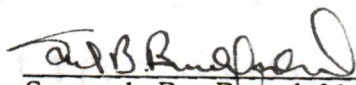


To the Graduate Council:

I am submitting herewith a thesis written by Kimberly J. Dye entitled "Physical, Acoustical, and Psychophysical Comparisons Between Earmolds Resulting from Poly(ethyl methacrylate) and Condensation Reaction Silicone Ear Impression Material." I have examined the final copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Arts, with a major in Audiology.



Samuel B. Burchfield, Major Professor

We have read this thesis
and recommend its acceptance:



Accepted for the Council:



Vice Provost and

Dean of The Graduate School

PHYSICAL, ACOUSTICAL, AND PSYCHOPHYSICAL COMPARISONS
BETWEEN EARMOLDS RESULTING FROM POLY(ETHYL METHACRYLATE)
AND CONDENSATION REACTION SILICONE EAR IMPRESSION MATERIAL

A Thesis
Presented for the
Master of Arts
Degree
The University of Tennessee, Knoxville

Kimberly J. Dye
December 1987

ACKNOWLEDGMENTS

The author would like to take this opportunity to express my sincere gratitude to those who assisted in the completion of this project. Dr. Samuel Burchfield, as my advisor and project director, continually offered guidance, patience, support, and encouragement to whom I am truly thankful. The remaining members of my committee, Ms. Deborah Arthur, Dr. Roberto Benson, and Dr. Allan Diefendorf, were very instrumental in the completion of this project by providing advise and suggestions concerning its quality. For their valuable assistance, I offer my appreciation.

A special expression of appreciation is due to Mr. Gary Ward and Mr. Moses Nakhle at EMTECH Laboratory for their assistance, cooperation, and guidance during this investigation. To Mr. John Tucker at Esschem Co., I offer my gratefulness in providing the impression materials and further assistance with this project.

I personally want to honor my Almighty God with whom all things are possible. To my classmates, thank you for your encouragement, advise, and listening hearts. To a dear friend, Patty Hooper, thank you for your guidance contributing to my understanding of hearing impaired individuals. And finally, a very special gratitude to my parents for their sincere love and support that made this educational experience possible.

ABSTRACT

One of the most pressing problems facing the hearing health care profession is the issue of remakes due to acoustic feedback and poor physical fit. Information regarding ear impression materials suggests that the problem lies within poor impression techniques, poor impression materials, or a combination of the two.

Ear impressions were obtained for twelve subjects with poly(ethyl methacrylate) and condensation reaction silicone ear impression materials at their amplified ear. These impressions were processed into lucite earmolds which were compared in terms of physical dimensions, real ear acoustic gain, and subjective preference.

The results do not seem to support a clear advantage for either impression material. Clinical experience with earmolds made from poly(ethyl methacrylate) impression material, however, continue to result in problems with acoustic feedback and poor physical fit. The results from this study, which did not exhibit difficulties with acoustic feedback or poor physical fit, indicated that poly(ethyl methacrylate) can be successfully used clinically only in conjunction with the controls, such as careful mixture ratios, completeness of mixing, and expediency of processing, which were utilized in the present study.

TABLE OF CONTENTS

CHAPTER	PAGE
I. INTRODUCTION	1
Purpose of the Study	4
II. REVIEW OF LITERATURE	5
Ear impression techniques	5
Ear impression materials	7
Silicone	8
Poly(ethyl methacrylate)	9
III. PROCEDURES	13
Subject criteria	13
Experimental method	13
Treatment of the Data	16
IV. RESULTS	17
Physical	17
Acoustical	20
Psychophysical	25
V. DISCUSSION	29
Physical	29
Acoustical	32
Psychophysical	36
VI. SUMMARY AND CONCLUSIONS	38
Suggestions for Future Research	39
BIBLIOGRAPHY	40
APPENDICES	44
A. Specific Procedures For Making The Impressions .	45
Poly(ethyl methacrylate)	45
Condensation Reactions Silicone	46
B. Earmold Questionnaires	49
Form 1	49
Form 2	50

C. Tables	51-56
D. Raw Data Tables	57-63
VITA	64

LIST OF TABLES

TABLE	PAGE
I. T-Statistical Results for the Physical Measurements	18
II. Reliability of Ear Impression/Earmold Physical Measurements and Correspondence of Ear Impression and Processed Earmolds	24
III. Analysis of Insertion Gain Results for the Earmolds	26
IV. Analysis of Subjective Results for the Earmolds ..	27
V. Post-Hoc Study: Results on Weight and Canal Length Differences	33
VI. Analysis of Physical Measurement Results at Position 1	51
VII. Analysis of Physical Measurement Results at Position 2	52
VIII. Analysis of Physical Measurement Results at Position 3	53
IX. Analysis of Physical Measurement Results at Position 4	54
X. Post-Hoc Study: Analysis of Physical Measurement Results for the Silicone Impression to Earmold Comparison	55
XI. Remake Results of Earmold/In-The-Ear Laboratory Surveys	56
XII. RAW DATA: Physical Measurements of Both Impressions at the Four Positions	57
XIII. RAW DATA: Physical Measurements of Both Earmolds at the Four Positions	58
XIV. RAW DATA: Physical Measurements of the Poly(ethyl methacrylate) Impression to Resultant Earmold at the Four Positions	59

XV.	RAW DATA: Physical Measurements of the Silicone Impression to the Resultant Earmold at the Four Positions	60
XVI.	RAW DATA: Subjective Measurements	61
XVII.	RAW DATA: (Post-Hoc Study) Physical Measurements of the Silicone Impressions and Resultant Earmolds at the Four Positions	62
XVIII.	RAW DATA: (Post-Hoc) Weight and Canal Length Measurements of the Earmolds	63

LIST OF FIGURES

FIGURE		PAGE
1.	Mean Outside Diameter Comparisons for the Poly-(ethyl methacrylate) Ear Impressions and the Condensation Reaction Silicone Ear Impressions..	19
2.	Mean Outside Diameter Comparisons for the Poly-(ethyl methacrylate) Impression and its Resultant Earmold at the Four Positions	21
3.	Mean Outside Diameter Comparisons for the Condensation Reaction Silicone Impression and its Resultant Earmold at the Four Positions	22
4.	Mean Outside Diameter Comparisons for the Earmolds Resulting from Poly(ethyl methacrylate) and Condensation Reaction Silicone Ear Impressions	23
5.	(Post-Hoc) Mean Outside Diameter Comparisons for the Silicone Impressions and the Resultant Earmolds at the Four Positions	31
6.	Mean Insertion Gain Comparisons for the Earmolds Resulting from the Poly(ethyl methacrylate) Ear Impressions and the Condensation Reaction Silicone Ear Impressions	35

CHAPTER I

INTRODUCTION

Individually worn electronic hearing aids have existed for approximately sixty years. During this period these instruments have undergone many technological advances. Carbon hearing aids existed for little more than one quarter of a century when the far superior vacuum tube instruments became commercially available. Vacuum tube instruments, in like manner, were superseded by vastly improved transistor instruments. Contemporary hearing aids contain integrated circuits which provide powerful and flexible instruments. These devices are efficient with respect to battery consumption and they enable miniaturization to the point where hearing aids will fit in the concha or even completely within the confines of the external ear canal.

Paralleling development in hearing aids have been advances in earmold or coupler technology. The first patent for custom earmolds was issued in 1922 (Mynders, 1985). The widespread employment of custom earmolds, however, was delayed until after World War II when plastics became widely available. In the past two decades, hearing health care professionals have realized the importance of custom earmolds (Bess and Konkle, 1974). This has resulted in almost exclusive custom fittings today. These same professionals

have also realized that coupler alterations can provide an almost infinite variety of frequency response characteristics (Lybarger, 1949, 1978; Killion, 1976, 1979; Studebaker and Cox, 1977; Gastmeier, 1981; Mueller, Schwartz, and Surr, 1981). This information is equally applicable to both behind-the-ear (i.e., the earmold) and in-the-ear (i.e., the shell) fittings.

In spite of the advancements in hearing aid and coupler technology, there has been little advancement in the area of ear impressions. In 1986, approximately 1.2 million hearing aids were sold in the United States (Mahan, 1986). Remake estimates for these range from three to ten percent. This means that somewhere between 36,000 and 120,000 remakes were required. The consequences of this repeated process are considerable. In a survey of sixteen earmold laboratories and five in-the-ear hearing aid manufacturers, cost estimates range from a low of \$2.00 per each earmold (Ryborczyk, 1987) to a high of \$100.00 for each in-the-ear remake (Unitron, 1987). Perhaps more importantly, this estimate does not include the intangible cost of the client's loss of confidence toward amplification and the hearing health care profession. The remake cost, whether tangible or intangible, is a result of either the impression-making techniques, the impression materials, or a combination of the two.

The remake dilemma has been reported for more than a decade (Rass, 1976; Hocks, 1978; Mahan, 1984). Poor

impression techniques and variables within the techniques have generally been thought to be the source of this dilemma. The manufacturers of impression materials and several authors (Juneau, 1983; Mynders, 1985; Beltone, 1986; Esschem, 1986; Microsonic, 1986; Unitron, 1987) have advocated different ways to obtain ear impressions. These have included the utilization of a cotton block versus a foam block, the insertion method, the hand smoothing of the impressed concha and helix area, and mobilization of the mandible during the curing process. Only one of the variables within impression techniques, mandibular movement, has been systematically investigated. Navarro (1987) found that in order to obtain a tightly fitting earmold, it is necessary to avoid jaw movement during the impression making process.

Another factor possibly contributing to inaccurate earmolds is impression materials. The most commonly used ear impression materials are poly(ethyl methacrylate) (acrylic) and condensation reaction silicone. The only reported study comparing these materials, as related to ear impressions, was conducted by Agnew in 1986. Agnew found that poly(ethyl methacrylate) exhibited canal shrinkage (linear shrinkage of 2%) which was found to a lesser degree (0.2% to 0.4%) in silicone. Additionally, poly(ethyl methacrylate) was overall found to be dimensionally unstable which was not found in silicone. These results

led Agnew to conclude that the silicone impression materials are less subject to dimensional changes and were found to provide impressions of greater consistency and accuracy.

Given this information, one would assume that most impressions are made with silicone, however, 70% are still made with the dimensionally unstable material, poly(ethyl methacrylate).

Purpose of the Study

The purpose of this study was to determine whether earmolds made from poly(ethyl methacrylate) and condensation reaction silicone ear impression material exhibit significant physical, acoustic, and psychophysical differences.

Specific objectives include:

1. To determine if there are physical differences in earmolds made from the two different impression materials.
2. To determine if earmolds made from different impression materials produce acoustical differences.
3. To determine if hearing impaired individuals prefer either the quality of sound or the subjective comfort of earmolds made from either impression material.

CHAPTER II

REVIEW OF LITERATURE

Ear Impression Techniques

The syringeable method for obtaining an ear impression was described by Mynders (1983). A medical history precedes the taking of an ear impression. Following the history, status of the external ear canal and the tympanic membrane are observed otoscopically. Special references should be given to the size and shape of the concha area as well as the presence of wax, integrity of the eardrum, and other disorders. Next, a foam or a cotton block is inserted into the external canal to stop the flow of the impression material and to achieve a more visible definition of the ear canal during the comparison stage. The block should be placed in the canal entrance and then inserted with a penlight or earlight just past the second directional bend of the canal. The string attached to the ear block should extend out of the ear canal near the patient's neck. The impression material is mixed according to the manufacturer's specifications and injected with a syringe. The canal, helix, and concha area are completely filled by maintaining contact between the syringe tip and the injected material. The ear impression material is allowed to polymerize/gel a full ten minutes, during which the client is not allowed to

talk or chew. The ear impression is gently removed and the ear canal is otoscopically inspected for possible debris. A critical procedure is to critique the impression with respect to a smoothness and completeness, a second bend in the canal, clearly shown helix, weld marks, and texture of the impression. The final procedure is shipping the impression to the earmold laboratory. The base of poly (ethyl methacrylate) impressions should be glued to the shipping container with the order form packed so it does not contact the impression. The silicone impression must simply be placed in the shipping container.

Our understanding of the techniques are based on the manufacturer's reports and general descriptions by hearing health care professionals. This has resulted in conflicting reports on several issues which include the use of a cotton block versus a foam block, hand smoothing the concha and helix areas, and restriction of mandible movement during the impression procedure. Only one of these issues, effects of mandibular movement, has been systematically investigated (Navarro, 1987).

The reports addressing mandibular movement during ear impression procedures have varied from those who advocate mobility (Belton, 1986; Bernafon, 1986) to those who advocate immobility (Juneau, 1983; Mynders, 1985). In discussing ear impression techniques, several other writers disregard mandibular movement effects. (Pollack and Morgan,

1980; Loavenbruck and Mandell, 1981; Esschem, 1986; Unitron, 1986). Navarro (1987) compared the physical size of earmolds which were obtained with and without mobility of the mandible during the impression procedure. The following four measurements were made using a Mauser Caliper that provided dimensional accuracy to one tenthousandth of a meter: (1) 0- to 180- degree dimension (superior to inferior); (2) 90- to 270- degree dimension (anterior to posterior), both at the tip of the impression; (3) 0- to 180- degree dimension; and (4) 90- to 270- degree dimension, both at the junction of the bowl and canal. This difference was significantly larger with the immobilized mandible. This prompted Navarro to conclude that in order to obtain a tightly fitting earmold, it is necessary to avoid jaw movement during the impression taking process.

Ear Impression Materials

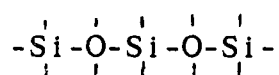
Ear impression materials commonly used today belong to a chemical group called polymers which are long chain molecules. The two impression materials, poly(ethyl methacrylate) and silicone contain additives such as initiators, inhibitors, accelerators, pigments, lubricants, fillers, and plasticizers that produce variations in both the chemical and physical characteristics of the final material.

The bonding process during the solidification of the

two impression materials is the main difference between the two materials. The poly(ethyl methacrylate) proceeds a gelation process upon mixture of the polymer (powder) and the solvent (liquid), whereas, a polymerization process begins when mixing the monomer and the chemical initiator of the silicone impression material. Both bonding processes cause the solvent or the monomer to change into a solid mass of material that bonds together internally through the formation of polymer chains.

Silicone

Silicone is a general term used to describe a family of organo-silicone compounds based on a molecular chain of alternate silicon and oxygen atoms:



Silicones can be classified as fluids, elastomers, and resins. Their physical form is determined by molecular weight, extent of crosslinking between polymeric chains, and type and number of organic groups attached to silicon atoms. The cross-linking process between the chains give rise to a firm rubbery polymer with excellent mechanical properties and good dimensional stability.

There are two available types of silicone impression materials, one formed by a condensation reaction and the other by an addition reaction. Condensation reaction occurs between silicone molecules with terminal hydroxy groups and an alkoxy or orthosilicate in the presence of an organo-tin

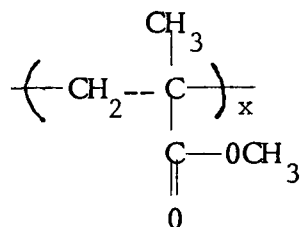
compound as the catalyst. During the condensation reaction an alcohol by-product is produced over a period of time and volatilization of this product leads to a small amount of shrinkage (Nolan and Combe, 1985). The condensation silicone impression material is most commonly used and produced in syringeable pastes and putty. Agnew (1985) states that the syringeable pastes contain 30% to 40% filler and the putty type contains 75% filler. The specific amount of shrinkage will depend on the filler content, being lower for the silicone with higher filler content. According to Agnew's study, the linear shrinkage figures for condensation silicone material typically were on the low side of the expected range of 0.2% to 0.4% after 24 hours, which was calculated by Craig and Peyton (1975).

A more recent silicone material available is the addition reaction silicone. Addition reaction setting takes place between an organo-hydrogen siloxane and a compound with a vinyl silance group in the presence of a platinum-containing catalyst. Since the organo-hydrogen siloxane has more than one hydrogen atom capable of undergoing addition reaction, this material offers good potential dimensional stability due to the lack of volatile by-products (Nolan and Combe, 1985).

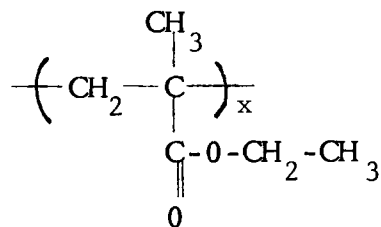
Poly(Ethyl Methacrylate)

The poly(ethyl methacrylate) ear impression material is supplied in a two part system, a powder and a solvent

(liquid). The powder is a physical blend of poly(ethyl methacrylate) and a small amount of poly(methyl methacrylate).



Poly(methyl methacrylate)



Poly(ethyl methacrylate)

Both poly(ethyl methacrylate) and poly(methyl methacrylate) are stiffened chained polymers. The most widely used acrylic plastics are poly(methyl methacrylate) (Lucite) or copolymers of methyl methacrylate with small amounts of methyl or ethyl acrylate (Plexiglas). The presence of two substituents on every alternate atom restricts chain mobility, therefore, poly(methyl methacrylate) is less flexible than poly(ethyl methacrylate).

The gelation process of the poly(ethyl methacrylate) begins with the addition of the liquid (solvent). The solvent's speed of attack to the polymer is controlled by additives such as plasticizers, and oils contained in the solvent. The accurate amount of these two ingredients contained in the solvent play a major role in dimensional stability of the ear impression.

Gurschkow (1978) described the following characteristics which should be considered when choosing an impression material:

- (1) Accuracy of impression material is determined by two factors: elasticity and dimensional stability.
- (2) Elasticity (the material should be capable of sustaining its shape without any permanent alteration remaining when it is removed from the ear).
- (3) Thorough mixing capability (any area having an incomplete polymerization act will result in distortion of the impression).
- (4) Dimensional stability during prolonged storage.
- (5) Release characteristics from the ear (no materials adhering to the skin).
- (6) Heat stability to insure temperatures as high as 500°F.
- (7) Tear strength with elasticity (ability to withstand stretching and tearing and return to the original shape).
- (8) Thermoset rubber instead of thermoset plastic (thermoset silicones react and cure by room temperature vulcanization with a catalyst and cross-linking agent).

The only comparison of ear impression materials in this country was conducted by Agnew (1986). This study compared three types of ear impression materials; putty-type silicone, syringeable paste-type silicone, and standard syringeable poly(ethyl methacrylate) liquid-powder mix. The time dependent measurements included linear shrinkage, volume shrinkage, canal warpage, and canal slumpage. Canal shrinkage (linear shrinkage) and dimensional stability were measured about halfway down the canal because that was thought to be the area most important for acoustic sealing. An optical comparator was used to observe the dimensions. The results indicated significant differences between both

types of silicone and the poly(ethyl methacrylate). Poly(ethyl methacrylate) impressions were found to have dimensional instability which was not found with the silicone impressions. The poly(ethyl methacrylate) impressions exhibited canal shrinkage (linear shrinkage of 2%) which was exhibited to a lesser degree (0.2% to 0.4%) in the silicone impressions.

The following listed information is a summarization of the most important aspects in the review of literature.

1. The amount of information regarding ear impression techniques is limited and generally based upon the manufacturer's reports.
2. The only documented study regarding ear impression techniques (Navarro, 1987) revealed that restricted mandibular movement during the impression process is necessary in order to obtain a tight fitting earmold.
3. The efficacy of ear impression materials is generally based on the manufacturer's reports and not on controlled comparisons.
4. Recent information concerning impression materials has shown that silicone material is stable over time, whereas, the poly(ethyl methacrylate) material is dimensionally unstable.

One of the most pressing problems facing the hearing health care profession is the issue of remakes. It has traditionally been thought that poor impression techniques cause this problem. Recent information about ear impression materials, however, suggests that a large part of the problem may lie within the material itself. The present study was undertaken to explore the role that these materials play in the remake dilemma.

CHAPTER III

PROCEDURES

Subject Criteria

Twelve subjects for the study were selected from cases seen at the University of Tennessee Hearing and Speech Center (South Stadium Hall). All subjects had documented hearing impairments and all were present hearing aid users. The subjects conformed to the following criteria:

1. Between the ages of 18 and 60 years of age.
2. A mild to severe hearing impairment.
3. Utilization of a behind-the-ear hearing aid for several years.
4. Utilization of lucite earmold.

Experimental Method

Three impressions were made of each subject's amplified ear. Two of these were made with condensation reaction silicone while one was made with poly(ethyl methacrylate). The procedures for the two impression materials are included in (Appendix A). The poly(ethyl methacrylate) and one of the silicone impressions were carefully measured using a Craftsman precision caliper and sent to the laboratory for processing. The physical dimensions measured were: (1) 0- to 180- degree dimension (superior to inferior); (2) 90- to 270- degree dimension (anterior to posterior), both at the medial canal tip of the impression; (3) 0- to 180- degree dimension; and (4) 90- to 270- degree dimension, both at the

junction of the bowl and canal. The remaining silicone impression was maintained to serve as a reference for future physical measurements of the earmolds. This insured that the original impression and the processed earmold were measured in the same manner.

The same style earmold which the subject wore were requested. EMTECH laboratories (Roanoke, Va.) processed the impressions into earmolds. Similar processing procedures were utilized for the different impressions. The processing of the earmolds only differed in one aspect due to the waxing procedures of the different impression materials. The earmolds were color coded by the laboratory which enabled a double-blind comparison. Neither the experimenter nor the subject knew which impression material was used in making the experimental earmolds. The same physical measurements of the processed earmolds were made with a Craftsman precision caliper using the reference ear impression for placement consistency of the caliper.

The acoustical differences in the earmolds were assessed via an Acoustimed HA 2000 Real Ear Spectroscope in terms of insertion gain at a preferred listening level. The procedures for obtaining insertion gain were as follows: The subjects faced a Realistic model loudspeaker at a 90 azimuth position and a distance of 0.7 meter (2 feet) in order to obtain a sound field reference level. A probe microphone, which was located against the cheek, about 50mm

to 75mm (2 to 3 inches) in front of the ear and away from the concha, received a series of clicks presented from the loudspeaker. The sound pressure levels produced at this location were determined and stored by the attached computer. Subsequently, the signals measured were "leveled" or corrected by these stored values. An "unaided equalization reference" was determined by placing the tube of the probe microphone in the lower part of the ear canal with the end of the tube about 10mm (0.4 inch) away from the tympanic membrane. Clicks were again presented from the loudspeaker. These clicks, captured near the tympanic membrane, in reference to the external signals, showed the resonance of the external ear canal. The hearing aid with its unique earmold coupling was fitted at the ear with the normal adjustments as worn by the owner. An "aided equalization response" was then determined from the click stimuli after processing by the hearing aid and measured near the tympanic membrane. The difference between the unaided and aided responses was the insertion gain of the hearing aid and the fitted earmold.

The experimental earmolds were subjectively rated in terms of sound quality and physical comfort. To accomplish this, the subjects were issued one of the experimental earmolds which they wore for one week. Following this period, each subject returned to complete a questionnaire (Appendix B) concerning their subjective impression about the earmold.

During the next week, each subject utilized the other experimental earmold. Their experience with this earmold was also evaluated using a similar questionnaire.

Treatment of the Data

The collected data was compared in the following manner:

Physical measurements.

1. The physical dimensions of the ear impressions were compared.
2. The physical measurements of the ear impressions were also compared to the resultant earmolds.
3. The physical dimensions of the earmolds were compared.

Acoustical measurements. The real ear insertion gain assessments of both earmolds were compared.

Psychophysical measurements. The questionnaire information, for each earmold, was compared to determine if there was a subjective comfort and acoustic preference.

Data regarding physical measurements, insertion gain, and subjective ratings were statistically compared using a paired sample t-test.

CHAPTER IV

RESULTS

The purpose of this study was to determine if there were physical, acoustical, and psychophysical differences between earmolds made from two different impression materials, poly(ethyl methacrylate) and condensation reaction silicone. The physical comparisons involved four ear canal outside diameter measurements for each impression and each earmold. These consisted of horizontal and vertical measurements at the tip of the canal and at the junction of the bowl and canal. Insertion gain was used to compare acoustical differences and a subjective questionnaire was utilized for the psychophysical comparisons.

Physical

The four physical measurements of the earmolds, the impressions and their resultant earmolds, and the impressions were compared with paired sample t-tests. Computed t-statistic values are shown in Table I. (t-test computations at each position are shown in Appendix C).

There was no significant difference in the physical size of the earmolds resulting from the two different impression materials. This relationship is shown in Figure 1.

Significant differences were found when the impressions

Table I. T-STATISTIC RESULTS FOR THE PHYSICAL MEASUREMENTS

Variable	Position 1 (vertical canal tip)	Position 2 (horizontal canal tip)	Position 3 (vertical bowl- canal junction)	Position 4 (horizontal bowl- canal junction)
Impression to Impression	0.90	1.93	1.28	2.63
Earmold to Earmold	1.15	-.87	.61	1.56
Poly(ethyl methacrylate)				
Impression to Resultant				
Earmold	2.36	1.79	3.38	-.02
Silicone Impression to				
Resultant Earmold	2.05	.91	2.50	-.15
Critical value +2.201				

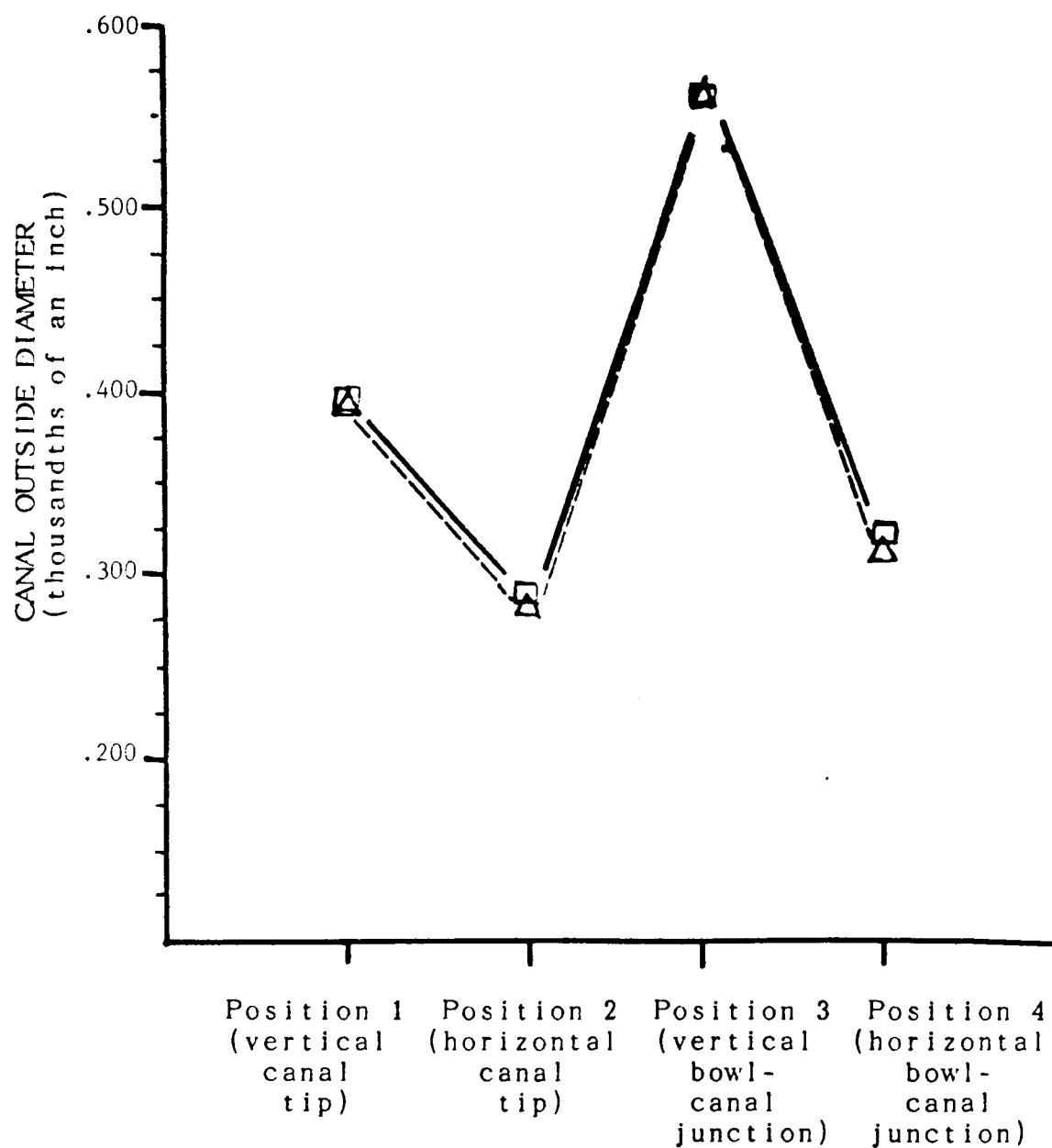


Figure 1. Mean outside diameter comparisons for the poly(ethyl methacrylate) ear impressions (□) and the condensation reaction silicone ear impressions (Δ).

were compared to their resultant earmolds. In Table I significant differences are shown at Position 1 (0- to 180- degrees, superior to inferior, at the medial tip of the canal) and at Position 3 (0- to 180- degrees, anterior to posterior, at the junction of the bowl and canal) for the poly(ethyl methacrylate) impression to its resultant earmold. This is graphically illustrated in Figure 2. Also seen in Table I is a significant difference between the silicone impression and its resultant earmold as shown in Figure 3.

The individual ear impressions obtained with the two different materials were significantly different at position 4, (90- to 270- degrees, anterior to posterior, at the junction of the bowl and canal). This difference is shown in Table I and the physical relationship is illustrated in Figure 4.

The reliability of ear impression and earmold outside diameter measurements was determined by measuring two impressions and their resultant earmolds twice. These results, which can be seen in Table II, show that ear canal outside diameter variations did not exceed .016 inch.

Acoustical

Insertion gain measurements were compared for six of the twelve subjects. Six subjects were excluded because they preferred different volume control settings with the two experimental earmolds. It was felt that different

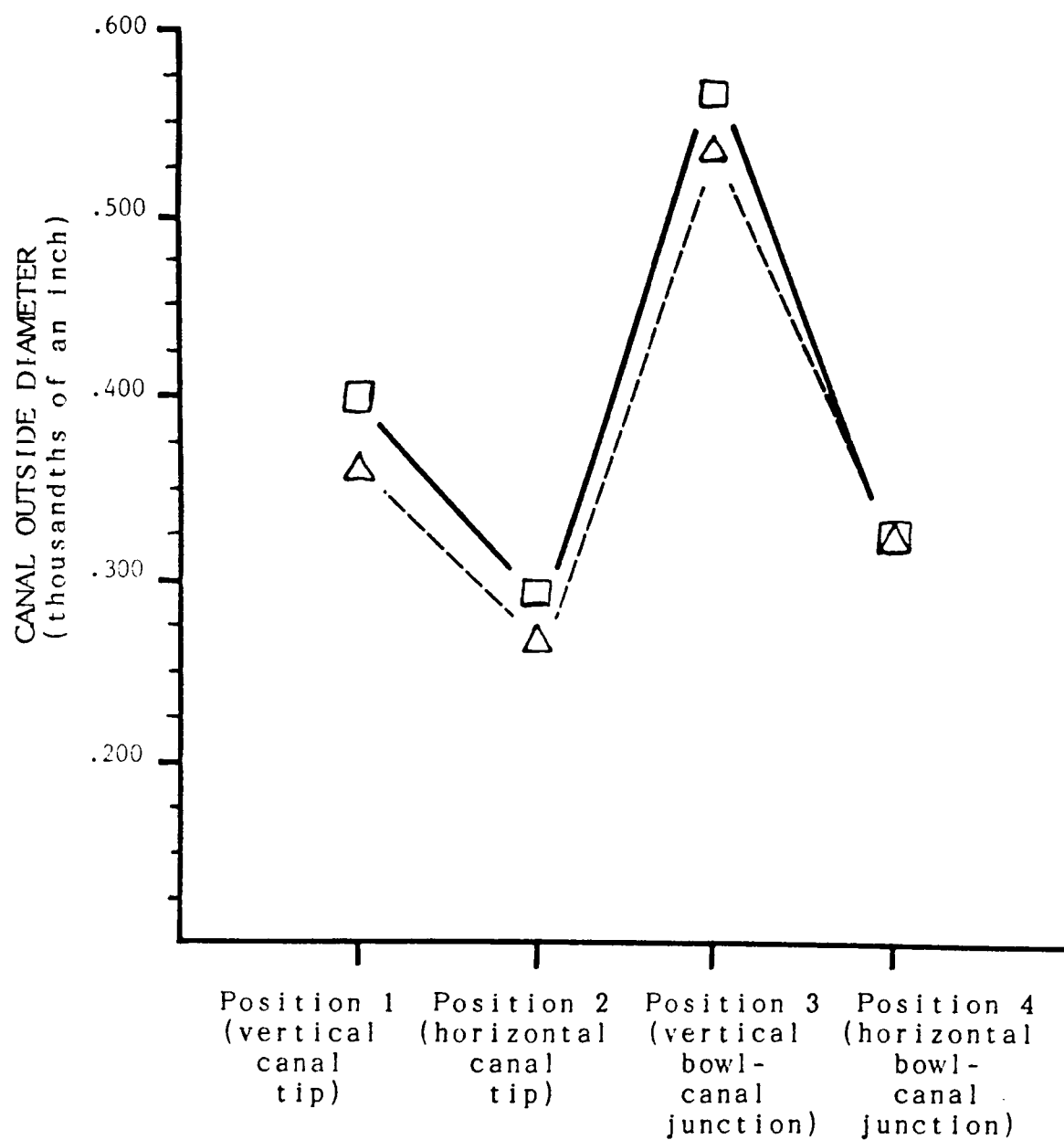


Figure 2. Mean outside diameter comparisons for the poly(ethyl methacrylate) impression (□) and its resultant earmold (△) at the four positions.

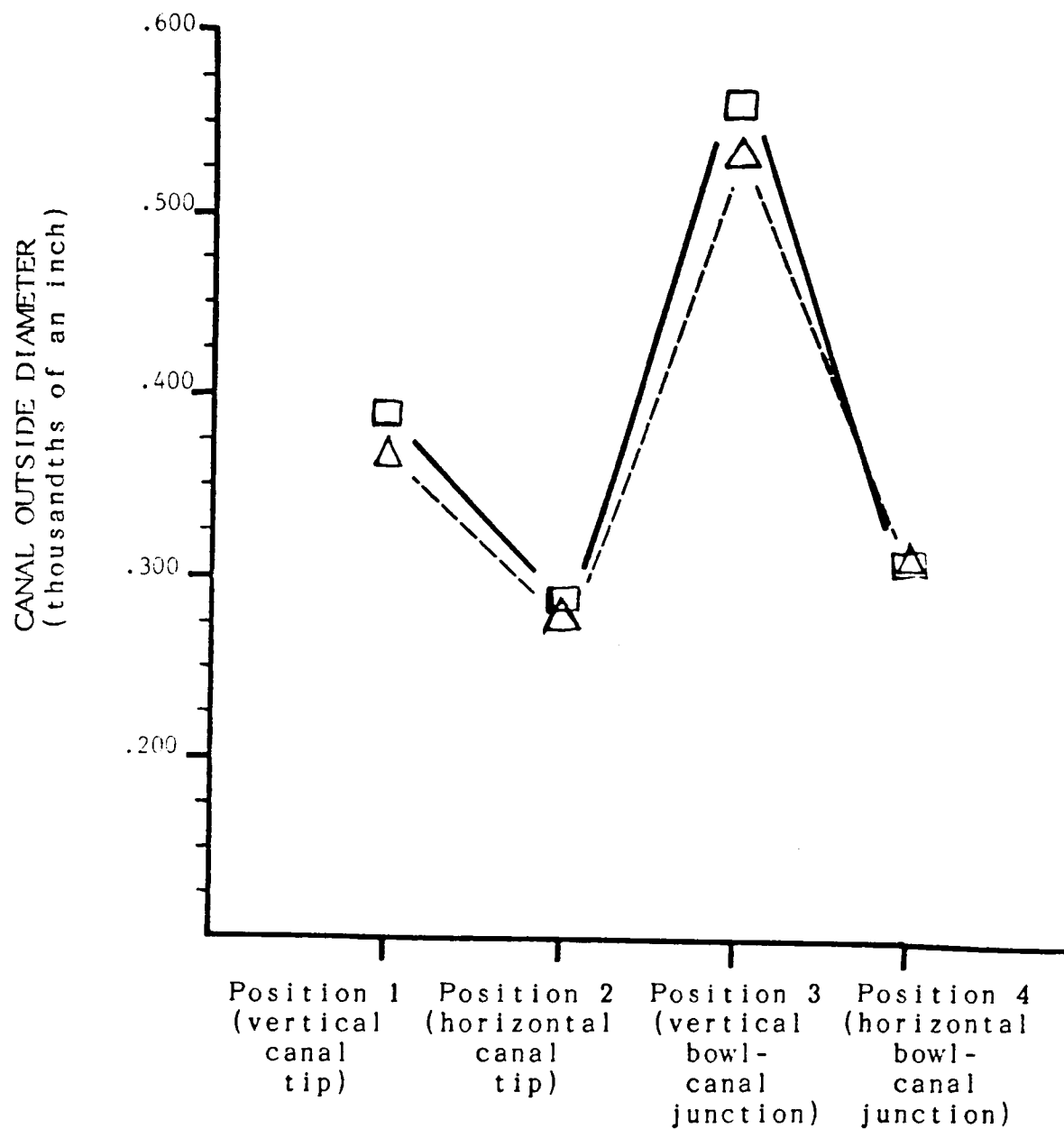


Figure 3. Mean outside diameter comparisons for the condensation reaction silicone impression (□) and its resultant earmold (△) at the four positions.

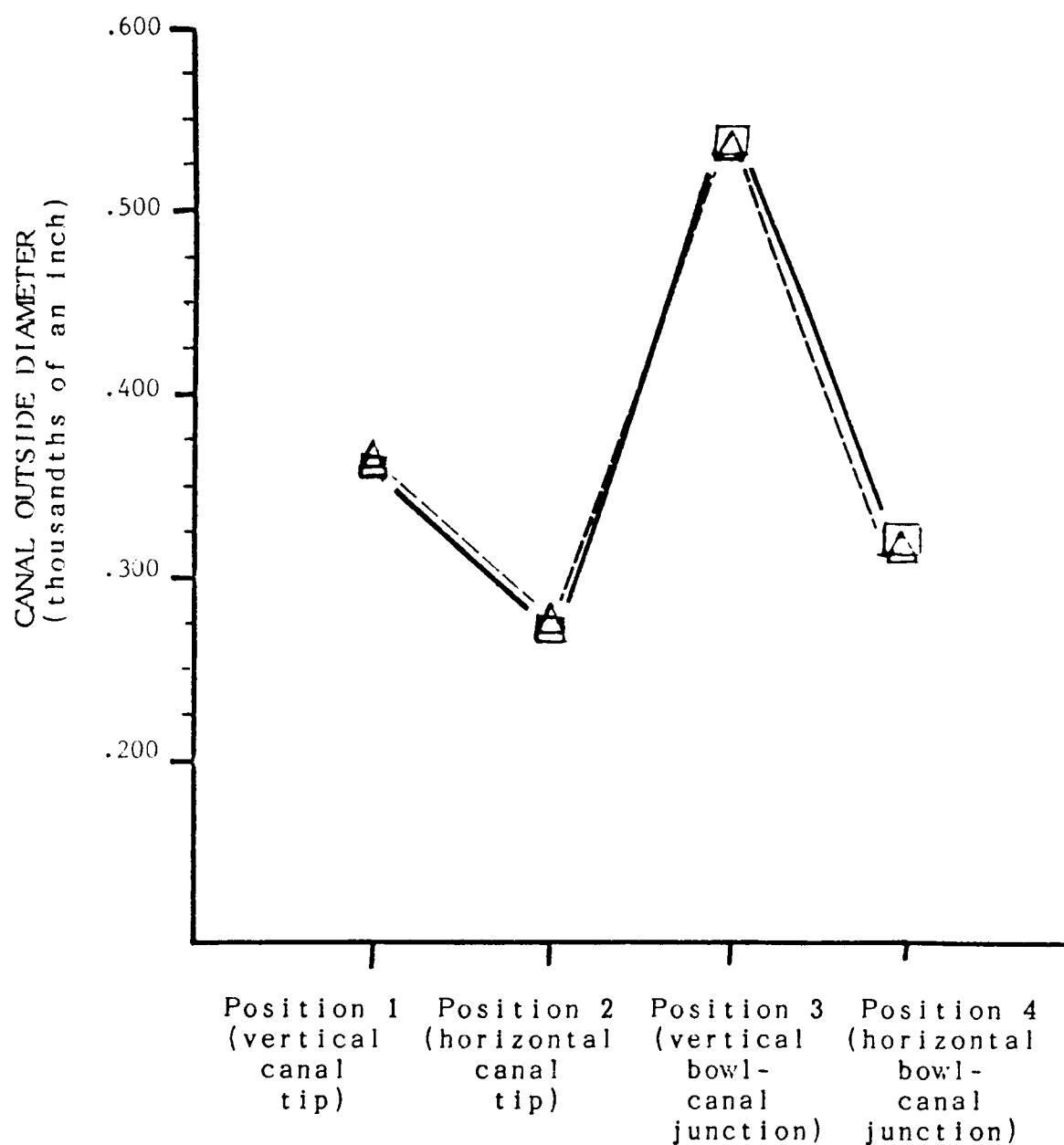


Figure 4. Mean outside diameter comparisons for the earmolds resulting from poly(ethyl methacrylate) (□) and condensation reaction silicone (Δ) ear impressions.

Table II. RELIABILITY OF EAR IMPRESSION/EARMOLD PHYSICAL MEASUREMENTS AND
CORRESPONDENCE OF EAR IMPRESSIONS AND PROCESSED EARMOLDS

Dimension (thousandths of an inch)	Impression I		Earmold I		Impression II		Earmold II	
	Test	Retest	Test	Retest	Test	Retest	Test	Retest
1. 0- to 180- at Canal Tip (superior to inferior)	.395	.395	.407	.412	.436	.428	.425	.420
2. 90- to 270- at Canal Tip (anterior to posterior)	.235	.247	.245	.242	.280	.264	.255	.253
3. 0- to 180- at Bowl/Canal Junction (superior to inferior)	.480	.475	.497	.481	.415	.410	.420	.411
4. 90- to 180- at Bowl/Canal Junction (anterior to posterior)	.248	.242	.259	.250	.208	.202	.212	.215
$\bar{x}$	.340	.338	.352	.346	.355	.326	.328	.325

volume control settings might contaminate these results. Table III shows t-test comparisons for the subjects wearing their own hearing aid and the two experimental earmolds. The insertion gain was significantly different at 2000Hz ($t = -2.89$).

Reliability of insertion gain was assessed by repeating the measures five times under controlled conditions (same subject, hearing aid, earmold, and volume control settings). Results show a range of 2dB at 500Hz, 3dB at 1000Hz, 9dB at 2000Hz, and 16dB at 4000Hz.

Psychophysical

A paired sample t-test was used to analyze the subjective ratings of the two earmolds. These results are shown in Table IV. A significant difference was found in the way the subjects rated the high pitch sound quality of the two earmolds. Six subjects preferred the earmold resulting from the silicone impression and five preferred the earmold resulting from the poly(ethyl methacrylate) impression. (One subject did not prefer either earmold because both produced acoustic feedback). Of the six preferring the earmold made from the silicone impression, four liked both the sound quality and physical comfort, one liked the sound of the silicone and both fit equally well. Finally, one liked the sound and physical comfort of both earmolds. In comparison, only one subject preferred both the sound quality and comfort of the earmold resulting from the poly(ethyl

Table III. ANALYSIS OF INSERTION GAIN RESULTS FOR THE EARMOLDS

Variable	t-statistic	P-value	Mean	Standard Deviation
500 Hz	-.08	.47085	-0.25	7.9608
1000 Hz	-1.21	.14095	-1.66	3.3862
2000 Hz	-2.89	.01705	-3.25	2.7523
4000 Hz	0.22	.41615	0.42	4.5762
Critical value ± 2.571				

The six subjects with the same volume control settings for both earmolds were utilized in order to maintain a better control of these measurements.

Table IV. ANALYSIS OF SUBJECTIVE RESULTS FOR THE EARMOLDS

Variable	t-statistic	P-value	Mean	Standard Deviation
Sound quality	1.48	.08305	.50	1.1677
Low pitch quality	0.48	.3190	.17	1.1934
High pitch quality	2.24	.02315	.58	0.9003
Overall comfort	0.94	.18415	.33	1.2309
Looseness	-0.32	.37725	-.08	0.9003
Overall rating	0.43	.33710	.16	1.3371
Critical value ± 2.201				

methacrylate) impression, two subjects chose the sound of the silicone but the fit of the poly(ethyl methacrylate), however, one subject felt that both earmolds were too large. The two remaining subjects preferred the sound of the poly(ethyl methacrylate) but the physical comfort of the silicone.

Reliability of subjective preference was determined by having four subjects wear an experimental earmold for a period of one week. Without knowing which earmold they were wearing, two of the subjects utilized earmolds made from poly(ethyl methacrylate) and two utilized earmolds made from silicone. When observing the reliability of the six questions, 86% of the questions were answered in exactly the same manner, however, only one of the four subjects chose the earmold which had been previously chosen.

CHAPTER V

DISCUSSION

Physical

Results of this study indicate that there are no differences in the physical size of earmolds from different impression materials. This finding was somewhat unexpected in light of differences that were observed between impressions and resultant earmolds and differences between the two impressions.

Physical measurements between the two impressions were significantly different when the impressions were made. Since the resultant earmolds are not significantly different, differences were expected between one or both of the impression versus earmold comparisons. This was evidenced by significant differences between both impressions and their resultant earmolds.

Observed differences between ear impressions and resultant earmolds could be due to the material's dimensional instability. In a study of ear impression materials, Agnew (1985), found poly(ethyl methacrylate) to be dimensionally unstable. Dimensional instability might account for the differences found between poly(ethyl methacrylate) impressions and their earmolds, however, a very similar relationship was observed for the silicone impression material.

(See Figures 2 and 3, pp. 21 & 22). Since silicone is dimensionally stable, it is not likely that these differences occurred because of material changes. It is more likely that the observed differences are due to the laboratory processing. In processing ear impressions, the laboratory compensates for the shrinkage of the poly(ethyl methacrylate) by adding wax. Wax is also applied to silicone impressions, but to a lesser degree. In other words, even though the original impressions were physically different, after laboratory processing, the earmolds were very similar. This means that the laboratory that processed the impressions in this investigation made a necessary correction. This brings up an interesting question: Would all laboratories make the same correction?

To answer this question a post-hoc study was undertaken, where a silicone impression of the Hocks rubber ear was processed by 16 earmold laboratories. A comparison of the impressions and resultant earmolds revealed significant differences at position 2 ($t = -2.22$) and position 3 ($t = 3.67$). Computed t -values are shown in Appendix D and this relationship is graphically illustrated in Figure 5. At first glance, the significant difference questions the laboratory's processing of these earmolds. When this data is interpreted in light of the above data regarding silicone, however, it probably means that the laboratories are making a similar correction.

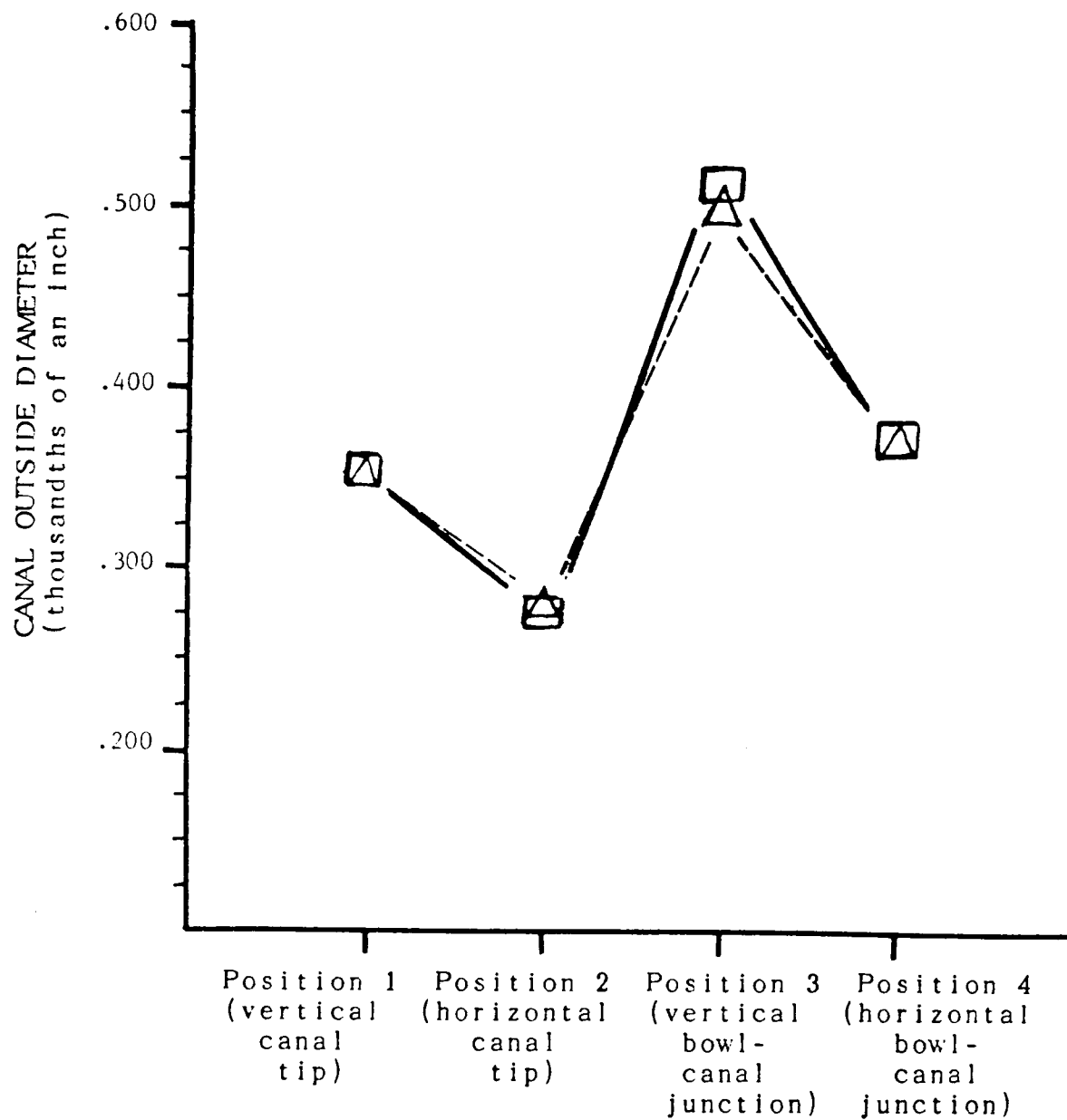


Figure 5. (Post-Hoc) mean outside diameter comparisons for the silicone impressions (□) and the resultant earmolds (△) at the four positions.

Data from the earmolds processed by the 16 earmold laboratories also revealed a wide range in weight and canal length. This data is presented in Table V. Not only were there wide ranges in weight and canal length, the laboratories also differ in the type of vent installed. Eight laboratories installed parallel vents while the remaining eight installed diagonal vents. Vent type has been reported to influence the acoustic characteristics of the amplification system. Juneau (1983) implies that the vent type is ideally selected on the basis of canal diameter. Data from this post-hoc data does not support this because all of the laboratories received almost exactly the same impression. The discrepancy between parallel and diagonal vents, along with the wide ranges of weight and canal lengths, suggests the need of more strict laboratory specifications regarding the processing of earmolds.

The results obtained in this study show no physical differences in earmolds made from poly(ethyl methacrylate) and condensation reaction silicone. In interpreting this information, one should remember that the physical measurements were obtained under controlled conditions. This involved careful monitoring of mixture ratios, completeness of mixing, care in packaging, and expediency in processing.

Acoustical

Insertion gain, for six subjects with the same volume control settings, was different with the two earmolds at

Table V. POST-HOC STUDY: RESULTS ON WEIGHT AND CANAL LENGTH DIFFERENCES

Variable	Mean	Standard Deviation	Minimum Value	Maximum Value	Range	Variance
Weight (grams)	2.09	.3006	1.47	2.73	1.26	.09
Canal Length (thousandths of an inch)	.198	.042	.145	.291	.146	1.797

2000Hz and can be seen in Figure 6. With the exception of 4000Hz, the earmold obtained from condensation reaction silicone uniformly provided more insertion gain. This is a very interesting finding and one of which we have no reasonable explanation. Unfortunately, the insertion gain data had large variability (especially at high frequencies) which may have been due to the test equipment and an improper test paradigm for non-linear hearing aids. In a study of variability using the same equipment, Mueller and Sweetow (1987), reported variability of 10dB at 500Hz, 7dB at 1000Hz, 10dB at 2000Hz, and 9dB at 4000Hz. Variability in this study was 2dB at 500Hz, 3dB at 1000Hz, 9dB at 2000Hz, and 16dB at 4000Hz.

The two earmolds produced an interesting acoustical result for one subject suffering from constant tinnitus. With the earmold made from the poly(ethyl methacrylate) impression material, the tinnitus was absent, however, with the silicone earmold the tinnitus was present and very annoying. The reason for this is unknown. Possibilities might include: slightly more gain with the earmold resulting from the poly(ethyl methacrylate) material which could obscure the tinnitus because of masking, and/or other physical variations which could produce acoustical differences.

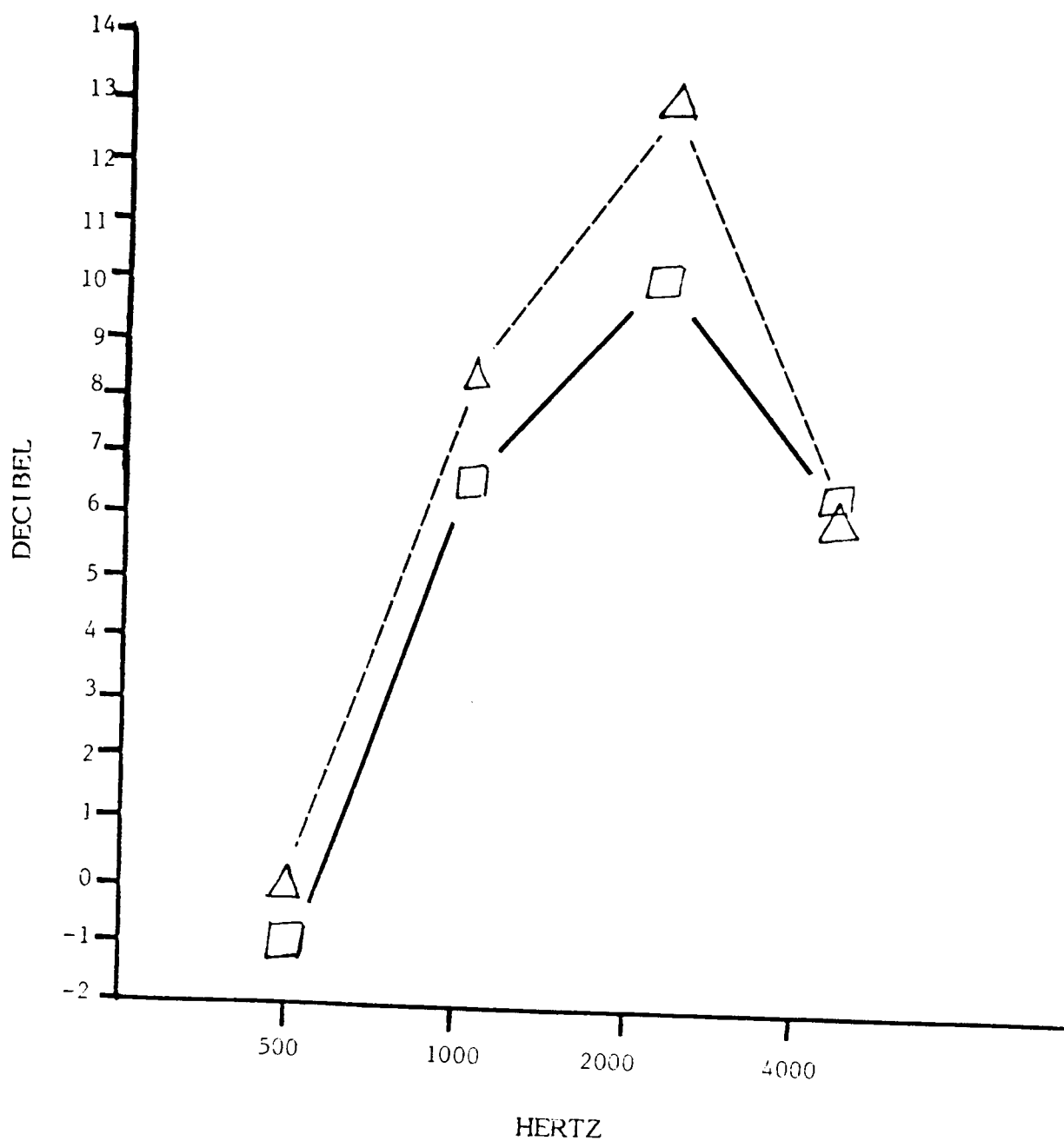


Figure 6. Mean insertion gain comparisons for the earmolds resulting from the poly(ethyl methacrylate) ear impressions (□) and the condensation reaction silicone ear impressions (Δ).

Psychophysical

The experimental earmolds were rated in terms of sound quality and physical comfort. Sound quality ratings show that seven subjects preferred the earmold made from silicone, three subjects preferred the poly(ethyl methacrylate), and one subject rated the sound quality equal for both earmolds. One subject did not like either earmold because both produced acoustic feedback. Results from the physical comfort show that six subjects preferred the earmolds resulting from silicone, three subjects preferred the poly(ethyl methacrylate), and two subjects rated the comfort equal for both earmolds. This data would suggest that the twelve subjects would select the earmolds resulting from the silicone impression, however, six subjects chose the silicone, five subjects chose the poly(ethyl methacrylate), and one did not like either earmold. When sound quality ratings are considered with physical comfort, some subjects select on the basis of sound quality and others select on the basis of physical comfort.

Recall that the primary concern in this study was to determine if earmolds made with different impression material are the same in terms of physical size and subjective information. The physical size data suggests that the earmolds are very similar and subjective comfort data supports this finding. It is important to note that even though the subjects indicated a preference from one earmold

to another, neither earmold caused discomfort in any subject. It is also important to remember that the physical measurements, even though significant, were very small. It may be that a significant difference would not be noticed in a typical subject.

CHAPTER VI

SUMMARY AND CONCLUSIONS

Ear impressions were obtained for twelve subjects with poly(ethyl methacrylate) and condensation reaction silicone ear impression materials. These impressions were processed into lucite earmolds which were compared in terms of physical dimensions, real ear acoustic gain, and subjective preference. Results of physical comparisons show that the size of the processed earmolds were not different. The acoustical results also show that the earmolds produced different real ear acoustical gain. Finally, the results of subjective quality judgments show that, when given preference, some subjects selected earmolds on the basis of acoustical properties while others based their selection on physical comfort.

The results do not seem to support a clear advantage for either impression material. Clinical experience with earmolds made from poly(ethyl methacrylate) impression material, however, continue to result in problems with acoustic feedback and poor physical fit. The results from this study, which did not exhibit difficulties with acoustic feedback or poor physical fit, indicated that poly(ethyl methacrylate) can be successfully used clinically only in conjunction with the controls, such as careful mixture

ratios, completeness of mixing, and expediency of processing, which were utilized in the present study.

Suggestions for Future Research

This study has given rise to the following questions:

- (1) What measured difference in earmold physical size is noticeable by subjects?
- (2) Are there acoustical differences between the earmolds which could be revealed by other measures?
- (3) Earmold physical measurements were confined to the canal portion of the impression and resultant earmold. Questions regarding data from other measured locations could be addressed in another study.
- (4) Are laboratory processing procedures for different impression materials, producing accurate earmolds in relation to the actual size of the ear?
- (5) Are more specifications needed among earmold laboratories concerning processing procedures, weight, canal length, and vent-types?
- (6) Would the same results be found for a different silicone impression material? (i.e. addition reaction silicone)

BIBLIOGRAPHY

- Agnew, J., (1986). The study of stability of ear impression materials. The Hearing Journal, 39, (6), 29-33.
- Bess, F., and Konkle, D., (1974). Custom earmolds in hearing aid evaluations. Maico Audiological Library Series, 12, (5).
- Bernafofon Inc., (1986). Otoform A/K Silicone Impression Material. Mountainside, N.J.
- Belton Electronics Corporation, (1986). Impress Instruction Sheet. Chicago, IL.
- Castleton, L., (1983). NAEL fitting facts (Part IV) Not the problem, the solution. Hearing Instruments, 34, (12), 24-26.
- Craig, R.G., and Peyton, F.A., (1975). Restorative Dental Materials. St. Louis, IL: C.V. Mosby Co.
- Esschem Co., (1986). Self Curing Silicone Impression Materials. Essington, PA.
- Gastmeier, W.J., (1981). The acoustically damped earhook. Hearing Instruments, 32, (10), 14-15.
- Gurschkov, S.M., (1978). What is silicone? Hearing Instruments, (July), 14-15, 29.
- Hocks, R., (1978). What are the remakes costing you? Hearing Instruments, (December), 13.
- Juneau, R.P., (1983). NAEL fitting facts (Part I) The ear impression. Hearing Instruments, 34, (3), 6-7, 49.
- Juneau, R.P., (1983). NAEL: Fitting facts, Part III: Venting of earmolds. Hearing Instruments, 34, (11), p. 38, 40, 53-54.
- Killion, M.C., (1976). An experimental wideband hearing aid. Paper CC5 presented at the 91st Meeting of Acoustical Society of America.
- Killion, M.C., (1979). Design and evaluation of high fidelity hearing aids. Ph.D. thesis. Northwestern University. (University Microfilms, Ann Arbor, Michigan).
- Loavenbruck, A.M., and Mandell J.R., (1981). Technical aspects of hearing aid dispensing. Hearing Aid Dispensing for Audiologists, Ch. 4.

- Lybarger, S.F., (1949). Damping elements for M-55 receivers. Radioear Voice, III, T1-T4.
- Lybarger, S.F., (1978). Extending the usefulness of adjustable vent inserts. Hearing Instruments, 12.
- Mahon, W.J., (1984). Earmold remakes: The bottom line. The Hearing Journal, 37, (5), 7-10.
- Mahon, W.J., (1986). 1986 U.S. hearing aid sales summary. The Hearing Journal, 39, (12), 9-22.
- Mars, H.A., (1987). Personal Correspondence. Unitron Industries, Inc., Port Huron, MI.
- Microsonic, Inc., (1986). Custom Earmold Manual. Ambridge, PA.
- Mueller, H., Schwartz, D.M., and Surr, R.K., (1981). The use of the exponential acoustic horn in an open mold configuration. Hearing Instruments, 12, (10), 16-17, 67.
- Mueller, H.G., and Sweetow, R.W. (1987). A clinical comparison of probe microphone systems. Hearing Instruments, 38, (6), p. 20-24, 57.
- Mynders, J.M., (1983). Custom Earmold Manual, Microsonic, Inc., Swickley, PA.
- Mynders, J.M., (1985). Human acoustic couplers. Hearing Instrument Science and Fitting Practices, Sandlin, R.E. (ed.), 313-386.
- Navarro, M.R., (1987). The effect of mandibular movement on ear impressions. The Hearing Journal, 40, (2), 13-14.
- Nolan, M., and Combe, E.C., (1985). Silicone materials for ear impressions. Scandanavian Audiology, 14, 35-39.
- Phillips, R.W., (1972). Science of Dental Materials. Philadelphia, PA: W.B. Saunders Co.
- Pollock, M.C., and Morgan, (1980). Earmold technology and acoustics. Amplification for the Hearing Impaired, Ch. 3.
- Raas, M.H., (1976). Good earmold impressions are important. Hearing Instruments, (December), 11.
- Ryborczyk, V., (1987). Personal Correspondence. Eastern Laboratories, Chicago, IL.

Schlaegel, N., (1976). The custom earmold. What role does it play in effective hearing aid fitting? Hearing Instruments, (December), 12.

Studebaker, G.A., and Cox, R.M., (1977). Sidebranch and parallel vent effects on real ears and in acoustical and electrical models. Journal of American Audiology, Inc., 3, (2), 108-117.

Unitron Industries Ltd., (1987). Professional Ear Impression Techniques for Custom In-The-Ear Hearing Aids. Canada.

Ward, G., (1987). Personal Correspondence. EMTECH laboratories, Roanoke, VA.

APPENDICES

APPENDIX A

Specific Procedures For Making the Impressions

The following preparation procedures were the same for both impression materials: The otoscopic inspection was performed prior to any impression insertions to observe the size and shape of the canal, excessive cerumen, foreign objects, perforations to the tympanic membrane, and collapsed canals. The subject was instructed to sit in an upright position and asked to not talk or chew until the impression was removed. A foam block was inserted to the second turn of the external ear canal with a pen light. The string attached to the foam block extended outside, near the subject's neck.

The following procedures are listed separately for the poly(ethyl methacrylate) and the silicone material, and specifically follow the manufacturer's recommendations.

Poly(ethyl methacrylate)

In preparation for the mixing of the poly(ethyl methacrylate) materials, set out a syringe and a spatula knife, shake the powder and the liquid compounds. Pour 5ml of fluid into a container and pour 14.5cc of powder into a small mixing bowl. To obtain an ear impression, combine the liquid and powder, and thoroughly mix for 30 seconds. Transfer the mixture from the mixing cup to the barrel of the syringe. Insert the plunger and force out the air

with the material to the tip. This material provides 1.5 minutes of injection time from the start of the mix. Inject the material with gentle pressure. Slowly withdraw the syringe as the ear canal fills keeping the tip in contact with the material to prevent voids or laminations of the impression material. Completely fill the outer portion of the ear with the impression material. Allow the material to cure 10 minutes in the ear before removing. Press the skin away from the edge of the impression to break the seal. Remove the impression carefully by lifting the ear upward and outward, and gently pull the impression with a wiggling motion.

The ear impression is properly labeled on the inserted card with the subject's name, file number, and the date the impression was made. The impression is glued on the card with cement glue and inserted in a box with the completed earmold order form. During shipment, nothing should be in contact with any portion of the impression other than the base where it is glued.

Silicone

In preparation for the mixing of the silicone materials set out a syringe, the putty base and accelerator, and a measuring teaspoon. To obtain an impression of the ear, place two level teaspoons of putty in the palm of your hand and form into a patty. Press the rim of the teaspoon scoop into the putty so that there is an impression of the circumference of the scoop. Extrude the accelerator 2 equal

lengths across the diameter of the impression of the scoop. The thickness of the extruded lengths should be the same as the orifice of the tube. Fold the base over the accelerator. Knead the mixture with your fingers or between the palms of both hands for 20 to 30 seconds. The mixture should be streak-free in color. Roll the mix into a rope between the palms of your hands. Place the rope into the syringe, insert plunger. Press the plunger and force out the air with the material to the tip. Approximately 1.5 minutes of injection time from the start of the mix is allowed. Inject the material with gentle pressure. Slowly withdraw the syringe as the ear canal fills, keeping the tip in contact with the material. Completely fill the outer portion of the ear with the impression material. The impression material in the outer ear may be smoothed with light finger pressure. Allow the material to set for 10 minutes before removing. To test the set, touch with a blunt instrument. The cured impression will spring back leaving no impression. Do not attempt to pull the impression from the ear. Press the skin away from the edge of the impression to break the seal against the tissue. Remove the impression carefully so that it is not distorted in the process by lifting the ear upward and outward, and apply a gently wiggling motion to remove the impression.

The ear impression is properly labeled on the inserted card with the subject's name, file number and the date the impression was made. The impression is placed (not glued)

in the shipping box with the earmold order form. During shipment, nothing should be in contact with the earmold.

APPENDIX B

Earmold Questionnaire Form 1

Earmold color code: _____

Name: _____

Address: _____

Telephone number: Home _____ Work _____

Time period of the earmold worn: ____/____/____ to ____/____/____

Estimated number of hours the earmold was daily worn: _____

Earmold Questionnaire Form 1 was completed: ____/____/____

Please rate the following questions as precisely as possible by circling your answer.

1. Rate the sound quality of your hearing aid with this earmold.
extremely good good average poor extremely poor
2. Rate the low pitch quality of your hearing aid with this earmold.
extremely good good average poor extremely poor
3. Rate the high pitch quality of your hearing aid with this earmold.
extremely good good average poor extremely poor
4. Rate the comfort of this earmold.
extremely good good average poor extremely poor
5. Rate the looseness of this earmold.
extremely good good average poor extremely poor
6. What is your overall rating of this earmold?
extremely good good average poor extremely poor

Earmold Questionnaire Form 2

Earmold color code: _____

Name: _____

Address: _____

Telephone number: Home _____ Work _____

Time period of the earmold worn: ____/____/____ to ____/____/____

Estimated number of hours the earmold was daily worn: _____

Earmold Questionnaire Form 2 was completed: ____/____/____

Please rate the following questions as precisely as possible by circling your answer.

1. Rate the sound quality of your hearing aid with this earmold.
extremely good good average poor extremely poor
2. Rate the low pitch quality of your hearing aid with this earmold.
extremely good good average poor extremely poor
3. Rate the high pitch quality of your hearing aid with this earmold.
extremely good good average poor extremely poor
4. Rate the comfort of this earmold.
extremely good good average poor extremely poor
5. Rate the looseness of this earmold.
extremely good good average poor extremely poor
6. What is your overall rating of this earmold?
extremely good good average poor extremely poor
7. Which earmold do you prefer?
Red Blue Either (circle one)

Table VI. ANALYSIS OF PHYSICAL MEASUREMENT RESULTS AT POSITION 1^a

Variable	t-statistic	P-value	Mean	Standard Deviation	Range
Impression to Impression	0.90	.19445	2.00	7.7225	25.0
Earmold to Earmold	-1.15	.1371	-5.58	16.8062	67.0
Poly(ethyl methacrylate)					
Impression to Earmold	2.36	.0190	33.83	49.7171	185.0
Silicone Impression to Earmold	2.05	.0325	26.25	44.3747	149.0
Critical value ± 2.201					

^a0- to 180- degrees, superior to inferior, at the medial tip of the canal.

Table VII. ANALYSIS OF PHYSICAL MEASUREMENT RESULTS AT POSITION 2^a

Variable	t-statistic	P-value	Mean	Standard Deviation	Range
Impression to Impression	1.93	.03981	6.42	11.5086	37.0
Earmold to Earmold	-0.87	.20235	-5.25	20.9897	60.0
Poly(ethyl methacrylate)					
Impression to Earmold	1.79	.05055	22.66	43.8828	171.0
Silicone Impression to Earmold	.91	.1910	11.0	41.8482	170.0

Critical value +2.201

a90- to 270- degrees, anterior to posterior, at the medial tip of the canal.

Table VIII. ANALYSIS OF PHYSICAL MEASUREMENT RESULTS AT POSITION 3^a

Variable	t-statistic	P-value	Mean	Standard Deviation	Range
Impression to Impression	1.28	.1137	3.42	9.2585	35.0
Earmold to Earmold	0.61	.27805	1.33	7.6078	26.0
Poly(ethyl methacrylate)					
Impression to Earmold	3.38	.0031	26.58	27.2546	98.0
Silicone Impression to Earmold	2.50	.01485	24.50	34.0040	101.0
Critical value ± 2.201					

^a0- to 180- degrees, superior to inferior, at the junction of the bowl and canal.

Table IX. ANALYSIS OF PHYSICAL MEASUREMENT RESULTS AT POSITION 4^a

Variable	t-statistic	P-value	Mean	Standard Deviation	Range
Impression to Impression	2.63	.0117	8.58	11.3013	41.0
Earmold to Earmold	1.56	.0739	6.33	14.0928	55.0
Poly(ethyl methacrylate)					
Impression to Earmold	-0.02	.4935	-0.25	51.9162	216.0
Silicone Impression to Earmold	-0.15	.4410	-2.50	57.0048	221.0
Critical value ± 2.201					

^a90- to 270- degrees, anterior to posterior, at the junction of the bowl and canal.

Table X. POST-HOC STUDY: ANALYSIS OF PHYSICAL MEASUREMENT RESULTS
FOR THE SILICONE IMPRESSION TO EARMOLD COMPARISON

Variable	t-statistic	P-value	Mean	Standard Deviation
Position 1 ^a	-0.07	.4726	-.25	14.2945
Position 2 ^b	-2.22	.02105	-6.00	10.8012
Position 3 ^c	3.67	.00115	14.81	16.1378
Position 4 ^d	0.08	.4675	.19	9.0496
Critical value ± 2.131				

a0- to 180- degrees, superior to inferior, at the medial tip of the canal.
b90- to 270- degrees, anterior to posterior, at the medial tip of the canal.
c0- to 180- degrees, superior to inferior, at the junction of the bowl and canal.
d90- to 270- degrees, anterior to posterior, at the junction of the bowl and canal.

Table XI. REMAKE RESULTS OF EARMOLD/IN-THE-EAR LABORATORY SURVEYS

Laboratories	Overall Remakes	Polyethyl Methacrylate		Remakes		Remakes		Cost	
		Silicone		% Earmolds	% ITE	Earmolds	ITE	Earmolds	ITE
Unitron	8%-10%	----	----	----	8%-10%	----	----	----	\$50-\$100
Precision	4%	2%	2%	4%	5%-6%	\$5.50	\$6-\$7		
Hocks	5%	3%	0	5%	----	\$3.80	----		
Southern	5%	2.5%	2.5%	5%	----	\$8.00	----		
Pacific Coast	5%	3%	2%	5%	----	\$11.00	----		
Argosy	2%-3%	----	----	----	2%-3%	----	----		
Oticon	----	----	----	----	4%-5%	----	\$15.00		
Eastern	----	----	----	----	----	\$2.00	----		
Entech	20%	----	----	5.2%	15.7%	\$4.00	----		

Table XII. RAW DATA: PHYSICAL MEASUREMENTS OF BOTH IMPRESSIONS
AT THE FOUR POSITIONS

	Position 1 ^a Subject Poly(ethyl Silicone methacrylate)	Position 2 ^b Poly(ethyl Silicone methacrylate)	Position 3 ^c Poly(ethyl Silicone methacrylate)	Position 4 ^d Poly(ethyl Silicone methacrylate)
1	.420	.320	.310	.590
2	.346	.296	.288	.596
3	.460	.237	.220	.500
4	.415	.252	.244	.538
5	.351	.215	.198	.615
6	.449	.217	.200	.638
7	.369	.302	.295	.567
8	.268	.380	.400	.460
9	.435	.275	.278	.555
10	.361	.258	.244	.567
11	.544	.495	.504	.499
12	.364	.289	.278	.476
$\bar{x}$	.399	.295	.288	.567
				.568
				.325
				.317

(thousandths of an inch)

a 0- to 180- degrees, superior to inferior, at the medial tip of the canal.

b 90- to 270- degrees, anterior to posterior, at the medial tip of the canal.

c 0- to 180- degrees, superior to inferior, at the junction of the bowl and canal.

d 90- to 270- degrees, anterior to posterior, at the junction of the bowl and canal.

Table XIII. RAW DATA: PHYSICAL MEASUREMENTS OF BOTH EARMOLDS AT THE FOUR POSITIONS

Subject	Position 1a		Position 2b		Position 3c		Position 4d	
	Poly(ethyl methacrylate)	Silicone	Poly(ethyl methacrylate)	Silicone	Poly(ethyl methacrylate)	Silicone	Poly(ethyl methacrylate)	Silicone
1	.385	.394	.308	.311	.590	.595	.303	.266
2	.349	.356	.279	.270	.499	.503	.324	.321
3	.439	.435	.238	.270	.528	.515	.311	.314
4	.380	.402	.245	.252	.573	.565	.330	.320
5	.344	.353	.236	.223	.590	.582	.354	.336
6	.392	.264	.226	.210	.514	.517	.310	.292
7	.360	.376	.284	.265	.475	.466	.322	.331
8	.274	.275	.341	.382	.527	.540	.330	.348
9	.432	.420	.265	.261	.550	.552	.309	.305
10	.340	.348	.251	.254	.490	.494	.332	.327
11	.265	.404	.345	.384	.675	.671	.354	.345
12	.320	.320	.246	.245	.473	.468	.326	.324
$\bar{x}$	.365	.371	.272	.277	.540	.539	.325	.319

(thousandths of an inch)

a0- to 180- degrees, superior to inferior, at the medial tip of the canal.

b90- to 270- degrees, anterior to posterior, at the medial tip of the canal.

c0- to 180- degrees, superior to inferior, at the junction of the bowl and canal.

d90- to 270- degrees, anterior to posterior, at the junction of the bowl and canal.

Table XIV. RAW DATA: PHYSICAL MEASUREMENTS OF THE POLY(ETHYL METHACRYLATE)
IMPRESSION TO RESULTANT EARMOLD AT THE FOUR POSITIONS

Subject	Position 1 ^a		Position 2 ^b		Position 3 ^c		Position 4 ^d	
	Impression	Earmold	Impression	Earmold	Impression	Earmold	Impression	Earmold
1	.420	.385	.320	.308	.596	.590	.296	.303
2	.346	.349	.296	.279	.500	.499	.302	.324
3	.464	.439	.237	.238	.538	.528	.298	.311
4	.415	.380	.252	.245	.615	.573	.340	.330
5	.351	.344	.215	.236	.638	.590	.294	.354
6	.449	.392	.217	.226	.567	.514	.300	.310
7	.369	.360	.302	.284	.460	.475	.310	.322
8	.268	.274	.380	.341	.555	.527	.329	.330
9	.435	.432	.275	.265	.567	.550	.292	.309
10	.361	.340	.258	.251	.499	.490	.321	.332
11	.544	.365	.495	.345	.758	.675	.510	.354
12	.364	.320	.289	.246	.510	.473	.310	.324
$\bar{x}$	.399	.365	.295	.272	.567	.540	.325	.325

(thousandths of an inch)

a 0- to 180- degrees, superior to inferior, at the medial tip of the canal.

b 90- to 270- degrees, anterior to posterior, at the medial tip of the canal.

c 0- to 180- degrees, superior to inferior, at the junction of the bowl and canal.

d 90- to 270- degrees, anterior to posterior, at the junction of the bowl and canal.

Table XV. RAW DATA: PHYSICAL MEASUREMENTS OF THE SILICONE IMPRESSION TO THE RESULTANT EARMOLD AT THE FOUR POSITIONS

Subject	Position 1a		Position 2b		Position 3c		Position 4d	
	Impression	Earmold	Impression	Earmold	Impression	Earmold	Impression	Earmold
1	.409	.394	.310	.311	.590	.595	.296	.266
2	.340	.356	.288	.270	.488	.503	.299	.321
3	.468	.435	.220	.270	.544	.515	.290	.314
4	.415	.402	.244	.252	.609	.565	.320	.320
5	.351	.358	.198	.223	.638	.582	.282	.336
6	.450	.364	.200	.210	.571	.517	.274	.292
7	.369	.376	.295	.265	.449	.466	.325	.331
8	.276	.275	.400	.382	.553	.540	.323	.348
9	.425	.420	.278	.261	.568	.552	.283	.305
10	.347	.348	.244	.254	.476	.494	.302	.327
11	.537	.404	.504	.384	.754	.671	.512	.345
12	.375	.320	.278	.245	.522	.468	.293	.324
$\bar{x}$	.397	.371	.288	.277	.568	.539	.317	.319

(thousandths of an inch)

a0- to 180- degrees, superior to inferior, at the medial tip of the canal.

b90- to 270- degrees, anterior to posterior, at the medial tip of the canal.

c0- to 180- degrees, superior to inferior, at the junction of the bowl and canal.

d90- to 270- degrees, anterior to posterior, at the junction of the bowl and canal.

Table XVI. RAW DATA: SUBJECTIVE MEASUREMENTS

Poly(ethyl methacrylate) resultant earmold				Silicone resultant earmold														
Subject	Q1a	Q2b	Q3c	Q4d	Q5e	Q6f	Q1a	Q2b	Q3c	Q4d	Q5e	Q6f	D1 ^g	D2 ^h	D3 ⁱ	D4 ^j	D5 ^k	D6 ^l
1	4	3	5	4	4	4	4	4	5	5	4	4	0	-1	0	-1	0	0
2	5	5	4	5	5	5	2	2	2	5	5	2	3	3	2	0	0	3
3	3	3	3	3	4	3	4	4	4	5	5	5	-1	-1	-1	-2	-1	-2
4	4	4	5	1	1	2	4	3	5	2	2	4	0	1	0	-1	-1	-2
5	4	4	3	4	4	4	4	4	3	4	4	4	0	0	0	0	0	0
6	5	4	5	4	5	5	4	4	3	4	4	4	1	0	2	0	1	1
7	4	3	4	4	4	4	3	3	3	3	4	3	1	0	1	1	0	1
8	3	4	3	4	4	3	3	4	3	3	4	3	0	0	0	1	0	0
9	2	2	2	5	5	3	3	3	2	4	4	3	-1	-1	0	1	1	0
10	4	3	3	4	1	2	2	2	2	2	3	2	2	1	1	2	-2	0
11	5	5	5	5	5	5	4	4	4	3	5	4	1	1	1	2	0	1
12	3	3	3	4	4	3	3	4	2	3	3	3	0	-1	1	1	1	0

Rating scale - (5) extremely good, (4) good, (3) average, (2) poor, (1) extremely poor.

a Question 1: sound quality

b Question 2: low pitch quality

c Question 3: high pitch quality

d Question 4: overall comfort

e Question 5: looseness

f Question 6: overall rating

g Difference between the two earmolds for question 1

h Difference between the two earmolds for question 2

i Difference between the two earmolds for question 3

j Difference between the two earmolds for question 4

k Difference between the two earmolds for question 5

l Difference between the two earmolds for question 6

Table XVII. RAW DATA: (POST-HOC STUDY) PHYSICAL MEASUREMENTS OF THE SILICONE IMPRESSIONS AND RESULTANT EARMOLDS AT THE FOUR POSITIONS

Laboratory	Position a		Position 2 ^b		Position 3 ^c		Position 4 ^d	
	Impression Earmold	Impression Earmold	Impression Earmold	Impression Earmold	Impression Earmold	Impression Earmold	Impression Earmold	Impression Earmold
1	.350	.356	.281	.271	.514	.498	.368	.372
2	.353	.359	.277	.287	.510	.498	.374	.366
3	.359	.363	.277	.285	.510	.479	.380	.390
4	.358	.360	.271	.285	.515	.470	.377	.368
5	.349	.360	.278	.305	.514	.520	.375	.371
6	.356	.368	.281	.278	.515	.505	.365	.369
7	.358	.354	.277	.280	.515	.488	.368	.370
8	.350	.357	.281	.285	.516	.520	.366	.366
9	.355	.365	.276	.290	.514	.498	.365	.365
10	.347	.298	.276	.280	.524	.530	.367	.386
11	.355	.355	.273	.290	.526	.515	.372	.378
12	.354	.355	.279	.270	.520	.520	.378	.365
13	.353	.357	.278	.294	.515	.491	.374	.384
14	.361	.360	.277	.266	.524	.479	.385	.370
15	.357	.347	.276	.276	.525	.515	.370	.365
16	.364	.369	.279	.291	.501	.495	.364	.360
$\bar{x}$	.355	.355	.277	.283	.516	.501	.372	.372

(thousandths of an inch)

a 0- to 180- degrees, superior to inferior, at the medial tip of the canal.

b 90- to 270- degrees, anterior to posterior, at the medial tip of the canal.

c 0- to 180- degrees, superior to inferior, at the junction of the bowl and canal.

d 90- to 270- degrees, anterior to posterior, at the junction of the bowl and canal.

Table XVIII. RAW DATA: (POST-HOC) WEIGHT AND CANAL LENGTH MEASUREMENTS OF THE EARMOLDS

Laboratory	Weight (grams)	Canal Length (thousandths of an inch)
1	1.97	.145
2	2.39	.224
3	2.08	.171
4	1.80	.245
5	1.47	.224
6	1.87	.152
7	2.30	.212
8	1.96	.159
9	1.93	.161
10	2.18	.252
11	2.19	.209
12	2.73	.291
13	2.11	.186
14	2.10	.200
15	2.48	.195
16	1.83	.145

VITA

Kimberly Jeanne Dye was born in Chattanooga, Tennessee on September 11, 1963. She graduated from Tyner High School in Chattanooga, Tennessee in 1981. She attended the University of Tennessee at Chattanooga from 1981-1982 and then transferred to Chattanooga State Technical Community College where she received an Associates Degree in the field of Interpreting for the Hearing Impaired. In September of 1984 she transferred to the University of Tennessee to later receive a Bachelor of Arts degree in the field of Audiology in June 1986. In September of that year she continued her studies in Audiology to receive a Master of Arts degree in December 1987.