Effects of Untrained Earmold Impression Taking on Custom Hearing Protector Device Performance

By Kelly R. Pack, Au.D.
Louisiana Tech University

Director: Melinda F. Bryan, Ph.D.
Committee: Dr. Matthew Bryan, Au.D.
    Dr. Steve Madix, Ph.D.
A Note of Thanks

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Introduction

• Custom made hearing protection devices (HPDs) are currently available for purchase through the internet.
• Impression is made by the consumer, and sent in via mail service to be cast into custom HPD.

  ▪ No research exists on the efficacy of custom HPDs made from do-it-yourself impression kits.
  ▪ Currently no law preventing impressions from being taken by untrained impression takers.
Purpose

• To compare the performance of HPDs produced from do-it-yourself earmold impressions to HPD performance made from impressions taken by trained professionals.
Review of Literature

**Effects of Noise on Hearing:**

- Significant change in outer hair cell emission can occur in a short exposure to impulse noise. (Olszewski, Miłoski, Sułkowski, Majak, and Olszewski, 2005).

- Permanent loss in hearing acuity has been shown from exposure to gun blast impulse noise. (Balatsouras, Homisoglou, & Danielidis, 2005).

- Permanent cochlear damage could happen at a moderate level of steady-state noise in a relatively short amount of time. (Sliwinska-Kowalska and Jedlinska, 1998).

  **Permanent damage can happen in short exposure times**
Impression Techniques and Impact on Attenuation:

- Impressions must reach the 2nd bend of the ear canal to create a good seal and create an effective HPD (Pirzanski & Berge, 2005).

- Movement of the jaw during impression taking may negatively effect the effectiveness of HPD (Pirzanski, Chasin, Klenk, Maye & Purdy, 2000).

- Impression material that does not sufficiently expand the ear canal in the area of the second bend may not produce an effective seal (Pirzanski & Berge, 2005).
Kimball (2008) – DIY Impression Taking

- Earmold impressions were taken by untrained impression takers
- Impressions were sent to two different earmold laboratories to be evaluate and graded. Grading was based on criteria that these labs have previously evaluated as important for effective HPD earmolds.
- On a Scale of 1 to 5, 80% of untrained earmold impressions were under 3, 50% were under 2.
- Indicating earmold impressions taken by untrained earmold impression takers may not be able to provide the necessary attributes needed to create an effective HPD.
Methods and Procedures

Participants:

Research Group
• 10 individuals –
• Criteria for candidacy include:
  - age 18 years or older
  - no prior training in methods of taking earmold impressions.

Control Group
• 3 licensed audiologists -
• Criteria for candidacy include:
  - age 18 or older,
  - previous formal training in creating earmold impressions, and
  - an active, licensed audiologist.
Methods and Procedures

Research Group Safety

• Self report patient history screened for contraindications
  - Pain, tenderness or recent drainage
  - HIV/ diabetes

• Otoscopic exam by licensed Audiologist for contraindications prior to impression taking.
  - Excessive cerumen
  - Abrasions
  - Unhealthy appearing ear canals or tympanic membranes

• Visual evaluation of otoblock placement by a licensed Audiologist to determine safety of amateur impression taking.

*Best case scenario – not like real-world conditions
Methods and Procedures

Replicated a Do-It Yourself Impression Kit, purchased from Internet*:

The kit included:
1) 1 Covidien brand blunt tipped plastic Monoject™ 35 mL syringe,
2) 3 double tipped cotton swabs,
3) 3 blue, medium sized, foam ear dams with cotton removal strings,
4) 3 small, black foam ear dams with cotton removal strings,
5) 3 containers of pre-measured one-to-one silicone earmold impression materials and
6) 1 set of directions for making earmold impressions using the provided kit.

*Earplug Superstore (2010)
Methods and Procedures

Each Participant had:

• 1 set of earmold impressions made by an amateur impression taker and

• 1 set of earmold impressions made by a professional impression taker.
Methods and Procedures

Each impression made into:

- Full-shell Westone brand model 40 custom-fit high noise multi-purpose ear plugs.
- Silicone OtoBlast™ material.
- NRR 29.
Methods and Procedures

Evaluations:

• Real Ear Measurements

• Real ear thresholds

• Visual grading of impressions by Westone
Methods and Procedures

**Real Ear Measurements**

- Measured Real Ear Unoccluded Gain (REUG) taken twice per ear*.
- Measured Real Ear Occluded Response (REOR) 3 times per ear with each HPD*.
- Between each REOR, administrator removed and reinserted HPD.
- Measurements averaged per condition and per ear.

*Measurements completed in soundproof booth. Made measurements with Audioscan RM500SL & 50 dB HL white noise signal.
Methods and Procedures

Real Ear at Threshold (REAT) Measure

- Unoccluded thresholds obtained twice at .25, .5, 1, 2, 4, 6 and 8 kHz*.
- Occluded thresholds (i.e., .25, .5, 1, 2, 4, 6 and 8 kHz ) performed with both amateur and professional sets of HPDs - three times each condition*.
- HPDs were removed and replaced between threshold measurements by the administrator.

*Measurements completed in soundfield (soundproof booth) w/ participant placed 1 meter from the speaker. Used pulsed, warbled tone using ascending/descending method
Visual Assessment

- Earmold impressions photographed from 5 angles.
- Assessed by 3 earmold impression experts using 4 attributes known to affect HPD fit and attenuation
  - sufficient canal length
  - sufficient amount of material in the canal
  - sufficient fill of concha, helix and anti-helix areas, and
  - evidence that the impression material had been pressed into the ear.

- Assigned one of the following classification:
  - Acceptable for manufacture
  - Unacceptable for manufacture
  - Acceptable for manufacture, but remakes would require a new impression to be made.
Results: Real Ear Measurements

- Both amateur and professional occluded ears showed significantly more attenuation than unoccluded ear canals.

- **Amateur HPD occluded ears showed significantly less attenuation than professional HPD occluded ears.**

- No significant difference between right or left ears.
Results: REAT

- Both amateur and professional occluded ear showed significantly more attenuation than unoccluded ear canal.

- Amateur occluded ears showed significantly less attenuation than professional occluded ears.
Results: Visual Assessment

Typical impression
Amateur

Typical impression
Professional
## Results: Visual Assessment

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Amateur Impressions</th>
<th>Professional Impressions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sufficient Material in Canal</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>Sufficient Canal Length</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>Sufficient Fill of Concha, Helix &amp; Anti-Helix Areas</td>
<td>7</td>
<td>20</td>
</tr>
<tr>
<td>Evidence of impression material pressed into the ear</td>
<td>20</td>
<td>0</td>
</tr>
</tbody>
</table>

**Rated as....**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Amateur Impressions</th>
<th>Professional Impressions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptable for Manufacture</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>Unacceptable for Manufacture</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>Acceptable for Manufacture but Remakes require New Impression.</td>
<td>5</td>
<td>6</td>
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Discussion

HPDs made from professionally made earmold impressions have significantly higher attenuation as showed through real ear measures and REATs than those made from amateur made earmold impressions.
Discussion

This study was a best case scenario

• Contraindications were controlled for

• Safety was monitored by a licensed Audiologist

• Otoblock placement was monitored by a licensed audiologist. (4 were repositioned)

• While Westone would have rejected most amateur impressions, it is unknown if all manufacturers would have the same high standards.
Discussion

- Previous research shows impression material needs to reach the second bend of the ear canal to create a proper seal and effectively attenuate noise (Pirzanski & Berge, 2005).

- Visual grading showed
  - 18 of 20 amateur impressions had insufficient canal length
  - 0 professional impressions had insufficient canal length.

Deep placement of the otoblock and impression material can be uncomfortable for both the impression taker as well as the patient. This could be the reason amateur impressions were not as long and attenuation was lower.
Discussion

• Previous research found that jaw position during impression taking had a significant impact on attenuation (Pirzanski, Chasin, Klenk, Maye & Purdy, 2000).

• Position of the jaw can have significant impact on the diameter of the impression between the first and second bend, ultimately effecting attenuation.

The amateur impression taker may be unaware that jaw movement during impression taking may reduce how snugly the HPD fits inside the canal resulting in a decrease of attenuations.
Clinical Implications

- HPDs should be made by a trained professional for optimal attenuation.

- Do-it-yourself earmold impression kits should be removed from the market as a safety concern.
  - Do not screen for contraindications.
  - Possibility of tympanic membrane perforation.
  - Increased risk of noise exposure due to reduced attenuation of subsequent HPD.
Clinical Implications

- Internet HPD providers could contract or refer to a trained healthcare provider for earmold impressions.
Questions or For More Information?

Kelly Pack: kellyrpack@gmail.com

Melinda Bryan: Melinda@latech.edu
References


