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Original Research

Balloon Dilation in Septal Surgery: An Experimental Analysis of Unguided Balloon Motion

Running title: Balloon Dilation in Septal Surgery

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ABSTRACT

Key Points

- Unguided nasal balloons displace with unintended motion at a critical angle of ~5 degrees.
- Closer plate spacing increases balloon migration even at small angles, amplifying instability.
- Results support guided dilation systems to limit unintended forces on critical anatomy.

Keywords: Nasal surgery; Balloon dilation; Mechanical phenomena; Equipment design; Endoscopy/methods

Introduction

Balloon sinus dilation (BSD) represents a minimally invasive technique used in sinonasal procedures to improve sinus patency without extensive mucosal disruption[1]. The popularity of BSD influenced the development of balloon-assisted septoplasty (BAS) techniques to minimize dissection while providing access for FESS and other transnasal procedures. One common FDA-approved septal mobilization balloon is the Relieva Tract Balloon Dilation System, an unguided 16x40 mm balloon[2].

Multiple studies cite favorable safety outcomes, reflecting the growing popularity of unguided balloons (UGB)[3]. Rare complications of CSF leaks and orbital injuries are reported[4-7]. UGBs' expansion between nonparallel surfaces create uneven force vectors and unintended motion in the nasal cavity, with the septum on one side and the lateral nasal wall and inferior turbinate on the other. This asymmetry creates uneven force vectors, causing unintended motion, a phenomenon consistent with complications in MAUDE analyses.

Despite widespread use of UGBs, limited quantitative data exists regarding how surface angle, spacing and friction influence balloon motion during dilation. Similar mechanical concerns are described in Eustachian tube balloon dilation procedures[8]. Guided balloons have emerged, addressing these issues by improving control and reducing unwanted motion[9]. However, to our knowledge, this pattern of angle-dependent instability during nasal balloon dilation has not been previously characterized in the published literature. This study presents a controlled benchtop evaluation of UGB motion to determine how these variables affect displacement and to identify the critical angle at which stability is lost.

Methods

Testing apparatus

The experimental apparatus consisted of two 5 x 5-inch steel plates mounted on threaded rods and spaced precisely with steel nuts and spacing washers. The plates were lined with 3.25mm of 38A platinum-cure silicone to provide a uniform elastic surface approximating soft tissue compliance.

Balloon and inflation system

A 16 mm x 40 mm high-pressure non-compliant nylon balloon was used for all tests. The balloon was inflated to a maximum pressure of 8 ATM using a 25cc quick-latch inflation device capable of 30 ATM.

Experimental procedure

The plates were first aligned parallel, then adjusted to create varying surface angles by inserting spacer washers at the upper bolts. The inferior plate distance remained constant. The balloon was positioned in the lower portion of the silicone-lined space and inflated initially to 1.5 ATM using manual plunger action, then to the maximum recommended pressure using the threaded piston screw mechanism.

Two dry and lubricated surface conditions were tested with a water-based surgical lubricant to simulate mucosal conditions. Each configuration was tested in five consecutive trials (total=65 trials). Angles and distances were measured before and after inflation using digital calipers.

High-resolution video documentation was used to record balloon displacement and motion patterns.

Results

Unguided balloon displacement began when the surface angle reached approximately 5° from parallel, with motion increasing as the angle widened. Angles were progressively widened from 0 to 6.1, with a median value of 5.05° [4.7-5.35]. No movement was observed below 2°. At 5°- 6°, displacement ranged from 1.5 to 13 mm, with initial plate spacing of 8 mm. Consistent motion occurred at angles of 5° or greater. Lubrication increased travel distance but not occurrence. Median displacement was 7.15 [3.54-10.51] and 7.75 [4.0-10.381] for non-lubricated and lubricated, respectively. At a 3.7°-angle, when plate spacing was reduced to 6.94 mm, 3 mm and 2.51 mm, balloon movement increased. A nonparametric Wilcoxon analysis confirmed a statistically significant difference (Wstat =0, Wcritical =5 [~p<0.01]). **(Figure 1)** summarizes the displacement trends with respect to angle with each point representing the average of 5 trials, for a total of 65 trials.

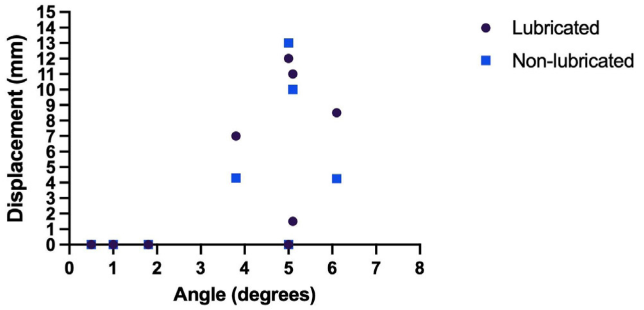

Figure 1: The displacement trends with respect to angle with each point representing the average of 5 trials, for a total of 65 trials.

Discussion

This study establishes a framework for understanding UGB mechanics in sinonasal procedures. Our findings revealed a consistent threshold of approximately 5° of angular divergence between opposing surfaces, at which a high-pressure nasal balloon transitioned from static to dynamic behavior. Beyond this threshold, the balloon consistently migrates towards the wider gap, regardless of lubrication conditions. Narrower plate spacing further amplified this effect, suggesting that confined anatomical spaces like the nasal cavity may promote UGB migration, even when tissue planes appear nearly parallel.

The identification of a critical angle for motion has important implications for device stability.

Displacement became more pronounced at reduced spacing, indicating that the narrow septal corridors encountered clinically can amplify balloon instability. Surface angle and spacing were the primary determinants of displacement.

The clinical relevance of these findings is underscored by the number of complications reported with sinus UGB systems. Analysis of the FDA MAUDE database has documented over 200 adverse events associated with balloon sinuplasty devices (Acclarent, Entellus, Medtronic) including CSF leaks, epistaxis, internal carotid artery dissections orbital swelling necessitating emergency canthotomy and four periprocedural deaths. Of these complications, 17.8% were related to imprecise catheter movement and 39.6% to guide catheter malfunction[7]. The predictable 5° critical angle provides a mechanical explanation for these events, emphasizing the need for device stability in confined anatomy.

These results highlight the need for angle-aware, guided balloon systems. Devices with rigid guiding elements, such as the ClearPathTM nasal balloon with a guide spatula, redistribute forces medially and shield lateral structures, directly addressing the angle-dependent instability revealed in this model[10]. In a recent study of endoscopic eustachian tube balloon dilations, surgeons used image-guidance integration for continuous catheter tracking and no major complications occurred[9].

This benchtop model simplifies complex in vivo anatomy. Rigid steel plates lined with silicone do not fully replicate tissue compliance, surface irregularity or mucosal friction. Additionally, the experimental pressures and spacing distances, while clinically relevant, do not account for dynamic tissue deformation or capillary adhesion. Cadaveric and computational models are necessary to validate these findings in more realistic anatomical conditions.

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Conflict of Interest

The authors have no conflicts of financial disclosures or conflicts of interests to declare.

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