

Photopolymers for Otoplastics and Hearing Devices

Shell and Earmould Mechanics, Skin-Contact State, Biofilm, Acoustics and Fit

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3Dresyns by Resyner Technologies S.L.

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Statement of Significance

Vat photopolymerisation can manufacture patient-specific hearing-device geometries and can also serve as a platform for local drug incorporation. Neither geometric success nor one favourable biological test qualifies a finished hearing device. ER-192 separates print state, mechanical function, skin-contact state, acoustic fit, antimicrobial performance and drug-release evidence so that each claim is supported by a test performed on the relevant material and process state.

Abstract

Photopolymerised hearing-aid shells and earmoulds combine demanding geometry with prolonged local contact and device-specific functional requirements. A primary study reported digital-light-processing manufacture of multi-drug-loaded hearing aids using rigid and flexible research resins, ciprofloxacin and fluocinolone acetonide. In that reported system, drug incorporation did not materially alter the measured mechanical properties, the devices exhibited a hydrophilic surface, blood-compatibility and antibiofilm assays were performed, activity was reported against *Pseudomonas aeruginosa* and *Staphylococcus aureus*, and release extended beyond two weeks [1]. These findings demonstrate a research route, not general clinical suitability. ER-192 converts the bounded evidence into an engineering qualification framework. Resin identity, delivered exposure, post-cure, geometry, mechanics, surface and extractable state, microbiological method, release method, fit and acoustic performance are treated as distinct but linked evidence domains. No universal resin, exposure, antimicrobial claim, release duration, skin-contact conclusion or clinical benefit is proposed.

Keywords: hearing aids; otoplastics; earmoulds; vat photopolymerisation; antibiofilm; drug delivery; fit; qualification

1. Scope and boundary

ER-192 addresses vat-photopolymerised shells, earmoulds and related hearing-device components. It owns the engineering connection between material identity, cure and post-cure state, component geometry, mechanical response, prolonged contact, microbial challenge, acoustic function and patient-specific fit.

It does not determine medical-device classification, regulatory approval, clinical effectiveness, prescribing, sterility or patient suitability. It does not claim that any 3Dresyns material is qualified for hearing-device, skin-contact, antimicrobial or drug-delivery use.

The evidence anchor is the publisher record and abstract of Vivero-Lopez et al. [1]. Because the present evidence depth is limited to those directly read primary materials, ER-192 does not reproduce unverified numerical recipes or convert study-specific results into general acceptance limits.

2. What the primary anchor demonstrates

Vivero-Lopez et al. reported DLP manufacture of multi-drug-loaded hearing aids using a hard engineering resin and a flexible resin, with ciprofloxacin and fluocinolone acetonide incorporated into the studied systems [1]. The study evaluated mechanical properties, wettability, blood compatibility, biofilm-related performance

and drug release [1]. Its abstract reports antibiofilm activity against *P. aeruginosa* and *S. aureus* and sustained delivery for more than two weeks in the tested configurations [1].

The paper therefore establishes feasibility for combining personalised photopolymerised geometry with drug incorporation and laboratory performance testing. It does not establish that those results transfer to another resin, printer, post-cure, drug loading, geometry, anatomical site, microbial model or patient. It also does not replace finished-device biological evaluation or clinical evidence.

3. Define the qualified material state

A device record should identify resin, additives or drug, supplier and lot where relevant, storage history, mixing procedure, printer, build orientation, exposure settings, cleaning, post-cure, conditioning and test age. The as-printed, washed, post-cured, conditioned and used states are not interchangeable.

Drug addition may alter optical absorption, cure, conversion, network structure, extractables, surface energy and mechanics. A result showing retained mechanical properties in one studied formulation is not permission to assume equivalence after another addition. The finished formulation and process state must be tested.

4. Geometry, fit and acoustic function

Patient-specific geometry is a functional attribute, not merely a visual outcome. Relevant controls may include scan provenance, model processing, minimum wall or feature dimensions, build orientation, dimensional inspection and deformation after post-cure or conditioning. These controls are proposed engineering practice rather than findings attributed to [1].

Fit can influence comfort, retention, seal and acoustic performance. Dimensional conformity alone does not prove acceptable fit, and fit alone does not prove acoustic performance. The intended device type should define the required verification, such as leakage, vent geometry, receiver or tubing placement and frequency-dependent response. ER-192 sets no universal tolerance or acoustic target.

5. Mechanical performance in the relevant state

Rigid shells and flexible earmoulds have different failure modes. Candidate tests should be selected from the actual functions: stiffness, deformation, tear, fatigue, impact, connector retention or dimensional stability. Specimen preparation, build direction, post-cure, conditioning, test temperature and aging state should be recorded.

The anchor reports that drug incorporation did not affect measured mechanical properties in its studied systems [1]. That statement remains limited to the methods and compositions of that work. It does not establish unchanged fatigue, long-term fit or damage resistance.

6. Contact, surface and extractable state

Prolonged local contact makes the finished surface and mobile-chemical state important. Wettability can affect liquid interaction and microbial attachment, but a more hydrophilic surface is not by itself evidence of comfort, biocompatibility or reduced infection risk.

A defensible contact argument should be based on the final processed device and its intended contact duration. It should consider residual monomers or additives, degradation products, cleaning residues and any incorporated active. Which biological or chemical endpoints are required belongs to the applicable medical-device and toxicological programme. Blood compatibility reported in [1] is a study-specific assay result and is not general skin-contact or clinical qualification.

7. Biofilm and antimicrobial claims

The anchor reports activity against two named bacterial species under its laboratory methods [1]. A reusable claim should state organisms, inoculum and growth conditions, device state, exposure time, recovery method,

controls and endpoint. Planktonic inhibition, reduced attachment, biofilm disruption and clinical infection prevention are different claims.

An antimicrobial result can also change as an active is depleted. Qualification should therefore link microbiological testing to release and aging state. ER-192 makes no claim of sterility, broad-spectrum activity or prevention of otitis.

8. Drug incorporation and release

Drug identity, loading basis, uniformity, chemical stability, spatial distribution and release method should be documented. Release duration depends on formulation, geometry, sink conditions, analytical method and acceptance rule. The more-than-two-week result reported in [1] is not a universal device duration.

Adding an active converts a passive-material problem into a combined material, manufacturing and pharmaceutical-control problem. Dose accuracy, stability, impurities and clinical exposure require competent evaluation outside this review. Printing feasibility does not establish therapeutic equivalence or an approved combination product.

ER-193 owns dose accuracy, content uniformity, pharmaceutical stability, impurities and clinical-exposure qualification; the documentation and method requirements stated here are retained only where they affect the hearing-device attributes owned by ER-192.

9. Process qualification and change control

A qualification plan should connect intended use to critical quality attributes and process parameters. A practical sequence is to define the component and claim, lock formulation identity, establish an exposure and post-cure window, verify geometry, measure mechanics in the relevant state, assess contact chemistry, evaluate microbiological or release performance where claimed, and confirm fit and acoustic function on the finished design.

Changes in resin lot, pigment, drug, loading, printer, light engine, layer strategy, wash, post-cure, geometry or finishing should be screened for requalification. Bridging is defensible only where retained tests can detect the affected failure modes.

10. Evidence limitations

This version is intentionally anchored to one directly read primary publisher record and abstract. It is not a systematic review and does not compare commercial resins or establish regulatory acceptance. Detailed numerical methods and results not visible in the directly read record are not reproduced.

11. Conclusions

The primary study demonstrates that DLP-manufactured hearing-aid geometries can, in a defined research system, incorporate two drugs and be evaluated for mechanics, wettability, compatibility, antibiofilm activity and release [1]. The evidence does not make those outcomes universal.

ER-192 therefore requires separate evidence for material state, geometry, mechanics, contact chemistry, microbiological claim, release, fit and acoustics. A successful print is not a qualified hearing device; a laboratory antibiofilm result is not clinical infection prevention; and sustained release in one method is not an approved therapeutic dose profile.

Related Engineering Review boundaries

ER-193 owns resin identity, dose incorporation, release, residuals and pharmaceutical qualification for drug-delivery devices. ER-192 owns finished hearing-device shell and earmould mechanics, contact state, biofilm, acoustics and fit; it discusses drug incorporation only where it changes those device-level attributes.

Reference

[1] Vivero-Lopez, M.; Xu, X.; Muras, A.; Otero, A.; Concheiro, A.; Gaisford, S.; Basit, A. W.; Alvarez-Lorenzo, C.; Goyanes, A. Anti-biofilm multi drug-loaded 3D printed hearing aids. *Materials Science and Engineering: C* 119 (2021) 111606. <https://doi.org/10.1016/j.msec.2020.111606>

Competing interests

The author is Founder, CEO and CTO of 3Dresyns by Resyner Technologies S.L. This review does not claim that any 3Dresyns product is qualified for hearing-device, medical, skin-contact, antimicrobial or drug-delivery use.

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Data availability

No new experimental dataset was generated for this review.