

Prevalence of Staged versus Single-Stage Operations for Bilateral Cleft Lip Repair: Analysis of a National Database

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Introduction:

Bilateral cleft lip repair techniques may be categorized into single-stage versus staged operations, with no universally accepted treatment protocol. Single-stage operations may require pre-operative naso-alveolar molding (NAM) to decrease cleft widths and reposition the premaxilla. Staged operations may be performed in centers or regions without easy access to NAM. Few studies to date have compared the national prevalence of such approaches. This retrospective study aims to examine the national prevalence of single-stage and staged bilateral cleft lip repairs over the past 23 years.

Methods:

This retrospective study used TriNetX, a national deidentified aggregate database encompassing over 110 million patients across 78 different healthcare organizations in the United States (US). Using Current Procedural Terminology (CPT) codes, the study compiled patients younger than 12 months who underwent either single-stage (CPT-40701) or staged (CPT-40702) operation for bilateral cleft lip repair between 1/1/2000 and 10/9/2023. Patients billed for both operations were excluded. Patients were categorized by the year of their cleft lip repair. Patient demographic data were extracted and analyzed through TriNetX, which divided the US into four regions: Northeast, Midwest, South, and East. Linear regression analysis was conducted using PRISM software.

Results:

Of the 1,303 patients who underwent bilateral cleft lip repair, 57 patients were billed for both operations and were excluded from analysis. In the remaining cohort, 1,136 (91%) patients had a single-stage and 110 (9%) had a staged bilateral cleft lip repair. No significant demographic differences were found between the two groups.

The incidence of staged operations increased from 0 patients in 2000 to 14 patients in 2022. The incidence of single-stage operations increased from 6 patients in 2000 to 81 patients in 2022. Staged operations were rare in the first decade, accounting for 2% (n=5) of all bilateral cleft lip repairs between 2000 to 2011. The prevalence of staged operations showed a positive linear correlation ($R^2=0.75$, $P<0.0001$) over the 23-year period, rising from 0% (n=0) in 2000 to 17% (n=12) in 2023.

Conclusion:

Although there has been a gradual increase in the prevalence of staged operations in the last 23 years, most bilateral cleft lip repairs have remained single-stage operations. Staged operations may be offered to patients with wider clefts and more prominent premaxillae, where the risk of a dehiscence of a cleft lip repair or necrosis of the prolabial segment may be estimated to be

elevated. NAM may not be as effective or successful in patients with wide, severe bilateral cleft lip and palate, and surgeons may need to rely on a two-stage approach for these patients.

Surgeons may not find NAM to be as successful in patients with bilateral cleft lip and palate and may be relying on a two-stage approach more often than in prior years.