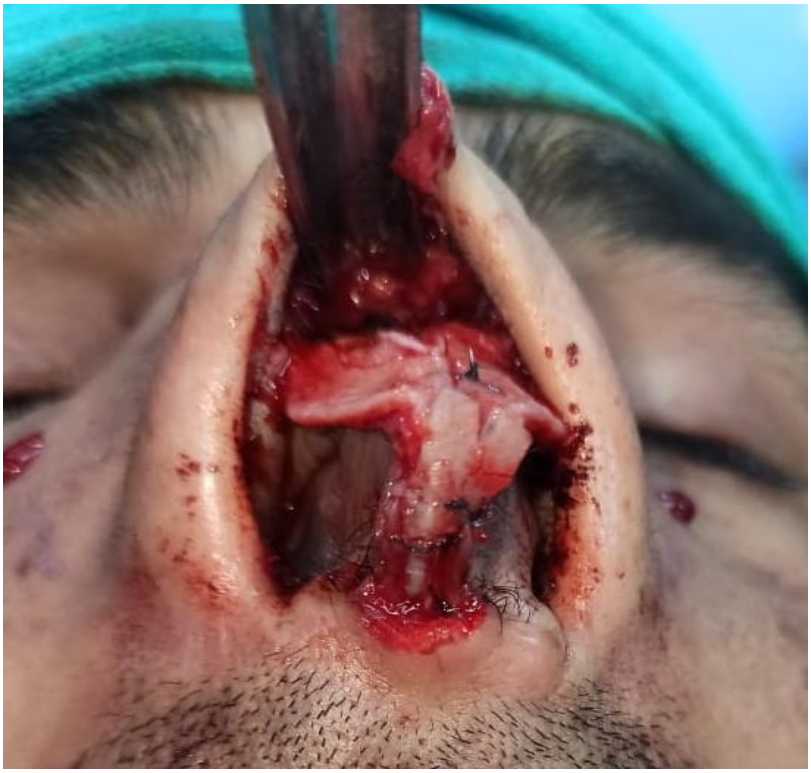


Figure 14. Showing a shield graft after placement

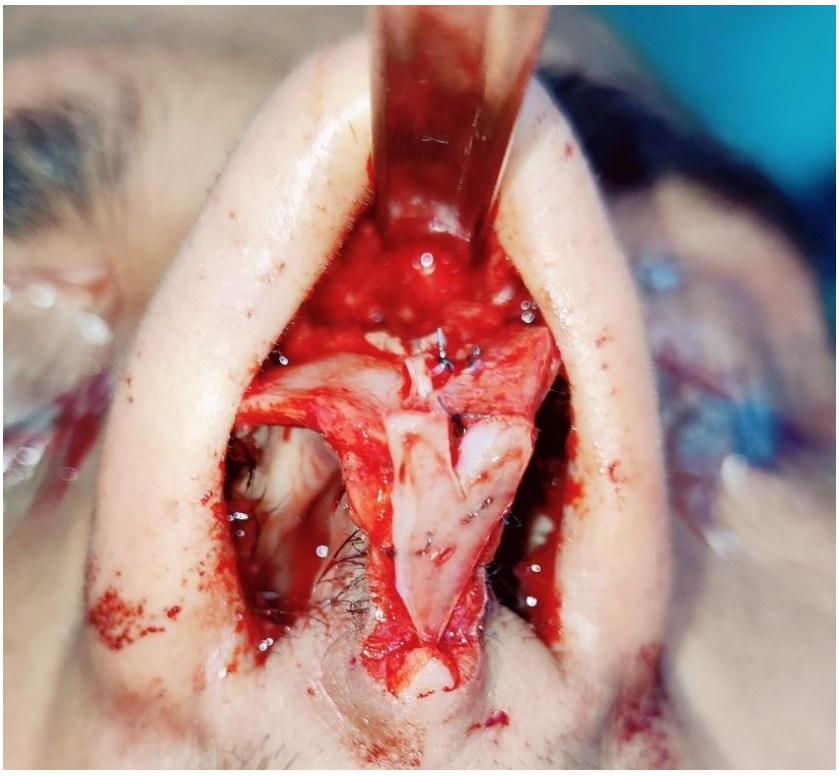


Figure 15. Showing a septal extension and shield graft in place

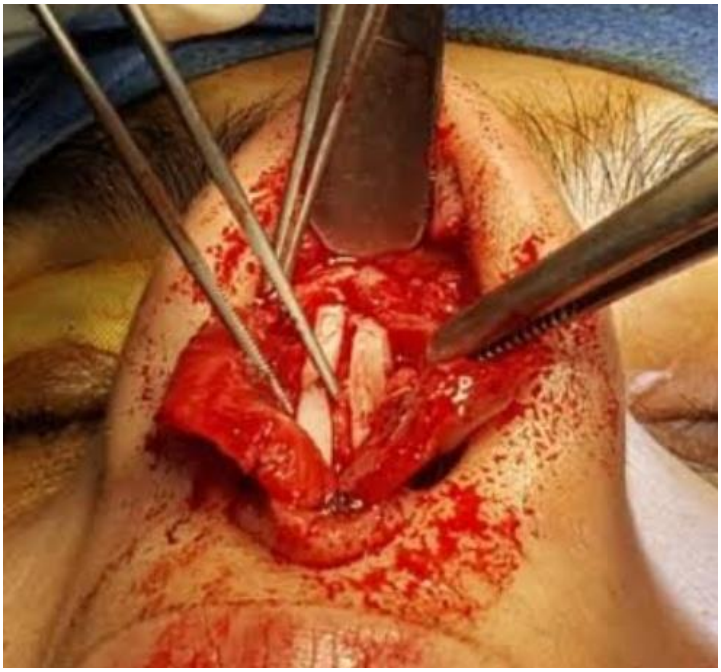


Figure 16. Showing spreader graft

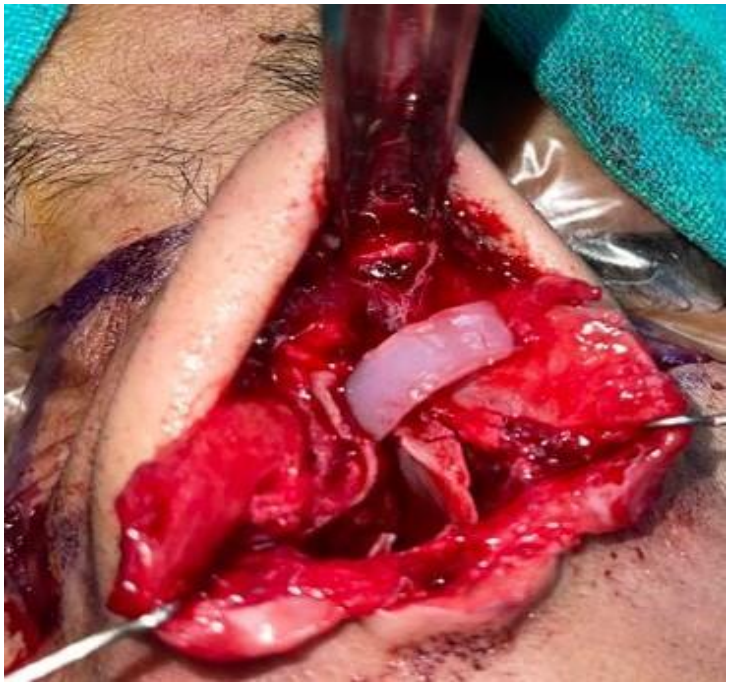


Figure 17. Showing a cantilever graft

- Depressed dorsum is corrected by augmentation rhinoplasty in which cartilage is harvested from the rib or concha.

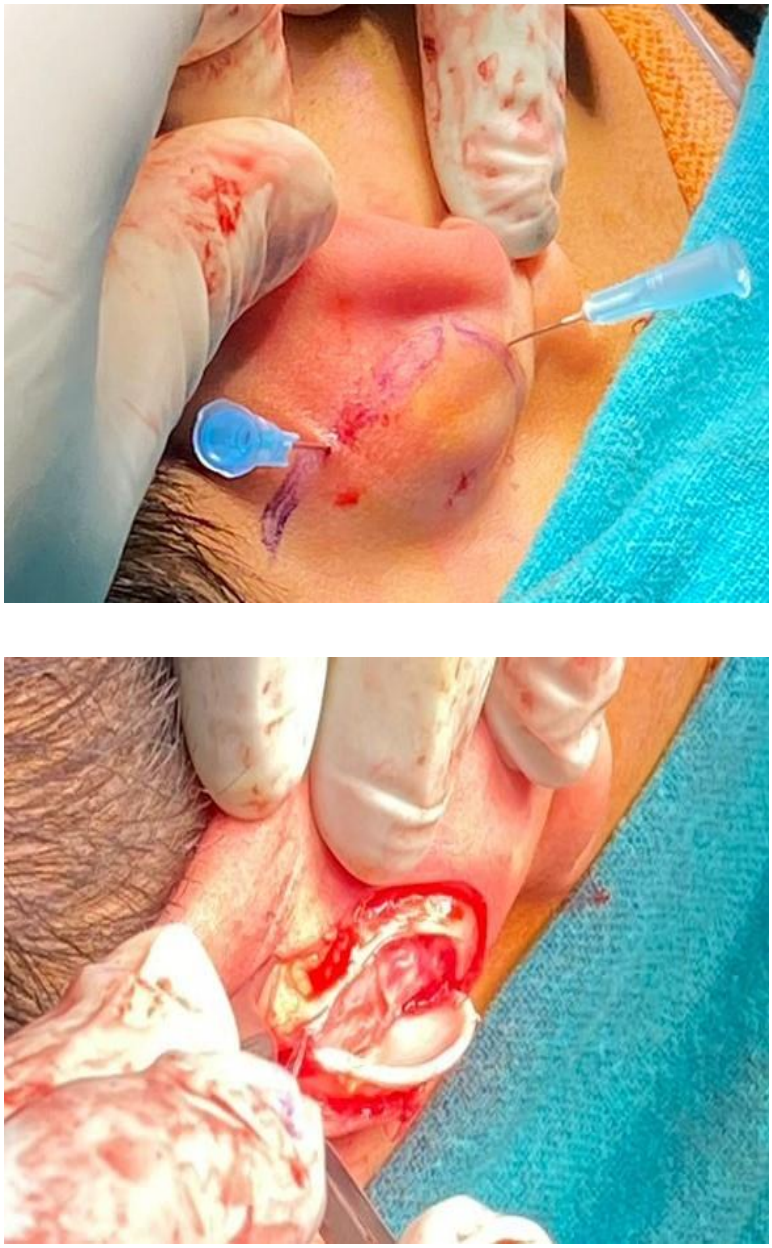


Figure 18. Showing the procedure of harvesting the conchal cartilage

- Intradomal and interdomal sutures were applied.
- Columellar incision closed with 5-0 PDS sutures.
- Haemostasis was achieved. Bilateral nasal cavity packed with medicated merocele.
- Steri-strips were applied.

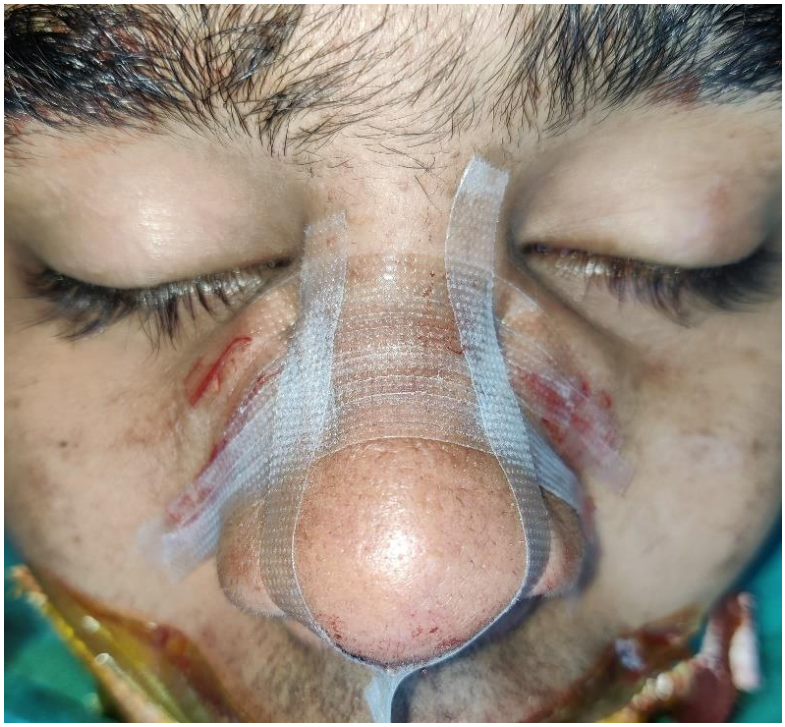


Figure 19. Showing the nose after completion of rhinoplasty with steri-strips

- Denver's Aluminium External nasal splint was applied.
- Bolster dressing done.

STATISTICAL ANALYSIS

Data was tabulated in MS Excel and analysed using Statistical Package for Social Sciences (SPSS) version 24.0 (IBM Corp) and MS Excel 2007. As the first step, descriptive statistics were computed along with the respective Box plots. Quantitative data were expressed as Mean ± Standard deviation (SD). Testing the significance of difference of paired observations were carried out using paired t-test considering the dependence of samples. Statistical significances were assessed at 5% level of significance. Linear relationship among the variables were assessed using Pearson correlation coefficient. Bar graph and line graph with error bars were also used for graphical representation of the quantitative data of relevant variables.

ETHICAL APPROVAL & CONSENT TO PARTICIPATE

Ethical approval was obtained from AIIMS Jodhpur; Institutional Ethical Committee certificate reference No. AIIMS/IEC/2021/3372, dated-12/03/2021 attached in annexure A. All participants were informed about the purpose and the benefits of the study. Informed consent was obtained from all the participants. The participants information sheet was given to all patients, and their role in the study was explained before administering screening tools. They were assured of the complete confidentiality of the information and were explained the option of withdrawing from the study at any point in time if they desired to do so. All the data collected were kept confidential. The study was registered under CTRI (Registration. No. CTRI/2021/05/033710).

RESULTS

We enrolled 32 patients with a mean age of 20.97±0.76 years of which 28 (87%) were males and 4 (13%) were females.

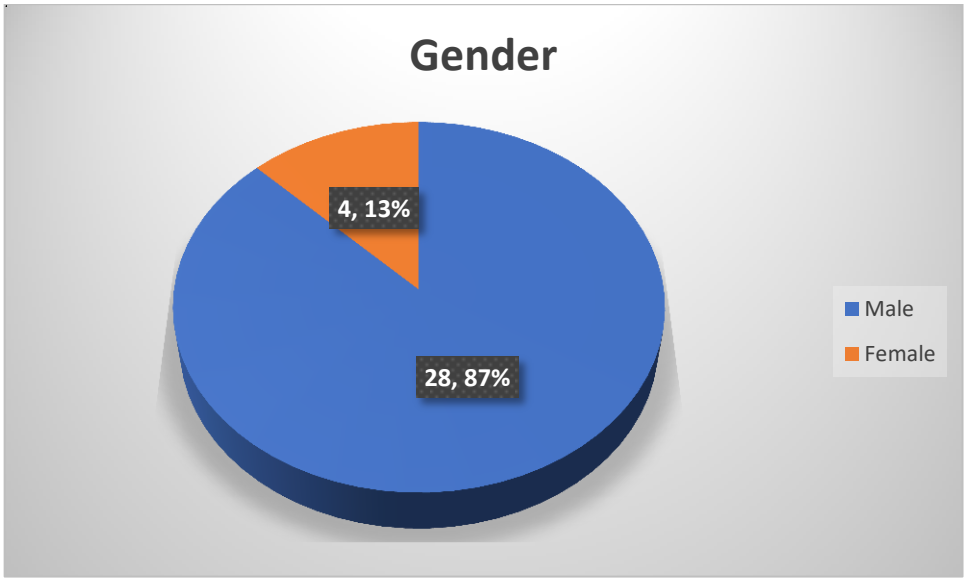


Figure 20. Pie chart showing gender distribution

In our study we have performed Cottle's test in all the patients included which was positive in 25 patients (78%) and was negative in 7 patients (22%).

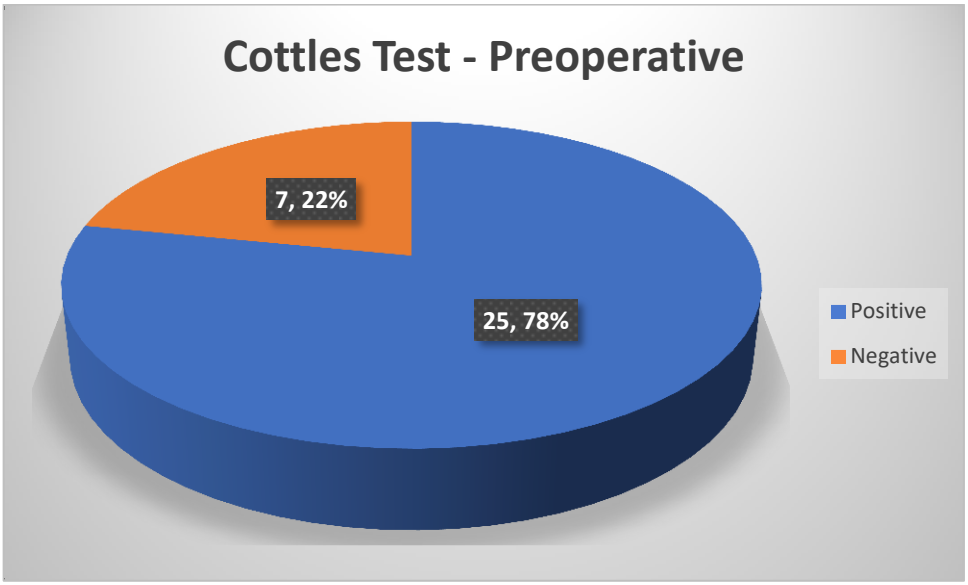


Figure 21. Pie chart showing pre-operative Cottle's test results

Out of these 25 patients 19 had increase in nasal airflow on application of snoring strip at the level of internal nasal valve area. Out of the 6 patients who did not show any improvement after application of snoring strip at the level of internal nasal valve area, one patient showed improvement in nasal airflow on application of snoring strips at the level of external nasal valve area and 5 patients did not show any improvement on application of snoring strips at either of these areas.

7 out of 32 patients showed negative Cottle's test. One among these 7 patients showed improvement in nasal airflow on application of snoring strip at the level of INV and another one patient showed improvement at ENV. Rest of the 5 patients showed no improvement in either of these areas.

Preoperatively the mean NOSE score was 55.78±3.64 which was reduced to 12.18±2.02 after 6 months post operatively ($p<0.01$)

Table1. NOSE score based measure of nasal obstruction

	PRE- OPERATIVE		POST-OPERATIVE	
	NUMBER OF PATIENTS	%	NUMBER OF PATIENTS	%
0-5	0	0	4	12.5
Mild (5-25)	4	12.5	26	81.25
Moderate (30-50)	11	34.37	1	3.1
Severe (55-75)	12	37.5	1	3.1
Extreme (80-100)	5	15.62	0	0

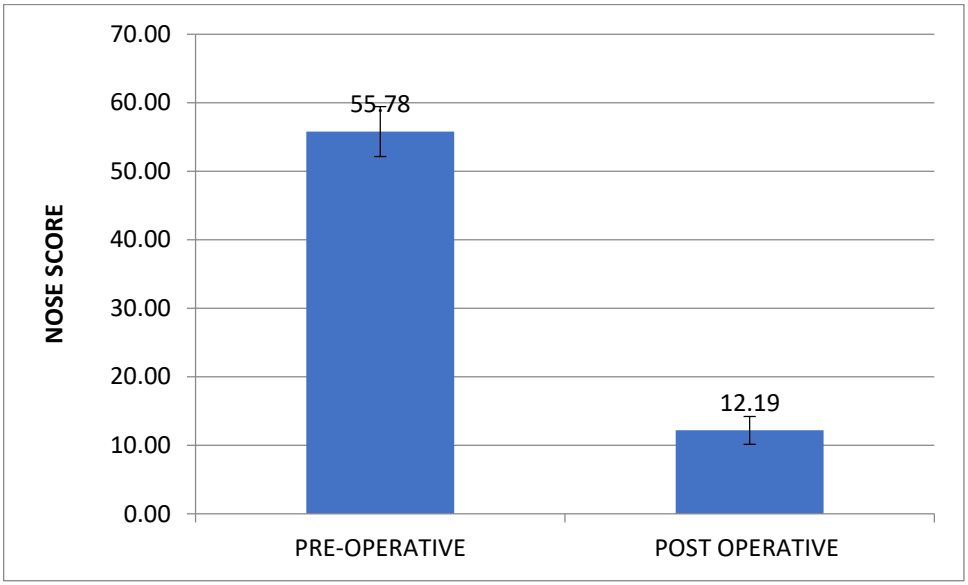


Figure 22. Bar diagram showing comparison of preoperative and post operative (at 6 months) NOSE scores

Mean NIPF value without application of nasal strip preoperatively was 61.75±22.08 L/min which later increased to 78.8±29.0L/min ($p<0.01$), 101.56±34.0 L/min ($p<0.01$), 113.06±38.67 L/min ($p<0.01$) post operatively after 2,4 and 6 months respectively. The maximum improvement in nasal airflow following surgery was 150 L/min (50 L/min preoperatively, 200L/min post operatively).

Preoperative NIPF assessment showed 10 patients (32%) with improvement in nasal airflow on application of snoring strip at the level of INV only, 2 (6%) patients with improvement at the level of ENV only, 10 (32%) patients with improvement at both INV & ENV and 10 (32%) patients with no improvement on application of strips neither at INV nor at ENV.

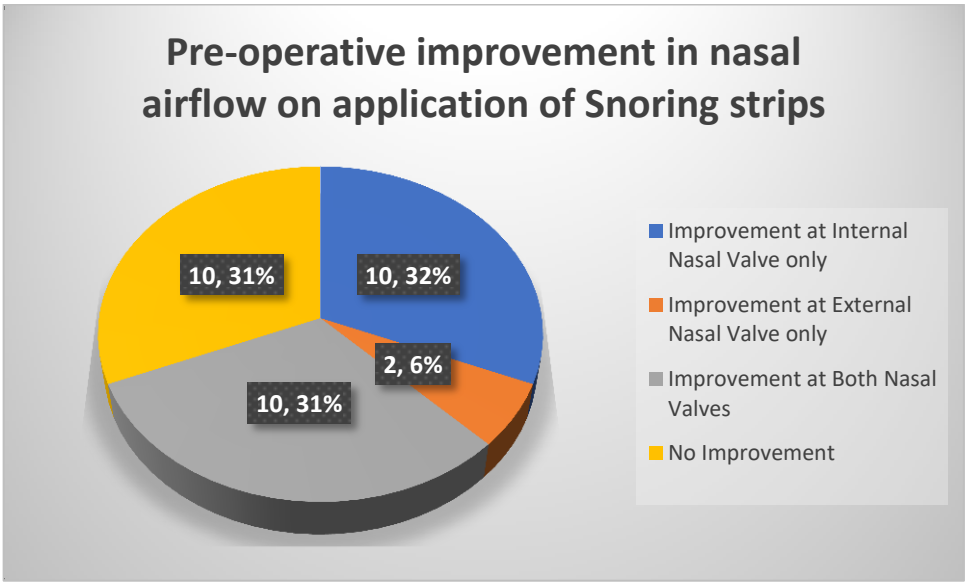


Figure 23. Pie chart showing change in nasal airflow on application of snoring strips at different levels preoperatively

NIPF values without application of snoring strip were compared with the same with application of snoring strip at the level of external nasal valve and internal nasal valve separately which showed the mean NIPF as 63.96±23.2 L/min ($p<0.002$, at External nasal valve area) and 69.83±25.0 L/min ($p<0.001$, at internal nasal valve area) respectively.

Table 2. Showing comparison of preoperative nasal airflow (L/min) without application of snoring strips and with snoring strip at the level of ENV

Statistic	Pre-operative without strips	Pre-operative with strip at ENV
No. of observations (Patients)	32	32
Minimum nasal airflow (L/min)	25.000	25.000
Maximum nasal airflow (L/min)	140.000	142.500
1st quartile	50.000	50.000
Median	60.000	63.250
3rd quartile	70.000	70.000
Mean	**61.747**	**63.963**
Variance (n-1)	487.913	541.168
Standard deviation(n-1)	22.089	23.263
Standard error	**3.905**	**4.112**
P value	**< 0.01**	

Table 3. Showing comparison of pre-operative nasal airflow (L/min) without application of snoring strips and with snoring strip at the level of INV

Statistic	Pre-operative, without strips	Pre-operative, with strip at INV
No. of observations (Patients)	32	32
Minimum nasal airflow (L/min)	25.000	30.000
Maximum nasal airflow (L/min)	140.000	155.000
1st quartile	50.000	58.750
Median	60.000	65.000
3rd quartile	70.000	79.475
Mean	**61.747**	**69.831**
Variance (n-1)	487.913	628.031
Standard deviation(n-1)	22.089	25.061
Standard error	**3.905**	**4.43**
P value	**< 0.01**	

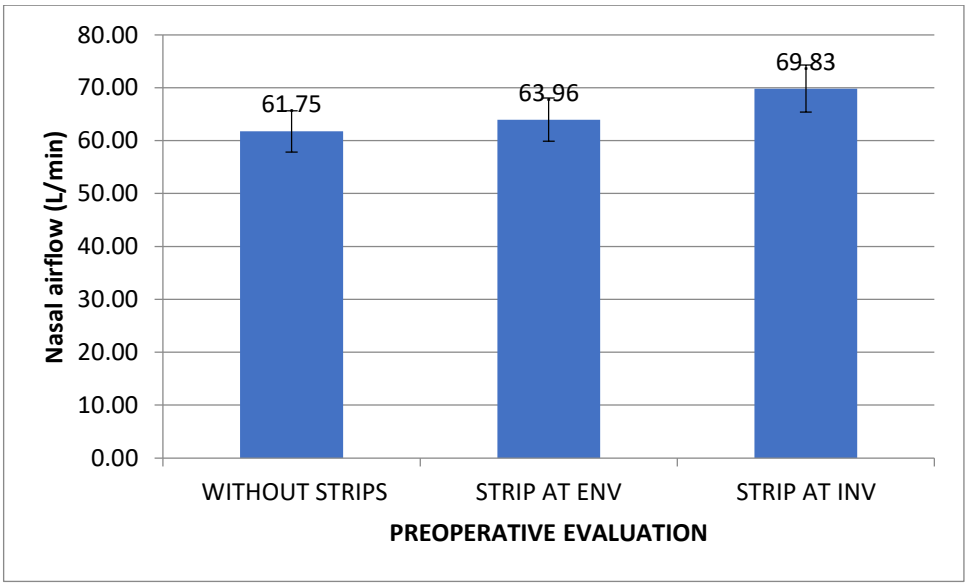


Figure 24. Showing comparison of pre-operative nasal airflow measurements without application of nasal strips, with strip at ENV and with strip at INV.

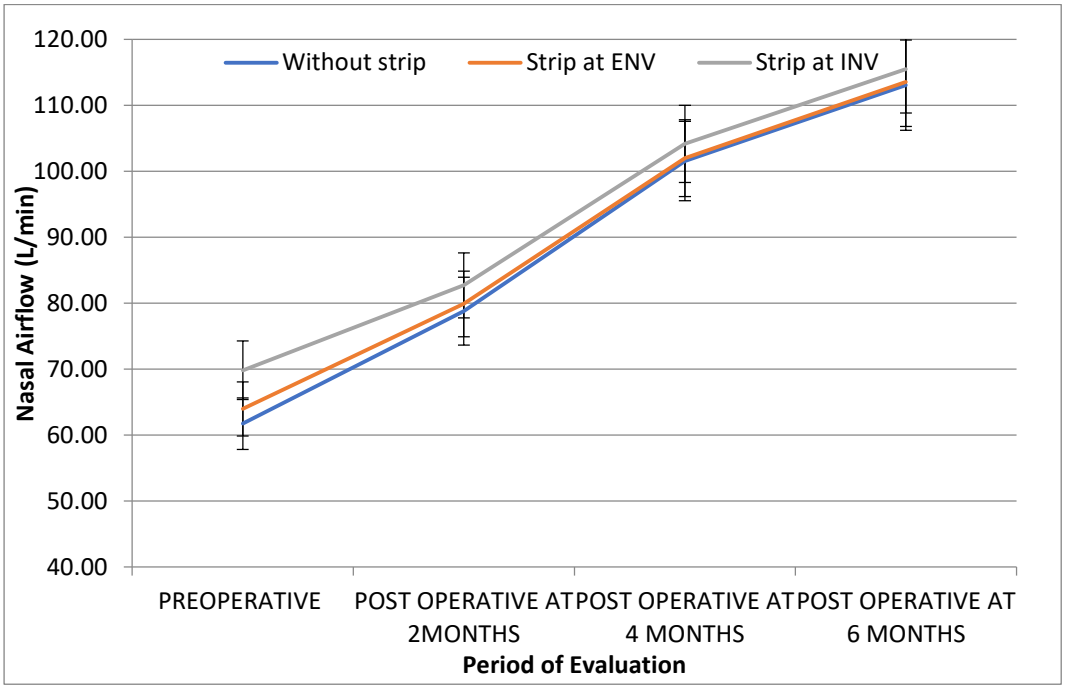


Figure 25. Line graph showing the change in nasal airflow preoperatively and 2, 4 and 6 months post-operatively

Table 4. Showing comparison of preoperative nasal airflow (without strips) with that of post operative at 2 months

Statistic	Preoperatively without strips	Post-operatively without strip at 2 months
No. of observations (Patients)	32	32
Minimum nasal airflow (L/min)	25.000	30.000
Maximum nasal airflow (L/min)	140.000	150.000
1st quartile	50.000	60.000
Median	60.000	80.000
3rd quartile	70.000	92.500
Mean	**61.747**	**78.800**
Variance (n-1)	487.913	843.506
Standard deviation(n-1)	22.089	29.043
Standard error	**3.905**	**5.134**
P value	**< 0.01**	

Table 5. Showing a comparison of preoperative nasal airflow (without strips) with that of post operative at 4 months

Statistic	Preoperatively, without strips	Post-operatively, without strip at 4 months
No. of observations (Patients)	32	32
Minimum nasal airflow (L/min)	25.000	50.000
Maximum nasal airflow (L/min)	140.000	180.000
1st quartile	50.000	80.000
Median	60.000	100.000
3rd quartile	70.000	112.500
Mean	**61.747**	**101.563**
Variance (n-1)	487.913	1160.383
Standard deviation(n-1)	22.089	34.064
Standard error	**3.905**	**6.022**
P value	**< 0.01**	

Table 6. Showing a comparison of preoperative nasal airflow (without strips) with that of post operative at 6 months

Statistic	Preoperatively without strips	Post-operatively without strip at 6 months
No. of observations (Patients)	32	32
Minimum nasal airflow (L/min)	25.000	50.000
Maximum nasal airflow (L/min)	140.000	200.000
1st quartile	50.000	85.000
Median	60.000	110.000
3rd quartile	70.000	130.000
Mean	**61.747**	**113.069**
Variance (n-1)	487.913	1495.967
Standard deviation(n-1)	22.089	38.678
Standard error	**3.905**	**6.837**
P value	**< 0.01**	

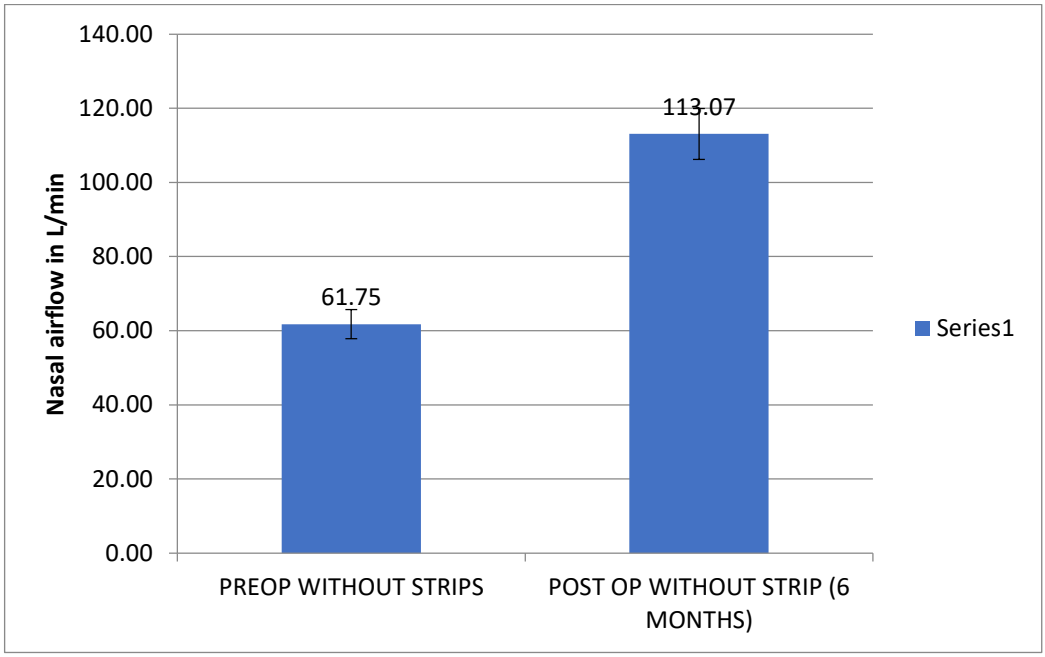


Figure 26. Showing a comparison of preoperative and post operative nasal airflow at 6 months (without application of snoring strips)

Change in nasal airflow was assessed after application of snoring strips at the level of ENV and INV separately in the post operative period as well. At 6 months, nasal airflow values after application of snoring strips were compared with the same without application of snoring strips.

Table 7. Showing comparison of nasal airflow without application of snoring strip and with application of strip at the level of ENV, at 6 months post operatively

	Post-operatively, without strips , at 6 months (L/min)	Post-operatively , with strip at ENV, at 6 months (L/min)	P value
Mean	113.06±38.6	113.528±38.4	**0.178**

Table 8. Showing comparison of nasal airflow without application of snoring strip and with application of strip at the level of INV, at 6 months post operatively

	Post-operatively, without strips , at 6 months (L/min)	Post-operatively , with strip at INV, at 6 months (L/min)	P value
Mean	113.06±38.6	114.35±37.2	0.06

Different types of grafts were used intraoperatively for the correction of various deformities of nose. 10 spreader grafts, 4 cap grafts, 4 batten grafts, 8 shield grafts, 8 columellar strut grafts, 6 alar grafts (alar rim/ alar batten/alar turn in), 10 septal extension grafts, 3 'L' strut grafts and 3 diced cartilage grafts are among these. More than one type of grafts were used in the same patient.

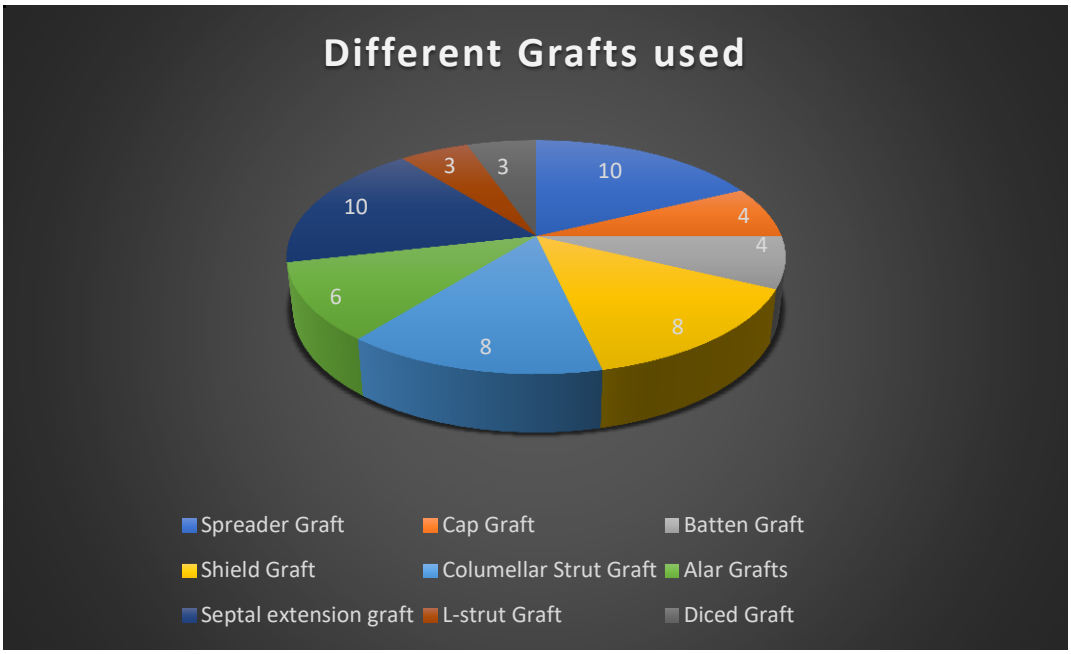


Figure 27. Pie chart showing different types of grafts used during septorhinoplasty

DISCUSSION

As **Unadat et al** said, even during COVID 19 pandemic, Functional Septorhinoplasty procedure should not be overlooked since it can affect the quality of life in patients awaiting for surgery (55).

In our study the mean age of the patients was 20.97±0.76 years which is almost similar to most of the previous studies (57–59). This may be due to the increased cosmetic concern in younger age group and also due to poor quality of life because of nasal obstruction in their growing age.

According to the study by **Sasindran et al**, 57.9 % of patients who presented for septorhinoplasty were females (57). Similarly, in a study by **Strasdinz et al** 60.2 % of septorhinoplasty patients were females (60). These studies showed the prevailing cosmetic and functional concerns among females, whereas our study included a total of 32 patients with 28(87%) males and 4(13%) females, in contrast to them. This may be because of the patriarchal views, norms and traditions in Indian society leading to less female patients seeking medical attention.

In this study, according to preoperative NOSE score evaluation, 12.5% patients had mild, 34.37% had moderate, 37.5% had severe and 15.62% had extreme nasal obstruction. The mean baseline NOSE score was 55.78±3.64 preoperatively. Post operatively there were no patients with extreme nasal obstruction. 81.25% patients still experienced mild nasal obstruction where as 12.5 % reported complete relief of symptoms. Among these patients 78.12 % showed a decrease in NOSE score of more than 30 after surgery (ie, 25 out of 32 patients showed a decrease in NOSE score of >30 postoperatively). This classification of NOSE score is based on a study conducted by **Lipan and Most** (56). This decrease in NOSE score indicates the subjective improvement in nasal obstruction and patient satisfaction after surgery. This finding is consistent with the previous studies (5,61–64).

Preoperatively the mean NIPF value of these patients was 61.75±3.90 L/min which is less than the normal values measured in healthy individuals (131.1L/min)(11). According to the previous studies by **Ottaviano et al** in 2006, the mean NIPF in normal adult male was found to be 143±48.6 L/min and in females it was 121.9±36

L/min (65). Another study by **Blomgren et al** in 2003 found this as145L/min in males and 128L/min in females (66). **Bouzgarou et al** in 2011 and **Klossek et al** in 2009 in their studies said the airflow ranges as 174±54 L/min & 104±54.8 (in males) and 126±33 L/min & 80.8±33.4 L/min(in females) respectively (67,68).

In our study we found the mean NIPF of male patients as 64.49±21.35 L/min and of female patients as 42.5±19.36 L/min.

This low NIPF values in our patients presented for Functional Septorhinoplasty indicates that NIPF can be a useful measure of nasal obstruction (6,9–16). It was also observed that the NIPF values in female patients enrolled in the study was much less than their male counterparts, which is consistent with prior studies (6,46,65,69,70) but the number of female patients enrolled in the study were significantly less than that of males. The low nasal airflow in female patients may be due to smaller nasal cavities and low nasal floor when compared to males of same size (71).

The NIPF values post operatively after 6 months showed maximum improvement (113.06±38.67L/min) when compared to 2 and 4 months. But these post operative values of nasal airflow showed a gradual increase with time which was both clinically and statistically significant. This may be indicative of resolution of post operative edema or sensation of heaviness and pain over time. This finding is consistent with a previous study conducted by Fuller et al(6).

It was observed that one of our patient with extreme nasal obstruction even though showed improvement in NOSE score more than 30 (Preoperative NOSE- 95, Post operative- 60), his NIPF did not show significant improvement. Clinical evaluation revealed that this patient had persistent inferior turbinate hypertrophy which was corrected later. All other patients included in the study had subjective and objective improvement in nasal airflow.

Preoperative assessment of nasal airflow showed improvement after applying snoring strip at the level of internal nasal valve in 20 patients (62.5%) and at external nasal valve in 12 (37.5%) patients. So according to our study internal

nasal valve area is the commonest level of nasal obstruction when compared to external nasal valve area.

25 patients (78.12%) had a positive Cottle's test pre-operatively. 19 out of these 25 patients showed improvement in nasal airflow on application of snoring strip at the level of internal nasal valve area. Though a relation between positive Cottles test and improvement in NIPF on application of snoring strip at internal nasal valve could not be explained as one patient with negative Cottle's test also had shown improvement in NIPF and vice versa. In a previous study by **Gruber et al**, it was found that use of nasal strips (external nasal dilator) are more accurate in diagnosing the area of obstruction in the nose when compared to Cottle's test which is non-specific (72).

The linear correlation between NOSE score and NIPF values was assessed both preoperatively and post-operatively. Pearson correlation coefficient(r) for this was -0.69 with a p value <0.01. The negative correlation indicates that as NIPF increases, NOSE score (nasal obstruction) decreases. This 'r' value is similar to most of the studies conducted earlier (6,12,16,70,73). Lack of strong correlation between NIPF and NOSE score was explained because of the subjective nature of NOSE score. Other reason being, a patient with unilateral severe nasal obstruction may report a high NOSE score whereas his NIPF can be still better as other side of the nose will not resist airflow.

Post operative nasal airflow without application of snoring strips were compared with the same after application of nasal strips at the level of internal and external nasal valve areas. There was no statistically significant improvement in airflow after application of snoring strips at these locations at 6 months post-operatively (P value with strip at ENV was 0.178 and INV was 0.06). This along with improvement in airflow when compared to preoperative values indicates correction of the deformity and relief of obstruction at both ENV and INV areas.

Rhinoplasty can be classified as "open" and "closed" based on the type of incision and the extent of exposure during surgery. Though closed rhinoplasty is the modern technique in terms of smaller incision, quick recovery, no post operative scar formation or reduced operative duration, the ease of doing the procedure and

better visualisation of the deformity and the structures make open rhinoplasty more successful (34). In our study also, all the enrolled patients underwent open rhinoplasty.

The grafts used in rhinoplasty also depends upon whether it is a closed or open surgery(34). In our patients we used a combination of different types of grafts - spreader grafts (31.25% patients), Batten grafts (12.5% patients), cap grafts (12.5% patients), shield grafts (25% patients), columellar strut grafts (25% patients), alar grafts(18.75% patients), septal extension grafts (31.25% patients), L strut grafts (9.3% patients) and diced cartilage grafts (9.3 % patients). The correction of the deformities during septorhinoplasty may not be done with a single graft, but a set of grafts depending upon the type of defect may be used. This can be explained by the presence of more than one type of deformity in single patient requiring multiple techniques for correction.

In our patients with preoperative NIPF improvement at the level of internal nasal valve area had various deformities like weak ULC and deviated nasal septum. Weak ULC was corrected by a batten graft to support the lower end of the ULC and DNS was corrected by spreader graft, or by extracorporeal septoplasty followed by L strut or septal extension grafts. According to **Goudakos et al**, spreader graft is the gold standard technique in correcting the deformities of middle vault of nose (74). Similarly in our study also we used a maximum of spreader grafts for correction of internal nasal valve area when compared to the other grafts. But a correlation between the graft material used and the improvement in nasal airflow could not be established.

In our study we also used auto-spreader grafts in 2 patients in which the ULSs after separating from the nasal septum, folded upon themselves and then were stabilized to the dorsal septum via non absorbable sutures. This is a good alternative to the traditional spreader grafts (30).

Preoperatively 2 patients had an improvement in nasal airflow by application of snoring strips at the level of ENV only. Both of these patients had a weak alar cartilage, corrected by alar turn in grafts (alar flip by 180 degree). They also reported subjective and objective improvement in nasal airflow postoperatively.

Calloway et al in 2019, conducted a study showed statistically significant improvement in NOSE scores after articulated alar rim grafting (48).

In 10 patients with a combined improvement both at ENV and INV, multiples grafts were used for correction of both these areas of obstruction. Majority of them had DNS with caudal dislocation. Caudal dislocation in these patients were corrected by tongue in groove technique. The aesthetic component was taken care of by the shield grafts/ cap grafts/ hump reduction/ augmentation.

CONCLUSION

All the patient's undergoing functional septorhinoplasty should ideally have improvement in nasal airflow unless develop any postoperative complications.

Nasal inspiratory peak flow is a simple, inexpensive, easy to carry instrument and quick test for detecting nasal obstruction and clinically significant increases in airflow after Functional Septorhinoplasty. It can be a better alternative to costly Rhinomanometer in daily practice. This when combined with the use of snoring strips, provide unique and complementary data that can be used to evaluate the degree of obstruction, analyse the site of obstruction, and to plan the appropriate surgical technique for better functional outcome.

Objective measurement of airflow using NIPF meter does not always correlate with the patient's perception of severity of nasal obstruction. Therefore preoperative and postoperative NOSE score evaluation can be combined with this as a measure of patient satisfaction.

STRENGTHS AND LIMITATIONS

STRENGTHS

1. All the patients were followed up to six months after surgery.
2. All the surgeries were done by a single surgeon.
3. All the pre-op and post-op nasal airway measurements and NOSE score assessments were done by a single person.

LIMITATIONS

1. Few patients could not turn up for follow up at exact 2-month and 4-month postoperative period. Hence, the comparison could not accurately evaluate the difference between 2 month and 4 months postoperatively.
2. NIPF measurement depends upon patient co-operation and the condition of the nose at the time of examination. Therefore, URI and nasal congestion at the time of examination also can affect the airflow through the nose.

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ANNEXURES

Annexure – A: IEC Certificate

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/3537 Date: 12/03/2021

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3372**

Project title: **"Comparison of preoperative and postoperative nasal airflow in patients undergoing functional septorhinoplasty"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.S. Dissertation**
Student Name:	**Dr. Swathi Krishna M**
Guide:	**Dr. Kapil Soni**
Co-Guide:	**Dr. Amit Goyal & Dr. Bikram Choudhury**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Basni Phase-2, Jodhpur, Rajasthan-342005; **Website:** www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

Annexure – B: Informed Consent Form to Participate in a Research Study

Title of the project: Comparison of preoperative and postoperative nasal airflow in patients undergoing Functional Septorhinoplasty

Name of Thesis Candidate: Dr. Swathi Krishna M Tel. No. 7726869065

Name of Chief Guide: Dr. Kapil Soni

Patient/Volunteer Identification No. : _____

I, _____ S/o or D/o _____

R/o_____

give my full, free, voluntary consent to be a part of the study "_____", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from _____(Company Name) or from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _____ _____

Place: _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____ _____

Place: _____ Signature of Principal Investigator

Witness 1 Witness 2

_____ _____

Signature Signature

Name: _____ Name: _____

Address: _____ Address: _____

Title: Comparison of preoperative and postoperative nasal airflow in patients undergoing Functional Septorhinoplasty

Subject's Name: _____ AIIMS ID:

Date of Birth / Age: _____

(i) I confirm that I have read and understood the information of Consent Form for the above study and have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my Medical care or legal rights being affected.

(iii) I understand that the investigator of the research and the Ethics Committee will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

(v) I agree to take part in the above study.

(Signature) Date:
Place:

Name of the Participant/ Legally Authorized Representative: _____
Son / Daughter / Spouse of: _____
Complete postal address: _____
This is to certify that the above consent has been obtained in my presence.

1) Witness – 2) Witness – 2

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Name: Name:
Address: Address:

Signatures of the principal investigator: Dr. Swathi Krishna M.
Place: Date:

Annexure-C : **सूचित सहमति पत्र**

सीरीयल नम्बर।_____

परियोजना का शीर्षक: कार्यात्मक सेप्टोरिनोप्लास्टी से गुजरने वाले मरीजों में ऑपरेशन के पहले तथा ऑपरेशन के बाद, नाक के वायु प्रवाह की तुलना l

शोधकर्ता : डॉ स्वाति कृष्णा एम्

मरीज का नाम: _____ AIIMS पहचान क्रमांक:

जन्म तिथि / उम्र: _____

(i) मैं पुष्टि करता/करती हूँ कि मैंने उपरोक्त अध्ययन के लिए सूचना और सहमति फॉर्म को पढ़ा और समझा है और मुझे प्रश्न पूछने का अवसर मिला है।

(ii) मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं किसी भी समय बिना कोई कारण बताये अपनी सहमती वापस लेने के लिए स्वतंत्र हूँ l इससे मेरी चिकित्सा देखभाल या कानूनी अधिकारों पर कोई प्रभाव नहीं पड़ेगा।

(iii) मैं समझता हूं कि शोधकर्ता और आचार समिति के अन्वेषक, वर्तमान अध्ययन के संबंध में और इसके संबंध में भविष्य में किए जाने वाले किसी भी अन्य शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी, भले ही मैं परीक्षण में भाग लेने की सहमती वापस ले लेता हूं। मैं इससे सहमत हूँ। हालांकि, मैं समझता हूं कि मेरी पहचान किसी भी अन्य व्यक्ति या प्रकाशन में नहीं बताई जाएगीl

(iv) मैं इस अध्ययन के परिणामों या किसी भी अन्य तथ्य के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं, बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्य के लिए हो।

(v) मई इस अध्ययन में अपनी ममर्जी से भाग लेने के लिए सहमत हूँl

हस्ताक्षर.. दिनांक..

भागीदार/ कानूनी रूप से अधिकृत प्रतिनिधि का नाम.. पिता /पति/ पत्नी का नाम..

पुरा स्थायी पता..

यह प्रमाणित किआ जाता है कि उपरोक्त सहमति मेरी उपस्थति में ली गयी है |

1. गवाह-1
नाम व पता

2. गवाह-2
नाम व पता

शोधकर्ता के हस्ताक्षर (डॉ स्वाति कृष्णा एम्)

तारीख: स्थान:

Annexure –D: Patient Information Sheet

Department of Otorhinolaryngology
All India Institute of Medical Sciences, Jodhpur

Title: Comparison of preoperative and postoperative nasal airflow in patients undergoing Functional Septorhinoplasty

Sponsor: None

Study Doctor: Dr. Swathi Krishna M

Site: All India Institute of Medical Sciences, Jodhpur

DESCRIPTION OF STUDY:

The patient following Rhinoplasty and who desired for any reasons will be called and asked to take part in a medical research study. Before you decide to participate, you should read this form. This form, called an *Information and Consent Form*, explains the study. This form will tell you what you will have to do during the study and the risks and benefits of the study. This form may contain words or information that you do not understand clearly. If so, please ask the study doctor or the study staff to explain those words or information. You may take home an unsigned copy of this form to help you decide whether or not to participate in the study. You can also discuss your participation with family, friends or anyone you choose before making your decision. If you decide to participate in the study and sign this form, you will be given a signed and dated copy of this form to keep for your records. Do not sign this form unless the study doctor or study staffs have answered all your questions and you decide that you want to be a part of this study.

When reading this form, please note that the words "you" and "your" refer to the person in the study rather than to a legally authorized representative who might sign this form on behalf of the person in the study.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

About the Study:

The purpose of this research study is to compare preoperative and post-operative nasal airflow measurements and subjective assessments in patients undergoing Functional Septorhinoplasty

This study will evaluate the nasal airflow before and after the surgery . You will also be evaluated on final outcome of your surgery and quality of life after regular intervals of surgery. The study is planned to include patients who will undergo functional Septorhinoplasty from December 2020 to June 2022. The patients will be assessed preoperatively, at the two months follow up; four months follow up and finally at six months follow up.

There may be other reasons why you are not eligible to participate in this study. The study doctor will talk to you about why you may or may not be eligible.

Study Conduct:

This is a prospective cohort study in which the patients fulfilling inclusion/ exclusion criteria will be assessed.

Responsibilities of study subjects

To participate in the study, you must tell your doctor if you are suffering from any physical or psychological illness or not and must be willing to follow all study procedures. You must follow the instructions you are given by the doctor or study staff.

What else should I know about the study procedures?

The study doctor or a member of a study staff can answer any questions you may have about the study procedures.

Risks

There are no risks involved in this study.

Benefits

Your participation in this study may benefit you directly in a way that your satisfaction levels with the surgery in the form of symptom relief will be calculated. The assessment of quality of life after the surgery will also be assessed. The study will also help us and others to plan health care strategies for betterment of our clients seeking surgical treatment of nasal obstruction.

Payment for participation:

You will not get paid being in this study.

Payment for investigations:

Not applicable

New Information

The study doctor will also tell you if new information become available.

Legal rights

By signing this information and consent form and the accompanying Informed Consent Form to participate in a Research Study, you are not waiving any of the legal rights that you have as a subject in a research study.

Source of funding

None

Confidentiality

Except where required by law or regulatory authorities, you will not be identified by name, address, telephone number or any other direct personal identifier in study records disclosed outside of the clinic.

Also individuals from Ethics Review Committee may also look and copy the health information generated or collected about you as part of this study, both to assure quality control and to analyse the information.

The results of this study conducted by the study doctor may be published or presented at meetings but will not include your name or any other information that reveals your identity.

Your authorization for use and disclosure of the health information generated or collected as part of study has no expiry date.

Voluntary participation / withdrawal

Your participation in the study is voluntary. You may choose not to participate in the study or, if you agree to participate in the study at any time. This will not affect on your treatment in anyway.

Your participation in the study may also be terminated at any time, without your consent, under the following circumstances:

If you do not follow the instructions of the study doctor or the study staff;
If the study doctor determines that participating in the study is not appropriate for your condition; or
If the sponsor cancels the study.
If you choose not to participate in the study or to withdraw from the study or if your participation in the study is terminated, you will not have any penalty or lose any benefits to which you are otherwise entitled.

Questions

If you have questions about the study or your condition, you should contact the study doctor:

Dr. Swathi Krishna M

Department of Otorhinolaryngology

All India Institute of Medical Sciences, Jodhpur, Rajasthan

If you have questions about the study or your rights as a research subject, you may contact

Ethics Review Committee

All India Institute of Medical Sciences, Jodhpur, Rajasthan

Do not sign this information and consent form or the accompanying Informed Consent form to participate in a research study unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Annexure-E: मरीज़ की जानकारी के लिए सूचना पत्र

ऑटोरहिनोलेरिंगोलोजी विभाग

अखिल भारतीय आयुर्विज्ञान संस्थान**,** जोधपुर

शीर्षक : कार्यात्मक सेप्टोरिनोप्लास्टी से गुजरने वाले मरीजों में ऑपरेशन के पहले तथा ऑपरेशन के बाद, नाक के वायु प्रवाह की तुलना l

प्रायोजक: कोई नहीं

अध्ययन डॉक्टर: डॉ स्वाति कृष्णा एम्

स्थान :अखिल भारतीय आयुर्विज्ञान संस्थान,जोधपुर

अध्ययन का विवरण

आपको मेडिकल रिसर्च स्टडी में भाग लेने के लिए कहा गया है। भाग लेने का फैसला करने से पहले, आपको इस फॉर्म को पढ़ना चाहिए। इस फॉर्म को एक सूचना पत्र कहा जाता है। यह फॉर्म आपको बताएगा कि अध्ययन के दौरान आपको क्या करना होगा और अध्ययन के जोखिम और लाभ क्या होंगे। इस फ़ॉर्म में ऐसे शब्द या जानकारी हो सकती हैं जिन्हें आप स्पष्ट रूप से समझ नहीं सकते हैं। यदि ऐसा है, तो कृपया उन शब्दों या जानकारी को समझाने के लिए अध्ययन डॉक्टर या अध्ययन कर्मचारियों से पूछें। अध्ययन में भाग लेना है या नहीं, यह तय करने में आपकी सहायता के लिए आप इस फॉर्म की एक हस्ताक्षरित प्रतिलिपि ले सकते हैं। आप निर्णय लेने से पहले अपने परिवार, दोस्तों या किसी भी व्यक्ति के साथ अपनी भागीदारी पर चर्चा भी कर सकते हैं। यदि आप अध्ययन में भाग लेने और इस फॉर्म पर हस्ताक्षर करने का निर्णय लेते हैं, तो आपको अपने रिकॉर्ड रखने के लिए इस फॉर्म की एक हस्ताक्षरित और दिनांकित प्रति दी जाएगी। इस फॉर्म पर हस्ताक्षर न करें जब तक कि अध्ययन डॉक्टर या अध्ययन कर्मचारी ने आपके सभी सवालों का जवाब नहीं दिया है और आप तय करते हैं कि आप इस अध्ययन का हिस्सा बनना चाहते हैं। इस फॉर्म को पढ़ने पर, कृपया ध्यान दें कि "आप" और "आपका" शब्द कानूनी रूप से अधिकृत प्रतिनिधि के बजाय अध्ययन में व्यक्ति को संदर्भित करते हैं जो अध्ययन में व्यक्ति की तरफ से इस फॉर्म पर हस्ताक्षर कर सकते हैं।

एक अध्ययन में भाग लेना नियमित चिकित्सा देखभाल के समान नहीं है। नियमित चिकित्सा देखभाल का उद्देश्य अपने स्वास्थ्य को बेहतर बनाना है। एक शोध अध्ययन का उद्देश्य जानकारी इकट्ठा करना है। इस अध्ययन में होने से आपकी नियमित चिकित्सा देखभाल नहीं बदली जाती है।

अध्ययन के बारे में:

इस शोध अध्ययन का उद्देश्य कार्यात्मक सेप्टोरिनोप्लास्टी से गुजरने वाले मरीजों में ऑपरेशन के पहले तथा ऑपरेशन के बाद, नाक के वायु प्रवाह की तुलना करना हैl यह अध्ययन सर्जरी से पहले और बाद में नाक के वायु प्रवाह का मूल्यांकन करेगा। सर्जरी के नियमित अंतराल के बाद आपकी सर्जरी और जीवन की गुणवत्ता के अंतिम परिणामों पर भी मूल्यांकन किया जाएगा। अध्ययन में उन रोगियों को शामिल करने की योजना बनाई गई है, जो दिसंबर 2020 से जून 2022 तक कार्यात्मक सेप्टोरिनोप्लास्टी से गुजरेंगे। रोगियों का ऑपरेशन के पहले, ऑपरेशन के दो महीने के बाद, चार महीने के बाद और आखिरकार छह महीने के बाद मूल्यांकन किया जाएगा l

इस अध्ययन में भाग लेने के योग्य नहीं होने के अन्य कारण भी हो सकते हैं। अध्ययन करने वाला डॉक्टर आपसे इस बारे में बात करेगा कि आप पात्र क्यों हो सकते हैं या नहीं।

अध्ययन आचरण:

यह एक भावी कोहोर्ट अध्ययन है जिसमें समावेश / बहिष्करण मानदंडों को पूरा करने वाले रोगियों का मूल्यांकन किया जाएगा।

अध्ययन विषयों की जिम्मेदारियां

अध्ययन में भाग लेने के लिए, आपको अपने डॉक्टर को यह बताना होगा कि क्या आप किसी भी शारीरिक या मनोवैज्ञानिक बीमारी से पीड़ित हैं या नहीं आपको डॉक्टर या अध्ययन कर्मचारियों द्वारा दिए गए निर्देशों का पालन करना होगा।

अध्ययन प्रक्रियाओं के बारे में मुझे और क्या पता होना चाहिए?

अध्ययन डॉक्टर या एक अध्ययन कर्मचारी के सदस्य अध्ययन प्रक्रियाओं के बारे में आपके किसी भी प्रश्न का उत्तर दे सकते हैं।

जोखिम

इस अध्ययन में कोई जोखिम शामिल नहीं है।

लाभ

इस अध्ययन में आपकी भागीदारी आपको इस तरह से सीधे लाभ पहुंचा सकती है कि लक्षण राहत के रूप में सर्जरी के साथ आपकी संतुष्टि के स्तर का मूल्याङ्कन किया जायेगा। सर्जरी के बाद जीवन की गुणवत्ता का आकलन भी किया जाएगा। अध्ययन हमें और अन्य लोगों को नाक की रुकावट के सर्जिकल उपचार की तलाश में हमारे मरीजों की बेहतरी के लिए स्वास्थ्य देखभाल रणनीतियों की योजना बनाने में मदद करेगा।

भागीदारी के लिए भुगतान:

आपको इस अध्ययन में भुगतान नहीं मिलेगा।

जांच के लिए भुगतान:

लागू नहीं

नई जानकारी

अध्ययन डॉक्टर आपको यह भी बताएगा कि क्या नई जानकारी उपलब्ध हो गई है।

क़ानूनी अधिकार

एक शोध अध्ययन में भाग लेने के लिए इस जानकारी और सहमति फॉर्म और साथ में सूचित सहमति फॉर्म पर हस्ताक्षर करके, आप एक अध्ययन के विषय के रूप में अपने किसी भी कानूनी अधिकार को छोड़ नहीं रहे हैं।

धन के स्रोत

कोई नहीं

गोपनीयता

अगर कानून या नियामक प्राधिकरणों द्वारा जहां आवश्यक हो, इसके सिवाय आपकी कोई भी व्यक्तिगत जानकारी जैसे नाम, पता, फ़ोन नंबर इत्यादि किसी भी अन्य व्यक्ति को नहीं दी जाएगी l

एथिक्स रिव्यू कमेटी के व्यक्ति भी गुणवत्ता नियंत्रण सुनिश्चित करने और जानकारी का विश्लेषण करने के लिए, इस अध्ययन के हिस्से के रूप में आपके स्वास्थ्य सम्बंधित जानकारी को देख और कॉपी कर सकते हैं।

अध्ययन डॉक्टर द्वारा किए गए इस अध्ययन के नतीजे सम्मलेन में प्रस्तुत या प्रकाशित किए जा सकते हैं लेकिन आपकी पहचान या कोई अन्य जानकारी शामिल नहीं होगी जो आपकी पहचान का खुलासा करे।

अध्ययन के के दौरान, आपके स्वस्थ्य के बारे में जो जानकारी इक्कठा होगी उसे भविष्य में कभी भी किसी और अध्यन के लिए इस्तेमाल किया जा सकता है l

स्वैच्छिक भागीदारी / वापसी

अध्ययन में आपकी भागीदारी स्वैच्छिक है। आप किसी भी समय, बिना कोई कारण बताये, अध्ययन से अपनी भागीदारी की सहमती वापस ले सकते है। इससे आपका इलाज पर प्रभावित नहीं होगा।

निम्नलिखित परिस्थितियों में, आपकी सहमति के बिना, अध्ययन में आपकी भागीदारी किसी भी समय समाप्त हो सकती है:

1. यदि आप अध्ययन डॉक्टर या अध्ययन कर्मचारियों के निर्देशों का पालन नहीं करते हैं;
2. यदि अध्ययन डॉक्टर निर्धारित करता है कि अध्ययन में भाग लेना आपकी हालत के लिए उपयुक्त नहीं है; या
3. अगर प्रायोजक अध्ययन रद्द कर देता है।

यदि आप अध्ययन में भाग लेने या अध्ययन से वापस लेने का चयन नहीं करते हैं या यदि अध्ययन में आपकी भागीदारी समाप्त हो जाती है, तो आपके पास कोई जुर्माना नहीं होगा या कोई लाभ नहीं होगा जिसके लिए आप अन्यथा हकदार हैं।

प्रश्न

यदि आपके पास अध्ययन या आपकी स्थिति के बारे में कोई प्रश्न है, तो आपको अध्ययन डॉक्टर से संपर्क करना चाहिए:

डॉ स्वाति कृष्णा एम्
पता
Otorhinolaryngology विभाग
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यदि आपके पास शोध विषय के रूप में अध्ययन या आपके अधिकारों के बारे में कोई प्रश्न है, तो आप संपर्क कर सकते हैं

नैतिकता समीक्षा समिति
अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर, राजस्थान

एक शोध अध्ययन में भाग लेने के लिए इस जानकारी और सहमति फॉर्म या साथ में सूचित सहमति फॉर्म पर हस्ताक्षर न करें जब तक कि आपको प्रश्न पूछने का मौका न हो और आपके सभी सवालों के संतोषजनक उत्तर प्राप्त न हो

Annexure-F: Patient Proforma

A. BIODATA **C.R.NO.:**

1. Name
2. Age
3. Sex
4. Occupation
5. Address
6. Date of Examination

B. HISTORY

ENT SYMPTOMS

1. Difficulty in breathing - Duration

2 Difficulty in hearing

-Tinnitus -

-Ear discharge -

-Neck swelling -

Any nasal symptoms like discharge, nasal dryness, nasal obstruction, sneezing, post nasal discharge, headache and epistaxis.

Any throat symptoms like recurrent attacks of upper respiratory tract infections, sore throat.

Any history of dysphagia, odynophagia or dyspnea**.**

PAST MEDICAL HISTORY

-Any significant medical disease

-History of tuberculosis, diabetes mellitus, hypertension

-History of injections in the past

-History of trauma

-History of any operation in the past

-History of drug reactions in the past

-History of measles, mumps, rubella, meningitis, other febrile illness etc.

SOCIAL AND PERSONAL HISTORY

-Occupation

-Economic status

-Addictions:

Smoking, alcohol consumption

FAMILY HISTORY

C. CLINICAL EXAMINATION:

I. General Examination

-Built, Weight and Height

-Pulse rate

-Blood pressure

-Pedal edema

-Pallor

-Respiratory rate

-Clubbing

-Lymphadenopathy

-Jugular venous pressure

-Cyanosis

-Icterus

-Congested eyes

-Ascites

-Skin

II. SYSTEMIC EXAMINATION

-Cardiovascular system

-Central nervous system

-Gastrointestinal system

-Respiratory system

III ENT EXAMINATION:

EARS	**Rt.**	**Lt.**
-Pre & Post auricular region –		
-Pinna -		

-External auditory canal -

Tympanic membrane -

Hearing Assessment

-Rinne's test -

-Weber test –

- Absolute bone conduction

NOSE

Root

Dorsum

Tip

Ala

Columella

Anterior Rhinoscopy

Posterior Rhinoscopy

THROAT:

-Tonsils -

-Posterior pharyngeal wall -

-Indirect laryngoscopy

-Orodental hygiene

F. LABORATORY INVESTIGATIONS:

1. Complete hemogram
2. Renal function test: Urea/Creatinine
3. Blood sugar
4. Urine Examination/Proteinuria
5. Chest X-ray

Annexure-G : Objective Assessment of nasal airflow table

Department of Otorhinolaryngology
All India Institute of Medical Sciences, Jodhpur

	Without Applying Snoring Strips				Snoring Strip At The Level of External Nasal Valve				Snoring Strip At The Level of Internal Nasal Valve			
	1	2	3	Mean	1	2	3	Mean	1	2	3	Mean
Preoperatively												
Postoperatively After 2 Months												
Postoperatively After 4 Months												
Postoperatively After 6 Months												

NB: The objective assessment of nasal airflow was performed by using Nasal Inspiratory Peak Flow Meter, which consists of a face mask which is applied over the nose with mouth closed and the patient is asked to take breath as hard and fast as possible, first without applying snoring strips and then by applying it at the level of the internal nasal valve followed by external nasal valve separately. This procedure is done preoperatively and 2,4,6 months postoperatively as well.

Annexure-H: Subjective assessment by NOSE score table

	Preoperatively	2 Months Postoperatively	4 Months Postoperatively	6 Months Postoperatively
Nasal stuffiness				
Nasal blockage or obstruction				
Trouble breathing through my nose				
Trouble sleeping				
Unable to get enough air through my nose during exercise or exertion				
Total score				

NB: The symptoms were analysed within a scale of scores between zero and 4,

0- Not a problem
1- Very mild problem
2- Moderate problem
3- Fairly bad problem
4- Severe problem

Then the sum of the all responses from each symptom was multiplied by 5 and obtained the final a value which varies between zero to 100 (zero represents minimum satisfaction and 100 the maximum one), and the final NOSE scores can be categorized into mild (range, 5–25), moderate (range, 30–50), severe (range, 55–75), or extreme (range, 80–100)