

Custom Earpieces: A Closer Look

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Since the mid 1950s hearing devices have been fitted using custom earmolds, either as stand-alone couplers or as integrated couplers. Custom earmolds are casts made from investments of impressions of the ear canal concha and include varying depths of the ear canal (Figure 1a) resulting in a finished product (1b). Prior to custom earmolds, and still in wide-ranging locations around the world, various configurations of stock earpieces are used (Figure 1c).

For new hearing aid patients, getting an appropriate earmold is often the most challenging task. During the initial hearing aid fitting procedures, new earmolds for BTE aids and re-casing of other types of aids are a frequent occurrence.

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As hearing aid development has advanced over the years, certain issues have persisted. The custom earpiece is often the harbinger of unsuccessful hearing aid use because of its intertwined relationship to acoustic feedback, the occlusion effect, discomfort, cosmetic concerns, remakes, patient listening downtime, cost, etc. The custom earpiece plays a major role in issues related to the problems or success of wearing hearing aids—whether the hearing aids are analog or digital. Does the custom earpiece render the hearing aid a custom-fit device? The answer may be that while the hearing aid may be custom fit, the earpiece is most likely not.

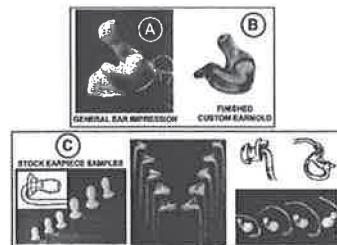


Figure 1

of unsuccessful hearing aid use because of its intertwined relationship to acoustic feedback, the occlusion effect, discomfort, cosmetic concerns, remakes, patient listening downtime, cost, etc. The custom earpiece plays a major role in issues related to the problems or success of wearing hearing aids—whether the hearing aids are analog or digital. Does the custom earpiece render the hearing aid a custom-fit device? The answer may be that while the hearing aid may be custom fit, the earpiece is most likely not.

A recent study of almost 2,000 hearing aid wearers shows high percentages of continued hearing aid problems six months post fitting, mostly earmold related (occlusion effect, discomfort, feedback, and ease of use); a combined 91% recognized that there is an expected overlap among the problems. When focusing on only a single complaint, the study shows unacceptably high incidences of earmold-

related problems in spite of the fact that decades have passed during which it should have been improved.

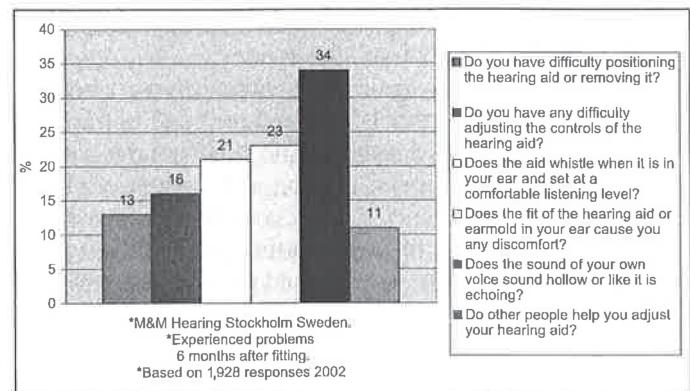


Figure 2

Problem

The custom earmold is made from an ear impression that is most often presented as an exact replica of the ear canal. Such a statement is known to be false because the ear canal is considered to be rather dynamic in its configuration, and no ear impression is able to capture it in its dynamic function (Termeer, 1992; Oliviera, et al., 1992; Staab, 1993, 1995; Staab and Martin, 1994; Garcia and Staab, 1995a, 1995b; Oliviera, 1995; Pirzanski, 1996). How much the actual ear impression varies from the dynamic ear canal depends on a number of issues: the chemical composition of ear impression material, whether the impression was taken during mandibular or other head movement (excessive or normal), the viscosity of the impression material, the shore hardness (durometer) of the ear impression material, the type of syringe used, the pressure applied by the syringe, the softness or hardness of the ear canal tissue, whether the ear impression was complete, how much of the ear canal replication is/was required, the temperatures/conditions of

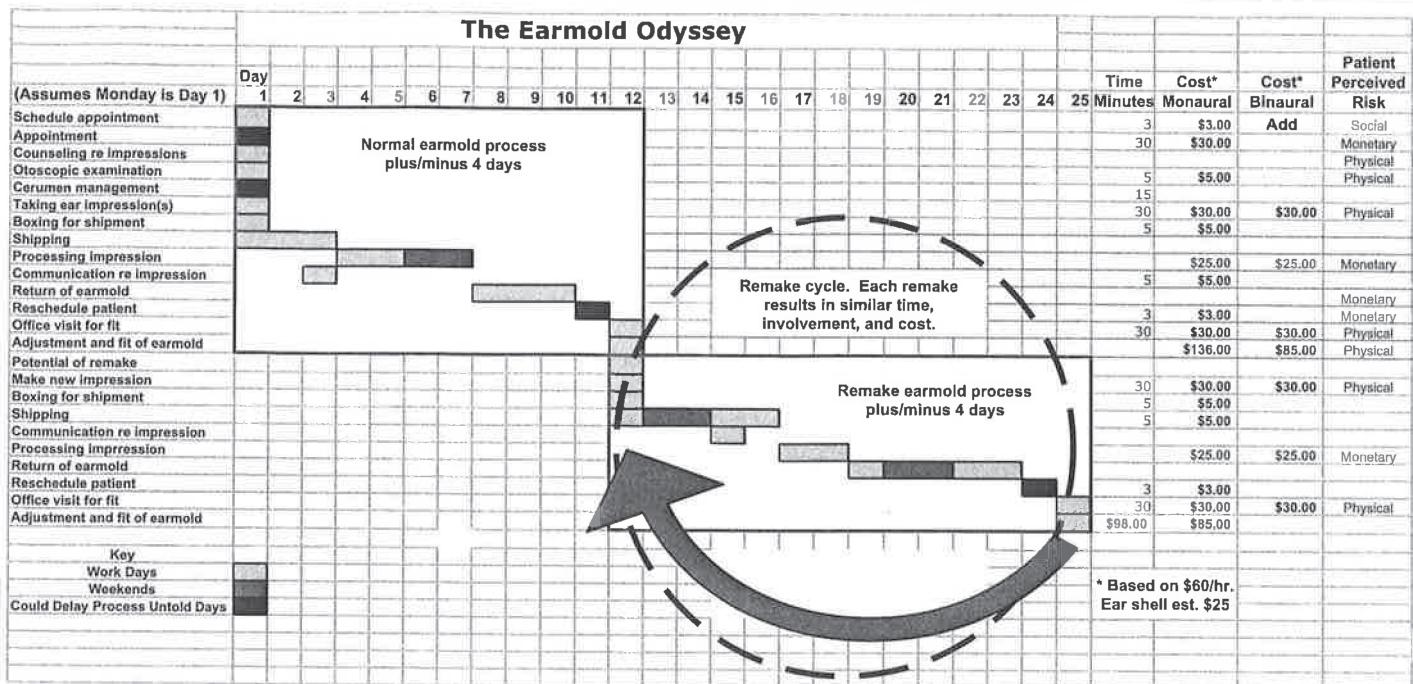


Figure 3

shipping, and other justified questions. Skills learned in taking ear impressions to produce a final product assume that answers to these questions have been resolved when, factually, we know the answers to almost none.

The primary issue of significance with custom earmolds is that they require substantial "care and feeding" to meet appropriately the comfort and acoustic needs of the patient. Some never do, which is not a strong endorsement of the accessory/product. Additionally, there is an efficiency and cost factor involved in custom earpieces that impacts a practice's professional image, responsibility, and profitability.

Figure 3 illustrates the magnitude and complexity involved in the odyssey of current hearing aid custom earmold processing and fitting required for satisfactory use and performance. One can easily argue with portions of the outlined timeline, but it is a fair representation of the events, costs, and times involved.

Not specifically quantified in the process outlined in Figure 3, but of significant importance to the dispenser and collaterally related to patient hesitancy in the purchase process are the following issues:

Time

The time involved in reaching a satisfactory conclusion with an earmold can easily be a turn-off for patients. This includes the total involvement in the impression and earmold process not just in fitting time, but also for shipment days, appointment scheduling, actual patient contact, and total internal office management/adjustment of the earpiece.

The earpiece fabrication cycle is approximately 8 to 12 days with additional time often required to complete the actual fitting. Of course, the hope is that the finished earmold/earpiece fits appropriately initially. If it does not, the process often has to be repeated, giving the patient the opportunity to have second thoughts about the potential pur-

chase. And, while this is not objectionable necessarily for the patient, it is not as good for the dispenser because of the time and effort that have already been expended.

The time involved and the subsequent potential setbacks associated with this process can be viewed as a negative experience by the patient.

Cost

The custom-molded earpiece and its fabrication have been used to justify the overall cost of the hearing aid. And because the earmold can have a significant impact on the total cost of the product to the consumer, it is useful to analyze these costs separately to determine how much this contributes to the overall cost and what impact this might have on a potential consumer.

Estimated costs (without markup) related to the earpiece are shown in Table 1. Based on \$60 per hour for a dispenser, these should be considered expected costs. With minimal patient contact these costs could be reduced approximately 50% but few would consider such rapid management good patient care. These costs multiply rapidly mostly due to counseling and reworks when the earmold does not fit properly and has to be remade or modified. While it is true that non-dispensers in the office can perform some of the listed activities, the difference in cost would be minimal.

After reviewing these costs for what in reality often turns out to be a non-custom earmold, it's reasonable to ask if this is an acceptable charge in the overall delivery package when all costs are factored in, but are the attending iterations and costs (overt or hidden) associated in providing an acceptable coupler considered by the patient to be an advantage or a disadvantage in the fitting process?

Based on the costs in Table 1, and using an often-applied pricing formula of a three-time markup, one could assume that a single earmold would cost approximately \$450 if

Conservative Costs for Earmold(s)

Activity	Monaural Time Involved	Binaural Add	Monaural Cost	Binaural Add
Schedule appointment	3 min		\$3.00	
Initial visit—front office paperwork	10 min		\$10.00	
Counseling/Explanation of process	30 min		\$30.00	
Ear canal inspection	5 min		\$5.00	
Cerumen management	15 min	15 min	\$15.00	\$15.00
Taking ear impression	30 min	30 min	\$30.00	\$30.00
Packaging ear impression and paperwork	10 min		\$10.00	
Delivery to postal carrier	20 min		\$20.00	
Mileage to postal carrier	10@\$0.50/mile		\$5.00	
Questions communication with man.	15 min		\$15.00	
Earmold cost			\$25.00	
Follow-up re order status	5 min		\$5.00	
Unpack and program earpiece	30 min	15 min	\$30.00	\$15.00
Schedule fitting appt.	3 min		\$3.00	
Fitting visit	30 min	30 min	\$30.00	\$30.00
Modification if required	15 min	15 min	\$15.00	\$15.00
Totals Monaural	3.9 hrs	1.5 hrs	\$251.00	\$150.00
Totals Binaural			\$401.00	

Table 1

true costs were applied to the dispensing process. It is doubtful, however, that this is calculated as such when the total cost of the hearing aid is considered.

The cost of earpiece management exceeds the non-hardware cost of the hearing evaluation and fitting in some facilities. Additionally, satisfactory resolution of the earpiece often involves more time, and hence cost, than does the management of the primary product—the hearing aid. This management ratio is worsened when the earpiece is the housing of the product itself, as in custom-molded hearing aids. Perhaps the earpiece should constitute 50% of the final product cost with the hearing aid hardware as the balance based on the time involved.

Overhead

Is the office/facility being used efficiently? How much space is involved in the management of the custom earpiece based on the income it produces? Are practices using too much physical space and associated cost in the management of a high-quality instrument on a questionable quality adjunct product?

Consumer Risk

Discussions of the hearing aid delivery system should include an understanding of consumer risk. When this topic is considered relative to hearing aids, the literature available seems to concentrate on two types of consumer risk: failure to get one's money worth, and failure of the hearing aids to live up to expectations.

In reality, five, and possibly even more types of risk exist that consumers face when making hearing aid purchases. These are identified as: monetary, functional, social, psychological, and physical risk (Staab and Jelonek, 1995). The magnitude of each kind of risk depends ordinarily on the personality of the buyer, and for hearing aids, on the type of products or services being considered.

Monetary risk is involved because the earpiece impacts the total cost of the hearing aid. Functional risk is related to a need for rapid resolution of the hearing problem often extended because of the earpiece. That one often has to make repeated visits to have the earpiece issue resolved suggests to the patient and his/her associates that something is not going right with the fitting, which adds to the monetary risk as well. Psychological risk is patients wondering if they have taken the correct action. And, while dispensers recognize that physical risk to those who wear hearing aids is seldom an issue, it may be a factor to those who have never worn hearing aids. How might this be? Patients currently know, or are made aware, that an ear impression will be made of their ear(s). This may be the first experience any have had with something placed in their ear canals. Patients have repeatedly been exposed to cautions about placing anything in their ears and this adds to the physical risk concern.

Is there apprehension to having ear impressions made? Because this issue is not specifically evaluated during the fitting process (the author is unaware of any studies that have addressed this), the assumption seems to be among dispensers that patient anxiety related to placing a cotton block in the ear canal and having ear impression material injected into their ear is a non-issue. But, is it known if this is a non-issue to potential hearing aid consumers? Anecdotally, there are numerous instances when individuals, including hearing aid dispensers, will decline participation in research studies or even licensing examinations where traditional ear impressions are to be taken because they are apprehensive about the process. If dispensers react this way, with their knowledge of the ear canal and subsequent expectations, why assume that this is a non-issue with the patient?

Reducing a prospective hearing aid purchaser's sense of risk may be one of the most important elements of the hearing aid sale. And, although the necessity of reducing consumer risk is understood intuitively, a systematic approach to defusing risk as a main source of resistance to purchasing hearing aids is seldom, if ever, followed. Perhaps another type of earpiece might help minimize this risk.

It is not inconsequential that the consumer asks: Am I prepared for all this? Am I prepared to not only make a commitment, admit my loss and take action to purchase hearing aids, but do I have apprehensions about the ear impression-taking process that might prevent taking this action? The consumer may not be conscious of the source of this ambivalence or how it affects his/her decision process, so this concern is seldom articulated clearly to the hearing aid dispenser. A study by Martin et al. (1989) in which adult patients were told they had a hearing loss, and how they reacted when told the results, may shed some light on the apprehension factor (Figure 4). Fear and worry

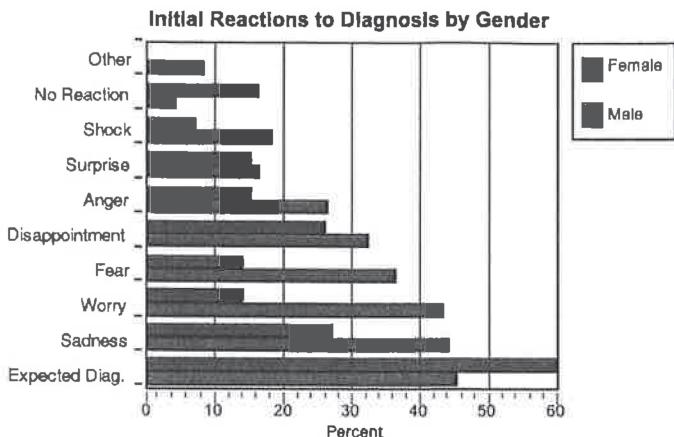


Figure 4

were reported between 15% and 44% of the time by males and females, with females showing greater concerns than males. If these reflect the concerns to the hearing diagnosis, it might be logical to suspect that their fears and worries would be even greater to the hearing aid process, which would include the taking of ear impressions.

Remakes

No published data is available relative to earmold remakes. However, the volume of all remakes compared with the volume of all new earmolds is 6% to 10% (Pirzanski, 2006). Some labs do a little better, and many are worse—up to 20%. His data shows that approximately 50% of all hearing aid remakes occur within the first 90 days of instrument use (40% within the first 60 days). These figures are fairly consistent with anecdotal hearing aid industry comments that about 15% of custom-molded hearing aids are remade within 90 days.

As problems with the fit occur, the efforts spent in resolving the complaint via remakes can increase substantially. The real issue is that this single, accessory-related product to the hearing aid fitting brings in little revenue, but contributes tremendously to patient dissatisfaction and apprehension, and to dispenser downtime. Multiple sessions to solve such problems are not uncommon. It should be understood that earmold issues contributing to the remake cycle are most likely due to the quality of the ear impressions received by earmold laboratories, rather than due to poor fabrication by the labs.

Discomfort

The earpiece associated with the initial fit of a hearing aid often produces discomfort (Figure 2). Resolution of discomfort of the earpiece is most often attempted initially by modification, in some way, of the existing earpiece. This usually involves grinding away portions of the custom earpiece, rendering it a “more custom” earpiece. A close examination of such modified earpieces would cast doubt on this suggestion. Earmold success does not come cheaply, or without potential additional problems. Modification of the earpiece often results in creating two or more problems with the fitting rather than resolving the initial problem. For example, making the earpiece more comfortable will most likely result

in greater acoustic feedback. To resolve this, the dispenser modifies the frequency response curve by rolling off the highs, reducing the gain or adding some form of feedback reduction which modifies the frequency response further from what was originally recommended.

Feedback

With the almost universal application and marketing of feedback reduction features in contemporary hearing aids, it should be obvious that the earpiece has not provided the required performance to manage this issue without additional assistance. Therefore, in a description of the earmold, to say that a good earpiece is required to manage feedback seems inconsistent with practice. And, if not to manage feedback, it is legitimate to ask what other significant feature the earpiece contributes to, because its use as a coupler can be managed using a variety of alternate approaches.

Acoustic Modification

In the era of post-auricular hearing aids, modifications were made to the earmold as an integral part of the hearing aid fitting process to adjust the hearing aid response to improve sound comfort acceptance. Lybarger (1991) noted that with the movement to custom-molded hearing aids, that the length and diameter of the sound bore in such instruments no longer lent themselves to significant earmold modifications. As a result, most attempts to modify the earpiece of custom-molded products are destined to make the acoustic fitting poorer not better.

Laser Technology

Ear impressions and the finished custom-molded product are a monumental problem that is evident by the expense involved recently by the hearing aid industry to develop laser scanning of ear impressions leading to subsequent shell-making improvements.

A number of hearing aid manufacturers have introduced this technology to scan the ear impression and then fabricate the earpiece from the measurements made, rather than from an investment of the ear impression itself. This process is believed to have improved the fabrication speed, quality, and tracking of the finished product such that it is closer in configuration to the received ear impression in its dimensional characteristics. This allows for controlled shell thickness, for reworking the product without having to make additional ear impressions, the elimination of changes due to buffing, migration of the acrylic as it is being poured and during setup, etc. This process appears to be good for production, especially for small custom-molded products where real estate is critical. The process should also be good to help determine ear canal dimensions most useful in making a conventional coupling device. A caveat that cannot be ignored, however, is that there are no assurances that the scanned ear impression was appropriate to begin with. When not, a poor impression is cataloged into the database. Garbage in, garbage out is just as applicable to this process as it is for traditional procedures. There is no guarantee that laser technology will solve the earpiece management issues.

Circumventing the Custom Earpiece—The Future?

Insistence on maintaining the custom earmold renders the industry open to encroachment from any number of non-industry sources that can provide alternate amplification devices not based on custom coupler fabrication. In fact, our listening environment is populated with quality audio devices that deliver high fidelity sound to the ear better than what hearing aids provide. Essentially, none use custom earpiece devices as the coupling agent. Instead, they use some form of stock device, with differing coupling configurations. It is unlikely that there will be mass movement toward custom-molded earpiece couplers for these products. And, if not for these high-fidelity devices, why for hearing aids?

Even within the hearing aid industry numerous approaches have been made to circumvent the inconvenience, time, and/or uncertainty involved in custom earpieces. In the early days of hearing aid fittings, all earpieces were some kind of stock fabrication. However, the need to direct sound to the impaired ear without feedback fostered the movement toward couplers that were molded from ear impressions. This was further advanced when ITE, ITC, and CIC instruments became the trend.

As often occurs in the discipline of hearing aids, the wheel is reinvented repeatedly, and the earpiece is no exception. There has recently been a renewed effort to facilitate hearing aid acceptance and use by employing a same-session hearing aid fitting process that bypasses the custom earpiece. A same-session fit allows the patient to experience immediately the benefit of amplification rather than working through a two-week or so process to make that determination. It also eliminates the custom earmold from the delivery system.

Same-session hearing aid fittings have a long history. Such instruments, often referred to as stock instruments, have always had a certain appeal to individuals seeking to sell and/or purchase hearing aids without the obstacles, costs, and timeline ordinarily encountered. In the past these were often offered via distribution systems considered unprofessional by mainstream dispensers of hearing aids, and as a result they were not endorsed. One argument presented by hearing aid professionals contends that such instruments do not provide appropriate amplification or fit and thus, discourage individuals from purchasing appropriate hearing aids—an argument never substantiated. Unanswered in such discussions is whether it is more discouraging to have a poor experience with a same-session fit instrument that may or may not have a lower cost than with a poor experience using a premium-priced instrument that involves multiple sessions to fulfill the fitting or end up as a non-sale? Armchair logic might suggest that a poor experience with an inexpensive device might be less of an obstacle to future potential trial than a poor experience with an expensive device.

Current, accepted same-session fittings include open earmold or deep fit applications. Open molds have evolved from small vents originally intended to reduce pressure

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sensation concerns, then larger to about 2 mm+ diameter to produce usable low-frequency suppression and reduction of the occlusion effect (Lybarger, 1978; Wimmer, 1986; Revit, 1992; Wynne and Williams, 2001; Kiessling, et al., 2003), to tubing only (Rowland, 1972, 1980; Courtois and Berland, 1972, 1973; Janssen, 1981 and Staab and Nunley, 1982).

Large vented and tubing-only systems are applied reasonably well to post auricular hearing aid modules provided the hearing loss is not too severe, or the hearing aid does not attempt to combine high-frequency electrical emphasis with the large vent or tubing only. However, they are impractical for custom-molded hearing aids.

Same-session fittings, and much of what is available from most other comparable devices, the ability to deliver sound to the ear without a custom-molded coupler. The purpose of such fittings is to give a patient the opportunity to instantaneously listen to and judge the comfort and quality of what is being used, in the exact way that the device will be worn. Same-session fit hearing aids allow:

- Instant fit in application
- The patient to determine immediately what amplification sounds like in exact fidelity
- Physical fit to be known immediately
- No time element delay in days from the first visit
- No discomfort issues that cannot be managed immediately
- No reason for ear impressions, remakes, or reworking of an earmold
- Tubing and tip size adjustments on the spot to accommodate individuals
- Instant gratification

- Less “jumping through the hoops” by the patient
- Dispenser to concentrate on electroacoustic features and not mechanical fit issues
- The dispenser to see and determine what the final fit will look like—during the fitting, and not one or two weeks later
- Improved bottom line for dispensers

Instant Gratification

Our listening environment is now populated with a plethora of listening devices that deliver high fidelity and/or standard sound to the ear using multiple methods to connect the device to the ear. iPods, MP3 players, Walkmans, and other high-fidelity devices used by millions of people each day suggest that there are other, less complicated and involved couplers that deliver sound to the ear, essentially none of which are custom-molded. Instead, they use some form of stock earpiece of varying sizes and configurations. It is unlikely that any of these will make mass migrations toward custom-molded earpieces, even as their numbers increase.

And, as high fidelity becomes more important in hearing aids, perhaps alternate-coupling devices will provide improved solutions over custom earpieces. Interestingly, this author can find no studies that identify improved listening performance related to a custom-molded earpiece. But, even if such studies could be found, is it not possible to include/manage high quality sound some other way? Current high-fidelity devices that use non-custom earpieces show that this *is* possible, and perhaps even desirable. Still, with hearing aids, we generally insist on coupling sound to the ear using a connector that has been the crux of fitting problems for many years, and continues to be so.

And, is it probable that the hearing aid industry will move forward if it insists on taking ear impressions, making earmolds, and managing problems with a process that does not fit into contemporary acceptance of instant gratification (i.e., food, clothing, general purchases, and the like)?

The hearing aid cost justification has been based heavily on a custom fit to your ear concept. Perhaps this *is* the problem. For example, even eyeglass fittings are not so encumbered as are hearing aids. This is more in line with same-session hearing aid fittings, except that the prescription relates to the hearing aid being custom, and not to the coupler. In other words, instant gratification, without the hassle!

Summary

The custom hearing aid earpiece, along with its complications and cost implications, may be the single most important obstacle to hearing aid market penetration. This is because it prevents same-session fitting and/or evaluation, the instant gratification that today's society seems to demand. It has become the primary management issue related to many hearing aid fittings, often involving more time and effort than the actual programming of the instrument itself. As adjusted and modified, this custom-molded coupler becomes a non-custom-molded device. Because of this, it is often currently replaced with a non-custom earpiece that has been designed to circumvent the problems associated with its fabrication and delivery.

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Regardless of future directions in the coupling of the hearing aid to the ear, there will probably always be a niche for custom earpieces, just as there are for a multitude of custom products for other items that consumers purchase. However, if hearing aid market penetration is to move forward, a movement away from the custom earpiece will most likely be required to drive the market. *THP*

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1. According to the article the following statement is most accurate relative to custom earmolds:

- a. they are required for a successful hearing aid fitting
- b. they provide the best option to connect the hearing aid to the ear
- c. custom earmolds are seldom, if ever, custom
- d. they function best for same-session fittings
- e. custom earmolds have been instrumental in market penetration

2. Which of the following was NOT listed as being a continuing problem related to hearing aids following six months post-fitting:

- a. feedback
- b. occlusion effect
- c. comfort
- d. positioning/fit
- e. continued "care and feeding" of the hearing aid for satisfactory use

3. What is the time involved in the normal custom earmold odyssey?

- a. 3 days
- b. 5 days
- c. 9 to 16 days
- d. 25 days
- e. 1 to 2 months

4. Remakes for new custom hearing aids/earmolds, according to Pirzanski, is:

- a. 1-2%
- b. 2-5%
- c. 6-10%
- d. 12-15%
- e. 18-20%

5. The real cost (without markup) of binaural earmolds is estimated at:

- a. \$50
- b. \$100
- c. \$200
- d. \$400
- e. \$600

6. The major concern related to laser modeling of earmolds is:

- a. garbage in, garbage out
- b. they are not able to duplicate the ear impression
- c. shell thickness is not controlled
- d. it is not guaranteed to solve the earpiece management issues
- e. the process is too time consuming

7. There are many problems with custom earmolds, but one of the following is NOT one of them:

- a. they are not really exact replicas of the ear canal
- b. they will most likely continue to be a part of hearing aid fittings, especially for certain cases
- c. perhaps more time is spent on the earmold, an accessory, than with the primary product, the hearing aid
- d. they render the industry open to encroachment from any number of alternate amplification sources and couplers
- e. getting an appropriate earmold is often one of the most challenging issues surrounding the hearing aid fitting

8. Functional risk is:

- a. always considered with the taking of ear impressions
- b. the patient wondering if they have made the correct decision in the purchase
- c. related to a need for rapid resolution of the hearing problem
- d. concern that there could be physical harm in the taking of the ear impression
- e. concern that others will question your actions in seeking hearing help

9. A current fitting procedure that circumvents the custom earmold is:

- a. real-ear measurements
- b. same-session fitting
- c. high-fidelity amplification
- d. the use of vented earmolds
- e. the use of programmable hearing aids

10. Same-session fittings have all the advantages except for one of the following:

- a. physical fit known immediately
- b. instant gratification
- c. less "jumping through the hoops" by the patient
- d. dispenser can concentrate on electroacoustic, rather than mechanical features
- e. the time element delay in days from first visit is kept very short

CUSTOM EARPIECES—SEPTEMBER/OCTOBER 2006—DEADLINE: OCTOBER 2007

Name _____

Address _____

City _____ State/Province _____ Zip/Postal Code _____

Email _____

Office Telephone _____

SS/SI# _____

Professional and/or Academic Credentials: _____

(PHOTOCOPY THIS FORM AS NEEDED)

Please check one: \$ 29 (member) \$ 59 (non-member)

ANSWER SECTION

(Circle the correct response from the test questions above.)

1. a	b	c	d	e	6. a	b	c	d	e
2. a	b	c	d	e	7. a	b	c	d	e
3. a	b	c	d	e	8. a	b	c	d	e
4. a	b	c	d	e	9. a	b	c	d	e
5. a	b	c	d	e	10. a	b	c	d	e