CLear: An At Home Ear Cleaning Device

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INTRODUCTION

According to Harvard Health Publications, earwax removal is the most common otolaryngologic procedure performed in American primary care settings. Although it is much safer and more effective to visit doctor's office, expensive co-pay and inconvenience for both doctors and patients have been brought to our attention which led to the development of an at-home earwax removing device.

Though earwax is meant to aid in self-cleaning and providing protection against the infection, excess or impacted earwax can cause various symptoms including dizziness, pain, temporary hearing loss as well as perforated eardrums.

Thus, by combining the efficacy of sophisticated devices with convenience and usability, this novel design aims to provide a preventative method against earwax impaction caused by inappropriate practices or simply due to earwax overproduction.

CLINICAL NEED

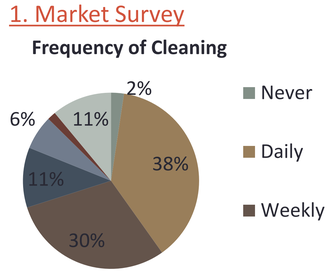
A major problem to the at-home earwax removal is that there is a lack of safe and effective device that people can use. Though statistics suggest that a significant percentage of population is suffering from the impacted earwax, there are not many treatment options that meet all three criteria that patients often want: safety, effectiveness and easy usability.

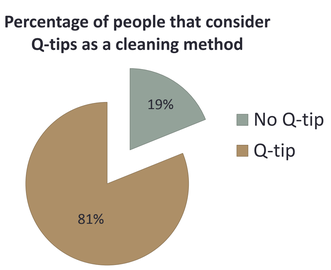
Currently, there are several options available for at-home usage: curette, drops and irrigation. However, these options often result in some uncomfortable side effects such as infections, perforated eardrums or dizziness that people rely on more readily available and easy-to-use Q-tips for an alternative.

Because Q-tip is one of major causes for earwax impaction, there is a need for an alternative to Q-tips that can safely remove earwax while allowing the safety and convenience of at-home products.

MARKET DESCRIPTION

1. Market Survey





- 2-6% of the population at any time suffers form impacted earwax.
- In GP survey (2000)- when asked about the most challenging part of ear cleaning
  - 38% responded - "complications while removing the earwax"
  - 29% responded- "failure of earwax removal"

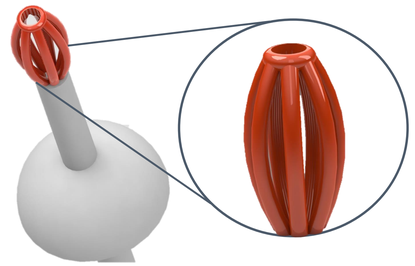
Potential target group includes:

1. Individuals with inappropriate earwax removing practices
2. Individuals with earwax overproduction, i.e. due to skin condition

2. Competitors – Most readily available products are compared and tested

Product	Quantity	Cost	Type
EarClear	1	$49.00	Syringe
WaxVac	2	$20.00	Vacuum – Battery Powered
Q-tips	500	$6.48	Multi-use Disposable Hygiene Product

FINAL DEVICE PROTOTYPE



MATERIALS USED

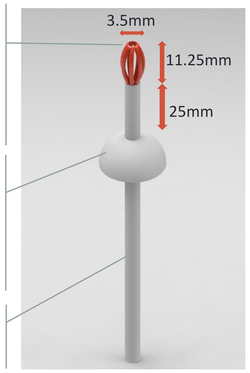
- Properties considered:
  - Price: Raw materials and processing
  - Young's Modulus: Restricted to 1E10 psi for balance between stiffness and flexibility
  - Safety factor: Measured via buckling to ensure no failure under pressure
- Materials chosen: Polypropylene (PP)
  - Due to compatibility, low price, high safety factor

PARTS DESCRIPTION

1. Tip
- Whisk-like design is able to scrape earwax off of the ear canal without damaging the sensitive skin
- Hollow shape prevents pushing earwax further into the ear canal and is able to collects the earwax through the openings.

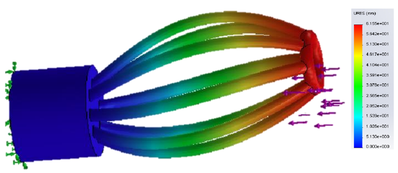
2. Safety Guard
- A safety guard at preset distance allows users to clean their ears without worrying about rupturing their eardrums.
- The location of safety guard is determined from the average ear canal length.

3. Rod
- Rod is made of a flexible plastic to follow the curvature of the ear.



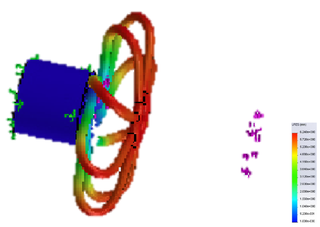
MECHANICAL ANALYSIS

1. Buckling-Displacement

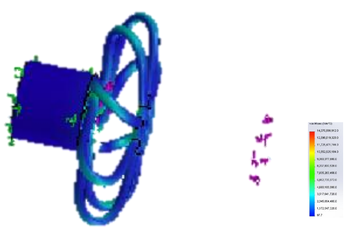


- Maximum buckling load of the device: 21 kN at its widest diameter
- Force applied to the device: 2N:
  - Factor of safety: 10E+3
  - Safe to use on a clinical level
- The weakest point for the buckling pressure is the edge with the narrowest diameter.

2. Displacement - Displacement



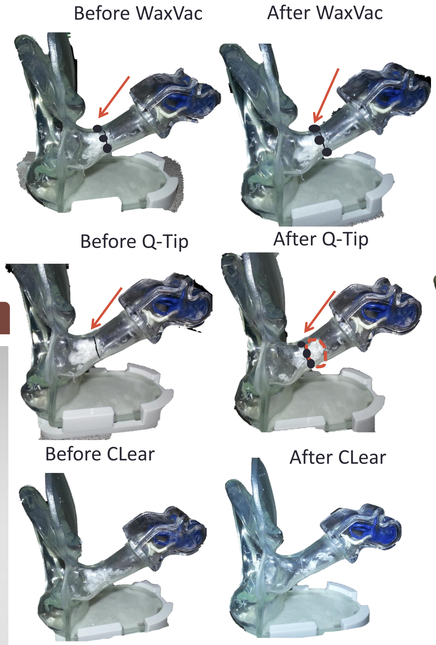
3. Stress-Displacement



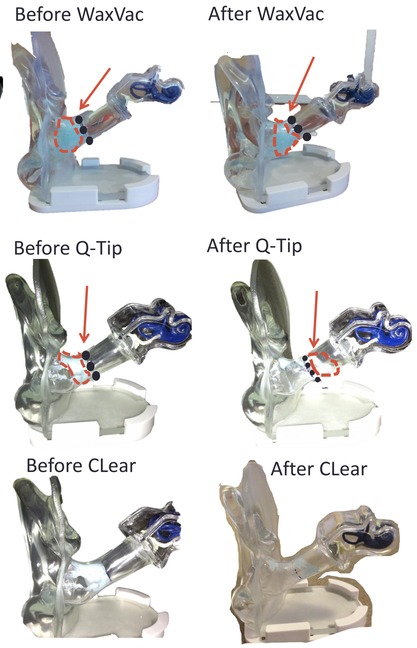
- Due to the flexibility of the material, stress and displacement are a non-issue.

TESTING EVALUATION

DRY EARWAX



WET EARWAX



Testing Materials: Clear Ear Model, Tooth Paste, Marker, ABS shavings

PRODUCTION COST

Volume	1651.3 mm^3
Injection Molded	10,000,000 parts
Material	$47,250 ($0.005 per part)
Production	$229,506 ($0.023 per part)
Tooling	$31,699 ($0.003 per part)
Total	$308,454 ($0.031 per part)

REGULATORY PATHWAY

- Ear, Nose and Throat Devices classification -manual surgical instrument
- Class I device
- Exempt from 510(k) or PMA
- Does not require FDA clearance before marketing in the U.S.
- The device must be registered within the generic category and exemption status prior to distribution

NOVELTY OF CONCEPT

- Hollow structure that does not push earwax further back
- Disposable product that does not involve complicated manufacturing processes or unnecessary cost for the users
- Safety guard that allows users to easily remove earwax without rupturing eardrums.

ACKNOWLEDGEMENT

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