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**“COMPARISON OF SOFT TISSUE NASAL  
CHANGES IN UNILATERAL CLEFT LIP AND  
PALATE WITH NON CLEFT LIP AND PALATE  
INFANTS USING 3-DIMENSIONAL IMAGING”**

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**By**  
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***Dissertation***

*Submitted to*  
*KAHER, Belagavi, Karnataka*  
*In partial fulfilment of the requirements for the degree of*

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KLE VISHWANATH KATTI INSTITUTE OF DENTAL SCIENCES,  
KAHER, BELAGAVI, KARNATAKA.**

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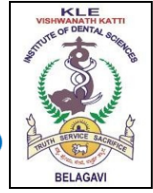
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## LIST OF ABBREVIATIONS USED IN THE STUDY

<b>CLP</b>	Cleft Lip and Palate
<b>UCLP</b>	Unilateral Cleft Lip and Palate
<b>BCLP</b>	Bilateral Cleft Lip and Palate
<b>2D</b>	2-Dimensional
<b>3D</b>	3-Dimensional
<b>NAM</b>	Nasoalveolar Molding
<b>ANOVA</b>	Analysis of Variance
<b>RCT</b>	Randomized Controlled Trial
<b>FE</b>	Finite Element
<b>SD</b>	Standard Deviation
<b>mm</b>	Millimeter
<b>sn'-prn</b>	Nasal tip projection
<b>sn-cm</b>	Columella length
<b>alr-all</b>	Maximum nasal width
<b>acr-acl</b>	Outer nasal width at base
<b>sbalr-sball</b>	Inner nasal width at base
<b>prn-ac</b>	Alar length
<b>sbal-sn</b>	Unilateral nasal aperture width

## **ABSTRACT**

### **Introduction:**

Unilateral cleft lip and palate (UCLP) is a common craniofacial anomaly characterized by nasolabial asymmetry and soft tissue deformities that can affect aesthetics and vital functions. Traditionally, two-dimensional (2D) assessments have been used to evaluate nasal morphology; however, they lack accuracy and depth perception. With the advent of three-dimensional (3D) imaging, precise evaluation of soft tissue changes before and after surgical intervention has become possible. This study aims to evaluate and compare the 3D nasal soft tissue morphology in UCLP infants and non-cleft controls across multiple time points, thereby assessing the effectiveness of surgical intervention in restoring nasal symmetry.

### **Materials and Methods:**

This prospective observational study was conducted at KLE VK Institute of Dental Sciences, Belagavi. A total of 24 infants were included, with 12 UCLP infants (Group A) and 12 age-matched non-cleft controls (Group B). Group A underwent 3D imaging at 3 given time points: T1 (initial presentation), T2 (pre-surgery), and T3 (post-surgery). Controls were scanned at TC1 (baseline) and TC2 (corresponding to post-surgery age in cases). 11 nasolabial landmarks were analyzed using Revopoint POP 2 3D scanner and MeshLab software to compute linear measurements such as nasal tip projection (sn-prn), columella length (sn-cm), alar base width (alr-all, acl-acr), and nostril width (sbal-sn). Statistical analysis involved repeated measures ANOVA, paired t-tests, and independent samples t-tests at 95% confidence intervals ( $p < 0.05$  considered significant).

## **Results:**

UCLP infants showed significant improvement in nasal parameters postoperatively. **Nasal tip projection (sn'-prn)** increased from 5.01 mm at T1 to 7.36 mm at T3 ( $p < 0.001$ ). **Columella length (cm-snl, cm-snr)** also significantly increased post-surgery ( $p < 0.001$ ). **Alar base width (acl-acr)** decreased significantly at T3 compared to T2 ( $p < 0.001$ ), indicating improved approximation of alar bases. When compared to controls, significant differences existed at T1 and T2 for most parameters, but postoperatively (T3 vs TC2), differences in sn-prn, cm-snl, and cm-snr were statistically non-significant, suggesting successful morphological correction. However, certain parameters, such as **inner nasal width (sbalr-sball)**, remained significantly different ( $p = 0.003$ ), indicating residual asymmetry. Intragroup analysis showed marked improvements in nasal shape between T2 and T3, reflecting the impact of primary cheilorhinoplasty.

## **Conclusion:**

Primary surgical repair in UCLP infants significantly improves nasal morphology, particularly nasal tip projection and columella length, as evidenced by 3D imaging. While complete symmetry is not always achieved—particularly in nasal width—surgical correction alone can closely approximate non-cleft nasal dimensions in vertical and anteroposterior aspects. These findings support the utility of 3D imaging as a precise tool for evaluating surgical outcomes and highlight the role of early intervention in cleft management. Further studies with larger cohorts and inclusion of presurgical nasoalveolar molding (NAM) protocols are needed to assess the full potential of combined approaches.

## CONTENTS

<b>SL NO.</b>	<b>PARTICULARS</b>	<b>PAGE NO.</b>
<b>1.</b>	<b>INTRODUCTION</b>	<b>1-4</b>
<b>2.</b>	<b>AIM AND OBJECTIVES</b>	<b>5</b>
<b>3.</b>	<b>REVIEW OF LITERATURE</b>	<b>6-14</b>
<b>4.</b>	<b>METHODOLOGY</b>	<b>15-25</b>
<b>5.</b>	<b>RESULTS</b>	<b>26-41</b>
<b>6.</b>	<b>DISCUSSION</b>	<b>42-48</b>
<b>7.</b>	<b>FUTURE SCOPE OF STUDY</b>	<b>49</b>
<b>8.</b>	<b>LIMITATIONS</b>	<b>50</b>
<b>9.</b>	<b>CONCLUSION</b>	<b>51</b>
<b>10.</b>	<b>SUMMARY</b>	<b>52-53</b>
<b>11.</b>	<b>BIBLIOGRAPHY</b>	<b>54-59</b>
<b>12.</b>	<b>ANNEXURES</b>	<b>60-64</b>

## LIST OF TABLES

<b>TABLE NO.</b>	<b>PARTICULARS</b>	<b>PAGE NO.</b>
<b>1.</b>	Anthropometric landmarks	<b>22</b>
<b>2.</b>	Anthropometric measurements	<b>23</b>
<b>3.</b>	Descriptive statistics of different parameters showing soft tissue nasal changes amongst Cases at different time intervals	<b>27</b>
<b>4.</b>	Descriptive mean and standard deviation of the linear measurements of transverse widths of patients	<b>28</b>
<b>5.</b>	Descriptive statistics of different parameters showing soft tissue nasal changes amongst Controls at different time intervals	<b>31</b>
<b>6.</b>	Intergroup comparison of different parameters showing soft tissue nasal changes between Cases and Controls at different time intervals (T1 VS TC1 and T2 vs TC2)	<b>34</b>
<b>7.</b>	Intergroup comparison of different parameters showing soft tissue nasal changes between Cases and Controls at different time intervals (T3 VS TC2)	<b>37</b>
<b>8.</b>	Intragroup comparison of different parameters showing soft tissue nasal changes in Cases at different time intervals (T1 vs T2 and T2 vs T3)	<b>38</b>
<b>9.</b>	Intragroup comparison of different parameters showing soft tissue nasal changes in Controls at different time intervals (TC1 vs TC2)	<b>39</b>
<b>10.</b>	Comparisons of different parameters showing soft tissue nasal changes in Cases between right and left side at 3 time intervals (T1, T2 & T3)	<b>40</b>

## LIST OF FIGURES

<b>FIGURE NO.</b>	<b>PARTICULARS</b>	<b>PAGE NO.</b>
<b>1.</b>	Revopoint Pop 2	<b>17</b>
<b>2.</b>	Capturing 3-D scan using Revopoint Pop 2	<b>20</b>
<b>3.</b>	Vertical measurements showing: (A,B) Nasal tip projection (C) Columella length (D) Alar length	<b>24</b>
<b>4.</b>	Horizontal measurements showing: (A) Maximum nasal width, (B) Outer nasal width at base, (C) Inner nasal width at base, (D) Unilateral nasal aperture width	<b>24</b>
<b>5.</b>	Frequency statistics of Cleft side amongst study participants (Cleft group)	<b>27</b>

## LIST OF GRAPHS

<b>GRAPH NO.</b>	<b>PARTICULARS</b>	<b>PAGE NO.</b>
<b>1.</b>	Mean values of different parameters showing soft tissue nasal changes amongst Cases at different time intervals	<b>30</b>
<b>2.</b>	Mean values of different parameters showing soft tissue nasal changes amongst Controls at different time intervals	<b>32</b>
<b>3.</b>	Mean values of different parameters showing soft tissue nasal changes amongst Cases and Controls at different time intervals	<b>35</b>

## LIST OF ANNEXURES

<b>ANNEXURE NO.</b>	<b>PARTICULARS</b>	<b>PAGE NO.</b>
<b>I</b>	<b>ETHICAL CLEARANCE CERTIFICATE</b>	<b>60</b>
<b>II</b>	<b>CONSENT FORM</b>	<b>61</b>
<b>III</b>	<b>PHOTOGRAPHS</b>	<b>62</b>
<b>IV</b>	<b>MASTER CHART (GROUP A)</b>	<b>63</b>
<b>V</b>	<b>MASTER CHART (GROUP B)</b>	<b>65</b>

## **INTRODUCTION**

Cleft lip and palate (CLP) is one of the most prevalent craniofacial anomalies present from birth, especially affecting facial aesthetics, function, and overall quality of life. This condition happens due to incomplete fusion of facial processes during embryonic development, leading to a cleft in the upper lip and/or palate. The prevalence of cleft lip and/or palate varies globally, with notable genetic and environmental influences contributing to its occurrence<sup>(1)</sup>. Infants born with unilateral cleft lip and palate (UCLP) show different degrees of nasolabial asymmetry due to structural deformities, including a deviated nasal septum, vermilion border lacking symmetry, and a deficient maxilla<sup>(2)</sup>. These anatomical differences affect more than just facial appearance—they can also interfere with vital functions like feeding, speech development, and breathing. Therefore, a precise evaluation and timely treatment are essential to achieving better clinical outcomes.

The evaluation of nasolabial symmetry in CLP patients has traditionally relied on two-dimensional (2D) photographs, cephalometry, and plaster models. However, these methods present inherent limitations, including distortion due to parallax effect, lack of depth perception, and inaccuracies in capturing complex facial topography. As a result, the introduction of three-dimensional (3D) imaging technology has revolutionized craniofacial assessment, allowing for more precise and reproducible measurements of facial soft tissue landmarks<sup>(3)</sup>. 3D imaging enables a better evaluation of nasal morphology in terms of assessing treatment outcomes following nasoalveolar molding and primary surgical repair in cleft patients.

Nasoalveolar Molding (NAM) has emerged as a widely adopted intervention to aid in improving nasal symmetry before primary surgical repair. NAM facilitates gradual approximation of the nasal and alveolar segments, reducing the severity of the cleft deformity and improving surgical outcomes<sup>(4)</sup>. Several studies have demonstrated that NAM significantly improves nasal tip projection, columellar length, and alar symmetry in UCLP infants<sup>(5)</sup>. Despite its benefits, NAM remains a subject of debate due to differences in treatment protocols, compliance, and the potential for overcorrection.

The role of 3D imaging in objectively quantifying soft tissue changes in UCLP patients before and after primary surgical repair has been extensively studied. Mancini et al. (2019) conducted a retrospective analysis comparing 3D nasal changes in UCLP infants treated with NAM and primary cheilorhinoplasty to noncleft controls. Their findings revealed significant improvements in nasal tip projection, columella length, and overall nasal symmetry post-treatment<sup>(4,6)</sup>. Similarly, Mishra et al. (2020) assessed nasal symmetry in UCLP patients with and without presurgical NAM and reported that NAM-treated infants exhibited better symmetry and reduced nasal deviation compared to non-NAM-treated infants<sup>(7)</sup>. These findings underscore the effectiveness of NAM in improving cleft-related nasal deformities and highlight the potential of 3D imaging as a robust tool for treatment evaluation.

The integration of 3D imaging in cleft assessment has addressed several shortcomings of traditional methods. Unlike 2D photography, which is limited by patient positioning and operator-dependent errors, 3D imaging provides an accurate representation of facial morphology, allowing for detailed analysis of soft tissue landmarks in multiple planes. Moreover, 3D imaging facilitates objective comparison between cleft and noncleft individuals, enabling clinicians to monitor postoperative

changes more effectively<sup>(8)</sup>. Grunwaldt et al. (2016) conducted a prospective randomized controlled trial evaluating the role of NAM in UCLP patients and emphasized the importance of 3D imaging in assessing nasal symmetry outcomes (6). Their study demonstrated that 3D assessments provided reliable and reproducible data, reinforcing the necessity of incorporating advanced imaging modalities in cleft care.

A crucial aspect of cleft treatment is the surgical correction of nasal and lip deformities. Primary cheilorhinoplasty, performed around 3 to 6 months of age, aims to restore nasolabial symmetry and improve nasal function. However, achieving optimal results remains challenging due to the complexity of cleft-related soft tissue deficiencies. Studies have shown that 3D imaging plays a pivotal role in evaluating surgical outcomes by providing precise measurements of nasolabial dimensions pre- and post-surgery<sup>(9)</sup>. Daskalogiannakis et al. (2012) reviewed the validity of NAM in CLP patients and concluded that 3D imaging serves as an essential tool for quantifying treatment effects and guiding surgical planning<sup>(7)</sup>. Their systematic review highlighted the superior accuracy of 3D techniques in capturing subtle soft tissue changes that may not be evident in conventional 2D analyses.

While the adoption of 3D imaging in cleft research has significantly advanced our understanding of facial morphology, challenges remain in standardizing imaging protocols and landmark identification. Variability in image acquisition techniques, software processing, and patient cooperation can influence measurement reliability. Additionally, accessibility to high-resolution 3D imaging systems may be limited in resource-constrained settings, posing a barrier to widespread clinical implementation. Future research should focus on refining imaging methodologies, developing automated landmark detection algorithms, and establishing normative 3D facial

datasets for cleft populations <sup>(10)</sup>. These advancements will further enhance the clinical utility of 3D imaging in cleft assessment and treatment planning.

In conclusion, the evaluation of soft tissue nasal changes in UCLP infants remains a critical component of cleft treatment. The introduction of 3D imaging has revolutionized cleft assessment by offering precise and reproducible measurements of nasal morphology, thereby improving treatment planning and outcome assessment. Presurgical NAM, combined with primary cheilorhinoplasty, has shown promising results in enhancing nasal symmetry in UCLP patients. However, continued research is necessary to optimize imaging protocols and explore novel techniques for refining cleft treatment approaches. By integrating advanced imaging technologies and evidence-based interventions, clinicians can achieve better aesthetic and functional outcomes for cleft patients, ultimately improving their quality of life.

## **AIMS AND OBJECTIVES**

### **AIM:**

To compare 3-Dimensional soft tissue nasal changes in infants with unilateral cleft lip and palate and compare to noncleft controls.

### **OBJECTIVES:**

- To determine the soft tissue landmarks on cleft infants and non cleft controls
- To compare the soft tissue landmarks between cleft infants after primary surgical repair and non cleft infants
- To compare the soft tissue landmarks between cleft infants before the surgical repair and non cleft infants
- To assess distances between soft tissue landmarks in unilateral cleft lip and palate infants using a 3-D camera at 3 different time points

### **RESEARCH HYPOTHESIS**

**Null hypothesis** – There is no difference between the soft tissue changes in unilateral cleft lip and palate and noncleft infants measured using 3-D photographs.

## **REVIEW OF LITERATURE**

- 1. Mancini et al. (2019)** conducted a retrospective study with sample of 50 infants with UCLP, where 30 received NAM followed by primary cheilorhinoplasty, and 20 were controls without NAM. Pre and post treatment nasal morphology were assessed using 3D imaging. Results suggested significant improvements in nasal tip projection, columella length, and overall nasal symmetry in the NAM group. However, due to minor overcorrections, they suggested that NAM might occasionally cause excessive nasal elongation. A key gap in the literature was the lack of long-term follow-up, making it unclear if these benefits persist into adolescence. Future studies should include prolonged monitoring and post-surgical evaluations to assess NAM's lasting impact <sup>[4]</sup>.
- 2. Mishra et al. (2020)** performed a meta-analysis of 10 trials involving 500 infants comparing NAM after surgery to only primary surgery without NAM. Their result indicated that there were no significant differences in the two groups regarding improvements in nasal morphology, indicating that NAM does not provide additional long-term advantages over primary surgery alone. The important gap in the literature was that the included studies lacked RCTs, eliminating the potential for a causal association to be made. Patient-reported outcomes and psychological effects of NAM were also not addressed in this study. Large-scale RCTs and long-term follow-up are warranted in future research to assess whether NAM provides long-term advantages. <sup>[5]</sup>.

3. **Ras et al. (1995)** conducted a longitudinal study on 100 children, including 50 with UCLP and 50 non-cleft controls, to assess facial asymmetry. The study tracked changes in nasal and facial morphology as the children grew. Results showed that facial asymmetry worsened with age in UCLP patients, particularly in those who did not receive early intervention. This reinforced the importance of NAM in minimizing nasal deviations before primary surgical repair. However, a gap in the literature was the lack of follow-up into puberty, making it unclear whether NAM's early benefits are sustained long-term. Future studies should include adolescent and adult assessments to determine NAM's lasting effects on facial symmetry <sup>[3]</sup>.
4. **Clark et al. (2018)** conducted a long-term study on 90 NAM-treated patients to assess nasal growth over time. Their investigations showed that NAM improves early aesthetics of nose, particularly in columella length and nasal tip projection. Its long-term impact on nasal development remained unpredictable till puberty, with some patients requiring additional surgical revisions. Future studies should incorporate genetic analysis, bigger sample sizes, and prolonged follow-up to understand NAM's lasting effects better. <sup>[12]</sup>.
5. **Schwenzer-Zimmerer et al. (2008)** conducted a study using 3D laser scanning to assess nasal and lip symmetry in infants with cleft lip deformities. The study included 60 patients, comparing NAM-treated infants with those who did not receive NAM before surgery. Results indicated that NAM significantly improved nasal tip projection, columella length, and upper lip alignment, leading to better surgical outcomes by reducing the severity of the cleft deformity before repair. However, a key gap in the literature was the lack of long-term follow-up to assess whether these improvements persisted into adulthood. Future studies should include longitudinal assessments and patient-

reported outcomes to evaluate the functional and aesthetic stability of NAM's effects <sup>[13]</sup>.

6. **Stebel et al. (2015)** contrasted 3D imaging with conventional 2D photography in the evaluation of nasolabial aesthetics in 40 cleft lip and palate patients. The aim was to compare whether imaging mode provided more accurate nasal symmetry measurements. Results showed that 3D imaging provided more accurate measurements of nasal symmetry compared to 2D photography. The authors had a major limitation, however—the 3D scans required special training to be interpreted by clinicians in a proper way. A major limitation in the literature was to have a small sample size and lack of post-surgical follow-up, which limited the study to assess NAM's long-term impact on nasal morphology. Additional studies need to be conducted on larger patient samples and post-surgical outcomes to confirm these results. <sup>[14]</sup>.
7. **Matsuo & Hirose (1991)** conducted a study on presurgical nasal molding in infants with UCLP, evaluating its effectiveness in improving nasal symmetry before surgery. Their findings revealed inconsistent outcomes, where some patients showed significant improvements in nasal form, while others exhibited little to no change. Factors such as severity of the cleft, patient compliance, and molding duration influenced results. A key gap in the literature was the lack of standardized treatment protocols, making it difficult to predict NAM's effectiveness across different patient groups. Future research should focus on developing uniform guidelines and assessing long-term nasal growth patterns to refine NAM's application. <sup>[15]</sup>.

8. **Cutting et al. (1998)** developed a one-stage bilateral cleft lip and nasal repair technique, showing that NAM-treated infants required fewer surgical interventions, thereby reducing overall treatment burden. However, the study lacked long-term follow-up to assess nasal growth stability. Future research should evaluate NAM's impact on revision surgeries and long-term facial symmetry.<sup>[16]</sup>
  
9. **Grayson et al. (1999)** were pioneers in developing NAM techniques, demonstrating their effectiveness in reducing cleft severity before surgery. Their studies showed that NAM improved nasal symmetry, columella length, and alveolar alignment, leading to better surgical outcomes and fewer secondary revisions. Additionally, NAM reduced tension on soft tissues, minimizing post-surgical complications. However, a limitation was the lack of long-term functional assessments, such as speech development and nasal breathing efficiency. Future research should evaluate NAM's lasting impact on facial growth and overall patient quality of life<sup>[17]</sup>.
  
10. **Maull et al. (van Aken et al., 1999)** developed stone cast models to investigate the effect of NAM on nasal alignment in infants affected by UCLP. They concluded that NAM improves preoperative nasal topography, which enables improved surgical planning and outcomes. NAM's resulted in more balanced nasal and alveolar alignment by decreasing cleft severity prior to surgery. But an important absence in the literature was the kind of long-term follow-up needed to ascertain if these initial gains continued in adulthood. Long-term effectiveness of NAM can be validated with prospective studies focusing on post-surgical nasal stability and functional outcomes<sup>[18]</sup>.

- 11. Pai et al. (2005)** investigated the impact of NAM on the symmetry of the nose in UCLP patients and noted marked improvements in nasal features after the presurgical therapy. Nonetheless, the study is criticized for not having a long-term follow up, making it uncertain if the benefits lasted. Later studies should explore how NAM affects the stability of the nose, as well as the surgical results. <sup>[19]</sup>
- 12. Singh et al. (2005)** conducted a study using finite element scaling analysis to evaluate the 3D changes in the nose in infants with UCLP. The analysis enrolled a total of sixty infants, of whom thirty were supplemented with NAM and thirty underwent direct surgical repair without NAM. It was noted that NAM patients demonstrated marked improvements in nose projection, decreased asymmetry in nasal width, and increased overall symmetry as compared to their counterparts before surgery. In comparison, infants who did not receive NAM treatment had significantly flatter nasal profiles associated with wider nasal bases which would need further extensive correctional surgery <sup>[20]</sup>.
- 13. Kecik & Enacar (2009)** studied NAM's impact on nasal and alveolar morphology in UCLP patients. Their findings showed that NAM improves early nasal aesthetics, particularly nasal tip projection and columella length. However, long-term follow-ups indicated that these improvements were not sustained, with some patients requiring secondary corrections. A gap in the literature was the lack speech assessments and nasal airflow studies, which could provide a broader evaluation of NAM's benefits. <sup>[21]</sup>
- 14. Chang et al. (2010)** conducted a study comparing NAM combined with primary rhinoplasty to surgery alone in infants with UCLP. The study found that the combined approach led to superior aesthetic and functional results,

including improved nasal tip projection, columella length, and better nasal airflow. However, a key gap in the literature was the lack of long-term follow-up to assess whether these benefits were maintained into adolescence. Future studies should explore long-term nasal growth patterns and patient satisfaction to confirm the sustained advantages of this combined treatment approach.<sup>[22]</sup>

**15. Garfinkle et al. (2011)** conducted a 12-year longitudinal study on bilateral cleft lip patients to assess the long-term effects of NAM on nasal growth. Their findings showed that NAM led to sustained improvements in nasal symmetry, with better columella length and nasal tip projection compared to non-NAM patients. However, a key gap in the literature was the lack of functional assessments, such as nasal breathing efficiency and speech outcomes. Future studies should include comprehensive evaluations to determine whether NAM provides both aesthetic and functional advantages in the long term.<sup>[23]</sup>

**16. Daskalogiannakis et al. (2012)** conducted a study evaluating the cost-effectiveness and clinical benefits of NAM in infants with UCLP. Their findings suggested that NAM may not be justified due to the additional financial burden, treatment time, and required parental compliance, especially since similar nasal symmetry outcomes were achieved with primary surgery alone. A key gap in the literature was the lack of long-term functional assessments, such as nasal breathing efficiency or speech development. Future studies should explore whether NAM provides benefits beyond aesthetics, particularly in terms of functional outcomes and long-term quality of life.<sup>[7]</sup>

- 17. Tse et al. (2014)** analyzed nasolabial anthropometric measurements in NAM-treated UCLP patients and found that NAM significantly improved nasal midline alignment, resulting in a more balanced facial profile. However, the study lacked long-term follow-up, making it unclear if these improvements persisted into adulthood. Future research should include extended evaluations and patient-reported aesthetic satisfaction <sup>[24]</sup>.
- 18. Desmedt et al. (2015)** conducted a study using 3D imaging to evaluate nasolabial symmetry in NAM-treated vs. non-NAM-treated infants with UCLP. Their findings showed that NAM significantly improved soft tissue alignment, leading to better presurgical preparation and enhanced post-surgical outcomes by reducing cleft severity. However, the study lacked long-term follow-up to determine whether these improvements persisted over time. A key gap in the literature was the absence of functional assessments, such as speech or nasal airflow studies, which could provide a more comprehensive evaluation of NAM's benefits beyond aesthetics <sup>[25]</sup>.
- 19. Patel et al. (2015)** conducted a study comparing the necessity of secondary nasal revisions in NAM-treated vs. non-NAM-treated cleft patients. Their findings showed that NAM significantly reduced the need for additional surgeries and non-NAM-treated cleft infants demonstrated a higher likelihood of requiring secondary nasal revisions compared to those who received NAM before surgery. The study found that infants who did not undergo NAM had more pronounced nasal asymmetry, including shorter columella length, wider nasal base, and greater nostril shape discrepancies. As a result, these patients required more extensive surgical interventions to achieve satisfactory nasal symmetry. A gap in the literature was the lack of long-term follow-up to determine if NAM's benefits persisted into adulthood. <sup>[26]</sup>

- 20. Huddart et al. (2015)** analyzed the effectiveness of NAM compared to direct surgical correction in infants with UCLP. Their study suggested that NAM introduces unnecessary delays in treatment, requiring months of presurgical molding without providing significant long-term advantages over surgery alone. They found that final nasal symmetry and function were comparable between NAM and non-NAM groups. A key gap in the literature was the lack of patient-reported outcomes, such as comfort, parental satisfaction, and long-term psychosocial effects. Future research should include quality-of-life assessments to determine NAM's overall impact. <sup>[27]</sup>.
- 21. Grunwaldt et al. (2016)** Grunwaldt et al. (2016) conducted a long-term follow-up study on 80 patients with UCLP to assess the lasting impact of NAM on nasal symmetry. While initial results showed improved nasal alignment in NAM-treated patients, these benefits diminished over time. By adulthood, nasal symmetry differences between NAM and non-NAM groups were no longer statistically significant. A key gap in the literature was the lack of functional assessments, such as breathing efficiency or speech outcomes. Future studies should include comprehensive long-term evaluations to determine whether NAM provides any lasting functional or psychological advantages. <sup>[6]</sup>
- 22. Spengler et al. (2017)** conducted a study assessing NAM's long-term impact on surgical needs in UCLP patients. Their findings showed that NAM did not reduce the total number of required surgeries over a patient's lifetime, questioning its necessity. A key gap in the literature was the lack of functional outcome assessments, such as speech or nasal airflow studies. <sup>[28]</sup>

- 23. Stuhaug et al. (2017)** conducted a study on patient satisfaction with long-term nasal aesthetics in NAM-treated vs. non-NAM-treated UCLP patients. Their findings indicated no significant differences in nasal symmetry or overall aesthetic outcomes between the two groups in adulthood. This suggests that NAM may not provide lasting esthetic advantages. A key gap in the literature was the lack of functional outcome assessments, such as nasal airflow and speech quality. Future research should incorporate patient-reported quality-of-life measures and functional evaluations to determine whether NAM offers any additional benefits beyond aesthetics <sup>[29]</sup>
- 24. Saltzman et al. (2018)** introduced digital overlay techniques for imaging analysis to assess nasal morphology in UCLP patients. Their study suggested that direct surgical intervention without NAM could achieve similar nasal symmetry improvements, questioning NAM's necessity. A key gap in the literature was the lack of long-term follow-up to compare nasal growth patterns. Future research should include extended post-surgical evaluations to determine whether NAM provides lasting advantages <sup>[30]</sup>
- 25. Desmedt et al. (2018)** used machine learning with 3D imaging to analyze nasal growth patterns in NAM-treated and non-NAM-treated UCLP patients. Their findings showed that NAM did not significantly influence nasal growth predictions, suggesting that genetic and environmental factors may play a larger role. Future research should explore multifactorial influences on nasal development. <sup>[31]</sup>

## **MATERIALS AND METHODS**

### **SOURCE OF DATA**

This study has been done on infants with unilateral cleft lip and palate reporting to KLE Academy of Higher Education & Research, KLE VK Institute of Dental Sciences, Belagavi. Surgery was conducted at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi.

### **INCLUSION CRITERIA:**

- Infants with Unilateral Cleft Lip and Palate
- Infants aged 0-4 weeks who presented for the first time to the department of Orthodontics and Dentofacial Orthopedics at KLE VK Institute of Dental Sciences, Belagavi
- Infants with birth weight >2kg
- Infants of either gender
- Infants whose parents give written informed consent

### **INCLUSION CRITERIA FOR CONTROLS:**

- Infants without any craniofacial anomaly
- Infants of either gender
- Infants whose parents give written informed consent
- Infants aged 0-4 weeks from Department of Paediatrics at Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi

**EXCLUSION CRITERIA:**

- Infants with Bilateral Cleft Lip and Palate
- Infants of age < 4 weeks
- Infants with systemic diseases

**SAMPLE SIZE ESTIMATION**

**Formula**

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (SD_1^2 + SD_2^2)}{(\bar{x}_1 - \bar{x}_2)^2}$$

$SD_1$	=	2.04	$SD_1$	: Standard deviation in the 1 <sup>st</sup> group
$SD_2$	=	1.25	$SD_2$	: Standard deviation in the 2 <sup>nd</sup> group
$\bar{x}_1$	=	22.51	$\bar{x}_1$	: Mean of 1 <sup>st</sup> group
$\bar{x}_2$	=	25.14	$\bar{x}_2$	: Mean of 2 <sup>nd</sup> group
$\alpha$	=	0.05	$\alpha$	: Level of significance
$1 - \beta$	=	0.95	$1 - \beta$	: Power
$Z_{1-\alpha/2}$	=	1.96		
$Z_{1-\beta}$	=	1.682		

**Estimated sample size for each group,  $n = 12$**

The sample size was estimated to be 11 children in each group at a power of 0.95 with a 0.05 alpha error (Mancini *et al.*, 2019). Taking into consideration a 10% dropout rate, this study included a sample size of 12 children in each group, accounting for a total sample size of 24 children.

**SAMPLING TECHNIQUE-** Convenience Sampling Technique

**INSTRUMENTS AND MATERIALS:**

- Initial records of unilateral cleft lip and palate infants using 3-D camera (Revopoint POP 2)
- Pre-surgical records of unilateral cleft lip and palate infants using 3-D camera (Revopoint POP 2)
- Post-surgical records of unilateral cleft lip and palate infants using 3-D camera (Revopoint POP 2)



**Figure 1 : REVOPOINT POP 2**

**METHODOLOGY:**

- The 2 groups were divided as follows :
  - Group A = Infants with Unilateral Cleft Lip and Palate
  - Group B = Non-cleft controls
- A 3-D photograph of the infants in group A was taken at the initial presentation (T1) i.e. from 0-4 weeks of age, 1-2 weeks prior to the surgical repair (T2), and 1-2 days following primary surgical repair (T3).
- Images were oriented in MeshLab software, and 11 nasolabial points were determined. 3-Dimensional photographs of infants in Group B were taken at the age of 0-4 weeks (TC1)
- Primary surgical repair was conducted by the Department of Plastic Surgery at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi.
- To match the age of group A, at 6 months of age, a 3D photograph of the infant was taken (TC2)
- A single operator identified the 11 nasolabial landmarks and calculated linear measurements of nasal morphology. Bilateral landmarks and measurements were denoted by the addition of 'l' for the left side and 'r' for the right side
- The distances between soft tissue landmarks were measured at all 3 time points as linear measurements and ratios. The measurements of cleft and non-cleft sides were compared at all 3 time points as T2-T1 and T3-T2. The measurements of group A taken at T3 were compared with measurements of group B taken at T2.

➤ 3-Dimensional photographs of infants in Group A were taken at 3 defined time points :

- T1, T2 and T3

➤ 3-Dimensional photographs of noncleft infants in Group B were taken at :

- TC1 and TC2



11 nasolabial soft tissue landmarks were determined on 3D photograph



Distance between soft tissue landmarks were measured on MeshLab



The measurements of cleft and non-cleft side were compared at all 3 time points as

T2-T1 vs T3-T2



The measurements of cleft and non-cleft infants were compared as

- T1 vs TC1
- T3 vs TC2



**Figure 2 : Capturing 3-D scan using Revopoint Pop 2**

**PATIENTS CONCERN:** Parents of the infants were informed and the records are taken with their consent

**Details of the procedures conducted during the research:**

- This study involved 2 groups of patients. Group A had infants with unilateral cleft lip and palate, whereas Group B had infants without cleft lip and palate (controls)
- 3-Dimensional photographs of the infants of both these groups were taken using Revopoint POP 2 3D camera.
- Landmarks were marked on the 3-dimensional images of the infants.

These include:

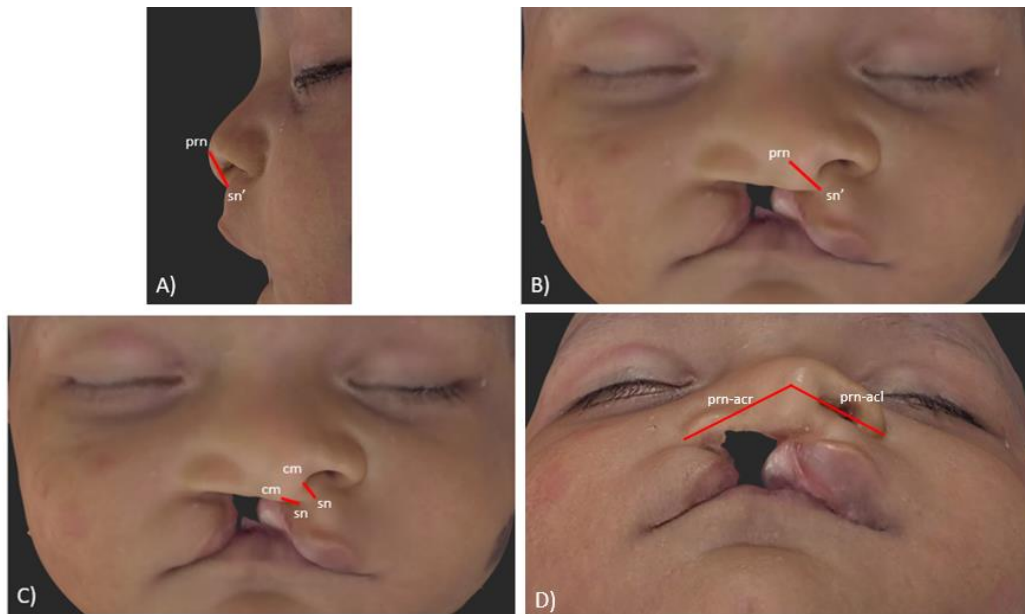
- 1) Midline landmarks as nasal tip, subnasale
  - 2) Bilateral landmarks such as alar curvature, subalare, alar, columella, and columellar insertion
- The distances between soft tissue landmarks before were measured in both groups.
  - The distances between the soft tissue landmarks 1-2 weeks before the surgery were measured in the UCLP group

**Table 1: Anthropometric Landmarks**

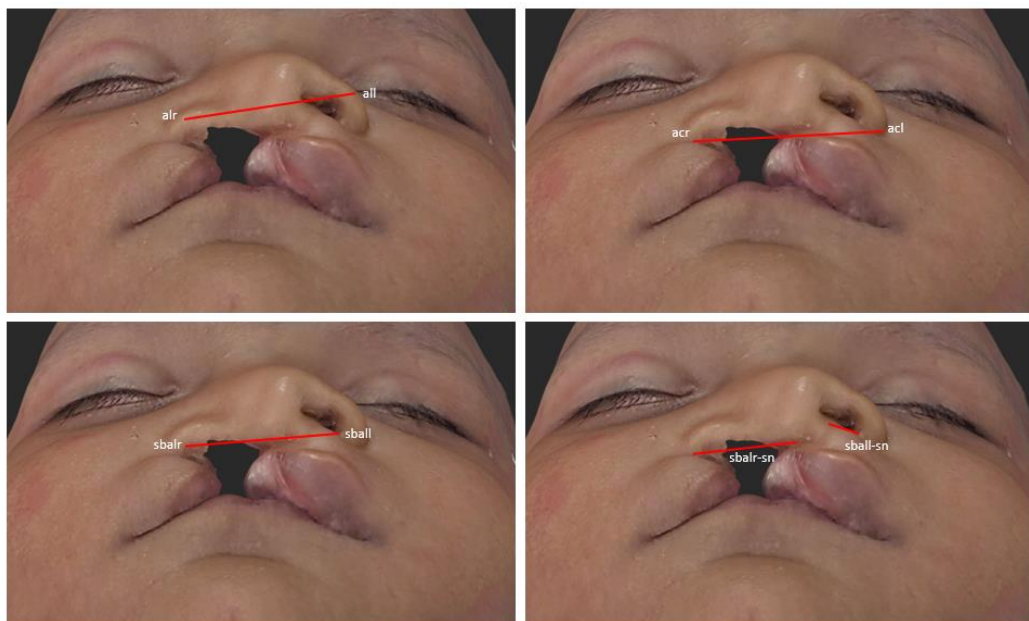
<b>LANDMARK</b>	<b>ABBREVIATION</b>	<b>DESCRIPTION</b>
Nasal tip	prn	Midline landmark - the most anterior point on the nasal tip
Columella	cm	Bilateral landmark – Highest point of curvature of columella
Columella Insertion	sn	Bilateral landmark – insertion of columella base and upper lip
Subnasale	sn'	Midline landmark - midpoint of columella insertion on either side
Alar curvature	ac	Bilateral landmark – insertion of rim of nose near upper lip
Alar	al	Bilateral landmark – lateral most point on widest part of nose seen from basal view
Subalare	sbal	Bilateral landmark – Medial insertion of rim of nose above upper lip

**Table 2: Anthropometric Measurements**

<b>MEASUREMENT</b>	<b>ABBREVIATION</b>	<b>FIGURE</b>
Nasal tip projection	sn'-prn	3A, 3B
Columella length	sn-cm	3C
Maximum nasal width	alr-all	4A
Outer nasal width at base	acr-acl	4B
Inner nasal width at base	sbalr-sball	4C
Alar length	prn-ac	3D
Unilateral nasal aperture width	sbal-sn	4D



**Figure 3: Vertical measurements showing: (A,B) Nasal tip projection (C) Columella length (D) Alar length**



**Figure 4: Horizontal measurements showing: (A) Maximum nasal width, (B) Outer nasal width at base, (C) Inner nasal width at base, (D) Unilateral nasal aperture width**

## **METHOD OF STATISTICAL ANALYSIS**

- Data obtained was entered and sorted in Microsoft Excel (v.2017).
- Statistical analysis was performed using Statistical package for social sciences (SPSS) software (IBM Corp) (v.26.0).
- Descriptive and inferential statistics was performed for all the different parameters assessed in the study.
- Data normality test was performed to determine normal distribution of the data.
- Intergroup comparison for continuous variables was performed by using independent samples t-test/Unpaired t-test to assess significant differences between cases and controls.
- Intragroup comparison between different time intervals in cases and controls was performed using Paired samples t-test to assess statistically significant differences.
- Comparisons between different time intervals T1, T2 and T3 for all different landmarks was performed using Repeated measures ANOVA test to assess significant differences.
- All statistical tests were performed at 95% confidence intervals.
- A p value of less than 0.05 was considered as statistically significant in the study.

## **RESULTS**

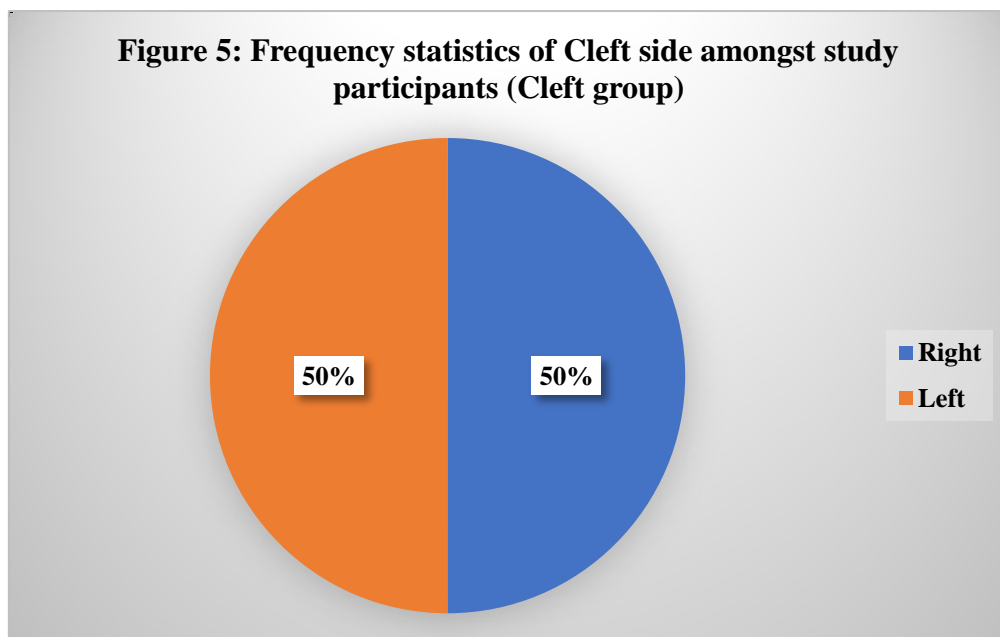
The collected data at 3 different time points were systematically entered and sorted in Microsoft Excel and subjected to statistical analysis.

A total of 12 patients who underwent primary cheilorhinoplasty at KLE Academy of Higher Education & Research, KLE VK Institute of Dental Sciences, Belagavi were considered in this study. Surgery was conducted at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi. In addition, 12 age-matched non-cleft infants were assessed and followed up as controls to provide a comparative baseline for normal nasal growth and morphology.

All statistical tests were performed at 95% confidence intervals.

**1) Frequency of Cleft Side:****Table 3 – Frequency statistics of Cleft side amongst study participants (Cleft group)**

<b>Cleft side</b>	<b>Frequency (n)</b>	<b>Percent (%)</b>
<b>Right</b>	6	50
<b>Left</b>	6	50
<b>Total</b>	12	100

**Figure 5: Frequency statistics of Cleft side amongst study participants (Cleft group)**

The above table and figure show that among the 12 infants with unilateral cleft lip and palate (UCLP) in the research group, 6 had clefts on the right side and 6 on the left, indicating an equal distribution (50% each). This balance ensures that the findings are not skewed by the laterality of the cleft and allows for better generalization of the results to the broader cleft population.

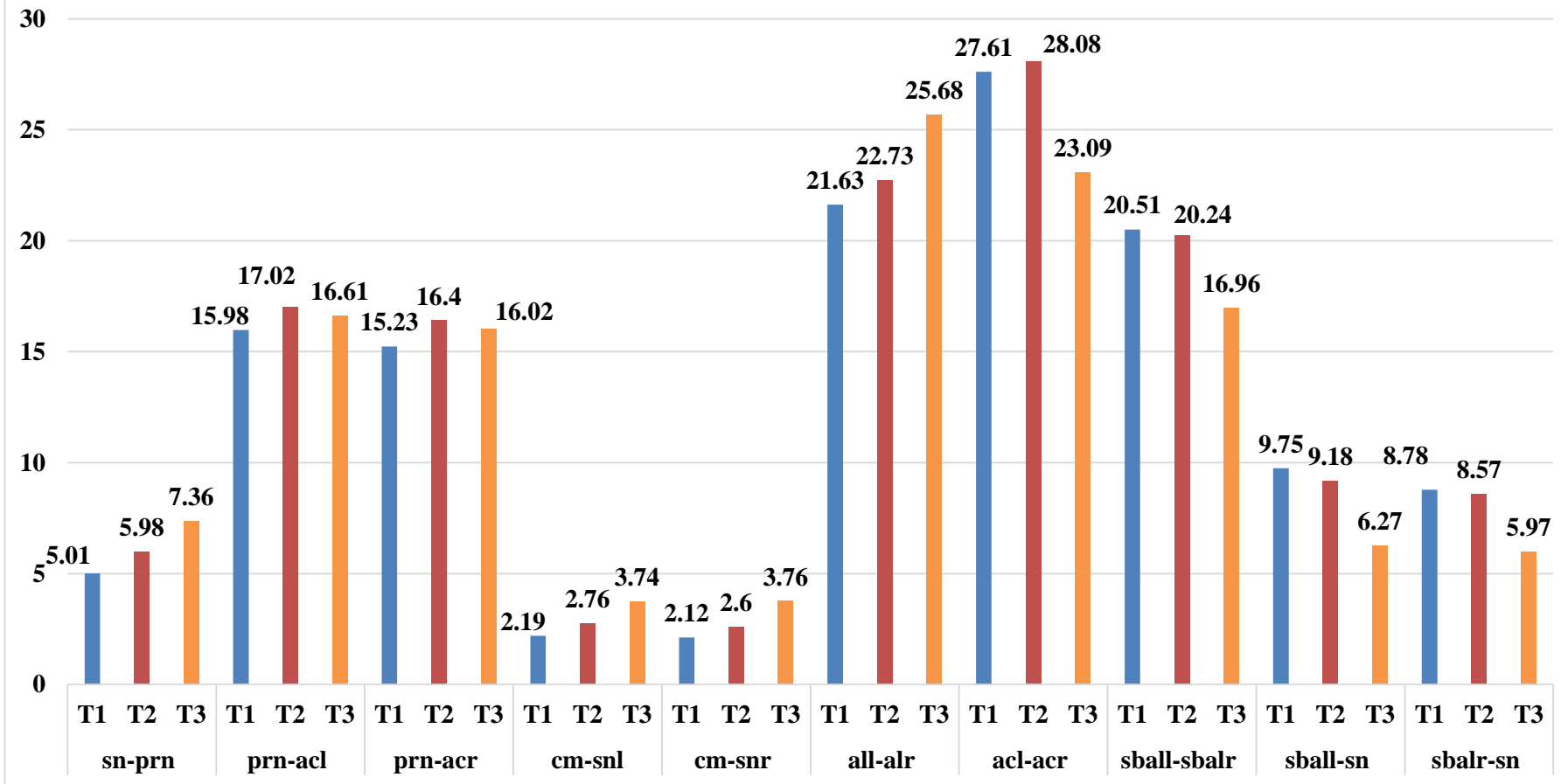
## 2) Descriptive Statistics in Cleft Cases (T1, T2, T3):

**Table 4 - Descriptive statistics of different parameters showing soft tissue nasal changes amongst Cases at various time intervals**

<b>Cases</b>	<b>Time interval</b>	<b>N</b>	<b>Mean</b>	<b>Std. Deviation</b>
<b>sn-prn</b>	<b>T1</b>	12	5.01	1.05
	<b>T2</b>	12	5.98	1.04
	<b>T3</b>	12	7.36	1.29
<b>prn-acl</b>	<b>T1</b>	12	15.98	2.76
	<b>T2</b>	12	17.02	2.62
	<b>T3</b>	12	16.61	1.84
<b>prn-acr</b>	<b>T1</b>	12	15.23	1.78
	<b>T2</b>	12	16.40	2.08
	<b>T3</b>	12	16.02	1.31
<b>cm-snl</b>	<b>T1</b>	12	2.19	0.47
	<b>T2</b>	12	2.76	0.42
	<b>T3</b>	12	3.74	0.83
<b>cm-snr</b>	<b>T1</b>	12	2.12	0.72
	<b>T2</b>	12	2.60	0.72
	<b>T3</b>	12	3.76	0.96
<b>all-alr</b>	<b>T1</b>	12	21.63	1.57
	<b>T2</b>	12	22.73	1.57
	<b>T3</b>	12	25.68	3.07
<b>acl-acr</b>	<b>T1</b>	12	27.61	1.76
	<b>T2</b>	12	28.08	1.77
	<b>T3</b>	12	23.09	1.35
<b>sball-sbalr</b>	<b>T1</b>	12	20.51	1.43
	<b>T2</b>	12	20.24	1.42
	<b>T3</b>	12	16.96	1.60
<b>sball-sn</b>	<b>T1</b>	12	9.75	4.78
	<b>T2</b>	12	9.18	3.83
	<b>T3</b>	12	6.27	1.17
<b>sbalr-sn</b>	<b>T1</b>	12	8.78	4.89
	<b>T2</b>	12	8.57	4.54
	<b>T3</b>	12	5.97	1.17

The above table and graph reveal a consistent increase in vertical nasal parameters like sn-prn (**nasal tip projection**), prn-acl, and prn-acr (**alar length**) from T1 to T2 and further to T3, suggesting progressive improvement post-surgery. Notably, the nasal tip projection (sn-prn) increased from 5.01 at T1 to 7.36 at T3. Columella lengths (cm-snl, cm-snr) also significantly increased across time points, reflecting **improved nasal symmetry and tip definition**. Conversely, measurements related to nasal width (e.g., acl-acr, sbalr-sball) show a reduction postoperatively at T3, especially in inner nasal width, indicating narrowing and better approximation of the alar bases.

**Graph 1: Mean values of different parameters showing soft tissue nasal changes amongst Cases at different time intervals**

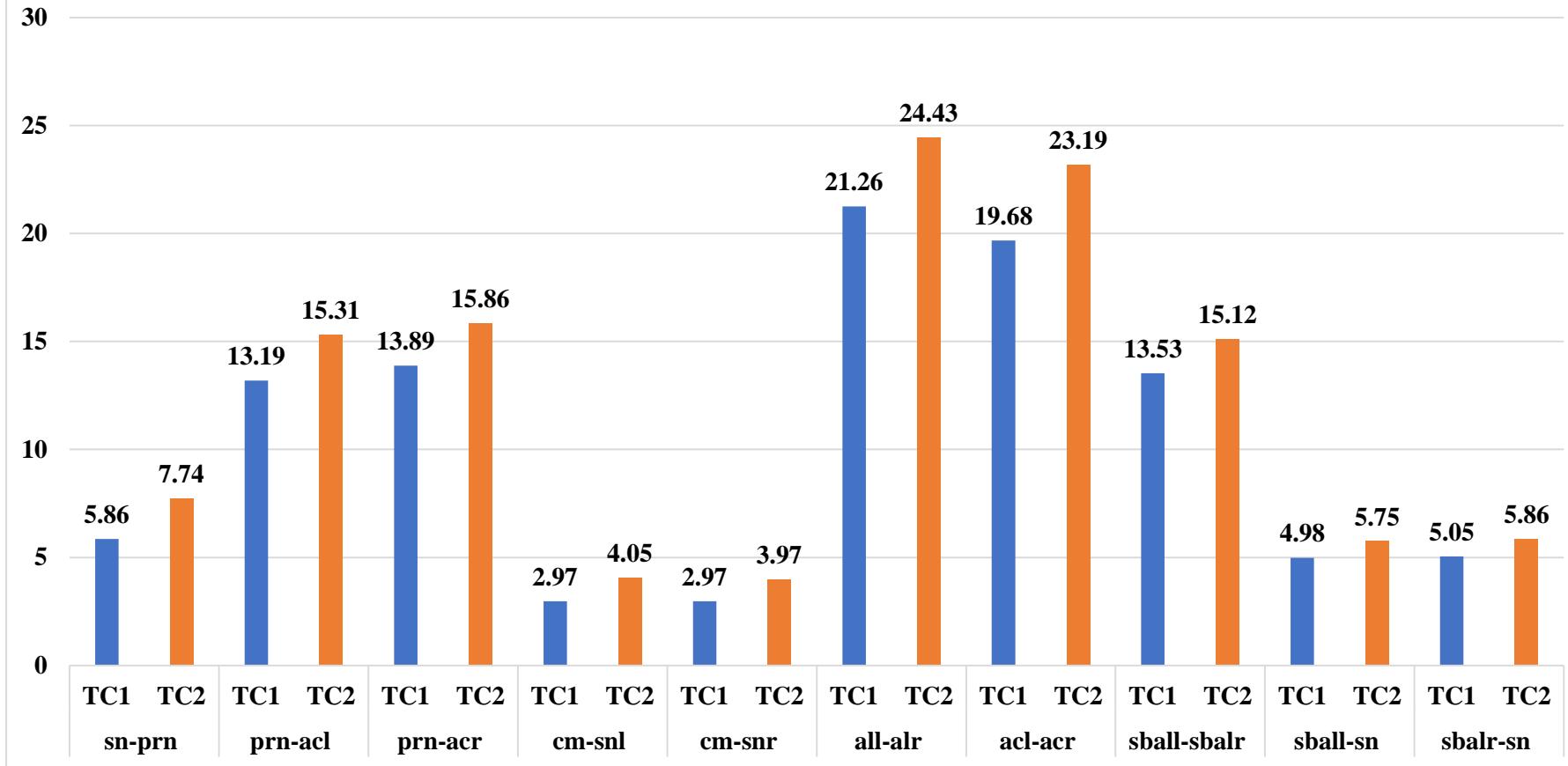


## 3) Descriptive Statistics in Control Group (TC1, TC2):

**Table 5 - Descriptive statistics of different parameters showing soft tissue nasal changes amongst Controls at different time intervals**

<b>Controls</b>	<b>Time interval</b>	<b>N</b>	<b>Mean</b>	<b>S.D.</b>
<b>sn-prn</b>	<b>TC1</b>	14	5.86	.75
	<b>TC2</b>	14	7.74	.61
<b>prn-acl</b>	<b>TC1</b>	14	13.19	1.02
	<b>TC2</b>	14	15.31	.97
<b>prn-acr</b>	<b>TC1</b>	14	13.89	1.02
	<b>TC2</b>	14	15.86	1.10
<b>cm-snl</b>	<b>TC1</b>	14	2.97	.43
	<b>TC2</b>	14	4.05	.50
<b>cm-snr</b>	<b>TC1</b>	14	2.97	.33
	<b>TC2</b>	14	3.97	.36
<b>all-alr</b>	<b>TC1</b>	14	21.26	1.74
	<b>TC2</b>	14	24.43	1.75
<b>acl-acr</b>	<b>TC1</b>	14	19.68	1.27
	<b>TC2</b>	14	23.19	1.34
<b>sball-sbalr</b>	<b>TC1</b>	14	13.53	1.10
	<b>TC2</b>	14	15.12	1.18
<b>sball-sn</b>	<b>TC1</b>	14	4.98	.61
	<b>TC2</b>	14	5.75	.71
<b>sbalr-sn</b>	<b>TC1</b>	14	5.05	.54
	<b>TC2</b>	14	5.86	.68

**Graph 2: Mean values of different parameters showing soft tissue nasal changes amongst Controls at different time intervals**



Control infants demonstrated consistent increases across all parameters from TC1 to TC2, highlighting normal nasolabial growth. The sn-prn increased from 5.86 to 7.74, and other parameters such as prn-acl, cm-snl, and acl-acr also increased significantly. These results provide a baseline for comparison with cleft infants and reinforce the idea that cleft-related nasal deficiencies are not simply due to developmental delay but structural disruption.

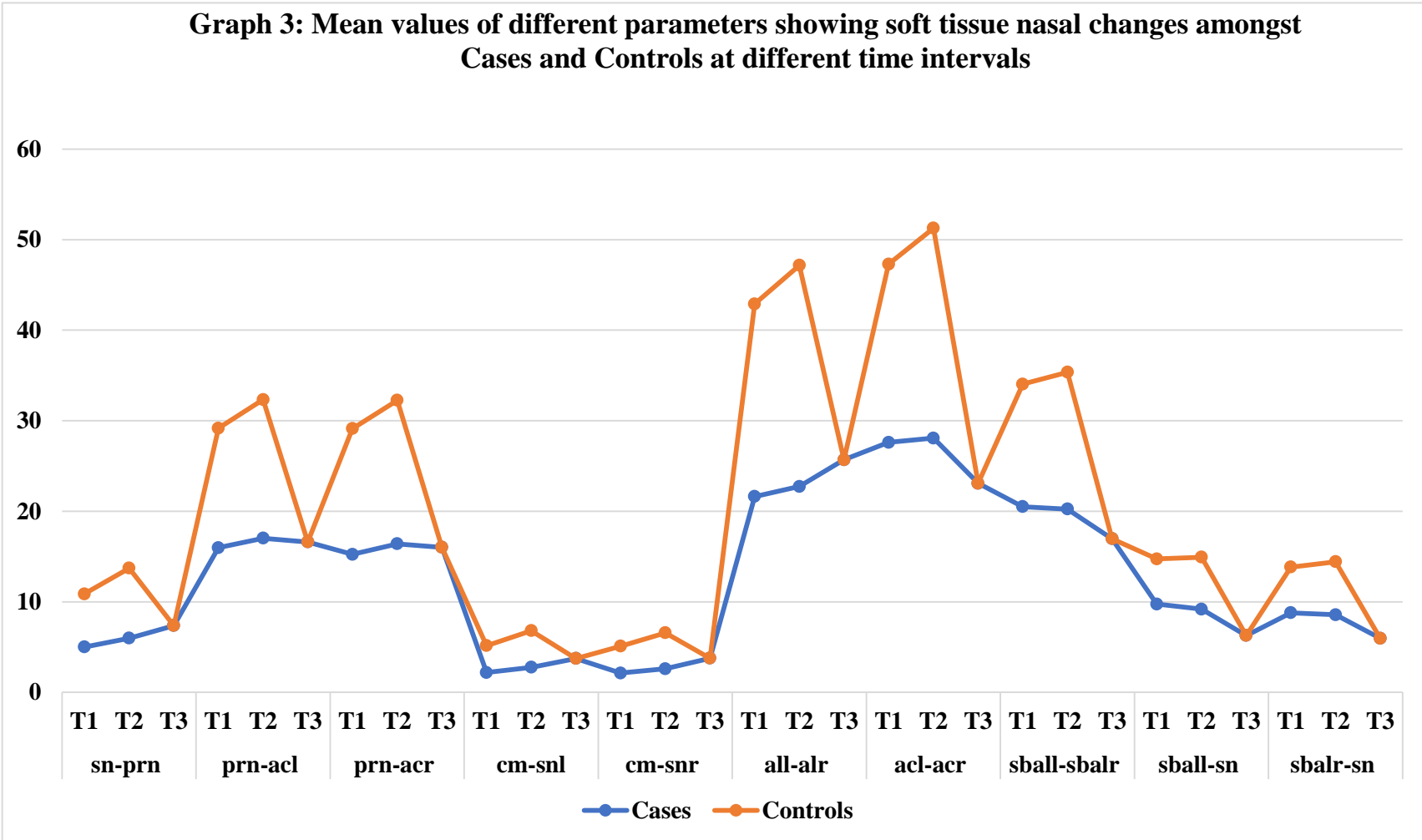
## 4) Intergroup Comparison at T1 vs TC1 and T2 vs TC2 :

**Table 6 – Intergroup comparison of different parameters showing soft tissue nasal changes between Cases and Controls at different time intervals (T1 VS TC1 and T2 vs TC2)**

Comparison groups	Parameter and	Time interval	Mean Difference	t value	p value
Cases vs Controls	sn-prn	T1 VS TC1	-.84583	-2.383	.025*
		T2 vs TC2	-1.76024	-5.336	.000*
	prn-acl	T1 VS TC1	2.78226	3.508	.002*
		T2 vs TC2	1.70726	2.262	.033*
	prn-acr	T1 VS TC1	1.34012	2.396	.025*
		T2 vs TC2	.53810	.838	.410
	cm-snl	T1 VS TC1	-.78774	-4.402	.000*
		T2 vs TC2	-1.28810	-7.021	.000*
	cm-snr	T1 VS TC1	-.85500	-3.987	.001*
		T2 vs TC2	-1.37071	-6.224	.000*
	all-alr	T1 VS TC1	.36917	.562	.579
		T2 vs TC2	-1.69393	-2.573	.017*
	acl-acr	T1 VS TC1	7.92833	13.236	.000*
		T2 vs TC2	4.89107	7.971	.000*
	sball-sbalr	T1 VS TC1	6.97571	14.012	.000*
		T2 vs TC2	5.11857	10.028	.000*
	sball-sn	T1 VS TC1	4.76512	3.701	.001*
		T2 vs TC2	3.42786	3.291	.003*
	sbalr-sn	T1 VS TC1	3.73369	2.841	.009*
		T2 vs TC2	2.70619	2.206	.037*

\*p-value <0.05 statistically significant, < 0.001 highly significant, < 0.001 very highly significant

**Graph 3: Mean values of different parameters showing soft tissue nasal changes amongst Cases and Controls at different time intervals**



Significant differences ( $p < 0.05$ ) were observed in most parameters between cleft and control groups at both preoperative stages (T1 vs TC1 and T2 vs TC2), highlighting the morphological disparity before surgical correction. Only prn-acr (T2 vs TC2) and all-alr (T1 vs TC1) were not statistically different, suggesting these specific dimensions may be less affected or more variable.

## 5) Intergroup Comparison at T3 vs TC2:

**Table 7 – Intergroup comparison of different parameters showing soft tissue nasal changes between Cases and Controls at different time intervals (T3 VS TC2)**

Comparison groups	Parameter and time interval	Time interval	Mean Difference	t value	p value
Cases vs Controls	sn-prn	T3 VS TC2	-.38190	-.983	.335
	prn-acl	T3 VS TC2	1.29976	2.294	.031*
	prn-acr	T3 VS TC2	.16393	.345	.733
	cm-snl	T3 VS TC2	-.30226	-1.139	.266
	cm-snr	T3 VS TC2	-.20905	-.751	.460
	all-alr	T3 VS TC2	1.25274	1.301	.206
	acl-acr	T3 VS TC2	-.10476	-.197	.846
	sball-sbalr	T3 VS TC2	1.83607	3.347	.003*
	sball-sn	T3 VS TC2	.52119	1.387	.178
	sbalr-sn	T3 VS TC2	.10369	.280	.782

\*p-value < 0.05 statistically significant, < 0.001 highly significant, < 0.001 very highly significant

Postoperative comparison between cleft and control groups showed significantly reduced differences in most parameters, with only prn-acl and sbalr-sball remaining statistically significant. This indicates that primary surgery was largely successful in bringing cleft morphology closer to normal, although complete symmetry was not achieved.

## 6) Intragroup Comparison in Cleft Cases (T1 vs T2, T2 vs T3)

**Table 8 –Intragroup comparison of different parameters showing soft tissue nasal changes in Cases at different time intervals (T1 vs T2 and T2 vs T3)**

Parameter	Comparison time int.	Mean diff.	t value	p value
sn-prn	T1 vs T2	-.96917	-11.662	.000*
	T2 vs T3	-1.37833	-4.278	.001*
prn-acl	T1 vs T2	-1.05000	-6.792	.000*
	T2 vs T3	.40750	.826	.426
prn-acr	T1 vs T2	-1.16583	-4.074	.002*
	T2 vs T3	.37417	.439	.669
cm-snl	T1 vs T2	-.57250	-4.761	.001*
	T2 vs T3	-.98583	-5.390	.000*
cm-snr	T1 vs T2	-.48000	-6.564	.000*
	T2 vs T3	-1.16167	-5.097	.000*
all-alr	T1 vs T2	-1.10333	-10.632	.000*
	T2 vs T3	-2.94667	-3.288	.007*
acl-acr	T1 vs T2	-.47417	-1.935	.079
	T2 vs T3	4.99583	9.236	.000*
sball-sbalr	T1 vs T2	.27000	.749	.470
	T2 vs T3	3.28250	7.549	.000*
sball-sn	T1 vs T2	.57083	1.516	.158
	T2 vs T3	2.90667	3.398	.006*
sbalr-sn	T1 vs T2	.21250	.813	.433
	T2 vs T3	2.60250	2.458	.032*

\*p value <0.05 statistically significant, <0.001 highly significant, <0.001 very highly significant

In the above table, significant improvements were seen for most parameters between T1 and T2 (natural growth and preoperative changes) and T2 and T3 (surgical impact). For example, sn-prn showed significant changes in both intervals (p < 0.001). However, parameters like prn-acl and prn-acr did not change significantly from T2 to T3, implying these dimensions may be less influenced by surgery alone.

## 7) Intragroup Comparison in Controls (TC1 vs TC2):

**Table 9 –Intragroup comparison of different parameters showing soft tissue nasal changes in Controls at different time intervals (TC1 vs TC2)**

Parameter	Comparison time interval	Mean difference	t value	p value
sn-prn	TC1 vs TC2	-1.88357	-37.412	.000*
prn-acl	TC1 vs TC2	-2.12500	-26.648	.010*
prn-acr	TC1 vs TC2	-1.96786	-14.079	.002*
cm-snl	TC1 vs TC2	-1.07286	-19.565	.000*
cm-snr	TC1 vs TC2	-.99571	-35.629	.000*
all-alr	TC1 vs TC2	-3.16643	-32.051	.011*
acl-acr	TC1 vs TC2	-3.51143	-23.003	.001*
sball-sbalr	TC1 vs TC2	-1.58714	-37.291	.000*
sball-sn	TC1 vs TC2	-.76643	-9.798	.003*
sbalr-sn	TC1 vs TC2	-.81500	-11.909	.032*

\*p-value < 0.05 statistically significant, < 0.001 highly significant, < 0.001 very highly significant

Controls showed statistically significant growth in all measured parameters (p < 0.05), confirming normal developmental progression. These findings validate the use of controls as a reference standard and further emphasize that improvements in the cleft group post-surgery exceed those due to natural growth alone.

## 8) Right vs Left Side in Cleft Cases at T1, T2, T3:

Table 10 – Comparisons of different parameters showing soft tissue nasal changes in Cases between right and left side at 3 time intervals (T1, T2 &amp; T3)

Comparison groups	Parameter	Comparison time interval	Mean difference	t value	p value
Right side vs Left side	sn-prn	T1	-1.04167	-1.914	.085
		T2	-1.04000	-1.926	.083
		T3	-.67333	-.891	.394
	prn-acl	T1	-5.05167	-10.213	.000*
		T2	-4.62833	-7.376	.000*
		T3	-2.35333	-2.818	.018*
	prn-acr	T1	1.69167	1.807	.101
		T2	2.62333	2.748	.021*
		T3	-.68833	-.896	.391
	cm-snl	T1	.54500	2.361	.040*
		T2	.37333	1.648	.130
		T3	.74833	1.677	.125
	cm-snr	T1	-1.00333	-3.355	.007*
		T2	-.98333	-3.188	.010*
		T3	-.75000	-1.403	.191
	all-alr	T1	-.82833	-.906	.386
		T2	-.91167	-1.006	.338
		T3	-2.89500	-1.788	.104
	acl-acr	T1	-1.31667	-1.335	.212
		T2	-.77833	-.743	.475
		T3	-1.12333	-1.512	.161
	sball-sbalr	T1	-1.34667	-1.784	.105
		T2	.03000	.035	.973
		T3	-.98833	-1.071	.309
	sball-sn	T1	-8.84833	-11.630	.000*
		T2	-7.15667	-13.879	.000*
		T3	-1.82333	-4.345	.001*
sbalr-sn	T1	8.92833	9.794	.000*	
	T2	8.41000	11.822	.000*	
	T3	1.69833	3.647	.004*	

\*p value <0.05 statistically significant, <0.001 highly significant, <0.001 very highly significant

This table highlights significant asymmetries between the cleft and non-cleft sides in several parameters such as prn-acl, cm-snr, sbalr-sn, and sbalr-sn at multiple time points. Though surgery reduced these discrepancies, significant differences persisted in some dimensions (e.g., prn-acl at T3), indicating that unilateral correction has limitations in achieving perfect symmetry. This underscores the complex nature of cleft-related deformities and supports the role of adjunctive procedures for refinement.

## **DISCUSSION**

This study assessed and compared soft tissue nasal changes in infants with UCLP and non-cleft infants using 3D stereophotogrammetry at different time intervals. It specifically focused on nasal tip projection, nasal base width, columella length, and unilateral nostril width before and after primary surgical repair.

The nasal tip projection is an important anthropometric parameter reflecting nasal protrusion and is key to facial aesthetics. In this study, UCLP infants showed significantly reduced nasal tip projection at baseline (T1) compared to non-cleft controls (TC1), consistent with previous findings that describe the cleft-side nasal cartilage as underdeveloped and laterally displaced<sup>[4,5,17]</sup>. Following surgical correction (T3), the nasal tip projection in cleft infants significantly increased ( $p < 0.001$ ), indicating substantial postoperative improvement. This aligns with studies that demonstrated increased nasal projection following primary repair<sup>[6,8,18]</sup>. Importantly, the difference between cleft and non-cleft groups at postoperative comparison (T3 vs TC2) was statistically non-significant ( $p = 0.335$ ), suggesting near normalization of tip projection, corroborating findings by Grunwaldt et al. and Jiao et al., who documented significant improvements post-surgery.<sup>[6,18]</sup>

Columella length was significantly shorter in UCLP infants at T1 and T2 compared to controls (TC1 and TC2), indicating a major nasal deformity in cleft pathology<sup>[8,10,21,22,32]</sup>. However, following surgical repair, there was a notable increase in columella length ( $p < 0.001$ ), and insignificant difference was seen between cleft and non-cleft infants at T3 vs TC2 ( $p > 0.05$ ). The progressive increase in columella length from T1 through T3 in UCLP infants reflects effective surgical intervention, as quoted by Grayson et al. and Cutting et al., who observed measurable

elongation of the columella post-operatively [8,17]. These results strengthen the significance of early surgical correction in restoring columellar height, an essential aspect of nasal aesthetics.

Measurements of nasal base width, particularly alar base width (alr-all) and outer nasal width (acl-acr), were significantly higher in UCLP infants at baseline and preoperatively compared to controls. These findings are in agreement with earlier reports describing lateral displacement and flaring of alar bases in cleft patients [4,18,21]. Although postoperative measurements (T3) showed a decrease in width, the acl-acr difference compared to controls remained statistically non-significant ( $p = 0.846$ ), indicating partial but incomplete correction. Similarly, inner nasal width (sbalr-sball) remained significantly different at all intervals, indicating persistent soft tissue asymmetry even after surgery. This outcome echoes the result found by Stebel et al., Clark et al., and Weatherley-White et al., who found that despite successful surgery, nasal base symmetry is challenging to achieve fully in early childhood [6,5,19].

Measurements of nostril width (sbal-sn and sbalr-sn) revealed significantly higher values on the cleft side at baseline and preoperatively, reflecting asymmetry. Postoperative measurements showed a significant decrease ( $p < 0.05$ ), reflecting a narrowing and improved contour. However, after comparing with non-cleft controls, the differences at T3 vs TC2 remained statistically non-significant ( $p > 0.05$ ), indicating limited surgical improvement. These results are consistent with those reported by Kecik and Enacar, who demonstrated improved symmetry postoperatively but noted persistent variations in nostril shape and aperture [21]. The nostril asymmetry is particularly resistant to correction, often requiring revision surgeries or presurgical nasoalveolar molding (NAM) for optimal results [3,7,20].

Following primary surgical repair (T2 and T3), significant improvements were observed in several nasal parameters, including sn-prn, prn-acl, cm-snl, cm-snr, and acl-acr ( $p < 0.05$ ). These improvements highlight the efficacy of primary cheilorhinoplasty alone, without the adjunct of presurgical nasoalveolar molding (NAM), in achieving better nasal projection, improved alar base symmetry, and columellar lengthening. The outcomes in this study underscore that, even in the absence of NAM, well-executed primary surgery can yield appreciable functional and aesthetic benefits.

Although NAM has demonstrated effectiveness in enhancing nasal and alveolar symmetry before surgery by directing the development of soft tissues and cartilage<sup>[3]</sup>, it remains resource-intensive and not universally available or accepted. In centers where NAM is not routinely practiced, or when parents opt out of this presurgical intervention, primary cheilorhinoplasty becomes the sole modality to correct nasal deformity in early infancy. Studies have shown that primary cheilorhinoplasty alone can still produce favorable outcomes in terms of nasal tip projection and columella lengthening, particularly when performed by experienced surgeons using techniques such as Millard's rotation-advancement with nasal correction or the Mulliken method<sup>[33,37]</sup>.

Studies assessing natural nasal growth in unrepaired unilateral cleft lip and palate (UCLP) infants reveal that intrinsic development alone does not significantly improve nasal deformities. Singh et al. found persistent asymmetry and alar base widening in 30 untreated infants using 3D imaging<sup>(42)</sup>. Law et al. noted only slight nasal changes in cases where surgery was delayed, highlighting the restricted capacity of natural growth to correct deformities<sup>(43)</sup>. Historical analyses further show exaggerated deformities persisting into adulthood without intervention<sup>(44)</sup>.

Collectively, evidence suggests natural growth alone fails to normalize cleft nasal morphology.

In our cohort, all infants underwent primary cheilorhinoplasty without prior orthopedic molding, allowing for a focused assessment of this approach's standalone efficacy. The results suggest that significant improvements in nasal symmetry are achievable with cheilorhinoplasty alone, particularly in the vertical and anteroposterior dimensions. This aligns with findings from Jiao et al. <sup>[36]</sup>, who reported similar improvements in nasal height and tip protrusion among UCLP infants treated without NAM.

However, residual asymmetries persisted, particularly in the inter-alar width (ac-ac) and nasal base width (sbal-sbalr). These findings suggest that while primary repair improves contour and projection, certain aspects of nasal morphology—especially transverse dimension correction—may benefit from presurgical orthopedic alignment. Without NAM, the preoperative soft tissue and cartilaginous distortion are left unaddressed until the time of surgery, possibly limiting the full correction potential. Furthermore, Matsuo and Hirose's landmark theory of neonatal cartilage plasticity suggests that early intervention—within the first weeks of life—can mold the nasal cartilage more effectively due to maternal estrogen levels <sup>[5]</sup>. This biologic window, though exploited by NAM protocols, remains untapped in infants undergoing cheilorhinoplasty alone after several weeks, potentially contributing to the persistence of asymmetries in our cohort.

Despite these limitations, it is vital to note that primary cheilorhinoplasty remains the global standard of care in many regions, especially where NAM is inaccessible due to cost, logistics, or parental preferences. The outcomes observed in

this study thus offer a realistic and encouraging picture of what can be achieved with surgery alone. As such, the efficacy of cheilorhinoplasty without NAM should not be underestimated, particularly when surgical timing, technique, and surgeon experience are optimized. Moreover, these findings invite a reconsideration of how essential NAM truly is in all cases. A recent systematic review by Eberle et al. found only modest long-term differences in nasal symmetry between NAM and non-NAM groups after primary repair, especially when assessed in later childhood <sup>[38]</sup>. These data suggest that while NAM may confer early improvements, its long-term benefits may be limited, especially if surgical outcomes are already satisfactory. Nevertheless, the lack of NAM in this study cohort provides a unique lens through which to view the pure surgical outcomes. The persistence of certain nasal width discrepancies reinforces the idea that adjunctive therapies like NAM may enhance early symmetry in specific dimensions, but are not strictly necessary for achieving functional or aesthetic success. This is critical for global cleft care programs, particularly in low-resource settings where NAM is not viable.

The comparison between the non-cleft and cleft sides within UCLP infants at all three time points revealed significant asymmetries, especially in prn-acl, cm-snr, sball-sn, and sbalr-sn parameters. The prn-acl measurement was significantly different between non-cleft and cleft sides at T1, T2, and T3 ( $p < 0.05$ ), reflecting lateral displacement of the nasal tip, as seen in previous studies <sup>[4,5,24]</sup>. Surgical correction significantly improved but did not entirely resolve the asymmetry. Similarly, parameters such as sball-sn and sbalr-sn showed persistent side-wise differences, despite improvements over time. These findings reinforce the conclusions of Ras et al., Desmedt et al., and Mulliken, who emphasized the structural limitations in achieving perfect symmetry in cleft anatomy <sup>[3,25,33]</sup>.

In the control group, all nasal parameters increased over time (TC1 to TC2), reflecting regular growth patterns of the nasolabial region in early infancy. These observations are consistent with expected developmental trends and support earlier findings by Singh et al. and Maull et al. <sup>[20,18]</sup>. In contrast, cleft infants displayed irregular growth trajectories, with marked changes observed particularly between T2 and T3, emphasizing the surgical impact on nasal morphology. For example, while parameters such as sn-prn and sn-cm showed gradual improvement, others like acl-acr decreased post-surgery, suggesting surgical manipulation rather than natural growth as the dominant influence. These findings support the hypothesis presented by Huddart et al. and Patel et al. that natural nasal growth is significantly altered in cleft anatomy, and surgical timing plays a vital role in modulating outcomes. <sup>[27,26]</sup>

The outcomes of this research underscore the importance of early surgical repair in improving nasal morphology in UCLP infants. Notably, enhancements in nasal tip projection, columella length, and nostril shape were substantial, supporting surgical protocols focused on early intervention. However, persistent asymmetries and deviations from control values stress the need for adjunctive procedures, such as NAM, to optimize outcomes <sup>[3,6,17]</sup>. Several studies have highlighted the benefits of NAM in improving nasal symmetry, reducing alar base flaring, and preparing tissues for optimal surgical results <sup>[3,4,5,7,19,20]</sup>. In the current study, NAM was not part of the treatment protocol, which may have influenced the extent of postoperative nasal symmetry achieved. Future research should explore integrated protocols that combine presurgical orthopaedics with early surgical intervention. Studies like those by Thakur et al., Chang et al., and Matsuda et al. support such integrated approaches for long-term aesthetic and functional gains <sup>[5,20,34]</sup>.

This study utilized advanced 3D stereophotogrammetry, allowing for accurate, reproducible measurements and visualizations of subtle morphological changes, as advocated by Weinberg et al. and Aldridge et al. <sup>[20,35]</sup>. The prospective design and multiple time point analyses enhance the reliability of the findings. Nevertheless, the study has limitations. The sample size was modest, and the absence of NAM limits comparisons with standard multimodal protocols. Additionally, an extended follow-up period would be essential to assess the stability and long-term impact of early surgical interventions. Further, future longitudinal studies should incorporate outcome tools like those proposed by Allori et al. and Daskalogiannakis et al. for cleft care <sup>[40,41]</sup>.

## **FUTURE SCOPE OF STUDY**

This study aims to enhance the understanding of soft tissue nasal changes in UCLP infants using 3D imaging by comparing outcomes between those treated with NAM followed by surgery and those treated with surgery alone.

Future directions include conducting multicenter randomized controlled trials to improve the generalizability and statistical power of findings. Extending long-term follow-up will allow for better evaluation of the sustained effectiveness of treatment protocols.

Incorporating patient-reported outcomes—such as quality of life, functional satisfaction, and esthetic perception—will provide a more holistic view of treatment success.

The study also encourages the integration of AI-assisted 3D image analysis to improve accuracy in soft tissue landmark detection.

Furthermore, a comparison between anthropometric and 3D measurement techniques will be explored to assess their reliability and clinical relevance in cleft care evaluation.

## **LIMITATIONS OF THE STUDY**

Despite some valuable findings in our study, there are certain limitations to be taken into consideration:

1. This was a 6-month follow-up study, therefore, to obtain more clarity about the benefits of only primary cheilorhinoplasty without nasoalveolar molding, long-term follow-up studies are required.
2. Since this study included smaller groups of patients, it cannot be set as a standard treatment protocol.
3. To evaluate the effectiveness of primary cheilorhinoplasty alone, it is essential to include a comparison group that undergoes NAM before the surgical procedure.
4. Large-scale RCTs and long-term follow-up are warranted in future research to assess whether this technique provides long-term advantages
5. Multi-center research with a bigger sample size can be considered for a more extensive study to overcome these limitations.

## **CONCLUSION**

This study evaluated 3D soft tissue nasal changes in unilateral cleft lip and palate (UCLP) infants compared to non-cleft controls across three time points. All key soft tissue landmarks were identified and measured. Preoperatively, UCLP infants exhibited significantly reduced nasal tip projection and columella length, with wider nasal base and nostrils, as compared to the non-cleft controls. These findings confirmed baseline asymmetry. Post-surgical assessment revealed substantial improvements in nasal projection, columella length, and nostril shape.

However, residual asymmetries in nasal base width and alar dimensions persisted. Longitudinal analysis across time points demonstrated significant postoperative improvements, particularly between T2 and T3. These findings highlight the effectiveness of primary cheilorhinoplasty in restoring nasal form and function, even without presurgical orthopedics. There were very

Although significant improvements were observed, additional methods such as NAM or presurgical infant orthopedics could further enhance symmetry in more complex cleft cases.

## **SUMMARY**

The goal of the research was to assess the changes in nasal soft tissue in infants with UCLP using 3-D imaging at baseline, before primary surgical lip repair, and after lip repair. A comparison of the measurements was done at all these given time points with non-cleft infants who served as control.

A total of 12 unilateral cleft lip and palate infants who underwent primary lip and nose repair surgery were considered in this study, whereas 12 infants without cleft lip and palate were considered as controls.

Comparisons between given time intervals (T1, T2, AND T3) for all different landmarks were done using Repeated measures ANOVA test to assess significant differences.

Primary cheilorhinoplasty caused a significant improvement in the symmetry of the nose as exhibited by a remarkable increase in the nasal tip projection suggesting a progressive improvement post-surgery.

The columellar length also increased significantly across time points aiding in gaining symmetry and indicating a mark difference between the nose and lip. The reduction in measurements related to inner nasal width indicated narrowing and better approximation of the alar bases

Though surgery reduced the discrepancies, significant differences persisted in some dimensions (alar length) indicating that unilateral correction has limitations in achieving perfect symmetry. This underscores the complex nature of cleft deformities and supports the role of presurgical orthopaedic procedures for refinement. The

control group showed normal developmental progression hence validating the use of controls as a reference standard.

Early surgical intervention significantly improves soft tissue nasal parameters in UCLP infants. Despite these improvements, complete normalization and symmetry are challenging to achieve, especially in nasal base width and nostril dimensions. Integration of presurgical NAM, individualized surgical techniques, and long-term follow-up are necessary for optimal outcomes.

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ANNEXURESANNEXURE-I-ETHICAL CLEARANCE CERTIFICATE

**Research and Ethics Committee**  
**KLE VK INSTITUTE OF DENTAL SCIENCES**

A Constituent Unit of KLE Academy of Higher Education & Research  
 Accredited 'A' Grade by RAAC Placed In Category 'A' by MHRD (GoI)

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SI. No. : 1652

**CERTIFICATE**

*This is to Certify that the synopsis titled*

*Comparison of soft tissue nasal changes in Unilateral  
 cleft lip and palate with non cleft lip and palate  
 infants using 3-dimensional imaging* Submitted by

Dr. REG. NO. II0222002 \_\_\_\_\_ P. G. Student /

Staff, Guided by \_\_\_\_\_ from Department of  
*Orthodontics and Dentofacial Orthopedics* has been critically evaluated by  
 committee members and granted ethical clearance to conduct the above  
 mentioned study

Date : 15/04/25

**Member Secretary**  
 Research and Ethical Committee  
 KLEVK Institute of Dental Sciences  
**MEMBER SECRETARY**  
 Research & Ethical Committee  
 KLEVK Institute of Dental Sciences  
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 Research and Ethical Committee  
 KLEVK Institute of Dental Sciences  
 Belagavi **Chairman**  
 Research and Ethical Committee  
 KLE VK Institute of Dental Sciences  
 Belgaum

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**ANNEXURE II-CONSENT FORM**

**KLE VK INSTITUTE OF DENTAL SCIENCES,**

**BELAGAVI –590010**

**CONSENT FORM**

**TITLE: COMPARISON OF SOFT TISSUE NASAL CHANGES IN UNILATERAL CLEFT LIP AND PALATE WITH NON CLEFT LIP AND PALATE INFANTS USING 3-DIMENSIONAL IMAGING OPERATOR: DR. ABHISHEK DESAI**

**NEED FOR THE STUDY:** The purpose of this study is to utilize a 3D camera system to analyse nasolabial soft tissue points in unilateral cleft lip and palate infants to be able to quantify the changes and compare them with noncleft controls.

I, \_\_\_\_\_ aged \_\_\_\_\_ have been informed about my involvement in the study:

- I agree to give my details like name, age, sex, address, and the details required for the study to the best of my knowledge.
- I am informed about the procedure and I agree and give my consent to the orthodontist for the procedure.
- I permit the orthodontist to utilize the information given by me and the results obtained from this study for presentation and publication purposes.
- I will not claim any returns for my cooperation in the study, even if it is being sponsored by any agency. I am participating with my own will and wish.
- I will follow the instructions given by the doctor.
- During the study, if I wish to resign from the study, I am free to do so and my treatment will still be completed in the department.
- In my full consciousness and presence of mind, after understanding all the procedures in my vernacular language, I am willing and give my consent to participate in this study.

Date:

Place:

Signature of witness

Signature

**ANNEXURE III- PHOTOGRAPH**



**ANNEXURE IV- MASTER CHARTS FOR NO NAM GROUP**

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
Patient Sr no.===	Cleft side	sn-prn			prn-acl			prn-acr			cm-snl			cm-snr		
		T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3
1 SHRIDEVI	RIGHT	5.16	6.23	10.06	15.05	16.11	17.11	15.05	16.11	17.11	2.1	3.36	5.73	1.67	2.53	5.69
2 SHREYA	LEFT	4.45	5.12	7.11	18.71	18.83	15.8	10.68	11.89	17.17	1.75	2.24	3.98	2.27	2.45	4.62
3 RENUKA	LEFT	6.12	6.83	9.23	18.23	19.69	20.34	16.78	15.86	19.21	2.09	2.97	4.02	2.89	3.52	4.71
4 PRIYA	LEFT	5.39	6.96	7.06	17.44	17.54	17.31	14.18	15.45	15.21	1.2	2.11	3.12	2.8	2.96	4.04
5 AARUSH	RIGHT	4.65	5.86	6.65	13.52	15.41	15.83	16.41	19.43	15.06	2.78	2.31	3.54	1.57	1.87	3.23
6 NAVEEN	LEFT	7.16	7.9	8.02	19.64	21.04	17.66	15.26	16.13	15.22	1.79	2.33	2.27	3.56	4.16	4.43
7 RADHA	RIGHT	3.57	4.55	5.12	12.34	13.72	13.48	17.17	19.38	15.51	2.86	3.18	3.93	1.89	2.31	2.96
8 CHANNAVA	RIGHT	4.84	5.32	7.02	13.82	14.79	16.92	17.01	17.54	16.1	2.42	3.14	4.12	1.43	2.11	3.02
9 PRIYANKA	RIGHT	4.99	5.97	6.42	13.45	14.83	14.59	16.26	18.47	14.09	2.44	2.86	3.51	1.92	1.98	2.53
10 FAIZ	LEFT	6.04	7.11	7.82	18.49	19.72	17.84	15.12	15.98	15.64	2.04	2.69	2.92	2.69	3.22	4.01
11 PAVITRA	LEFT	4.05	5.1	6.95	18.5	19.22	17.82	14.32	15.23	15.78	2.64	3.12	3.94	1.52	2.24	3.01
12 GANGAVA	RIGHT	3.75	4.85	6.88	12.52	13.41	14.72	14.59	15.35	16.23	2.18	2.85	3.91	1.23	1.85	2.89

T1	all-alr		acl-acr			sball-sbalr			sball-sn			sbalr-sn		
	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3
20.1	21.03	24.37	26.41	25.13	22.13	19.72	18.8	16.51	6.2	6.45	6.19	14.33	12.23	6.11
20.1	22.12	33.03	26.41	26.92	22.46	19.72	17.92	16.51	13.72	12.84	5.51	3.99	3.72	4.94
22.1	22.54	25.12	29.45	28.77	26.13	22.31	21.65	19.38	15.21	13.76	7.23	6.02	6.22	5.67
20.8	21.69	26.26	26.44	26.33	23.38	20.33	19.72	17.25	14.55	13.46	7.81	4.28	4.1	5.47
21.84	22.91	23.51	25.25	27.06	22.48	18.53	21.35	15.6	5.32	5.78	5.03	12.63	12.77	5.68
24.36	25.46	24.74	30.15	30.69	22.69	20.43	19.55	14.84	11.03	11.59	8.03	3.13	3.76	3.96
19.78	20.87	20.91	26.68	27.86	21.57	19.99	20.96	15.73	5.29	5.83	5.56	13.12	13.47	8.15
23.05	24.12	28.43	29.7	30.22	24.84	22.43	21.68	19.52	3.78	3.92	4.82	15.6	14.92	7.54
22.16	23.24	23.19	28.61	29.78	21.52	19.89	20.86	15.63	5.34	5.89	5.61	11.99	12.34	7.02
20.82	21.89	25.76	28.28	28.94	23.11	21.89	20.92	17.83	15.33	11.68	7.21	2.04	3.23	5.74
24.11	25.46	27.88	28.9	29.21	24.15	22.45	21.62	18.93	15.21	13.22	7.32	6.47	5.18	4.95
20.39	21.52	25.01	25.08	26.14	22.64	18.49	17.91	15.82	6.03	5.74	4.96	11.83	10.94	6.42

**ANNEXURE V- MASTER CHARTS FOR CONTROL GROUP**

Patient Sr no.==	sn-prn		prn-acl		prn-acr		cm-snl		cm-snr		all-ahr		acl-acr		sball-sbalr		sball-sn		sbalr-sn	
	TC1	TC2	TC1	TC2	TC1	TC2	TC1	TC2	TC1	TC2	TC1	TC2	TC1	TC2	TC1	TC2	TC1	TC2	TC1	TC2
1	5.31	7.41	13.44	15.23	14.33	15.12	3.33	4.84	3.19	4.34	24.78	28.36	21.11	25.37	15.16	17.03	5.83	6.38	5.72	6.36
2	5.47	7.65	13.01	15.63	13.98	16.43	2.51	3.76	2.85	3.88	22.43	25.67	20.52	24.66	11.86	13.3	3.61	3.95	3.92	4.21
3	4.71	6.87	12.92	15.52	13.16	16.23	2.14	3.21	2.43	3.31	20.73	23.72	18.83	22.63	12.77	14.32	4.96	5.43	5.12	5.89
4	5.08	7.18	12.03	14.23	11.91	13.34	2.13	3.13	2.29	3.34	19.23	23.43	17.4	21.09	12.83	14.23	5.32	6.56	5.02	6.23
5	7.56	9.12	15.01	17.13	16.47	18.22	3.2	4.62	3.07	4.27	20.23	23.42	18.4	22.12	12.69	14.11	4.84	5.53	5.19	5.72
6	5.84	7.53	11.46	13.52	13.41	15.38	2.89	3.91	2.82	3.71	19.72	22.49	18.27	21.89	11.99	13.45	4.89	5.31	4.54	5.15
7	6.55	8.33	14.77	16.91	14.91	16.89	3.53	4.77	3.55	4.62	22.35	25.53	21.01	24.95	14.25	16.02	4.44	5.12	4.33	5.06
8	6.39	8.12	12.71	14.98	13.1	15.31	3.16	4.02	2.93	3.85	19.74	22.94	18.46	22.64	13.63	15.38	5.21	6.02	5.36	6.18
9	5.01	6.89	12.19	14.37	13.45	15.22	2.94	3.84	3.01	3.92	20.89	23.67	19.75	22.41	13.21	14.92	5.62	6.21	5.39	6.45
10	6.53	8.27	13.83	15.91	14.1	16.42	3.31	4.21	3.41	4.37	21.05	24.32	19.61	22.98	14.86	16.21	5.27	6.14	5.49	6.31
11	5.8	7.62	12.25	14.68	14.1	16.11	3.32	4.28	3.14	4.05	24.27	27.15	21.47	24.83	13.31	15.02	4.47	5.78	4.95	5.93
12	6.16	8.05	13.49	15.32	13.89	15.81	2.92	3.97	2.99	4.09	18.99	22.12	20.7	23.89	13.56	15.14	4.85	5.91	4.96	6.18
13	6.04	7.94	13.8	15.41	13.61	15.27	3.26	4.14	3.08	3.98	21.59	24.63	19.26	21.82	15.44	17.03	5.91	6.77	5.95	6.84
14	5.59	7.43	13.8	15.62	14.12	16.34	3.06	4.02	2.89	3.86	21.71	24.59	20.8	23.47	13.99	15.61	4.58	5.42	4.79	5.63