

Engineering World Health Design Competition 2021

MidazoClamp

A Minimally invasive, Fast-acting, transbuccal drug delivery device that deploys seizure drugs easily and with minimum risk.

University College Dublin Centre for Biomedical Engineering

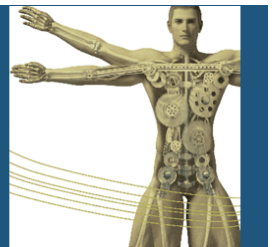
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1. Problem Definition

Around 50 million people worldwide suffer from epilepsy, with nearly 80% of those living in low- and middle-income countries. With proper diagnosis and treatment, the World Health Organisation estimates that 70% of those could live seizure-free lives [1].

Transbuccal drug delivery allows rapid absorption and therefore fast action of drugs due to the characteristics of the buccal mucosa present in regions like the cheek and gums, which allows the drug to reach the bloodstream directly. That is why this approach seems promising for the administration of emergency rescue drugs. In the field of epilepsy, muscular relaxants such as Midazolam need to be administered when a seizure lasts for more than 5 minutes, called ‘Status Epilepticus’, one of the most common neurological emergencies. Some of the existing devices used for this task follow a similar approach but require training to accurately deliver the drug, which limits the use of these devices to trained caregivers and therefore limits the patient’s independence. Existing solutions also struggle with delivering the drug to the correct location during release which decreases the efficacy of the medicine and increases the time required for drug absorption. Moreover, in the case of certain epileptic seizures, the use of devices for administering rescue drugs may not be safe enough for both the patient and the administrator.

Buccal Midazolam is an emergency rescue medication that works as a relaxant to assist in controlling seizures. It is typically administered inside the cheek if a seizure has continued for a prolonged time, usually longer than 5 minutes [2]. However, there are a number of issues associated with this method of administering the drug:

- Firstly, training is required for those administering the drug. Professional caregivers, parents, teachers and medical professionals must undergo specialised training in order to be able to administer Buccal Midazolam. One study found that 33% of trained caregivers deployed the drug in the wrong location, thus reducing the effectiveness of the treatment [3].
- Secondly, the current method involves a risk of choking [4]. To administer the drug, the cap needs to be removed correctly from the syringe. The clear tip-cap of BUCCOLAM syringes can sometimes remain attached to the syringe after the red cap has been taken off. If this happens, the tip-cap can detach in the patient’s mouth and they might breathe it in or swallow it.

Due to the nature of trans-buccal drug administration, a second party must deploy the drug in the patient’s mouth. This can lead to discomfort for the patient as well as the risk of germ transmission.

Our device increases patient and caregiver safety by removing the need for the caregiver to place their hands close to the patient’s mouth during a seizure.

This gives rise to the following clinical needs statement our device is curated to address:

“To provide a low-cost, minimally-invasive, fast-acting transbuccal drug delivery device to deploy seizure drugs that is easy to use and minimizes the risk for both parties while mitigating stigmas relating to epilepsy in low and middle income countries.”

The device will act as a clamp on the buccal mucosa, allowing the medication to be administered in the appropriate location in a safer and more efficient manner than a caregiver syringing the medication directly onto the inner cheek.

2. Impact in Low and Middle Income Countries

Epilepsy is a chronic disease that affects up to 50 million people worldwide, 80% of which are located in Low-Middle Income Countries (LMICs) [1]. A person is defined as having epilepsy when they experience two or more unprovoked seizures. It is a non-contagious disease but its cause is varied and estimated to be unknown in half of cases globally. Although the causes of epilepsy are similar throughout the world, there is a much higher incidence rate in LMICs compared to High Income Countries (HICs), 139 and 49 per 100,000 respectively.

Nigeria is considered an LMIC [5] and has a higher prevalence of epilepsy than most other countries, varying from 3.1 to 37 per 1000 throughout the country. At a 95% confidence interval, it is seen that the prevalence is 8 per 1000 people [6]. This is much higher than the international figures, and nearly six times more than the average LMIC. It is believed that with the use of anti-seizure medication, such as Diazepam/Midazolam, 70% of people affected could be seizure free [7]. Our solution will help to administer anti-seizure medication to the 40 million people living with epilepsy in LMICs.

In low income countries the World Health Organisation estimates that three quarters of people with epilepsy do not get the help that they need in what is known as the 'treatment gap' [8]. This can be attributed, in part, to the lack of training in the administration of emergency epileptic medications. Our MidazoClamp solution aims to address the 'treatment gap' by providing a reliable and effective way to dispense Midazolam into the buccal cavity.

The current solutions to this problem are the use of a syringe to deploy the medication into the space between the gum wall and cheek. There are difficulties associated with this - it can be difficult to place the syringe correctly, resulting in inaccurate dosages and loss of/ineffective medication. That is where this solution comes in; there is no other device available on the market that assists with the administration of buccal medication.

Current solutions for the administration of Buccal-Midazolam involves syringing the medication onto the reception site which is prone to errors in both the placement and absorption of the drug. MidazoClamp is carefully designed to be compliant to the characteristics of an ideal buccoadhesive system [9] and therefore is not susceptible to these errors. The clamp is tailored to adhere to the buccal mucosa and release the drug in a way that prevents it from moving from the reception site either by saliva or by movement of the tongue or jaw.

In addition to an improvement in the precision of Midazolam administration, another important benefit offered by MidazoClamp over the traditional method, is the convenience and dignity it offers patients. The incorporation of the clamp and drug tray element of the design means that once the clamp is in the correct position the medicine can be administered quickly and easily without the need for medical personnel holding the syringe in place or placing their fingers in or near the patient's mouth. This helps to make it a less invasive and a safer experience for all involved.