Validation of an effective, low cost, Free/open access 3D-printed stethoscope

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# Abstract

The modern acoustic stethoscope is a useful clinical tool used to detect subtle, pathological changes in cardiac, pulmonary and vascular sounds. Currently, brand-name stethoscopes are expensive despite limited innovations in design or fabrication in recent decades. Consequently, the high cost of high quality, brand name models serves as a barrier to clinicians practicing in various settings, especially in low- and middle-income countries. In this publication, we describe the design and validation of a low-cost open-access (Free/Libre) 3D-printed stethoscope which is comparable to the Littmann Cardiology III for use in low-access clinics.

# Introduction

Since its introduction in 1819 by René Laennec1, the acoustic stethoscope has been an integral part of clinical medicine. Despite the lack of  major structural design innovations over recent decades, modern stethoscopes can be an expensive part of the physician’s armamentarium, often costing several hundred US dollars. The high cost of modern stethoscopes remains a significant barrier to physicians practicing in some developing countries, where few affordable high-quality options exist. Traditionally, the selection of a stethoscope often does not involve the acoustic properties of the model2 with most users selecting an expensive brand-name stethoscope such as the Littmann Cardiology III. . However, previous studies which have compared stethoscope brands have concluded that cost does not correlate with better diaphragm sound quality at relevant frequencies, compared with lower-cost alternatives3,4. While other 3D printed stethoscope models that would be low-cost to produce can be found online, we are not aware of any that have been used clinically or research-validated.

Numerous groups have previously attempted to standardize methods to determine the efficacy of acoustic stethoscope models2,5–9, but currently no accepted standardized modality exists. Consequently, the performance of any acoustic stethoscope is little more than the manufacturer’s claim or the subjective opinion of the user. Some groups have attempted to objectively compare acoustic stethoscope models and currently two competing methods of measuring frequency response exist. The first method uses air coupling to transmit frequencies 2–6 while the other uses a phantom to simulate vibrations of the chest wall8,10,11. These methods allow investigators to quantitatively compare the sensitivity of a stethoscope model compared with another.

In this article, we describe the construction and validation of a low cost, Free/open access 3D printed acoustic stethoscope - referred to here as the ‘Glia model’. The aim of this research is to give low budget health care systems affordable access to an effective stethoscope for a cost under $5 USD. To achieve this, we utilized 3D printing, a technology which is advancing rapidly and becoming increasingly inexpensive. The flexibility of 3D printing technology also allows users to augment our design to fit their own needs. We also attempt to make our validation methods accessible and low cost, allowing others to validate our design independently with ease.

# Methods

## ***Stethoscope design***

Design of the Glia model 3D printed stethoscopes was done using Free/Open Source Software (FOSS) so as to keep costs low and allow others easy access to examine and modify code. CrystalSCAD (https://github.com/Joaz/CrystalScad, Germany) was used to create digital models of the stethoscope head, two ear tubes and an ear plug mold due to its ability to create complex shapes in a way that was not possible with OpenSCAD at the time. OpenSCAD (http://openscad.org, Canada) was used to create digital models of the Y-piece, stethoscope ring and spring (Fig 1A). Since its original creation as documented in this paper, the eartubes have been completely ported to OpenSCAD. The stethoscope head is presently a hybrid of CrystalSCAD and OpenSCAD. As the ear plug mold is no longer used in our current production process, its archived version also remains in CrystalSCAD.

Other accessory hardware is required, such as the plastic diaphragm, tubing, ear plugs (optional if the mold is not used) and steel spring (optional if the printed spring is not desired). These can be found in Table 1.

**Figure 1. Computer aided design and assembly of the 3D printed stethoscope.** Digital models of the 3D printed stethoscope parts are shown in Figure 1A. From left to right: the head, Y piece and ear tube are shown. An earplug mold design is also shown in Figure 1B. Each part was 3D printed in ABS, with the assembled stethoscope is shown in Figure 1C using the bill of materials listed in Table 1. Figure 1D shows an updated version of the stethoscope with commodity earbuds replacing the original silicone earplugs.

All print designs can be downloaded for free at https://github.com/GliaX

## ***Stethoscope printing and assembly***

Each part was printed on a commodity 3D printer (Prusa Mk II, 1.75mm filament diameter, 0.4mm nozzle diameter, no scaffolding or support) using acrylonitrile butadiene styrene (ABS) with 100% infill as indicated and 0.2mm layer height. A 40 cm silicone 12mm outer diameter (OD), 8mm inner diameter (ID) tube was attached between the stethoscope head and the larger bore of the Y piece. Two 9 cm silicone 6mm OD, 4mm ID tubes were attached between the smaller bore of the Y piece and the ear tubes. A diaphragm was cut from a Staples brand PVC report cover (Swing-lock report cover, clear with black spine; UPC 718103160223) by turning a sharp caliper and creating a circular diaphragm with a 40mm diameter. This diaphragm was attached to the stethoscope head with a slotted rubber O-ring. However, in more recent models and due to difficulty finding such O-rings, we have replaced the O-ring with a printed ABS ring. Spring steel was cut and crimped to form the ear tube spring. In more recent models, due to difficulty manipulating and acquiring spring steel, we have used a printed ABS truss that has some spring properties by design.

In the original design, silicone (SF13 2k-Silikon, Silikon Fabrik, Batch Nr 180415, Shore A 13) was mixed added to the ear plug molds (Fig 1B) for 8 hours. The mold was separated and the silicone ear plugs were attached to the ear tubes. In the present model in use at the time of publication, these ear plugs are replaced by generic earbuds from commodity earbud-style headphones, as they were found to be widely available and of negligible cost. The final construction of the original model can be seen in Fig 1C. The final construction of the current model can be seen in Figure 1D.

Costs in Table 1 were calculated using the density of ABS (1.03g/cm3) and the filament length, which is calculated by the printer driver. We assumed the price of 10 lbs (4.54 kg) of ABS pellets to be 31 USD.

***Acoustic transfer***

The frequency response of Glia model stethoscopes, compared with the Littmann Cardiology III, was determined using an experimental setup modelled from a phantom-based frequency response setup previously described8. A latex balloon filled with 2L (2000g) of water was used as a phantom and each stethoscope was applied to the surface by hand. Phantom excitations were supplied by an external vibrating speaker which was placed in contact with the balloon and sound was played at 86 Hz intervals between 0 and 5000 Hz (white noise) for 15 seconds. The output of each stethoscope was recorded by a microphone which was placed in a silicon tube attached to the stethoscope head for spectral analysis. Spectral analyses such as these have been used successfully in the past to analyze breath sounds recorded from individuals with lung pathology12. The simplicity of this design was intended to allow other users to validate our design independently.

# Results

After many iterations, we successfully designed a working stethoscope, known as the Glia model (Fig 1), at a total cost of $2.83 USD using recycled ABS pellets. A bill of materials and cost breakdown can be found in Table 1. Commercial ABS filament was assumed to cost $30/kg.

|  |  |  |  |
| --- | --- | --- | --- |
| Item | Dimensions | Cost using ABS pellets (USD) | Cost using commercial ABS (USD) |
| Stethoscope head | 44.30mm x 62.45mm x 17.80mm | $0.206 | $0.91 |
| Stethoscope Y piece | 70.89mm x 29.94mm x 9.00mm | $0.09 | $0.12 |
| Stethoscope ear tube | 170.79mm x 83.62mm x 5.80mm | $0.07 | $0.25 |
| Stethoscope ring | r = 21mm, h = 7mm | $0.012 | $0.03 |
| Stethoscope spring | 91.25mm x 111.62mm x 15.05mm | $0.032 | $0.31 |
| Silicone tubing | 40 cm – 12mm OD, 8mm ID / 2x 9 cm – 6mm OD, 4 mm ID | $1.93 | $1.93 |
| Diaphragm | r = 20mm | $0.06 | $0.06 |
| Ear plugs with mold | n/a | $0.43 | $0.43 |
| Total | | $2.83 | $4.04 |

**Table 1. Bill of materials for the Glia model stethoscope (100% infill)**

We compared the Glia stethoscope to the Littmann Cardiology III using a phantom, as described in the methods. At all frequencies tested, the Glia model performed similarly to the Cardiology III (Fig 2A). The difference in attenuation (dB) of the Glia model to the Littmann Cardiology III is shown in Figure 2B with values greater than 0dB indicating that the Glia attenuated less sound.

**Figure 2. Calibration and comparison of 3D printed Glia model stethoscopes to the Littmann Cardiology III.** Stethoscope output responses were measured using the equipment setup described in the methods. Each stethoscope model recorded input sound at multiple frequencies and the change in amplitude between input and recorded sound was documented (lower log attenuation is better) for each stethoscope (Figure 2A). The decibel difference in attenuation (Glia minus Littmann) is shown across all frequencies tested where values above 0dB indicate the Glia model attenuated less sound (Figure 2B).

# Discussion

The stethoscope is one of the most widely used instruments in modern medicine, allowing clinicians to detect subtle changes in heart, lung and vascular sounds. Despite a lack of major innovation in design or fabrication since Dr. Littmann patented his stethoscope in 1963, the acoustic stethoscope remains an expensive piece of equipment that creates a cost barrier for physicians practicing in developing nations. This study aims to create a high quality acoustic stethoscope at a cost under 5 USD.

The quality and intensity of the sound reaching the earpiece from the diaphragm is dependent on nearly every piece of the stethoscope as well as the physiology of the user. These variables have been previously well summarized3 and include the size and volume of the bell7,13; hardness of the inner cavity of the bell14; improperly fitted components allowing air leaks and loss of sound13; the thickness, size and tautness of the diaphragm and the interior smoothness, rigidity, length and diameter of the tubing15,16. Additional user related factors include improperly fitted ear pieces that allow air exchange4,13,16,17; anatomical variations of the auditory canal of the user17; background noise18 and training19. Many of these variables needed to be considered when designing the Glia model stethoscope, particularly physical properties such as channel diameter through the 3D printed parts and infill percentage, which ultimately determines the density and hardness of the parts. We also tried several printing materials including poly-lactic acid (PLA) and ABS. Of particular challenge was creating the ear tubes to ensure that they could universally accept either molded ear plugs or purchased plugs, as well as creating the interface between the ear tube and the spring to prevent rotation when the ear tubes were pulled apart.

As previously mentioned, no standard method of determining the acoustic response of stethoscope models currently exists. Previous studies have attempted to objectively quantify stethoscope efficacy8,10,11,13 and previous comparisons between brands indicate that no significant correlation between cost and quality exists3,4. However, there may be some subjective decrease in efficacy when using low-quality disposable stethoscopes19. ]. The current cost of the Littmann Cardiology III is $221, which is comparable to other brand name stethoscopes such as the Welch Allyn Harvey Elite ($190) and less expensive than the new Littmann Cardiology IV ($270). Ultimately, however, the usefulness of any stethoscope is dependent on user preference and so we encourage those with access to a 3D printer to build and test our model independently. The protocol listed in the methods has been purposely designed to be replicable using commonly available materials. Any printer capable of printing in ABS should be able to create our device, including RepRap printer designs used by our group20. Printers of sufficient quality and reliability can be easily obtained or built internationally for less than $1,000. X

The Glia model stethoscope is a class I medical device according to Health Canada and the FDA. In Canada, a non-profit company was incorporated to manufacture stethoscopes and has received a Medical Device Establishment Licence from Health Canada. The stethoscope is in clinical use in London, Canada at the London Health Sciences Centre. It has also been trialed and was gradually introduced in the Gaza strip, an area with extremely limited access to medical devices. Hospitals in Gaza are self-sufficient producers of these stethoscopes.

This project was the first of several planned open access projects. Future plans include expanding access by providing validated models of other pieces of medical equipment, including pulse oximeters and ECG machines, allowing health institutions to sustainably produce affordable, high quality equipment for many clinicians.

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