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***In Vitro* Efficacy of a Consumer-Marketed Ear Cleaning Tool**

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Abstract

Hypothesis—The WaxVac ear cleaning device may be a useful adjunct for patients requiring aural toilet.

Background—Cerumen removal and routine aural toilet is a common complaint that presents to the otolaryngology clinic. We tested this device in order to make an appropriate recommendation to our patients.

Methods—We conducted *in vitro* testing of the WaxVac device on an artificial ear canal model and cadaveric temporal bones testing the strength of the suction, noise created by the device, and the ability of the device to remove foreign bodies from the external auditory canal. These foreign bodies included a PE tube, baby powder, a q-tip head, saline, and artificial cerumen.

Results—The WaxVac created very little suction as compared to Frazier tip suctions used in clinic. The device produced very little noise in the canal which was equivalent to a #3 Frazier tip suction. The WaxVac was unable to remove q-tip heads or artificial cerumen from the ear canal model or the cadaveric temporal bones. Very little of the saline could be removed by the WaxVac and only 20–50% of trials demonstrated removal of a PE tube. However, a large amount of the powder was able to be removed by the device.

Conclusion—While the concept of this device is good, the actual product does not produce adequate suction to remove cerumen or most common foreign bodies from the external auditory canal. It is unlikely to be useful for aural toilet.

Keywords

Cerumen; Ear wax; WaxVac; consumer marketed device

Introduction

Cerumen removal is commonly performed in both otolaryngology and primary care clinics. It is estimated that cerumen removal accounts for twelve million visits to physicians per year and require eight million removal procedures every year. The patients that most frequently

require removal are in the geriatric population and the mentally disabled¹. While removal of cerumen under the microscope is safe there are significant risks to other methods performed in the primary care clinic as well as at home^{2,3}. Commonly cerumen is removed in primary care clinics via an irrigation method that has been estimated to have a 1:1000 risk of a complication including tympanic membrane perforation, ear canal laceration, and otitis externa. This equates to roughly 8000 complications annually in the United States⁴. Additionally in elderly it has been linked to dangerous cardiac depression during the procedure⁵.

Outside of the clinic patients frequently try various methods to remove their own cerumen. Q-tip use is mostly associated with external otitis and retained foreign bodies than tympanic membrane perforation^{6,7}. In a primary care population, 36% of respondents to a survey admitted to cleaning their ears by placing a foreign body in the canal at least one time per day. The population had a 2% complication rate and despite counseling regarding the risk of this behavior only 24% were willing to stop⁸. Another common home remedy is ceruminolytic agents. Trials comparing these agents have found them no more effective than using water⁹. Less commonly patients will use water irrigators designed to remove cerumen. An *in vitro* trial of these irrigators demonstrated a 6% incidence of tympanic membrane injury. There are also case reports of ossicular disruption, round window fistula, and subluxation of the stapedial footplate from using these devices^{10,11}. Additionally candling has been used more frequently as a home remedy for cerumen but it was not found to create significant suction and there was a significant danger of facial burns^{12,13}.

Currently all home cerumen removal devices are less than ideal, but recently a new device, the WaxVac, has been advertised to consumers claiming to suction out the ear canal of “dirt particles and moisture”. These advertisements have produced many questions from patients regarding our recommendations for this device. Due to the fact that there are very few options for patients to remove impacted cerumen, discharge, and fluid without intervention from an Otolaryngologist, it was our hope that in testing this product we would be able to reduce the risk of external ear complications from home cerumen removal, but also to determine if this product was worth recommending to patients.

Materials and Methods

Devices

4 WaxVac devices (Product Trend LLC) were assembled by manufacturer’s instructions. Replaceable tips were placed on the devices prior to use and changed between uses. One of the devices was labeled and used for the *in vitro* experiments due to contact with cadaveric tissues. Fraizer tip #3, 5, 7 suctions were also used to compare the negative pressure and dB level produced in the external auditory canal.

Artificial Cerumen

Cerumen was created using medium chain triglycerides (Palmitic acid, Stearic, Arachidic, Oleic and Alpha-linolenic acids) and plant sterols (B-sitosterol, B-sitostanol, Campesterol, Campestanol) combined using a mortar and pestle. This formula was based on data from a

veterinary trial of ceruminolytic formula used in canines¹⁴. A 50/50 mixture was created using the medium chain triglycerides and plant sterols which had a consistency similar to human cerumen.

Sound Testing

The clinic suction and the WaxVac devices were placed in an external auditory canal model created using hard plastic tubing 7mm in diameter and 2.5 cm in length which is the average size of the adult external auditory canal. At the end of the tubing a microphone (Sony ECM-DS70P) was placed attached to an iPhone running “Decibel 10th” software (version 3.6.1, SkyPaw Co. Ltd) to measure the absolute dB level of the devices in the canal.

Suction Testing

An automotive vacuum gauge (Autometer, part 2350) was used to determine the PSI of the suction of the WaxVac device and the clinic suctions. To simulate the conditions of the external auditory canal, a 2.5 cm L x 7 mm D hard rubber tube, the average size of an adult external auditory canal, was connected to the vacuum gauge. As well, the microphone of a decibel meter was placed at the ending of the tube and levels were recorded from both the WaxVac and clinic suctions. The same rubber tubing was covered at one end with plastic wrap to simulate the tympanic membrane and various materials were placed in the tube to test the suction of the WaxVac. Materials placed in the external auditory canal model were a Paparella grommet tube, 1 gm dry baby powder, the cotton tip of a q-tip, 1cc of sterile saline, and 1cc of artificial cerumen.

In Vitro Efficacy Testing

Four cadaveric temporal bones with external auditory canal, tympanic membrane and pinna intact were used in our department’s temporal bone lab. The external auditory canals were filled with various substances and the efficacy of the WaxVac was tested. Residual material was removed with Frazier #5 suction. Materials placed in the ear canal included a Paparella grommet tube, 1g dry baby powder, a q-tip cotton tip, 2ccs of sterile saline, and 1 cc of artificial cerumen.

Results

The strength of the suction produced by the WaxVac was tested on the “High” setting of the device. The PSI meter detected a level less than 1 PSI (pounds per square inch) or <6.9 kPa (Kilopascal) (Table 1). On the same PSI meter the strength of suction was tested on the ENT Treatment Drawers at the open tubing, and with #3, #5, #7 suctions with the finger valves occluded. The open tubing measured at 24 PSI (16.5 kPa). The suction tips measured 6–10 PSI (41.4–68.9 kPa), 20–22 PSI (137.9–151.7 kPa), and 22–24 PSI (151.7–165.5 kPa) for the #3, #5, and #7 suctions, respectively (Table 1).

Using the plastic ear canal model we tested the noise level produced from all of these suction devices. The WaxVac was placed at the external meatus of the tube with the microphone at the “tympanic membrane” end of the tubing. The WaxVac produced 75 dB on the “Low Setting” and 85 dB on the “High” setting (Table 2). The #3, 5, and 7 Frazier tip

suctions were tested with the finger valve occluded held at the meatus and lowered closer to the “tympanic membrane” end. The results are reported as the average dB at the meatus and the average dB at the tympanic membrane. The #3 suction produced 80 dB at the meatus and 85 dB at the tympanic membrane. The #5 suction produced 92 dB at the meatus and 95 dB at the tympanic membrane. Finally, the #7 suction produced 94 dB at the meatus and 101 dB at the tympanic membrane (Table 2).

The effectiveness of the WaxVac to remove foreign bodies from the ear canal was first tested in the external canal model tubing. With each substance the efficacy was tested over ten trials. A Paparella tube was placed in the tubing and in 5 out of 10 trials the WaxVac was able to remove the tube from the canal. Baby powder was placed in the canal and an average of 60% of the powder was removed with the WaxVac. A q-tip head was placed in the canal and the WaxVac was unable to remove this from the tubing in any of the trials. Saline was placed in the tubing and an average of 10% of the saline was removed by the WaxVac. Only the meniscus of the saline that was touching the tip of the WaxVac was removed from the canal. Finally artificial cerumen was placed in the tubing, however none of it was able to be aspirated from the canal with the WaxVac (Table 3).

To better mimic the external canal in patients, five temporal bones with intact pinnae, canals, and TMs were taken from our temporal bone lab. The same substances tested in the tubing external canal model were also placed sequentially in the external canals of the temporal bones and the WaxVac was tested each with 10 trials. The Paparella PE tube was able to be removed in 10 out of the 50 total trials. The prominence of the anterior canal affected the ability of the WaxVac to remove tube. The powder was easily removed by the WaxVac with an average of 90% of the wax able to be removed over all 50 trials. In none of the trials was the q-tip head able to be removed from the cadaveric canal. In most cases the WaxVac tip pushed the cotton further into the canal. Only 10% of the saline was able to be removed. Only if the saline met the tip of the WaxVac would any of the fluid be aspirated. None of the artificial cerumen was able to be removed from the canals in any of the trials (Table 4).

Discussion

Overall, from these *in vitro* experiments, the WaxVac appears to be less efficacious than clinical cerumen removal. The soft tips of the device and low suction strength do make the device very safe to use and eliminate the risk of canal laceration or TM perforation from q-tips. However, the suction strength created by this device is significantly less than that used in the clinic for cerumen removal from the most common sized suction. The company claims the device is “powerful, yet gentle”, however the latter claim appears to be truer than the former. Additionally, the company’s claim is that the device is “quiet” which appears to be substantiated by our experiments. The noise created by the device is significantly less than clinical suction. Our measurements of the absolute dB level of clinic suction were similar to those previously seen in an *in vitro* trial¹⁵. This suggests that the device would not pose a significant noise exposure risk if the WaxVac is used regularly at home.

The rubber tubing external auditory canal model has obvious limitations since it does not take into account the curvature of the canal or the quality of epithelium and/or hair in the anatomic canal. However as a “first pass” model it was useful because the tubing was clear and the effect of the WaxVac suction could be directly observed. As well we could obtain better estimate of the amount of foreign materials that could be removed. Going into this study we were excited about this device as a way to remove fluid or discharge from the external auditory canal which could be important clinically for children prone to external otitis after swimming or patients with chronic drainage. In the plastic model it was clear that the WaxVac would only remove fluid that could touch the tip of the device. The meniscus in the tube would drop slightly during suctioning with the WaxVac but the majority of the tube remained full of water.

The WaxVac was more useful for removing a PE tube from this model than the cadaveric external auditory canal likely to the lack of curvature. The device was most efficacious in removing the baby powder from the external auditory canal model and the cadaver ears. The goal of this test was to simulate dry skin and wax that frequently builds up in the external auditory canal. No matter how deep or curved the canal a large portion of the powder was removed in all trials. However, this powder is smaller in particle size and weight than skin and may not perfectly predict the response in human subjects. The commercial for this device demonstrates that water is easily removed from the external with the WaxVac. In these experiments only a small amount of saline could be aspirated from the canals, and only when the meniscus was in direct contact with the WaxVac tip. Therefore it appears that this device would not be adequate to dry ear canals after water exposure in patients with a high risk of otitis externa. Additionally, the company recommends using a ceruminolytic to remove cerumen from the canal, but it does not appear that the device would be able to completely remove this fluid if placed in the external canal.

It is our experience that patients generally believe that the WaxVac is intended for removing cerumen as the name of the device implies. However the advertising for the device seems carefully worded to avoid saying that it actually removes wax or cerumen. Instead the claim is that “draws dirt particles and moisture out.” In our tests it was able to remove a small amount of water and small particles of powder thus it may technically meet the marketing claims.

One of the most common foreign bodies seen in the external canal is cotton heads from q-tips. The WaxVac was unable to move these at all from either the external auditory canal model of the cadaver external auditory canals. These cotton tips were then easily removed using a #5 Frazier tipped suction. Additionally in the clinic these cotton tips are usually found impacted in cerumen making it even less likely that the WaxVac would remove these foreign bodies. Finally, the artificial cerumen was also not easily removed with the WaxVac. Even when the tip of the device was in contact with the wax none would enter into the vacuum container. We initially planned to test human subjects but due to the poor efficacy of this device we decided not to pursue further experimentation. Ironically, because the device is not FDA approved for cerumen removal our institutional review board would not allow us to test it with living humans without getting it approved as an investigational device. From these *in vitro* studies it is unlikely that this device would be useful either in the

clinic or for regular home use in patients with frequent cerumen impaction due to the low PSI of the suction.

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Table 1

Measurement of Suction Strength

Device	Average PSI	kPa (SI)
WaxVac	<1	<6.9
From Wall	24	16.5
#3 Frazier Tip Suction	6 to 10	41.4 to 68.9
#5 Frazier Tip Suction	20 to 22	137.9 to 151.7
#7 Frazier Tip Suction	22 to 24	151.7 to 165.5

Table 2

Measurement Noise Produced By Each Suction Device

Device	Average dB at the Meatus	Average dB at the Tympanic Membrane
WaxVac (Low)	75	N/A
WaxVac (High)	85	N/A
#3 Frazier Tip Suction	80	85
#5 Frazier Tip Suction	92	95
#7 Frazier Tip Suction	94	101

Table 3

Efficacy of the WaxVac in the Tubing External Canal Model

Foreign Body	Percent Removal Over 10 Trials
Paparella PE Tube	50%
Powder	60%
Q-tip Head	0%
Saline	10%
Artificial Cerumen	0%

Table 4

Efficacy of the WaxVac in the Cadaveric Model

Foreign Body	Percent Removal
Paparella PE Tube	20%
Powder	90%
Q-tip Head	0%
Saline	10%
Artificial Cerumen	0%