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Tetrahydrofurfuryl Methacrylate and Isobornyl Acrylate: Possible New Sensitisers in Hearing Aid Ear Moulds

Norbertus A. Ipenburg | Anton C. de Groot | Thomas Rustemeyer

Dermato-Allergology and Occupational Dermatology, Amsterdam University Medical Center, Amsterdam, the Netherlands

Correspondence: Anton C. de Groot (antondegroot@planet.nl)

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ABSTRACT

Background: Allergic contact dermatitis from hearing aid ear moulds is infrequently reported.

Objectives: To identify cases of allergic contact dermatitis from hearing aid moulds in a cohort of patients investigated between 2022 and 2025 at Amsterdam University Medical Center.

Materials and Methods: Retrospective analysis of patients referred for investigation of suspected allergic reactions to ear moulds.

Results: Of 20 patients with suspected allergic reactions to ear moulds, 8 (40%) had positive patch tests to (meth)acrylates considered to be probably relevant. All eight reacted to tetrahydrofurfuryl methacrylate, of whom five had a positive reaction to this hapten only. The other three all co-reacted to isobornyl acrylate and 1,6-hexanediol diacrylate. None had positive patch tests to hydroxyethyl methacrylate.

Conclusions: There are strong indications that tetrahydrofurfuryl methacrylate and isobornyl acrylate are relevant contact allergens present in hearing aid ear moulds. Hydroxyethyl methacrylate did not identify a single case of contact allergy to these materials.

1 | Introduction

Allergic reactions to ear moulds of hearing aids causing contact dermatitis in the ear canal (allergic otitis externa) are reported infrequently [1–13]. (Meth)acrylates are the most commonly documented culprit allergens, notably methyl methacrylate [3, 7, 8, 11, 12]. Isolated case reports have implicated other (meth)acrylates: polyethylene glycol dimethacrylate [4], hydroxyethyl methacrylate (HEMA) [4], urethane acrylate [10], triethylene glycol dimethacrylate [8] and urethane dimethacrylate [8].

The aim of this study was to retrospectively investigate patch test results in patients referred for suspected allergic contact dermatitis due to ear moulds or ear plugs.

2 | Materials and Methods

Patients with suspected allergic contact dermatitis due to ear moulds or earplugs were identified by reviewing the referral reasons of all 392 patients patch tested with the (meth)acrylate series between 2022 and 2025. Of these, 20 patients were referred with suspected ear mould or ear plug allergy and were included in this case series. All have been patch tested with the European baseline series, our additional routine series of 27 haptens (not containing (meth)acrylates or any related haptens), the (meth)acrylate series, the isocyanate series and selected additional series and patients' personal products based on the medical history. The European baseline series and the additional routine series were (with the exception of some specific haptens in the latter) purchased from SmartPractice (www.smartpracticeeurope.com,

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brand Allergeaze). The composition of the (meth)acrylate series is shown in Table 1, together with test concentrations, suppliers, period of testing the individual haptens and number of patients with suspected allergy to ear moulds tested with these haptens.

Patch testing was performed with Van der Bend patch test chambers (Van der Bend, Brielle, The Netherlands), with fixation using Omnifix elastic (Paul Hartmann BV, Nijmegen, The Netherlands). The occlusion time was 48 h, and the results were read on day (D) 2 with a second reading on D3 according to ESCD criteria [14]. Patients had been instructed on two occasions to contact the department when new reactions were observed after the final reading. Informed consent was obtained from all participants. Positive results were categorised as certain, probable, possible, unlikely, or unknown/no clinical relevance and were determined based on the assessment of the dermatologist. 'Certain' and 'probable' relevance scores were considered clinically relevant.

3 | Results

In the period 2022–2025, 20 patients with suspected allergic reactions to ear moulds or earplugs had been investigated at the Department of Dermato-Allergology and Occupational Dermatology of Amsterdam UMC. Eight of these (40%) had one or more positive patch tests to (meth)acrylates (described here). Of the other 12, 10 wore a hearing aid with ear moulds and two in-ear earplugs. Two had not a single positive patch test and eight had only reactions not considered to be relevant. One individual reacted only to scrapings of his ear mould, another to dimethyl-*p*-toluidine scored as 'possible relevance' and two had allergic reactions to topical corticosteroids and neomycin.

Of the eight patients with reactions to one or more (meth)acrylates, seven individuals had been referred by the Department of Otolaryngology–Head and Neck Surgery (ENT department) for suspected allergy to ear moulds of hearing aids and one for possible allergy to in-ear earplugs. All patients suffered from itching and 'rash' in the ear canal, some also of the adjacent skin of the concha, which they related to the wearing of the ear moulds. The majority of patients had mild dermatitis with erythema and dry scales, but some had suffered periods of subacute or acute dermatitis with erythema, papules, vesicles and oozing. Topical corticosteroids had usually been prescribed by the ENT specialist and often provided symptomatic relief. The patient reacting to in-ear earplugs (patient 6, Table 2) had fierce otitis externa with oozing and later developed dermatitis from headphones

TABLE 1 | The (meth)acrylate series: Results of testing in eight patients reacting to one or more (meth)acrylates.

Hapten	Test conc.	Supplier	Test period	*n* tested	*n* positive	%
Hydroxyethyl methacrylate	2% pet.	A	2022–2025	8	—	—
Benzyl methacrylate	2% pet.	I-H	February 2025 – end 2025	1	—	—
Hydroxypropyl methacrylate	2% pet.	A	2022–2025	8	2	25
Ethylene glycol dimethacrylate	2% pet.	A	2022–2025	8	—	—
Ethyl acrylate	0.1% pet.	C	March 2023–2025	2	—	—
Trimethylolpropane trimethacrylate	2% pet.	I-H	February 2025 – end 2026	1	—	—
Tetrahydrofurfuryl methacrylate	2% pet.	A	2022–2025	8	8	100
1,4-Butanediol dimethacrylate	2% pet.	A	2022–2025	8	2	25
1,6-Hexanediol diacrylate	0.1% pet.	C	2022–2025	8	3	37.5
Methyl methacrylate	2% pet.	A	2022–2025	8	—	—
Triethylene glycol dimethacrylate	2% pet.	A	2022–2025	8	—	—
Isobornyl acrylate	0.1% pet.	C	2022–2025	8	3	37.5
	0.3% pet.[a]	I-H	January 2024–2025			
Urethane dimethacrylate	2% pet.	A	2022–2025	8	—	—
Butyl methacrylate	2% pet.	C	2022–2025	8	1	12.5
Dimethylaminoethyl methacrylate	0.2% pet.	C	2022–2025	8	—	—
Isobornyl methacrylate	2% pet.	I-H	January 2024–2025	2	—	—
Epoxy acrylate	0.5% pet.	C	2022 - January 2024	6	—	—
Bisphenol A dimethacrylate	2% pet.	A	2022–2025	8	1	12.5
Bisphenol A-glycidyl methacrylate	2% pet.	A	2022–2025	8	—	—

Note: A: Allergeaze (www.smartpracticeeurope.com); C: Chemotechnique (www.chemotechnique.se); I-H: Prepared in-house, materials purchased from Sigma-Aldrich (www.sigmaaldrich.com).
[a]Reactions to both concentrations (either single or dual) were counted as positive.

around the ears. None of the 8 had used modern nail cosmetics or diabetes devices (glucose sensors, insulin pumps) and none had a history of intolerance to medical plasters, dental fillings, adhesives or other products that may contain (meth)acrylates.

Patient parameters and results of patch testing with (meth)acrylates are shown in Tables 1 and 2.

All eight patients (100%) reacted to THFMA and the three patients who were tested with scrapings of their personal ear moulds all had positive reactions to the material. There were three reactions each (37.5%) to HDDA and IBOA and two (25%) to hydroxypropyl methacrylate and 1,4-butanediol dimethacrylate. Bisphenol A dimethacrylate (BIS-MA) and butyl methacrylate each scored one positive patch test (12.5%) (Tables 1 and 2). Of the eight patients included in this study, 5 (62.5%) had a single reaction to THFMA. All other three patients co-reacted to both IBOA and HDDA. All reactions were—tentatively, knowing that these products usually contain (meth)acrylates, but in the absence of exact ingredient information—scored as probably relevant.

Patient 7 also reacted to various metals (nickel, cobalt, palladium, titanium), which reactions were considered to be clinically relevant. This patient had developed allergic dermatitis from her ear moulds; therefore, they had been covered with a metal coating (composition unknown). This, however, worsened rather than alleviated her symptoms.

The patients were instructed to avoid contact with products containing (meth)acrylates and were informed that these chemicals in the ear moulds very likely were the cause of the allergic reactions they experienced. The referring ENT specialists were advised to seek moulds not containing (meth)acrylates. Long-term follow-up to assess the results of these interventions was not possible.

4 | Discussion

Allergic contact dermatitis from hearing aid ear moulds has been reported in a number of publications [1–13, 15]. Several chemicals have been implicated, including resorcinol monobenzoate [1, 13], bisphenol A epoxy resin [2], gold (used for cover-plating a mould that had caused allergic symptoms in the patient) [5], *p-tert*-butylphenolformaldehyde resin [6], diethyl phthalate [9], polyvinyl chloride [11], triphenyl phosphate [13], Vulcanite [11], and (meth)acrylates: methyl methacrylate [3, 7, 8, 11, 12], polyethylene glycol dimethacrylate [4], HEMA [4], urethane acrylate [10], triethylene glycol dimethacrylate [8] and urethane dimethacrylate [8].

TABLE 2 | Patient parameters and patch test results.

Pat. Nr.	Gender	Age	Period of use of hearing aids	Period of complaints	Patch test results[a]
1	M	68	30 years	4 years	Tetrahydrofurfuryl methacrylate (+) Isobornyl acrylate (+) 1,6-Hexanediol diacrylate (+)
2	F	77	3.5 years	3 years	Tetrahydrofurfuryl methacrylate (+); scrapings of personal ear moulds (++).
3	M	65	1 year	7 months	Tetrahydrofurfuryl methacrylate (++)
4	F	19	15 years	1.5 years	Tetrahydrofurfuryl methacrylate (+); scrapings of personal ear mould (+)
5	F	61	? (at least 1.5 years)	10 months	Tetrahydrofurfuryl methacrylate (+); scrapings of personal ear mould (+)
6	M	53	Unknown; this patient reacted to in-ear ear plugs and later to headphones and noise-cancelling devices	3 years	Tetrahydrofurfuryl methacrylate (++) Isobornyl acrylate (+++) 1,6-Hexanediol diacrylate (+) 1,4-Butanediol dimethacrylate (++) Hydroxypropyl methacrylate (++) Bisphenol A dimethacrylate (BIS-MA) (++) Butyl methacrylate (++)
7	F	63	2 years	Started after a few weeks	Tetrahydrofurfuryl methacrylate (++)
8	M	77	10 years	6 months	Tetrahydrofurfuryl methacrylate (+++) Isobornyl acrylate (+) 1,6-Hexanediol diacrylate (+) 1,4-Butanediol dimethacrylate (+) Hydroxypropyl methacrylate (+)

[a]Non-relevant reaction to other haptens are not shown.

In the 1980s and early 1990s, cases of allergic otitis externa may have been rather frequent. Meding and Ringdahl in Sweden, for example, patch tested 22 hearing aid users with longstanding and severe dermatitis in the ear canal. In 6 (27%) individuals, contact allergy to the ear mould material was diagnosed [8]. Cockerill had collected 25 hearing aid users with otitis externa, of whom 14 tested positive to methyl methacrylate, 2 to polyvinyl chloride, and 1 to Vulcanite [11]. However, in these publications, the presence of the implicated allergens in the hearing aid ear moulds was not ascertained [8, 11]. Finally, investigators from Denmark reported on 13 patients with suspected allergy to ear moulds. Seven were patch tested, of whom 4 were found to be sensitised to methyl methacrylate, which had also sensitised three laboratory technicians engaged in the production of UV-light-cured acrylate ear moulds containing methyl methacrylate [7].

During the past 25 years, only few new cases have been reported [1–5, 15]. This may be the result of using less sensitising (meth)acrylates and/or currently used optimised UV-hardening protocols which leave a very low level of residual monomers in the final product. Occupational allergic contact dermatitis has been reported from Denmark in three technicians who produced hearing aids using ultraviolet-cured acrylate compounds containing hydroxypropyl methacrylate, urethane acrylates, diurethane dimethacrylate, ethyl methacrylate, phenoxyethyl acrylate and tetraethylene glycol dimethacrylate. The patients were patch tested with methyl methacrylate 2% pet., ethyl methacrylate 2% pet., HEMA 2% pet., 2-hydroxymethyl acrylate 0.5% pet. and 1,6-hexanediol diacrylate (HDDA) 0.1% pet. (tested in one patient), which were positive in all three patients [16].

The 8 patients with presumed allergic contact dermatitis of the ear canal (allergic otitis externa) from (meth)acrylates presented here represent only 0.28% of the total 2022–2025 test population ($n = 2906$) and 2.0% of the cohort tested with the (meth)acrylate series ($n = 392$). Yet, ours appears to be one of the largest case series reported thus far.

We have scored the reactions to the (meth)acrylates in these eight patients as probably relevant to their complaints, albeit only tentatively, as it is unknown whether these (meth)acrylates—or other possibly cross-reacting (meth)acrylates—were present in the ear moulds used by the patients and with residual monomers in a concentration high enough to induce contact allergy and elicit allergic contact dermatitis. Because the exact nature of the ear moulds was unknown to us, the manufacturers could not be contacted to obtain information on their composition.

We observed a striking pattern of (meth)acrylate reactivity in these patients. All eight patients with hearing aid ear mould–related allergic contact dermatitis reacted to THFMA (100%), and in five this was the only positive (meth)acrylate. Among the other patients in our group of 176 reacting to (meth)acrylates (data on file), 71 of 168 (42.3%) reacted to THFMA. This difference is statistically significant (Fisher's exact test, two-sided $p \approx 0.002$). After applying a Haldane–Anscombe correction to account for the zero cell, the odds ratio for the association between hearing aid ear mould exposure and THFMA sensitisation was 23.2 (95% confidence interval 1.3–408). This strong association (albeit with a very broad confidence interval) suggests that THFMA is likely to be a relevant constituent of the ear mould materials involved, further supported by the finding that in five of the eight patients THFMA was the sole (meth)acrylate eliciting a reaction. To the best of our knowledge, THFMA has not been reported as a cause of allergic contact dermatitis from ear moulds thus far.

The three patients with positive patch tests to (meth)acrylates in addition to THFMA co-reacted to IBOA and HDDA. The same analysis as used for THFMA, applied to IBOA and HDDA, did not demonstrate a statistically significant association with hearing aid ear mould exposure (Fisher's exact test, both $p > 0.05$). Nevertheless, the occurrence of three reactions to IBOA among the eight ear mould cases is noteworthy. None of these patients had diabetes, making sensitisation from the most common sources of IBOA exposure, glucose sensors or insulin pumps, unlikely. Cross-reactivity with THFMA also appears improbable, as only eight of 79 patients (10%) with THFMA sensitisation showed co-reactivity to IBOA. In addition, two of these eight had been referred for allergic reactions to diabetes devices (data on file). Moreover, IBOA positivity was significantly overrepresented in the ear mould subgroup compared with the remaining THFMA-sensitised patients (3/8 [37.5%] vs. 5/71 [7.0%]; Fisher's exact test, $p = 0.031$; odds ratio 7.9, 95% CI 1.4–44.2). However, given the small sample size, this finding should be interpreted with caution.

Taken together, these findings suggest that IBOA may also be a relevant allergenic constituent of the ear mould materials involved. To the best of our knowledge, IBOA has not been reported as a cause of allergic contact dermatitis from ear moulds thus far.

In contrast, the findings for HDDA may also be explained by cross-reactivity. Among our patients with THFMA sensitisation, 42 of 79 (53%) showed concomitant reactions to HDDA. Cross-reactivity may also explain the concomitant reactions to 1,4-butanediol dimethacrylate and hydroxypropyl methacrylate observed in patients six and eight, given the high co-reactivity rates to these allergens in THFMA-positive patients (61% and 80%, respectively; data on file), particularly in the presence of strong (++/+++) reactions to THFMA in these patients.

Assuming that THFMA and IBOA (and possibly HDDA) may indeed act as relevant allergens in ear moulds, we have investigated whether these substances are used in the production of these devices and how frequently. However, we encountered similar difficulties as previously described for allergic reactions to diabetes medical devices [17]. Under the EU Medical Device Regulation (EU) 2017/745, manufacturers of medical devices such as hearing aids are required to provide only limited information on device composition in labelling and instructions for use, which do not include disclosure of full polymer or monomer composition [18]. Consequently, manufacturers of ear moulds and 3D-printed shells rarely disclose the exact monomer composition of the materials used, and virtually no publicly available information exists regarding the presence of THFMA, IBOA or HDDA in hearing-aid ear moulds.

Technical data sheets from several major suppliers (Dreve, Detax, Egger) indicate that modern ear moulds and in-the-ear

shells are manufactured from UV-curable (meth)acrylate resins and finished with UV-curable acrylic lacquers, but individual monomers are not specified. One exception is documented: the safety data sheet of e-shell 300 (Deltamed GmbH, Friedberg, Germany), a light-curing resin explicitly marketed 'for hearing aid devices', lists THFMA (10%–25%) as a constituent monomer [19]. In addition, a recent study in RSC Advances confirms that e-shell 300 'is commonly used in the manufacture of hearing aids and other implants' [20]. As further indirect evidence of its relevance within this product category, a Detax Audio 3D Resins brochure explicitly advertises several ear mould resins as 'THFMA-free', implying that THFMA is a formulation component of significance for performance or biocompatibility [21].

4.1 | Limitations

The study design was retrospective. Readings at D7 were not routinely performed. Brand names of hearing aid moulds were often not recorded. The exact composition of the products perceived to be the cause of allergic otitis externa was unknown, which made scoring of certain relevance de facto impossible. Scrapings of ear moulds were tested in three of eight patients only. Chemical analyses were not performed. Long-term follow-up was not possible. The investigation was performed in a tertiary referral center, which has influenced the composition of the patient population referred for patch testing.

4.2 | Suggestions for Further Research

Manufacturers of hearing aids which have caused allergic reactions should be contacted and asked for detailed qualitative and quantitative information on the composition of their products. Specific allergenic chemicals may be identified by gas chromatography–mass spectrometry (GC–MS) analyses of extracts of the devices.

5 | Conclusions

Although it is largely unknown how frequently THFMA and IBOA are used in hearing aid ear moulds, and the composition of the devices used by our patients is completely lacking, our data provide strong indications that these were relevant allergenic constituents of the ear mould materials involved. Testing only HEMA in a routine series would have missed all cases of (meth)acrylate sensitisation.

Author Contributions

Norbertus A. Ipenburg: conceptualization, investigation, data curation, writing – review and editing. **Thomas Rustemeyer:** supervision, writing – review and editing. **Anton C. de Groot:** conceptualization, visualization, writing – original draft.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Research data are not shared.

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