Attenuation Measurements of Open Versus Closed Jaw Impressions in Custom Hearing Protector Devices

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Disclosures

• This research was funded by the National Hearing Conservation Association Scholarship Foundation.

• Westone was an invited commercial partner for this research and contributed in the following ways;
  • Donation of the ear impression material and hearing protectors.
  • Collaboration with researchers regarding the standardized manufacturing and quality control processes for the production of the custom hearing protection devices.

• The research design, data collection and analysis were completed independently from the commercial partner.

• Mention of the Westone commercial product does not constitute an endorsement.
Purpose

To investigate how ear impressions obtained in \textit{2 different jaw positions} and \textit{using 2 different viscosities of ear impression materials} influence the amount of personal attenuation provided by custom hearing protectors when measured using individual fit-testing in the field.
It has been reported in the literature that sound is attenuated more effectively in custom molded earplugs compared to other earplugs because they fill the canal more fully and tightly (Berger, 2000).

Berger (2003) reported a range of minimum to maximum attenuation values of 15 to 45 dB using REAT.

Huttunen, Sivonen, & Poykko (2011) found average attenuation values up to 15 dB from 0.125 to 8 kHz for ER-15 custom earplugs using REAT technique.
Recommended Ear Impression Techniques for Custom Hearing Aids

- Open Jaw
- High Viscosity

Pirzanski and Berge (2005) found that ear impressions should be taken with higher viscosity (firmer) silicone and the patient’s mouth wide open to provide the most anatomically accurate ear imprints for custom hearing aids and hearing aid earmolds.
Open vs. Closed Jaw Anatomy as it Relates to the Ear Canal

- The opening of the jaw causes the condyle to swing anteriorly and slightly inferiorly, which can then cause distortion of the ear canal (Oliveria & Hoeker, 2003; Willigen, 1976).

- The diameter of the ear canal opening exhibits dynamic variability during mandibular movement (Oliveria & Hoeker, 2003; Musiek & Baran, 2007).
Ear Impression Materials

- Low viscosity material
- High Viscosity material
Methodology
Participants

- 35 adults between the ages of 22 and 54 years were recruited from a local beverage manufacturing workplace.
- Subjects were eligible to participate in the study if they met the specified criteria.
- 5 subjects were excluded.
- The mean age of the remaining 30 participants was 37.3 (±7.4) years. Of these eight (26.7%) were females and 22 (73.3%) were males.
Experimental Procedures

- Subjects were seen on two separate occasions.
- The first session established formal enrollment in the research study and bilateral ear impressions were completed on each subject.
- The second session was for the purposes of measuring custom HPD attenuation using the NIOSH HPD Well-Fit.
Initial Visit: Ear Impressions

- 60 Bilateral sets of ear impressions were taken in four conditions
  - Open jaw-low viscosity
  - Open jaw-high viscosity
  - Closed jaw-low viscosity
  - Closed jaw-high viscosity
Jaw Position

- During the closed jaw impressions subjects were asked to sit in a resting position with their jaw closed.

- During open jaw impressions a Styrofoam bite block was placed lengthwise in the center of the mouth.
Experimenter training and expertise in impression taking was validated by audiology clinical faculty and manufacturing laboratory prior to initiation of the study.

- Visual inspection for creases, marks, gaps, and bubbles
- In two cases ear impressions were subjectively judged to be “inadequate” by the experimenter, in these cases repeat ear impression were taken and utilized
Custom Hearing Protectors

- The custom earmold laboratory also inspected the ear impressions upon arrival and confirmed their adequacy for production purposes.
- Style 40 Otoblast, NRR 29 dB
- Proprietary manufacturing process, which has been routinely standardized for all custom device orders received by the manufacturer.
Second Visit: Fit-Testing

- Attenuation measurements were completed in a security trailer at the site of the local employer using the NIOSH HPD WellFit™ system.
- The experimenter inserted the custom earplug.
- A 7-frequency PAR score was obtained for each custom earplug and ear:
  - 125, 250, 500, 1000, 2000, 4000, and 8000 Hz
Data Analysis

- Repeated measures two-way ANOVA ($\rho \leq .05$) using the 7-frequency PAR score as the dependent variable
- The independent variables were jaw position and impression material
- Analysis was performed using SPSS v22
Results
Hearing Protector Fit Testing

<table>
<thead>
<tr>
<th>Condition</th>
<th>N</th>
<th>Minimum dB SPL</th>
<th>Maximum dB SPL</th>
<th>Range dB SPL</th>
<th>Mean</th>
<th>Std. Dev</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closed Jaw with High Viscosity</td>
<td>30</td>
<td>8.0</td>
<td>42.1</td>
<td>34.1</td>
<td>21.1</td>
<td>7.7</td>
</tr>
<tr>
<td>Open Jaw with High Viscosity</td>
<td>30</td>
<td>13.6</td>
<td>34.7</td>
<td>21.1</td>
<td>22.6</td>
<td>4.9</td>
</tr>
<tr>
<td>Closed Jaw with Low Viscosity</td>
<td>30</td>
<td>4.9</td>
<td>26.6</td>
<td>21.7</td>
<td>15.3</td>
<td>5.1</td>
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<tr>
<td>Open Jaw with Low Viscosity</td>
<td>30</td>
<td>5.4</td>
<td>32.7</td>
<td>27.3</td>
<td>17.6</td>
<td>7.2</td>
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</tbody>
</table>
Mean PAR Scores

- Closed Jaw High Viscosity: 21.1 dB
- Open Jaw High Viscosity: 22.6 dB
- Closed Jaw Low Viscosity: 15.3 dB
- Open Jaw Low Viscosity: 17.6 dB

Test Conditions:
- PAR Score (dB)
- Closed Jaw High Viscosity
- Open Jaw High Viscosity
- Closed Jaw Low Viscosity
- Open Jaw Low Viscosity
Mean PAR Scores

Test Condition

<table>
<thead>
<tr>
<th>PAR Score (dB)</th>
<th>Closed Jaw_High Viscosity</th>
<th>Open Jaw_High Viscosity</th>
<th>Closed Jaw_Low Viscosity</th>
<th>Open Jaw_Low Viscosity</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAR Score</td>
<td>21.1 (CLOSED)</td>
<td>22.6 (OPEN)</td>
<td>15.3</td>
<td>17.6</td>
</tr>
</tbody>
</table>

The diagram shows the mean PAR scores for different test conditions. The PAR scores are as follows:
- Closed Jaw_High Viscosity: 21.1 dB
- Open Jaw_High Viscosity: 22.6 dB
- Closed Jaw_Low Viscosity: 15.3 dB
- Open Jaw_Low Viscosity: 17.6 dB
Statistical Analysis

- The two-way repeated measures analysis of variance (ANOVA) showed a **significant effect for jaw position** ($F = 5.308, p < .05$).

- There was also a **significant effect for viscosity** of the impression material ($F = 31.533, p < .05$).

### Results of Two-Way Repeated Measures ANOVA

<table>
<thead>
<tr>
<th></th>
<th>df</th>
<th>F</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jaw Position</td>
<td>1</td>
<td>5.308</td>
<td>.029*</td>
</tr>
<tr>
<td>Viscosity</td>
<td>1</td>
<td>31.533</td>
<td>.000*</td>
</tr>
<tr>
<td>Jaw Position * Viscosity</td>
<td>1</td>
<td>.234</td>
<td>.632</td>
</tr>
</tbody>
</table>

*$p \leq .05$
There was no significant interaction between jaw position and viscosity of the impression material ($F = .234$, $p > .05$).
Conclusions

- These results suggest that using an open jaw position and high viscosity material impression technique for custom molded earplugs provides significantly higher attenuation values than using closed jaw position or low viscosity material.

- Fit-testing provides important information relative to the amount of attenuation achieved when fitting custom hearing protectors.
Practical Impression Technique Considerations

- Jaw position
  - Subjects tolerated open jaw position
  - Individuals with TMJ dysfunctions may be less likely to be able to perform or tolerate this approach in any setting

- Impression material

- Instructions

- Infection control
PAR Comparison to NRR

- Custom molded earplugs provided an average of 15.5-22.6 dB of protection when the earplug was fit by the researcher.

- The NRR over-estimated the amount of actual protection (Style 40 Otoblast NRR=29 dB)

- Individual fit-testing is vital
Conclusions

- The results of this study suggest that the preferred ear impression technique for CMEs dispensed in an industrial setting is the open jaw position combined with the use of high viscosity impression material.
  - Impression material viscosity seems to have a more substantial effect on PAR scores
  - Jaw position considerations is secondary and may not be practical in an industrial setting
  - Field attenuation is less than labeled NRR for the Otoblast custom earplug.
  - Fit testing is necessary for verification
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Questions?
References


References


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