Soft Robot for Drug Delivery to the Inner Ear via the Intratympanic Approach

A novel solution capable of safely guiding an inserted needle through the ear canal to inject a therapeutic into the tympanic cavity.

Background

Injection of drugs through the eardrum (also known as the tympanic membrane) is a first-line treatment option for a range of ear pathologies, such as sudden sensorineural hearing loss and Meniere's disease. Such delivery of therapeutics has inherent advantages over systemic treatments as larger doses can be delivered locally with fewer systemic side effects. The blood-cochlear barrier, which limits the amount of drug reaching the cochlea from the bloodstream, can be bypassed by depositing the drug in close proximity to the round window membrane on the cochlea from where it perfuses into the inner ear. As a result, this delivery method is the focus for development of novel therapeutics for inner ear diseases1.

These procedures are commonly performed by skilled ear, nose & throat (ENT) surgeons to minimize the risk of damage to the middle ear during the needle insertion, which could result in hearing loss. Precise targeting of the needle, which is performed manually by the clinician, is therefore of paramount importance. Besides manipulating the needle during the insertion, dosing of the respective therapeutic remains challenging and endoscopic monitoring of the therapeutic injection close to the injection site is often omitted, which complicates assessment of the treatment. The round window membrane, which offers access to the cochlea is approximately 2 mm in diameter, and only small volumes can be delivered to the inner ear to avoid pain and/or damage. Moreover, prolonged treatments at low dosing rates are not commonly undertaken due to the lack of delivery technologies.

Technology Overview

To address the clinical demand for a robust and precise platform to deliver drugs to the inner ear via the intratympanic approach, we have developed a novel soft robotic solution capable of safely guiding a manually inserted needle through the ear canal to the desired point of injection. The design leverages inflatable actuators that once inflated are in contact with the surrounding ear canal walls. This enables the device to:

steer the needle relative to the surrounding lumen by inflating the actuators by different amounts;

stabilize itself within the ear canal thus compensating for undesirable external motion or tremor induced by the operating clinician during needle insertion.

An overview of the soft robot is provided in Figure 1 and more detail is available in a publication2. It is fabricated from two types of biocompatible silicone rubber, with the stiffer rubber forming the central core and the softer outer membrane inflatable actuators.

The softness of the robot enables safe insertion of the needle while local sensing can be provided during the intervention. The on-board camera can aid in identifying the desired injection site. For this purpose machine learning-based algorithms can be employed to autonomously identify anatomical landmarks on the tympanic membrane which provide the necessary information to deduce the appropriate target. Besides the on-board camera, the tip of the robot could be equipped with miniaturized sensors to provide a close-up assessment of the injection with the potential to monitor the deposition of the administered drug beyond the visually-occluding tympanic membrane through novel means of biomedical imaging. Sensing modalities requiring contact with the investigated medium could also be employed and facilitated through the compliant anchoring of the soft robot within the ear canal. Hence, the here-presented soft robot could offer new means to efficiently perform intratympanic injections in a safe and more controlled manner.

Further Details:

Anderson, C. R. et al. Local Delivery of Therapeutics to the Inner Ear: The State of the Science. Front. Cell. Neurosci. 13, (2019).

Lindenroth, L., Bano, S., Stilli, A., Manjaly, J. G. and Stoyanov, D. A fluidic soft robot for needle guidance and motion compensation in intratympanic steroid injections. IEEE Robotics and Automation Letters, (2021) doi: 10.1109/LRA.2021.3051568.

Stage of Development

The device is currently at TRL 3 to 4 with early proof of concept prototypes under development.

Benefits

There are no existing solutions developed specifically for ENT surgical use. Clinicians currently deliver intratympanic injections manually and use needles developed for other applications. Visual feedback during the intervention is commonly provided by external microscopes which renders accurate assessment of the injection procedure difficult. The here-presented soft robot could alleviate risks associated with the procedure and enable wider adoption of intratympanic injections.

Applications

Any therapy that would benefit from delivery via intratympanic injection eg. steroid injection or gene/cell-based therapies to treat various inner ear diseases.

Opportunity

The team is seeking market feedback on the opportunity and future commercial and collaboration partners.

Patents

UK priority application number 2020301 has been filed.

Seeking

Development partner, Commercial Partner

IP Status

Patent application submitted,

Provisional patent.