A Development of Sensorized Ear Model for New Behind-the-ear (BTE) Hearing Aid

Ramona B. Damalerio*
*Institute of Microelectronics (IME), Agency for Science, Technology and Research (A*STAR)*
Republic of Singapore
damaleriom@ime.a-star.edu.sg
ORCID 0000-0003-3119-9545

Wei Da Toh
*Institute of Microelectronics (IME), Agency for Science, Technology and Research (A*STAR)*
Republic of Singapore
toh_wei_da@ime.a-star.edu.sg
ORCID 0009-0005-2275-9696

Rui Qi Lim
*Institute of Microelectronics (IME), Agency for Science, Technology and Research (A*STAR)*
Republic of Singapore
limrq@ime.a-star.edu.sg
ORCID 0009-0007-7081-9918

Ming-Yuan Cheng*
*Institute of Microelectronics (IME), Agency for Science, Technology and Research (A*STAR)*
Republic of Singapore
chengmyn@gmail.com
ORCID 0000-0001-6322-1255

Abstract*— Behind-the-ear (BTE) hearing aids have become indispensable devices for individuals with hearing impairments. However, one common issue faced by users is external ear discomfort or pressure points caused by improper fitting or dimensions of the device. Comfort remains a critical factor in user satisfaction and long-term usage. Currently, there is no available ear model device that measures and quantifies the pressure points or pain points on the external ear. Comfort level assessment is qualitative and conducted through user survey. This paper aims to quantify the pressure points through development of sensorized ear model. Quantifying the pressure points can aid in optimization of the hearing aid tubing length and bend and correlate them to comfort level during hearing aid fitting. Five (5) MEMS-based force sensors that each has a resolution of 10 mN are assembled on polyimide flexible printed circuit board (FPCB) substrates that is 3.0 mm in width, 150 mm in length, and 0.15 mm in thickness. Each force sensor was tested from 0-500 mN on a micromanipulator stage with a force gauge set-up. To read the analog output of each sensor, a separate reader circuit board is fabricated. AD623 single-supply instrumentation amplifier, passive components, FPC connector, and input/output wires are assembled on the circuit board. The force sensors are characterized on PCB and further tested on FPCB before integration with silicone ear model. The measured average output voltage at zero force load (0 mN) is 537 mV on PCB and 589 mV on FPCB. The sensors can read and differentiate 10 mN (1.0 g-f) iterations; this coincides with the resolution of the force sensor at 0.01 N (10 mN). The measured sensitivity is 2.2 mV/mN. The force sensors also exhibited high linear relationship between the input force load and the output voltage. Five different BTE hearing aids are utilized as force loads which were subsequently quantified, on both left and right silicone ear models.

Keywords—sensorized ear model, MEMS force sensor, BTE hearing aid, flexible PCB

I. Introduction

Hearing loss affects over 5% of the global population or 430 million people, of which 34 million are children. It is estimated that by 2050, 1 in every 10 people are at risk of developing some degree of hearing loss that is disabling. Over 1 billion young adults are at risk of permanent hearing impairment due to unsafe listening practices such as exposure to loud noises or prolonged listening to loud music through earphones [1] [2]. Hearing loss can happen any time during life – from before birth to adulthood. It may be mild, moderate, severe, or profound, and may affect one or both ears. Those with profound hearing loss often has very little or no hearing and use sign language to communicate. Those with mild to severe hearing loss benefit from cochlear implants [3], assistive listening devices (ALDs) [4], or hearing aids [5].

Hearing aid is a small device that is worn either in or behind the ear to amplify sound for people with hearing impairment. Hearing aid is composed of speaker, microphone, amplifier circuit, and battery. It has various styles and weight depending on the severity of hearing loss and needs or lifestyle of the user. Behind-the-ear (BTE) hearing aid is a common solution to address hearing impairment. It is the most preferred style by approximately 75% of the hearing aid users [6]. Despite the effectiveness of BTE devices in improving hearing abilities, users often experience discomfort and pain or pressure points associated with improper fitting or dimensions and prolonged wear, particularly on the external ear. The design of the device, materials used, and final placement of hearing aid play crucial roles in alleviating these pressure points on the external ear. Quantifying these pressure points and correlating them to comfort level enables optimization of the device in terms of casing size, tubing length and bend, among other factors. By enhancing external ear comfort, user acceptance and adherence to hearing aid usage could increase [7], ultimately improving overall quality of life for individuals with hearing loss.

This work explores to quantify the pressure points or pain points from BTE hearing aid during fitting or final placement on external ear. To do this, a silicone ear model is sensorized to detect load, i.e., it is integrated with force sensors that are assembled on polyimide flexible printed circuit board (FPCB). Aside from the sensitivity or resolution of the force sensor, a small footprint is also necessary. There are various types and form factors of force sensor for load detection. Some are a combination of one-part interdigitated silicon platform and one-part conductive FPCB and has an overall thickness of less than one (1) millimeter [8]. Some are made of two-part FPCB stack-up where in the top side is printed with conductive ink and the bottom side is etched with interdigital metal traces. They are either in a wide array format [9] [10]or in a single micrometer-size profile [11] [12] . For this work, micro-electromechanical system (MEMS)-based force sensors are employed. The load

*Corresponding authors

(force) is detected by the piezoresistive element fabricated using MEMS manufacturing processes. The resolution is less than 0.01 N, and the overall form factor is within 1.0 mm^3.

The ear model utilized is made of silicone rubber and is commercially available. The ear model selected is typically utilized for medical training and for ear piercing training, thus the hardness is as close to actual ear and skin as possible. Using silicone rubber also ensures that the BTE hearing aid will sit securely behind the ear model during testing. FPCB substrate is utilized for flexibility and bendability to follow the contour of the ear model during integration.

II. Design Concept and Fabrication

The design concept of the sensorized ear model is shown in Fig. 1. A silicone ear model is integrated with polyimide flexible printed circuit board (FPCB) that is assembled with five (5) MEMS-based force sensors. The FPCB is placed and attached at the gap between the external ear and the side of the head. The end of FPCB will be connected to the reader circuit. When a BTE hearing aid is placed on the sensorized ear model, the weight (force load) of the hearing aid is distributed and measured by the MEMS force sensors. The force sensor output (mV) will be correlated to force load (mN). The pressure points at the location of the hearing aid tube bending and length will be quantified.

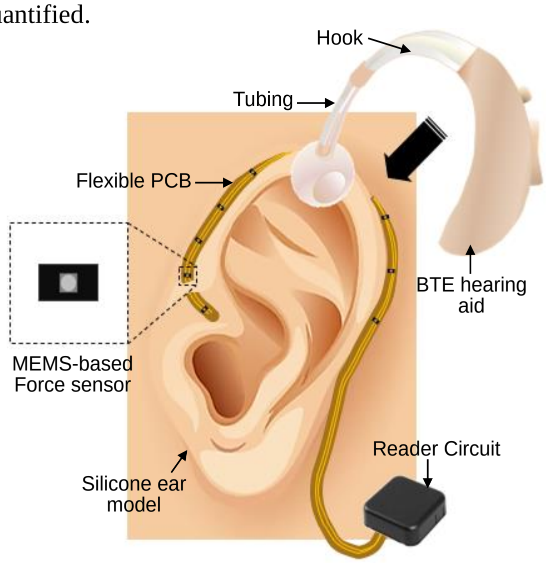


Fig. 1. Proposed sensorized ear model consists of silicone ear integrated with MEMS-based force sensors on flexible PCB. The force sensor detects and reads the force load of behind-the-ear (BTE) hearing aid. The reader circuit can store, and export data read by each sensor.

A. *Silicone ear model*

The ear model utilized is commercially available and is made of silicone rubber with hardness Shore 00-30. The groove behind the ear where the FPCB will be attached on has an average width of 3.0 millimeter. The orientation of the silicone ear model is not relevant since this work utilizes hearing aids that are compatible for both left and right ears.

B. *Polyimide Flexible PCB*

The substate of the force sensors used for this work is a 2-layer polyimide FPCB that is 150 µm in thickness. The maximum width is dependent on the gap width or groove behind the ear, which is a maximum of 3.0 mm. The length is 150 mm and can be fabricated longer when necessary. The FPCB can accommodate a series of five (5) MEMS force sensor chips. Silicon stiffeners, each with size of 1.50 mm x 0.85 mm x 0.10 mm, are placed at the bottom of each MEMS chip during integration with the ear model. The output is designed for FPC connector of the readout circuit.

C. *MEMS-based Force Sensor*

The requirements for the force sensor are (1) small footprint to fit the FPCB width of 3.0 mm, (2) able to detect as low as 1.0 g-f or 10 mN force load, and (3) can be attached to FPCB. For this work, the minimum force load is based on the weight of the lightest hearing aid available on hand, which is 5.0 grams. Direct division of weight by the five (5) force sensors that are assembled on FPCB is assumed, thus resulted to 1.0 gram (10mN) per sensor.

The force sensor utilized is HSFPAR007A MEMS force sensor from Alps Alpine Co. Ltd. The force detection (change in resistance) happens when a strain (force load) is applied on the piezoresistive element of silicon diaphragm. The output of the sensor is analog voltage. The sensor profile is 1.50 mm x 0.85 mm x 0.68 mm and fits well within the 3.0 mm FPCB width. The datasheet states that the force sensor has a high sensitivity of less than 0.01 N (10 mN). Other basic information of the MEMS force sensor is listed in Table1.

D. *Sensorized ear model.*

After the silicone ear model and MEMS force sensors are identified and FPCB is fabricated, integration of these three components is performed. First, the MEMS force sensors are assembled by reflow on FPCB. Then, the ear model is wiped cleaned and dried with isopropyl alcohol before FPCB attachment. Lastly, Dow Corning 3140 RTV coating is utilized to attach and integrate the assembled FPCB with the silicone ear model. The RTV coating is selected after trying several epoxies but does not permanently attach the FPCB on silicone ear model (e.g., UV light-curable epoxy with hardness Shore A40). Two-pass curing process is employed. The parts are cured at room temperature for 24 hours at first pass and additional 24 hours at second pass. The thickness of the coating was done up to half of the force sensor thickness of 0.68 mm.

Two different ear models are integrated with MEMS force sensors, i.e., left ear and right ear. The difference only is the starting point of the first sensor, S1 (closest to ear opening). As shown in Fig. 2(a), the first sensor of the left ear model is located above the ear opening while in Fig. 2(b) it is directly at the level of ear opening of the right ear. This makes the right ear read more on the tubing portion while the left ear reads more on the casing portion.

Visual inspection and FPCB peel-off test (from the silicone ear model) were conducted after first and second coatings. Fig. 3 shows the sensorized ear model after integrating all the components. It should be noted that the FPCB can be designed and populated a few force sensors as necessary. For this work, we focused on five sensors that are located at the tubing bend and BTE hearing aid bottom casing.

TABLE I. MEMS FORCE SENSOR OTHER INFORMATION

S/N	***Part No.: HSFPAR007A***	
	Description	***Specification Range***
1	Function	Loads Detection
2	Force range	0 to 8N
3	Supply voltage	1.5 to 3.6V
4	Max load rating	55N
5	Operating Temperature Range	-40℃ to +85℃
6	Sensitivity	2.5mV/N
7	Linearity	<2% FS

E. Reader Circuit

A reader circuit is necessary to read the analog output voltage of the sensors during force load testing. A 70 mm x 25 mm rigid PCB is fabricated to accommodate the components needed. The assembly comprises of AD623 instrumentation amplifiers, decoupling capacitors, resistors, FPC connector, and input/output test points. The FPC connector compatible with the FPCB pads of the force sensors is placed at north of the PCB. All test points are placed at south of the PCB. The decoupling capacitors are placed as close as possible to each amplifier. No component is placed at the bottom layer of the PCB. The reader circuit facilitated the reading of either one sensor or all five sensors altogether.

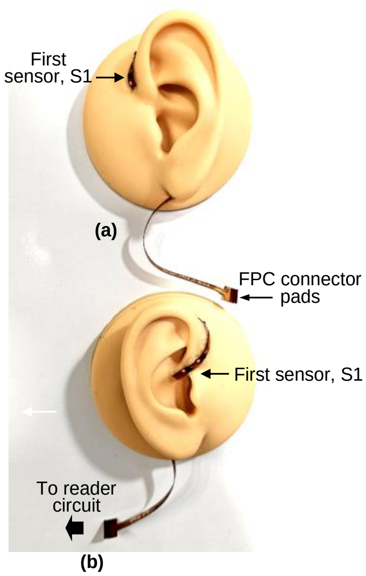


Fig. 2. Two ear models are assembled. (a) The left ear has the first sensor S1 located above the ear opening while (b) the right ear has the first sensor S1 located directly at the level of the ear opening.

III. EXPERIMENTAL RESULTS AND DISCUSSION

A. Characterization of MEMS Force Sensor

Characterization of the MEMS force sensor is conducted individually. A rigid PCB is designed and fabricated, and force sensor is attached on it together with AD623 industrial amplifier, a 0.1 µF capacitor, and resistors with values of 4 KΩ, 10 KΩ, and 3 KΩ. The characterization set-up is shown in Fig. 4. The whole PCB assembly is placed on micromanipulator stage of the force test set-up. A dual input power supply Agilent E3646A (Keysight Technologies) is utilized to input 2.2 V to the sensor and a digital multimeter Agilent 3.4410A (Keysight Technologies) is attached to the output wires of the sensor to measure the output voltage in mV DC. The micromanipulator stage with z-axis movement is slowly raised (one rotation equals 0.5 mm) so that the MEMS sensor touched the flat tip of M5-012 force gauge (Mark-10, U.S.A.). The output voltage is measured when the force load increases from 0 mN up to 500 mN, with 10 mN iterations.

Results showed that each force sensor can detect the targeted maximum load for this study, which is 500 mN. The sensitivity of the three (3) different force sensors tested is 223.89 mV/N. Fig. 5 shows the linearity of the MEMS sensors tested.

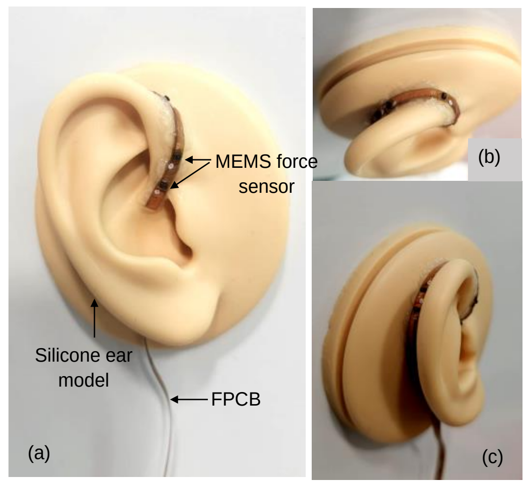


Fig. 3. Photo of the sensorized ear model (a) side view (b) top view and (c) back view. The RTV coating is transparent to show the FPCB length from the external side of the ear up to behind the ear.

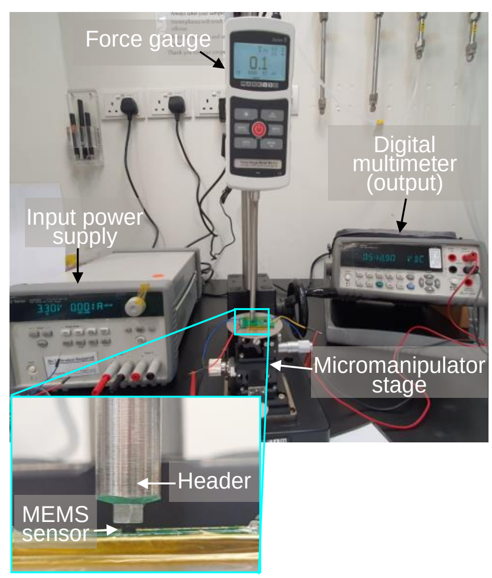


Fig. 4. Experimental set-up of the MEMS force sensor characterization. The force sensor is raised to touch the flat tip of force gauge (labeled as header) to readout the corresponding output voltage.

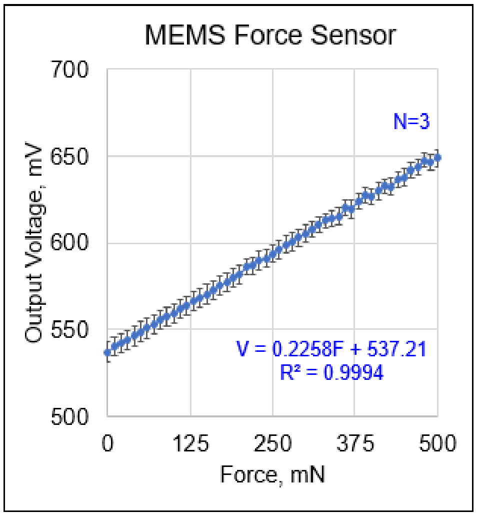


Fig. 5. Graph showing the selected MEMS force sensor is highly linear. At 0mN, the expected output voltage is approximately 537.2 mV.

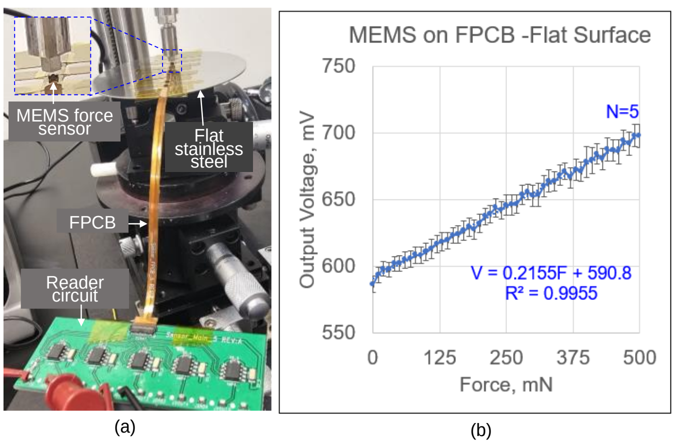


Fig. 6. (a) Test set-up of FPCB with MEMS force sensor on flat stainless-steel stage of micromanipulator. The reader circuit for this test can read either one sensor or five sensors altogether. (b) Graph showing a highly linear response of the sensor to applied force load. At 0mN, the expected output voltage is approximately 590 mV.

B. Testing in FPCB Substrate

After the characterization of the MEMS force sensors and verification that a minimum force load of 10 mN can be detected, testing using the FPCB substrate follows. Five (5) force sensors are assembled on the FPCB. The same input power supply, force gauge set-up, and output multimeter are utilized. The difference this time is the reader circuit can read either an individual sensor or five sensors altogether. Shown in Fig. 6(a) is the set-up of the FPCB on the flat stainless-steel of the micromanipulator stage. The segments of the FPCB which do not have the force sensors are taped down on the stainless-steel stage. The same force gauge header which has a tip dimension of 2.0 mm x 2.0 mm is used. As the micromanipulator move up, the MEMS force sensor establishes contact with the force gauge. Both the force load value and output voltage are read. Fig. 6(b) shows the readings of the five force sensors. It shows that the force sensors exhibit good linearity of the output voltage as the force load increases. The expected output of the sensor without load is approximately 590 mV, with a sensitivity of 222.76 mV/N.

C. Using Hearing Aid

After the completion of the force sensor verification on FPCB substrate, test using different BTE hearing aid designs follows. For this work, five different types of BTE hearing aids are used. They differ in tubing size and length; casing material and shape; and ear plug size and shape. Their individual weight ranges from 5.81 grams to 9.75 grams. As shown in Fig. 7, each hearing aid have red dots and label S1. The red dots represent the force sensor on silicone ear model that touches the hearing aid. S1 means the location of first force sensor and is close to ear plug. The sensors are placed in serial, which means the last sensor is S5, farthest from ear plug. It is observed that for hearing aid sample number 5, the force sensor S1 is not used. This is due to hearing aid tubing length that is too short.

The characterization on PCB and testing using FPCB substrate showed that there is a linear relationship between the output voltage in response to change in force load. The sensitivity of the MEMS force sensor from two previous tests is the same at approximately 0.22 mV per mN. Fig.9 shows the output voltage response of the five hearing aids. From the graph it shows that the sensors S2, S3, and S5 have higher output voltage.

The output voltage readings need to be converted to force load values. By using the linear equation from the testing of MEMS force sensors using FPCB substrate, the force load values corresponding to the output voltage can be computed. The equation is $V_{out} = 0.2155F + 590.8$ (or initial value of the force sensor at no load, V_i); or $F = (V_{out} - V_i)/0.2155$. The output voltage of sensors without load for left ear model is 590 mV while right ear model is 588 mV. Table II summarizes the results of the readings in terms of force load. The data shows that sensors at locations near the joining between the hearing aid casing and the hook read higher force load. This is also due to the curvature and stiffness of the hook.

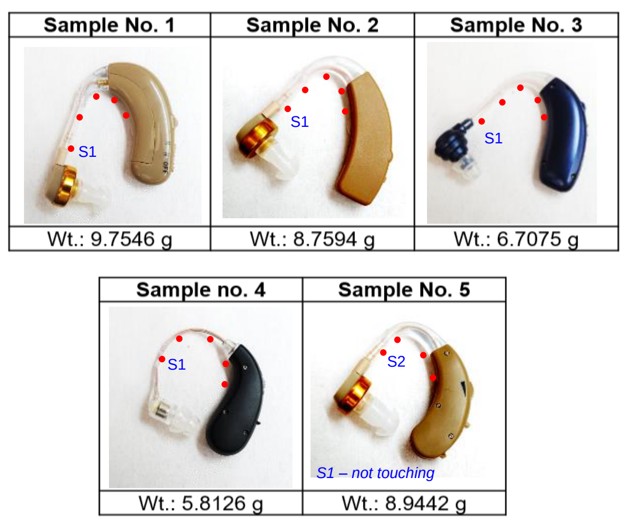


Fig. 7. Several types of behind the ear (BTE) hearing aid. Red dots represent the location of the force sensor on the silicone ear model. S1 means force sensor no.1. Sample no. 5 does not have S1 due to its too short tubing length.

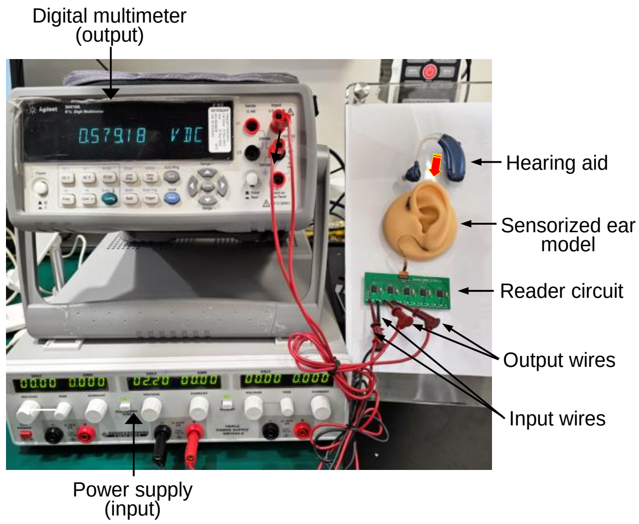
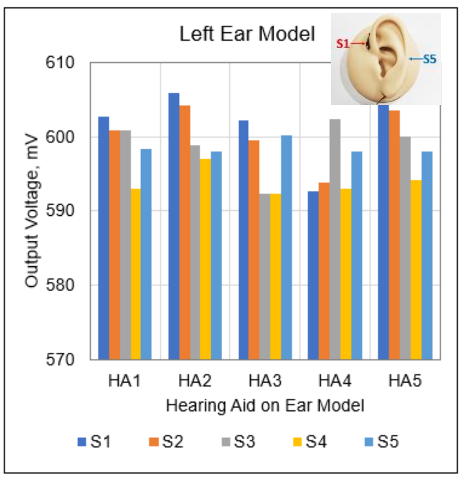
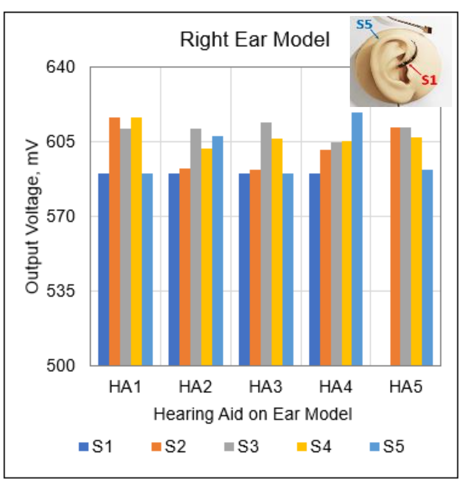


Fig. 8. Experimental set-up using sensorized ear model to measure force load from hearing aid.



(a)



(b)

Fig. 9. Output voltage of MEMS force sensor from (a) left ear model and (b) right ear model. The data shows that sensor locations S2, S3, and S5 have higher output voltage.

TABLE II. FORCE LOAD READINGS FROM HEARING AID

Hearing Aid Info	***Hearing Aid 1***	***Hearing Aid 2***	***Hearing Aid 3***
			
	9.7546 g	*8.7594 g*	*6.7075 g*
Sensor No.	**Left Ear - Hearing aid force load, mN**		
1	58.7	73.4	56.5
2	50.5	65.8	44.5
3	50.2	41.2	11.1
4	13.8	32.8	10.5
5	38.8	37.2	47.2
Sensor No.	**Right Ear - Hearing aid force load, mN**		
1	9.3	9.3	9.3
2	132.9	20.6	19.2
3	106.7	106.9	121.5
4	132.9	65.0	86.6
5	9.3	92.8	9.3
Hearing Aid Info	***Hearing Aid 4***	***Hearing Aid 5***	
			
	5.8126 g	*8.9442 g*	
Sensor No.	**Left Ear - Hearing aid force load, mN**		
1	12.7	70.0	
2	17.7	62.9	
3	57.5	46.6	
4	14.0	19.2	
5	37.2	37.4	
Sensor No.	**Right Ear - Hearing aid force load, mN**		
1	9.3	No contact	
2	61.6	111.4	
3	77.8	110.2	
4	79.8	88.2	
5	143.1	18.6	

Fig. 8 shows the experimental set-up. The FPCB of the sensorized ear model is connected to the reader circuit. The input wires of the reader circuit are supplied with 2.2 V from the power supply. The output wires of the reader circuit are connected to digital multimeter. Each force sensor has a corresponding set of output wires. Before testing with the hearing aids, the output voltage of each force sensor without force load is measured. After this, each of the five BTE hearing aids is placed sequentially on the sensorized ear model, i.e., placed similarly as how BTE hearing aid is worn behind the ear of a person. The output voltage of each force sensor is then measured.

Using the left ear model, sensors S1, S2, and S5 read higher force loads. Comparing force loads from the hearing aids, it is noted that hearing aid 4 (HA4) has lower readings. This may be because it has no hook and has more flexible small tubing. The small tubing is very flexible to adjust to the actual curvature of the ear. This freedom does not induce too much pressure on the external ear.

Using the right ear model, sensors S2 and S3 mostly read higher force loads. When using hearing aid 5 (HA5), sensor at location S1 did not have a reading due to non-contact of tubing to sensor. The tubing is too short. The trade-off of too short tubing is the hearing aid hook and casing being pulled more towards the ear. The values are read by sensors S2 and S3. When using hearing aid 4 (HA4), sensor S5 reads the higher load because the bottom end of the casing rests directly on top of the sensor.

IV. Conclusion

In this work, we presented a sensorized ear model comprising of MEMS-based force sensor, silicone ear model, and polyimide flexible PCB. The force sensors are positioned at the groove part of the ear model where the BTE hearing aid is worn. A reader circuit composed of single-supply instrumentation amplifiers, decoupling capacitors, resistors, FPC connectors, and input/output wires is also fabricated. The input voltage, V_{cc}, used for characterization of MEMS force sensor on rigid PCB is 3.3V, while testing on FPCB and silicone ear model is 2.2V. These are within the input supply range of 1.5V – 3.6V stated in the datasheet. The results showed a high linearity between the output voltage, V_{out}, and the force load, F. The sensitivity of the sensors is 2.2 mV/mN. Five different styles of BTE hearing aids are utilized and measured for force load (pressure points) along the sensors of the ear model. Left ear and right ear sensorized ear models are used. The measured output voltage (mV) is correlated to force load (mN) using the equation, $F = (V_{out} - V_i)/0.2155$. Based on the data from both ear models, the most critical part of the hearing aid that needs to be optimized is the location where the casing and the hook joins. The hook is what connects the casing to the tubing leading to the earplug. The measured force load on this area reaches to maximum of 132 mN. The length of the tubing and the curvature of the hook also affect the pressure point (force load) on the ear. Too short tubing pulls the casing toward the ear and induces pressure point to the skin at root of helix. Of the five BTE hearing aids tested, the hearing aid 3 and 3 has the lesser pressure points induced on the ear models. Hearing aid 3 has a soft hook and tubing, but the length is short enough to pull the casing to top of the ear. Hearing aid 4 has no hook and has the longest flexible tubing. Overall, the sensorized ear model can be utilized to quantify the force load induced by the hearing aid on the ear.

V. Acknowledgment

This work was supported by the Science and Engineering Research Council of A*STAR (Agency for Science, Technology and Research), Singapore under IME MedTech WBS code SC24/20-130009-0000.

References

[1] World Health Organization (WHO), "Deafness and hearing loss," WHO, 02 Feb 2024. [Online]. Available: https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss. [Accessed 13 Feb 2024].

[2] M. Pienkowski, "Loud Music and Leisure Noise Is a Common Cause of Chronic Hearing Loss, Tinnitus and Hyperacusis," *International Journal of Environmental Research and Public Health,* vol. 18, no. 8, p. 4236, 2021.

[3] L. K. Entwisle, S. E. Warren and J. J. Messersmith, "Cochlear Implantation for Children and Adults with Severe-to-Profound Hearing Loss," *Seminars in Hearing,* vol. 39, no. 4, pp. 390-404, 2018.

[4] Food and Drug Administration, "Other Hearing Devices and Products," USA.gov, 18 Nov 2022. [Online]. Available: https://www.fda.gov/medical-devices/hearing-aids/other-hearing-devices-and-products. [Accessed 13 Feb 2024].

[5] T. Lunner, M. Rudner and J. Ronnberg, "Cognition and hearing aids," *Scandinavian Journal of Psychology,* vol. 50, pp. 395-403, 2009.

[6] E. M. Picou, R. A. Roberts, G. Angley and T. A. Ricketts, "Applying the Hearing Aid Fitting Standard to Selection for Adults," *Semin Hear,* vol. 43, no. 2, pp. 66-78, 2022.

[7] J. Northern, "Strategies of adult hearing aid selection," *Audiology Research,* vol. 1, no. 20, pp. 74-78, 2011.

[8] R. Lim, R. B. Damalerio, M. Sikkandhar, J. W. Yap, E. J. Park, R. Y. Lim, I. H. Bae and M.-Y. Cheng, "A Deployable Multifunctional Sensor for a Catheter Device for the Renal Denervation of Resistant Hypertension," *IEEE Sensors Journal,* vol. 23, no. 20, pp. 25401-25410, 2023.

[9] M. Sikkanghar, R. Lim, R. B. Damalerio, W. D. Toh and M.-Y. Cheng, "Conductive Polymer-Based Interactive Shelving System for Real-Time Inventory Management," *Sensors 2023,* vol. 21, no. 8857, 2023.

[10] R. Lim, M. Sikkandhar and M.-Y. Cheng, "Development of Smart Sensor Array Mat for Retail Inventory Management," in *2022 IEEE 72nd Electronic Components and Technology Conference (ECTC)*, San Diego, Ca., USA, 2022.

[11] D. S. W. Choong, R. Lim, R. B. Damalerio, W. Chen and M.-Y. Cheng, "Development of a Flexible Printed Multi-Functional Sensor Platform for Medical Applications," in *2018 IEEE 20th Electronics Packaging Technology Conference (EPTC),* Singapore, 2018.

[12] R. B. Damalerio, R. Lim, J. V. Yap, R. Lim and M.-Y. Cheng, "Evaluation of Screen Printing Process in Fabrication of Small Profile Conductive Ink-based Contact Force Sensor," in *2023 IEEE 73rd Electronic Components and Technology Conference (ECTC)*, Orlando, Florida, 2023.