An Open-Access and Inexpensive 3D Printed Otoscope for Low-Resource Settings

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Research Article

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Abstract

Limited access to key diagnostic tools is detrimental to priority health needs of populations. Ear pain, tenderness, itching, and different degree of hearing loss are common problems which require otoscopy as first diagnostic assessment. Where an otoscope is not available because of budget constraints, a self-fabricated low-cost otoscope might represent a feasible opportunity. In this paper, we share the design and construction process of an open-source, 3D printed, otoscope. The prototype was compared to a commercial solution, demonstrating similar overall quality between the instruments.

Introduction

Over the last few years, the widespread use of the Internet as a free source of technical information led to the development of a Maker movement, an intellectual community devoted to the creation of new devices and in advancing the existing ones [1]. In medicine, Makers take advantage of innovative technologies, such as 3D printing [2, 3], micro-soldering, and electronic circuit design, to create assistive technologies that make clinical practice more effective, safer, or cost-effective. The ability to access and to improve “open” projects for free, and the capability of easily customizing them to the final user’s needs, determined the increasing success of Maker’s fabrication laboratories (fab labs) in medicine, especially for prosthetics [4, 5], splints, [6] and preoperative planning [7]. It has also been reported that the role of Maker’s fabrication during health crises, such as the COVID-19 pandemic, has been substantial [8–10].

The purpose of this article is to provide a description of a self-fabricated, affordable, yet meeting high-quality standards, medical otoscope. The cost of commercially available otoscopes remains high, ranging in the hundreds of euros, making them unaffordable in most low-resources medical settings globally. Here we share our design and construction process as an open-source project realized through inexpensive 3D printing, hoping others can replicate and validate our free prototype, where commercial solutions are demanding.

Methods

The otoscope modern forms have undergone little evolution since their invention [11]. The technologies involved are easy to replicate using commonly available electronics and magnifying systems, making them ideal targets for Maker’s reverse-engineering.

Early prototype design and its disadvantages

Our first prototype, which was inspired by otoscopes currently available for sale, included an ABS shell enclosing an AA battery compartment, a small incandescence light bulb, a magnifying lens and an optic-fiber light distribution system (Fig. 1). However, this approach presented several limitations. Some components, i.e., the optic fibers, are not easily available in the market and may require long times for delivery. For these reasons are not commonly used by Makers, preferring as alternative LED light sources.
Another issue was the brightness of the single light bulb we used, that proved to be insufficient when light had to cross “transparent” 3D printed resin. Consequently, we abandoned this design.

**Modular advanced prototype design**

We envisaged that we could significantly decrease costs by adopting a modular approach: designing a multi-use handle, which contains the batteries and alimentation system, compatible with multiple heads that can serve different medical scopes. In this design, heads can be switched, potentially transforming the device in an otoscope, a dermatoscope, or even an ophthalmoscope depending on needs.

We designed the otoscope handle, and head, using TinkerCAD ([www.tinkercad.com](http://www.tinkercad.com), Autodesk Inc., San Rafael, California, USA). Then we manufactured the two items using a Prusa i3 Pro-B (Geeetech Ltd, Shenzhen, China) fusion deposition modeling (FDM) 3D printer, and a Mars Pro (Elegoo Inc., Shenzhen, China) stereolithography (SLA) printer. All these technologies are open source. We used a nickel plating for a facilitated head change and a six LEDs lightning system as light source. We accommodated the LEDs in a ring shape around the visual pathway of the user and placed them as close to the target as possible, to minimize the loss of light through resin (Fig. 2). We designed a 3D printed lens system: SLA printers have a sufficient resolution to print an entire optical block with acceptable results [12]. However, the post processing steps which are needed to produce lenses of sufficient quality are time consuming, and require a specific, optical clear, expensive resin that should be managed by experienced Makers, limiting feasibility. For these reasons we privileged as pragmatic solution the use of a magnification system based on industrial Fresnel lenses. These are inexpensive and can be easily acquired on e-commerce websites.

Then, we designed a second interchangeable head lodging UV LEDs. Wood’s lamp is normally used in dermatology to diagnose fungal infections. Differential diagnosis between fungal and bacterial external otitis poses important challenges to clinicians by sharing common signs. We hypothesized that many fungal infections of the ear canal, as well as some bacterial infections, could show the specific fluorescence patterns recognized during dermatologic examinations [13, 14]. As fluorescence requires direct illumination from short wavelength light, resin diaphragms between the LEDs and their targets were removed. The resulting prototype was able to elicit fluorescence on test materials (e.g. UV polymerizing resin for 3D printing, industrial soap).

Finally, we compared the technical features of our self-fabricated white- and UV-light 3D printed otoscopes with a commercially available otoscope (Sigma F.O. LED, G.I.M.A. S.p.A., Milan, Italy) in terms of magnifying power, field of view, focal distance, intensity, color of light and costs. Brightness provided by the instruments was measured with a professional exposimeter (Bowens flash meter III, Sekonic Electronics Inc, Japan) and converted in lux in order to account for the distance between light source and target.

In order to test the devices, we mimicked real use. We used a semi-transparent, imaging quality millimeter scale, designed for comparing photographic lenses [15]. Then, to recreate the lightning conditions of the...
tympanic membrane, we adapted a 3D model derived from actual CT-scans of the external ear [16]. The object was cut in two parts by a plane passing through the tympanic membrane. In this way, the imaging quality scale was positioned exactly in place of the eardrum at the inner end of the ear canal. The external part, which comprises the ear lobe, was printed using flexible TPU at 10% infill, in order to mimic the typical elasticity of ear tissue and to allow the otoscope tip to fully insert into the ear canal. This recreated the diagnostic maneuvers performed in usual clinical practice. The ear was put atop a base printed using white ABS, forming a fixed support for the millimeter scale (Fig. 3).

Results

In Fig. 4 the otoscope is shown as a 3D rendering and as a picture. 3D final models - head and handle - of the otoscope are freely available at http://bit.ly/3b6DEZq in printer-friendly .stl format. Full building instructions are reported in Appendix 1.

Comparison of otoscopes

Results of the comparison of otoscopes are reported in Table 1.

| Otoscope                  | Magnifying factor | Field of view (mm) | Focal distance (cm) | Brightness (lux) | Color temperature (kelvin) | Cost       |
|---------------------------|-------------------|--------------------|---------------------|------------------|----------------------------|------------|
| - White light, self-fabricated | 3x (6x with a second lens) | 4                  | 0–2                 | 70               | 6700                       | < 5 Euros  |
| - UV, self-fabricated     | 3x -(6x with a second lens) | 4                  | 0–2                 | 7                | n.a.                       | < 5 Euros  |
| - Gima                    | 3x                | 4                  | 0–3                 | 40               | 5000                       | Around 100 Euros |

The magnifying factor of our self-fabricated otoscope was determined in 3x power, which was comparable to the commercial otoscope. However, our design includes the possibility of implementing a second Fresnel lens in the central part of the otoscope head. This could increase magnification power up to 6x, depending on the power of the lens chosen. In other dimensions we registered a substantial overlap between the two devices, while the commercial solution has a better ability to focus on distant objects. Since the length of the ear duct is about 2.5 cm and the tip of the head of the otoscope is inserted in the ear, the capability to focus at 2 cm from the tip should provide a clear vision of the eardrum. UV light was seemingly less intense than white light. This was expected since the amount of visible light provided by UV LEDs is limited. When a fluorescent material is illuminated, however, the amount of colored light reflected is sufficient for an easy visualization of the target. Color temperature between the white-light
prototype and the medical device resulted similar, since both implemented a similar LED technology. The costs of the two devices differed by more than tenfold, the self-fabricated otoscope with one Fresnel lens costing about 5 Euros. In Appendix 2 we provide a detailed reporting of costs associated with self-fabrication of an otoscope.

Quality of vision

Both otoscopes were able to clearly see the gaps between the smallest test lines, which are placed at a 0.2 mm distance. This result demonstrates similar overall quality between the instruments, largely sufficient to clearly see the malleus and the vast majority of lesions of the tympanic membrane (Fig. 5).

Safety

Devices used in clinical practice must meet precise safety criteria. Employed materials should be washable and antibacterial. FDM 3D prints are not impermeable nor sterilizable. However, the otoscope tip is not directly at contact with the patient’s skin. The prototype makes use of certified, disposable specula as usual, which are fixed in a specific location of the tip. We also used a washable tape on the handle to improve grip and to allow easy decontamination. Circuits should be certified and waterproof to limit risks (e.g., short circuit). Otoscopes use a low voltage (3V) which is reassuring against major electric shocks.

Discussion

Otoscopy is an important diagnostic procedure. The main diagnoses associated with its use are cerumen impaction, acute otitis media, and movements and lesions of the tympanic membrane. These problems are frequently seen in general practice, pediatrics and otorhinolaryngology. Severe complications of otitis media, including mastoiditis, intracranial abscesses, meningitis and sinus thrombosis, are rare but early diagnosis is necessary in optimizing prognosis [17]. Our key assumption moving us in developing a low-cost otoscope is that otoscopes are not as frequent as they should be in community and hospital settings. One potential barrier might be the relatively high cost of these devices, particularly in low-resource settings where affordability is a key driver. We did not find data in the medical literature that supported or contradicted our hypothesis. Therefore, we developed a low-cost otoscope platform, with technical features that support the diagnosis of common ear problems. Our self-fabricated otoscope represents a small opportunity, as it should be considered a micro-scale production serving single clinicians or underserved communities.

When compared with commercial products, self-fabricate otoscopes have important limitations. Our design is rough, and this might have implications in terms of usability and user experience. Performance does not depend entirely on the quality of design, but also on the practical skills of those in charge of the assembly. When building our otoscope, we observed that even a millimetric difference in LED positioning resulted in a noticeable change in light focus, which translated during tests in a consistently darker or brighter eardrum. Therefore, it is important to check every assembly directly with final users, in order to
adapt the products to the clinicians’ needs and ensure the otoscope meets the standards required in clinical practice. Registered medical devices have to meet strict safety criteria to be approved for clinical use. The Maker's approach to technology does not follow industrial standards, which may constitute an insurmountable barrier when trying to reach a certification of the production process. However, quality of vision of our otoscope was comparable to the performance of a high-standard product.

The Makers’ community has an important role also in exploring potential improvements of devices. We were able to rapidly design and develop an UV otoscope. These devices are available in the market but are rare and procurement might be difficult. Mycotic external otitis is a recurrent problem in general practice. Therapy is largely empirical and prone to mistakes, due to clinical features overlapping with bacterial external otitis. A precise diagnosis currently requires microscopical examination of the fungal infection in the outer ear. The opposite is also true. Excluding an otomycosis will limit the use of antifungal therapies. This simple instrument could provide a faster and direct diagnosis, supporting better treatment decision-making.

There could be some interesting progress of 3D printed instruments. Some attempts have been made to connect otoscope to a smartphone camera facilitating telemedicine and remote monitoring [18, 19]. However, this approach also raises questions. Plastic covers could provide significant damage if used improperly; the quality of the examination is highly dependent on technical specifications of the smartphone cameras and on their relative positioning to the adapter, which should be customized for every model. Makers should devote their time and expertise to work together with health professionals, hospitals and universities, avoiding doing themselves medical actions. At present time Fab Labs are usually installed in technical institutes, while their partnerships with health care institutions are still limited. The potential of the cooperation between these actors has to be fully exploited and supported by dedicated research resources.

**Conclusion**

Low access to key diagnostic tools is detrimental to priority health needs of populations. Ear pain, tenderness, itching, and different degree of hearing loss are common problems which require otoscopy as first diagnostic assessment to be considered. Where an otoscope is not available because of budget constraints, a self-fabricated low-cost otoscope might represent a feasible opportunity.

**Declarations**

**Conflict of Interest Statement**

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

**Author Contributions**
All authors contributed to the conception and design of the study. MC designed and assembled the otoscope and dermatoscope. MC and LM drafted the manuscript, critically revised and gave final approval for publication of the final report.

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**Ethics Statement**

Not applicable

**Data Availability Statement**

All data, building instructions, and 3D printer files for this study are open source and can be downloaded for free from http://bit.ly/3b6DEZq.

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Figures
Figure 1

The first prototype, inspired by currently available otoscopes
Figure 2

3D representation and picture of the adopted LED lightning system.

Figure 3

3D representation and picture of the model of the external ear used for otoscope testing.
Figure 4

3D model of the prototype and visual comparison with a commercial otoscope.

Figure 5

Comparison using a photographic lens quality scale (left: prototype; right: medical device).

Supplementary Files
This is a list of supplementary files associated with this preprint. Click to download.

- Appendix1.docx
- Appendix2.docx