



A bioabsorbable microclip for laryngeal microsurgery: Design and evaluation

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ABSTRACT

Epithelial flaps created during laryngeal microsurgery require apposition to facilitate proper healing. Current technologies are restricted by minimal access of the surgical site, posing various limitations in application. In this paper, we propose a novel magnesium-based bioabsorbable microclip, discuss our design considerations and evaluate the microclip's feasibility as a miniature wound closure device. *Ex vivo* experiments demonstrate that the microclip fastens securely to the vocal fold, while *in vivo* studies show bioabsorbability and a lack of adverse side effects, suggesting that the microclips are viable as implantable devices.

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1. Introduction

Laryngeal microsurgery involves operating on the vocal folds under general anaesthesia using microlaryngeal instruments [1]. Epithelial microflaps may be created and elevated with microlaryngeal instruments during surgery and these microflaps require reapproximation on completion of the procedure. Current techniques for apposition of epithelial flaps during laryngeal microsurgery include using microsutures to reapproximate the edges [2–4], or the application of fibrin glue to seal the flaps [5].

Suturing of tissue may be challenging in laryngeal microsurgery due to restrictions imposed by the laryngoscope. These restrictions include limitation of instrument movement to four degrees of freedom, reduced force feedback and loss of stereopsis. A high level of skill is required during suturing, and surgeons must exercise care not to grasp the deeper structures of the vocal folds. Even then, suturing during laryngeal microsurgery and other types of minimal access surgery is time consuming and adds considerably to the total operating duration [2,6].

Despite the good wound healing results demonstrated by microsutures, many surgeons prefer using adhesives to hold down the epithelial flaps in order to achieve wound closure. Tissue adhesives such as cyanoacrylates and fibrin glue have been used [7], and may be easier to apply than sutures. Limitations in using cyanoacrylates include increased scar tissue formation due to adhesive between epithelial edges preventing proper approximation, rapid curing, which restricts the surgeon from reapproximating

malpositioned flaps, and lack of tensile strength of the adhesive. Fibrin glue, on the other hand, takes several minutes for initiation of curing after application over a wound surface and takes several hours to develop its full strength. Furthermore, it cannot create sufficient tensile strength to withstand moderate stresses without rupture of its bond [2]. As the vocal folds vibrate at high frequencies during speech, constant shearing against the adhesive glue causes wear and the resultant debris may impede the vibratory properties of the vocal fold.

An alternative approach for wound closure post-laryngeal microsurgery involves the use of surgical clips. Surgical clips have been used in various areas of the body, but have not been described previously for use in the vocal folds. This may relate to challenges facing the design of a surgical clip for application in this area, including the need for extremely small size, ability to withstand high vibration frequencies and shearing stresses during phonation, and the need for reabsorbability. A number of materials have been studied in the design of surgical clips in other areas. Stainless steel clips and newer materials such as titanium and tantalum have been used in areas where surgical dissection is difficult, such as ligating the cystic duct and artery in laparoscopic cholecystectomy [8]. However, major limitations of these materials include significant foreign body reaction, poor holding power and significant interference with roentgenologic studies like computerized tomography and magnetic resonance imaging, making them unfavourable for application [9–12]. The introduction of ligating clips manufactured from novel polymers such as polydioxanone in laparoscopic cholecystectomy helped to address these limitations. These clips are completely absorbed in the process of ester bond hydrolysis over a period of 180 days, and the by-products are

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