Novel Therapeutic Strategy for Pharyngoesophageal Stricture following Total Laryngectomy

Peter I. Wu, PhD1,2, Michal M. Szczesniak, PhD1,2, Dart A. Fox, Julia Maclean, PhD2,3, Eric D. Blom, PhD4, and Ian J. Cook, MD1,2

Abstract
Current therapeutic strategies for pharyngoesophageal stricture, while effective in the short term, are protracted and costly in the longer term. Conceptually, if a stricture can be dilated with minimal tissue injuries, the rate of fibrosis and the resultant stricture recurrence could be reduced. We evaluated a prototype computer-controlled syringe pump device programmed to distend a commercially available balloon dilator at variable rate, asserting incremental lumen distension pressures tailored to the resistive force encountered within the stricture. We completed 17 graded dilatation procedures among 4 total laryngectomy patients. All patients had a short-term response (1 month), with a mean decrement (improvement) in Sydney Swallow Questionnaire score of 448 (total score range, 0-1700; normal <234). The overall procedural tolerability and safety were encouraging; the only complication was the displacement of the voice prosthesis during 1 dilatation. From a technical viewpoint, the main challenge was to maintain the balloon in position during dilatation.

Keywords
dysphagia, strictures, pharyngoesophageal junction, radiotherapy, laryngectomy, dilatation

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Endoscopic dilatation of pharyngoesophageal junction (POJ) stricture is performed as a costly day-operative procedure requiring anesthesia and a large clinical team. While the procedure is effective, multiple sessions are required (median, 3)1 to achieve a response. The durability of treatment is disappointingly short, with 50% of patients experiencing dysphagia recurrence within a year.2

The high stricture recurrence rate may be due to fibrogenesis following dilatation-induced tissue damage. A novel approach to dilate slowly and progressively while minimizing tissue damage could reduce subsequent fibrogenesis and stricture recurrence.

Current handheld manual syringe pump systems used in commercially available balloon dilators, dilate POJ strictures abruptly, lack fine control and feedback from the lumen. The Fox Tissue Modification Device (FTMD; US patent 2015/0073466) was designed to dilate in a controlled, gradual manner while monitoring tissue response. This can also allow the procedure to be performed on unsedated patients in an outpatient setting.

This current study aimed to provide proof of principle to demonstrate feasibility and obtain preliminary data on the efficacy and safety of the device.

Methods
The study was approved by the South East Sydney Local Health District HREC (reference 16/052). The FTMD dilatation was performed in 4 laryngectomees with demonstrable POJ stricture. Laryngectomees were chosen as their separated upper airway would not be compromised by the dilator.

The fundamental component of the FTMD is a computer-controlled syringe drive that delivers fluid into a commercially available balloon dilator (Boston Scientific, Marlborough, Massachusetts) placed across a stricture. The device’s programmable microcontroller unit (Figure 1a) continually monitors pressure within the dilator; as the tissue is being stretched (ie, lumen enlarges), it increases the distension volume to maintain constant force exerted on the tissue. If the stricture is recalcitrant for a given pressure and the lumen does not increase in size (ie, no further fluid

1Department of Gastroenterology and Hepatology, St George Hospital, Sydney, Australia
2St George Clinical School, University of New South Wales, Sydney, Australia
3Speech Pathology Department, St George Hospital, Sydney, Australia
4Center for Ear Nose Throat and Allergy, Carmel, Indiana, USA

Corresponding Author:
Peter I. Wu, PhD, Department of Gastroenterology and Hepatology, St George Hospital, Gray St, Sydney, NSW, 2217, Australia.
Email: PeterIungChiang.Wu@health.nsw.gov.au
is delivered into the balloon), the machine increases the distension pressure at intervals programmed by the operator.

The initial endoscopic assessment was performed under sedation to assess the severity of the POJ stricture and measure the transnasal distance to the middle of POJ to facilitate accurate placement of the dilator balloon. The stricture was not dilated at this stage.

Dilations were performed unsedated after topical anesthesia (Xylocaine 10% spray) to nose and throat. The first session began at 10 psi, and once set pressure was reached with no measurable change in balloon volume for 1 minute, the pressure increased by 1 psi. If balloon volume increased, indicating tissue yielding to the dilator, the same pressure was maintained for another minute. A maximum 20-psi increment per session was allowed. Participants could stop the procedure at any time by the handheld "stop" button. Subsequent dilatations commenced from the highest pressure achieved during the previous session (Figure 1b).

Seven dilatation sessions were allowed to a target of 80 psi; however, participants' preference and tolerability ultimately determined the total number of dilatation sessions.

Dysphagia severity was assessed with Sydney Swallow Questionnaire (SSQ) at baseline and at 1 month after completion of FTMD dilatations.

**Results**

Seventeen procedures were performed among 4 patients, an average of 4 per patient (range, 4-5). The mean highest pressure achieved in the final dilatation session was 59 psi (range, 48-68).

The average procedural duration was 20 minutes (range, 11-30). Catheter placement resulted in minimal discomfort, with a mean pain score of 1 of 10 (range, 0-2). During balloon distension, the mean pain score was 6 (range, 1-9). There was a trend of increasing pain level with higher balloon inflation pressure (Figure 2).

At 1 month, dysphagia severity measured by SSQ scores improved for all 4 patients (Figure 3). The average change in the total SSQ scores was -448 points (95% CI, -902 to 6; *P* = .052).
Dilatation was abandoned by the operator during 2 procedures: (1) The tracheoesophageal voice prosthesis was displaced during the third dilatation and replaced immediately; the displacement did not recur. (2) In the case of a 5-cm-long stricture, 1 procedure was abandoned due to balloon migration from the stricture (Figure 4). In subsequent procedures, manual inflation of the dilator and fluoroscopic confirmation of satisfactory placement were performed before commencing FTMD dilatation.

There were no perforations; however, minor throat discomfort requiring simple analgesia (lignocaine and paracetamol) for several days postdilatation was common.

Discussion

Preliminary results from 4 patients were encouraging, showing unsedated dilatation to be feasible, well tolerated, and safe.

Transnasal catheter insertion was well tolerated among all 4 patients, with low pain scores (range, 0-2). Not surprising, pain scores increased with higher inflation pressures. However, despite a recorded maximal pain of 9, none of the patients used the emergency deflation button. The likely explanation for this high tolerability was that the pressure increment was gradual, providing enough time for sensory adaptation.

The only adverse event was the displacement of the voice prosthesis; however, in retrospect, the POJ stricture was within 2 cm of voice prosthesis, and the patient reported that it had been loose prior to the dilatation. Nonetheless, voice prostheses displacement should be considered a potential complication during these procedures.

The most challenging aspect was the balloon migration during inflation. Factors contributing to balloon migration include long stricture length, swallowing, and movement during inflation. Wire-guided balloon dilators have an axial balloon length of 5.5 to 6 cm, which is particularly problematic in the setting of a long-segment stricture. If this technique is to be adapted in a setting where fluoroscopy is not available, a longer dilator balloon would be required.

Author Contributions

Peter I. Wu, study concept and design, dilatation procedures, interpretation of data, manuscript revision; Michal M. Szczesniak, the acquisition, analysis, interpretation of data, manuscript preparation; Dart A. Fox, Fox Tissue Modification Device concept, design and manufacturing, manuscript revision; Julia Maclean, participant recruitment, manuscript revision; Eric D. Blom, Fox Tissue Modification Device concept, manuscript revision; Ian J. Cook, overall project supervision, study concept and design, manuscript revision.

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