Salivary Stone Pneumatic Lithotripsy in a Live Porcine Model

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract
The purpose of this study is to evaluate the efficacy of endoscopic fragmentation and removal of artificial calculi in a live porcine model employing intracorporeal pneumatic lithotripsy. In this experimental study, 7 submandibular ducts were accessed and artificial calculi placed. A salivary pneumatic lithotripter probe was inserted through an interventional sialendoscope to fragment the calculi. A salivary duct catheter was then used to flush stone fragments, followed by endoscopy to assess complete fragmentation and ductal trauma. Ultimately, 7 artificial stones (3-10 mm, 4F/5F) were successfully fragmented without causing significant endoluminal trauma. Number of pulses for adequate stone fragmentation averaged 20 (range, 5-31). In all cases, stone fragments were successfully flushed out with the salivary duct catheter. Postprocedure endoscopy confirmed ductal integrity in all 7 ducts. While more studies are needed, this preliminary animal model demonstrates efficacy of endoscopic pneumatic lithotripsy for the management of sialolithiasis.

Keywords
sialolithiasis, salivary gland, sialadenitis, salivary stone, lithotripsy, sialendoscopy, endoscopic, minimal access surgery, pneumatic lithotripsy

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Sialolithiasis accounts for 50% of major salivary gland disorders and is frequently encountered in general otolaryngology clinics today.\(^1,2\) With a new focus on gland preservation, Marchal and Dulguerov proposed an algorithm for the management of sialolithiasis, including criteria for endoscopic lithotripsy and stone removal.\(^3\) Different lithotripsy techniques have since been developed, including intracorporeal lithotripsy, of which laser and pneumatic techniques are the most common.\(^4,7\) While both laser and pneumatic lithotripsy techniques have proven efficacy for the management of renal calculi, there remains a paucity of literature regarding pneumatic lithotripsy in the management of sialolithiasis.

The primary objective of our study was to evaluate the efficacy of a new salivary pneumatic lithotripter device and salivary duct catheter in complete endoscopic fragmentation and removal of artificial calculi in a live porcine model.

Methods
This study was approved by the Institutional Animal Care and Use Committee (reference 054-05-13; Synchrony Labs, Durham, North Carolina), and it followed the Guide for the Care and Use of Laboratory Animals.\(^8\) Four palmetto swine were utilized, undergoing a physical examination by a veterinarian and acclimatization period of at least 5 days. Lithotripsy was performed under general anesthesia in all circumstances. The study was sponsored by Cook Medical USA (Bloomington, Indiana), and authors have disclosed relevant conflicts of interest.

Salivary Duct Access and Placement of Artificial Calculi
The submandibular papilla was cannulated and gradually dilated. A 5F Kolenda salivary-access introducer sheath (Cook Medical USA) was then introduced and left in situ (Figure 1A). A 1.3-mm interventional all-in-one sialendoscope was used to visualize the duct to identify any trauma while obtaining access. Artificial cement calculi that could mimic human salivary stones (4F or 5F in diameter, 4-10 mm long) were characterized chemically, physically, and mechanically. One calculus was placed in each duct as close to the hilum as possible.

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Lithotripsy and Removal of Stone Fragments

The flexible-tip nitinol contact probe of the StoneBreaker Salivary Pneumatic Lithotripter (Cook Medical USA) was inserted through the 0.6-mm working channel of the salivendoscope. The probe was advanced under vision to contact the stone, and fragmentation was continued with repeated pulses until the stone fragments were small enough to be removed with irrigation using the salivary duct catheter SialoCath (Cook Medical USA; Figure 1B; see Video 1 at www.otojournal.org/supplemental). Suction-irrigation was connected to the salivary duct introducer, and stone fragments were flushed with the salivary duct catheter. A postprocedure endoscopy was performed to assess any procedural injury to the ductal wall and complete stone removal.

Results

Eight submandibular ducts were successfully accessed; however, significant trauma to 1 duct in the course of artificial stone placement precluded its inclusion in the study. Consequently, results are reported on 7 submandibular ducts. Access was possible via the Seldinger technique in 2 cases (29%) and with a papillotomy in 5 cases (71%); 5F calculi were used in 4 ducts (58%) and 4F calculi in 3 ducts (42%; Table 1).

All 7 stones were completely fragmented with the pneumatic lithotripter. There was no evidence of clinically significant trauma to the ductal wall, as evidenced by postprocedure endoscopy. The total number of pulses fired until complete fragmentation varied from 5 to 31 (Table 2). The salivary duct catheter via the irrigation-suction technique was successful in removing all stone fragments. There was no evidence of trauma to the duct after successful irrigation of stone fragments in all experiments.

Discussion

Current techniques for management of sialolithiasis are effective but involve a combination of endoscopic and open techniques. Sialendoscopy is effective for small floating stones within endoscopic access; however, its benefit is limited in discussion of larger or unfavorable stones. Lithotripsy has the capability of overcoming some of these difficulties. Although laser lithotripsy has been shown to be effective, larger stones require longer operative times. Forty percent of the shock wave energy generated by laser is reflected off the stone or causes adverse thermal effect. Consequently, in spite of favorable results with the laser, the concern of ductal trauma, stenosis, and residual stones with laser lithotripsy is justified, especially with large and/or impacted stones.

At this time, the ideal lithotripter for sialolithiasis does not exist. Albeit with a small sample size, Arzoz et al showed that pneumatic lithotripsy could be safely performed for the management of sialolithiasis. Our study demonstrates that the pneumatic lithotripter device and probe were effective in efficient stone fragmentation under direct visualization without causing lateral thermal damage. There was no instance of ductal injury due to retropulsion of the artificial calculi or direct trauma from the probe in our study. After fragmentation, removal of calculi with the irrigation-suction technique was effective, as evidenced by the postprocedure endoscopy. Our live porcine study mimics in vivo human circumstances and provides support that the introducer sheath, pneumatic lithotripter, and salivary duct catheter together are effective as a complete stone removal system. Although this study demonstrates effectiveness with artificial calculi, additional studies using the system on human stones and in clinical settings are necessary to validate our results. An ongoing ex vivo study analyzing the pneumatic lithotripsy system in human stones supports this contention.

Conclusion

Endoscopic lithotripsy with the salivary pneumatic lithotripter and the irrigation of stone fragments with the salivary duct catheter were found to be an effective system that allowed complete fragmentation and removal of artificial calculi within porcine submandibular ducts. More studies
are needed to further validate these results, but this may provide another treatment modality to achieve gland preservation in the management of sialolithiasis.

**Author Contributions**

Rohan R. Walvekar, performed the experiments in the lab, data collection, review of literature, manuscript writing and intellectual contributions, approval of final version, accountability for content; Henry T. Hoffman, contribution to design, manuscript preparation and intellectual editorial contributions, final approval, accountability for content; Jack Kolenda, performed experiments in the lab, editorial contributions to manuscript preparation and editing, final approval and accountability for content; Stephen Hernandez, data acquisition and analysis, review of the literature, manuscript preparation and editing, final approval and accountability for content.

**Disclosures**

**Competing interests:** Rohan R. Walvekar—consultant for Cook Medical USA, Hood Lab (Pembroke, Massachusetts; Walvekar Salivary Stent), Medtronic Xomed USA; Henry T. Hoffman—research consultant for Cook Medical USA, author of patent owned by University of Iowa Research Foundation licensed by Cook Medical USA; Jack Kolenda—consultant and royalties patent, Cook Medical USA.

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