Case Report

Novel Use of Drug-eluting Stent in Otologic Surgery to Prevent Restenosis

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Abstract

Objectives: The primary objective of this case series is to assess the effectiveness of the off-label use of the PROPEL drug-eluting stent, traditionally FDA-approved for sinus surgery, in preventing restenosis following canalplasty in patients with chronic otologic conditions or congenital anomalies. The stent provides both mechanical support to maintain canal patency and localized steroid delivery to reduce inflammation and scarring.

Methods: Four patients with various otologic conditions underwent canalplasty, followed by the placement of drug-eluting stents into the external auditory canal. The stents were inserted to address postoperative stenosis. Clinical outcomes, including ear canal patency, hearing improvement, and the rate of restenosis, were evaluated through regular follow-ups.

Results: All patients showed improved ear canal patency, with minimal restenosis observed during follow-up. Hearing improvement was reported in 3 out of 4 patients. The pediatric case exhibited mild medial canal stenosis despite stent placement, but overall improvement was noted. No adverse effects were associated with the stent usage.

Conclusions: The off-label use of a drug-eluting stent in canalplasty appears to reduce restenosis rates and maintain canal patency in adults effectively. Further research is warranted to standardize protocols and expand its indications for otologic surgery, particularly in pediatric cases where outcomes may vary.

Keywords

restenosis, stent, canalplasty, drug-eluting, PROPEL

Introduction

The primary challenge following canalplasty includes managing post-operative restenosis of the external auditory canal (EAC). Some physicians have reported using prostheses or packing materials to prevent restenosis, though with limited success; as such, residual hearing loss and restenosis remain a common post-operative issue.[1,2] The PROPEL drug-eluting stent (Intersect ENT, Menlo Park, CA, USA), currently FDA-approved for sinus surgery, offers a novel solution with its dual functionality: mechanical support to maintain canal patency and controlled, localized delivery of steroids to prevent restenosis.

Methods and Results

In this case series, we focus on the novel application of a drug-eluting stent to reduce restenosis rates and improve post-operative recovery. By integrating this device into perioperative management in canalplasty, we explore its potential to maintain canal patency through mechanical support and controlled, localized delivery of anti-inflammatory medication.

Ethical Considerations

Our institution does not require ethical approval for reporting individual cases or case series, and therefore this study received IRB exemption from the University Hospitals Institutional Review Board (IRB; STUDY20240443).

Case 1

A 32-year-old male with a history of prolonged bilateral non-infectious chronic otitis externa (COE) presented with severe scarring in the right EAC, leading to canal obliteration and

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resultant conductive hearing loss. The patient subsequently underwent canalplasty, accompanied by a split-thickness skin graft (STSG) on the right ear.

One month postoperatively, the patient exhibited signs of concentric narrowing in the mid-portion of the bony EAC. Despite the administration of both topical (Pred-Forte) and infiltrated steroids (Kenalog-10), stenosis developed, prompting the decision to position a drug-eluting stent within the narrowed area. This procedure was conducted in-office, under direct microscopic visualization, with the stent left in place for 21 days.

Upon removal, the concentric scarring had resolved, and the canal was fully epithelialized. Nine months postoperatively, the patient reported no further COE occurrences and demonstrated significant hearing improvement. Examination at this follow-up revealed a fully visible tympanic membrane (TM).

Case 2

A 67-year-old male presented with bilateral mid-canal EAC stenosis that was significantly worse on the left, resulting in skin trapping and left conductive hearing loss. CT was concerning for cholesteatoma development.

He underwent left-sided lateral graft tympanoplasty, canalplasty with an STSG, and middle ear dissection of cholesteatoma. The incus was removed as part of the cholesteatoma dissection, but the decision was made not to perform ossiculoplasty. The ear canal was packed with Gelfoam and an Ambrose ear wick.

The Ambrose ear wick was removed at the first clinic visit 1 week after the operation, demonstrating wide patency of the EAC. The patient returned to the clinic 2 weeks later with early fibrosis and stenosis developing at the bony cartilaginous junction. At this point, a drug-eluting stent was placed in the EAC.

The patient returned to the clinic 2 weeks after the stent was placed. The EAC was significantly more patent than at the previous visit, and the stent was left in place at that time. He returned to the clinic 6 weeks later, at which point all remnants of the stent and cerumen were removed. The ear canal was patent, and the TM appeared to have entirely healed, with epithelialization of the ear canal.

Case 3

A 23-year-old male presented with a complex otologic history, including multiple tympanostomy tube insertions and a persistent perforation in the left TM that had previously necessitated a tympanoplasty. Following the treatment of acute otitis externa, a large perforation at the tympanoplasty site on the left became evident with extensive mucosalization of the medial portion of the bony ear canal.

The patient underwent a left tympanoplasty with canalplasty to address medial EAC stenosis. Approximately one month after the canalplasty, a drug-eluting stent was placed in the left ear to manage postoperative mid-canal stenosis.

Postoperative immittance testing indicated a normal right tympanogram and a flat left tympanogram with a normal ear canal volume. Follow-up examinations demonstrated considerable improvement, with a significant reduction in scar tissue along the medial aspect of the ear canal and the TM, mostly visible without effusion.

Case 4

A 5-year-old presented for EAC atresia repair. He was born with left grade 1 microtia and EAC atresia and had anatomy amenable to reconstruction. He underwent uneventful atresia repair with tympanoplasty with a temporalis fascial graft. Two months postoperatively, the patient's EAC was noted to be stenotic, and he subsequently underwent revision atresia repair. A drug-eluting stent was trimmed to fit the EAC and placed intraoperatively into the canal with a Merocel wick in the center. This was repeated one month later to ensure maintenance of canal patency. Eight months postoperatively, examination demonstrated a patent EAC with only mild soft tissue medial canal stenosis.

Discussion

The management of postoperative restenosis in canalplasty and atresiaplasty has traditionally relied on methods such as serial stenting with expandable material wicks or dressings to maintain canal patency, though no formal guidelines exist.[1]

While these have been the mainstay of treatment, these necessitate frequent clinic visits for the replacement or adjustment of wicks, without fully resolving the issue, with restenosis rates as high as 30%.[3] In this case series, we demonstrate how use of drug-eluting stents may effectively reduce restenosis. Our findings are similar to 1 study that demonstrated efficacy in using custom prostheses with drug-eluting properties to reduce the risk of restenosis.[4]

It is worth noting that in the case of the pediatric patient, the stent did not result in complete resolution of stenosis, as seen in the first 3 patients. Nevertheless, improvement was still noted, as stenosis was limited to only the most medial portion of the canal into which the stent could not be advanced. Thus, the utility of the stent may be limited based on the size of the canal, the patient's age, and the presenting etiology. Further research is needed to determine the precise indications for which a drug-eluting stent would be most beneficial.

The use of a drug-eluting stent following canalplasty has yielded promising clinical results in this case series. Given

the limited sample size, as well as the lack of standardized placement timing and follow-up, future research should aim to elucidate the efficacy of the stent to prevent restenosis following canalplasty within a larger cohort and outline standardized protocols for its use, ultimately expanding its FDA approval for additional indications.

Declaration of Conflicting Interests

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References

1. Renard L, Charles A, Marianne S, David B. Evaluation of postoperative practices regarding packing of the external auditory canal. *J Int Adv Otol*. 2022;18(2):145.
2. Weber PC, Davis B, Adkins WY Jr. Canal atresia reconstruction with dental impression material. *Am J Otolaryngol*. 1999;20(4):236-240.
3. Savion I, Good J, Sharon-Buller A. An acrylic resin conformer for the prevention of external auditory meatus stenosis. *Laryngoscope*. 2005;115(11):2006-2009.
4. Matin-Mann F, Gao Z, Schwieger J, et al. Individualized, additively manufactured drug-releasing external ear canal implant for prevention of postoperative restenosis: development, in vitro testing, and proof of concept in an individual curative trial. *Pharm*. 2022;14(6):1242.